Ontario Health
Cancer Care Ontario

NEW DRUG FUNDING PROGRAM (NDFP), EVIDENCE BUILDING PROGRAM (EBP) & HIGH COST THERAPY FUNDING PROGRAM (HCTFP)

Approved Drugs and Eligibility Criteria

The information in this document is a summary of the funding criteria for the New Drug Funding Program, Evidence Building Program and High Cost Therapy Funding Program. It is updated on a regular basis. Although we strive to ensure that all information is accurate at the time of posting, some items may be subject to change from time-to-time. Confirmation that patients meet eligibility criteria in Ontario Health (Cancer Care Ontario) eClaims is required at the time of enrolment. The information contained herein is intended to be for informational purposes only. It is not intended to constitute medical advice and should not be relied upon in any such regard. The information contained herein does not create a physician-patient relationship between Ontario Health (Cancer Care Ontario) and you. Ontario Health (Cancer Care Ontario) does not recommend the use of any drug or treatment method described in this document. Anyone using the information does so at his or her risk. Any use of the information is subject, at all times, to Ontario Health (Cancer Care Ontario)'s Terms and Conditions. For detailed information on treatments, consult a qualified healthcare professional.

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New Drug Funding Program (NDFP)

The New Drug Funding Program (NDFP), created in 1995, is a publicly funded drug program under the Ontario Public Drug Programs (OPDP). NDFP directly covers the cost of many newer, and often very expensive, injectable cancer drugs administered in hospitals and cancer centres.

Eligibility – NDFP

Patients must be residents of Ontario and have a valid Ontario Health Card. Reimbursement is for the drug costs for patients who meet the NDFP eligibility criteria for the specific approved injectable cancer drug. Completed enrolment forms and supporting clinical documents (when required), must be submitted by the prescribing physicians before treatments begin. All eligibility criteria must be met as specified. Treatment claims and supporting documentation, if applicable, must be submitted to Ontario Health (Cancer Care Ontario) according to the monthly submission schedule. All enrolment forms, treatment claims and supporting clinical documents, must be submitted through Ontario Health (Cancer Care Ontario) eClaims.

Reimbursement for Cancer Drugs

- The program funds new and expensive injectable cancer drugs that are administered in outpatient chemotherapy clinics in hospitals and regional cancer centres and have been evaluated and approved for coverage.
- The program funds the majority of injectable cancer drug costs in Ontario. The remaining costs are covered by other sources.
- Reimbursement is for the drug costs of those patients who meet the eligibility criteria for the specific approved drugs.
- Treatments administered in the inpatient setting are not eligible for funding via this program, unless otherwise specified and approved by Ontario Health (Cancer Care Ontario).
- The program does not fund cancer drugs administered in private clinics.
- The program does not reimburse individuals or retail pharmacies for the cost of cancer drugs. Instead, reimbursements are made to Ontario's regional cancer centres and more than 80 community hospitals.

Evidence Building Program (EBP)

The Evidence-Building Program (EBP) complements and strengthens Ontario's New Drug Funding Program (NDFP) and the process for making drug funding decisions in Ontario by maintaining rigour and consistency. The EBP seeks to resolve uncertainty around clinical and cost-effectiveness data related to the expansion of cancer drug coverage within Ontario.
For a cancer drug to be included in Ontario's EBP there must be evolving, but incomplete evidence of benefits. This will allow us to fund the drug on a time-limited basis to collect real-world data on its clinical and cost effectiveness. This data will be used by the Ministry of Health to help inform a final change to existing funding criteria.

Eligibility – EBP

To receive drug coverage under the EBP, patients must be residents of Ontario and have a valid Ontario Health Card. Reimbursement is for the drug costs of those patients who meet the EBP eligibility criteria for the specific approved cancer drug.
Completed enrolment forms and supporting clinical documents (when required), must be submitted by the prescribing physicians before treatments begin. All eligibility criteria must be met as specified.
Treatment claims and supporting documentation, if applicable, must be submitted to Ontario Health (Cancer Care Ontario) according to the monthly submission schedule. All enrolment forms, treatment claims and supporting clinical documents, must be submitted through Ontario Health (Cancer Care Ontario) eClaims.

Supplemental Forms – EBP

As a condition of participating in the EBP, Supplemental Forms are required and must be submitted at specific time intervals to ensure continued reimbursement. Supplemental Forms are also required following the completion of therapy to facilitate continued real-world data collection, in order to conduct analyses to inform permanent funding decisions. Please see Supplemental Forms for respective EBP drugs in Ontario Health (Cancer Care Ontario) eClaims for additional detail.

High Cost Therapy Funding Program (HCTFP)

The High Cost Therapy Funding Program (HCTFP) is administered by Ontario Health (Cancer Care Ontario) on behalf of the Ministry of Health. The HCTFP is established by Ontario Health (Cancer Care Ontario) in collaboration with the Ministry to provide funding for therapies that require specialized administration or delivery in a hospital setting.

To be funded under the HCTFP, therapies are evaluated through an evidence-informed process to ensure they are effective, safe, and provide value for money. To receive coverage under the HCTFP, prescribers must submit individual funding requests on behalf of their patients. For patients that meet the required eligibility criteria, the HCTFP will directly reimburse hospitals/cancer centres.

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Funded Drugs and Eligibility Criteria under NDFP

The following is a list of drugs and indications that are approved for reimbursement in NDFP. All information corresponds to the most current enrolment forms found in Ontario Health (Cancer Care Ontario) eClaims, including funded dose, regimen, schedule, and other eligibility criteria. Note that ALL criteria must be met to be eligible for reimbursement, unless otherwise specified.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
Aldesleukin (all-dess-LOO-kin) Other name: Proleukin®	In-Transit Metastases from Melanoma	The patient has in-transit metastases from melanoma and has failed or is not a candidate for surgery or other treatments	• 1 vial (22 million IU) of aldesleukin will be funded per cycle for intralesional injection	NDFP funding is for patients who receive aldesleukin as an intralesional injection. This drug may be referred to as aldesleukin or interleukin-2.
Arsenic Trioxide (AR-se-nik tri-OX-ide) Other name: Trisenox®	First Line Induction of Acute Promyelocytic Leukemia (APL)	Arsenic trioxide will be used in combination with all-trans retinoic acid (ATRA) in the first-line setting for acute promyelocytic leukemia (APL) as an induction treatment	Low to Intermediate Risk (WBC ≤ 10 x 10^9/L) • Arsenic trioxide is administered intravenously at a dose of 0.15 mg/kg daily until complete remission. High Risk (WBC > 10 x 10^9/L) • Arsenic trioxide is administered intravenously at a dose of 0.15 mg/kg daily on days 9 to 36	A separate enrolment is required for consolidation treatment with arsenic trioxide. Arsenic must be administered with ATRA. The ATRA portion is not funded by CCO and therefore, it is advised that sites confirm ATRA will be covered by another funding source prior to initiation of therapy.
Arsenic Trioxide (AR-se-nik tri-OX-ide) Other name: Trisenox®	Relapsed/Refractory Induction of Acute Promyelocytic Leukemia (APL)	Arsenic trioxide will be used in combination with all-trans retinoic acid (ATRA) in the relapsed/refractory setting for acute promyelocytic leukemia (APL) as an induction treatment.	Low to Intermediate Risk (WBC ≤ 10 x 10^9/L) • Arsenic trioxide is administered intravenously at a dose of 0.15 mg/kg daily until complete remission. High Risk (WBC > 10 x 10^9/L) • (APML4) Arsenic trioxide is administered intravenously at a dose of 0.15 mg/kg daily on days 9 to 36	A separate enrolment is required for consolidation treatment with arsenic trioxide. Arsenic must be administered with ATRA. The ATRA portion is not funded by CCO and therefore, it is advised that sites confirm ATRA will be covered by another funding source prior to initiation of therapy.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
Arsenic Trioxide (AR-se-nik tri-OX-ide) Other name: Trisenox®	First Line Consolidation of Acute Promyelocytic Leukemia (APL)	Arsenic trioxide will be used in combination with all-trans retinoic acid (ATRA) in the first-line setting for acute promyelocytic leukemia (APL) as a consolidation treatment	Low to Intermediate Risk (WBC ≤ 10 x 10^9/L): • Arsenic trioxide is administered intravenously at a dose of 0.15 mg/kg/day for 5 days per week, 4 weeks on and 4 weeks off, for a total of 4 cycles. High Risk (WBC > 10 x 10^9/L): (APML4) Two cycles of arsenic trioxide, are administered as follows: • Cycle 1: arsenic trioxide 0.15 mg/kg/day intravenously days 1-28 • Cycle 2: arsenic trioxide 0.15 mg/kg/day intravenously on days 1 to 5, 8 to 12, 15 to 19, 22 to 26, 29 to 33 • APML4 consolidation IS followed by maintenance. High Risk (WBC > 10 x 10^9/L): • (APL0406) – Arsenic trioxide, in combination with ATRA, is administered intravenously at a dose of 0.15mg/kg/day for 5 days per week, 4 weeks on and 4 weeks off, for a total of 4 cycles. APL0406 consolidation is NOT followed by maintenance.	Arsenic must be administered with ATRA. The ATRA portion is not funded by CCO and therefore, it is advised that sites confirm ATRA will be covered by another funding source prior to initiation of therapy.
Arsenic Trioxide (AR-se-nik tri-OX-ide) Other name: Trisenox®	Relapsed/Refractory Consolidation of Acute Promyelocytic Leukemia (APL)	Arsenic trioxide will be used in combination with all-trans retinoic acid (ATRA) in the relapsed/refractory for acute promyelocytic leukemia (APL) as a consolidation treatment	Low to Intermediate Risk (WBC ≤ 10 x 10^9/L): • (APL0406) - Arsenic trioxide is administered intravenously at a dose of 0.15mg/kg/day until complete remission. High Risk (WBC > 10 x 109/L): • (APML4) - Arsenic trioxide is administered intravenously at a dose of 0.15mg/kg daily on days 9 to 36.	Arsenic must be administered with ATRA. The ATRA portion is not funded by CCO and therefore, it is advised that sites confirm ATRA will be covered by another funding source prior to initiation of therapy.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
Atezolizumab (A-teh-zoh-LIZ-yoo-mab) Other Name: Tecentriq®	Adjuvant Treatment for Non-Small Cell Lung Cancer	Atezolizumab monotherapy is used for the adjuvant treatment of adult patients with resected stage II or III non-small cell lung cancer (NSCLC) (excluding T2bN0)* whose tumours have PD-L1 expression on 50% or more of tumour cells and do not have epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumour aberrations. Treatment is only for patients who have completely resected NSCLC, no disease progression after platinum-based adjuvant chemotherapy, and who have a good performance status. Treatment with atezolizumab should be initiated within 3 to 8 weeks from the completion of chemotherapy. *Based on the American Joint Committee on Cancer TNM staging system, 8th edition.	Atezolizumab 840 mg as an intravenous (IV) infusion every 2 weeks, 1200 mg as an IV infusion every 3 weeks, or 1680 mg as an IV infusion every 4 weeks. Treatment should continue until disease recurrence, unacceptable toxicity, or up to a maximum of 48 weeks (i.e., 12 cycles every 4 weeks, 16 cycles every 3 weeks, or 24 cycles every 2 weeks), whichever comes first. [ST-QBP regimen code: ATEZ]	1. Patients who are not eligible for surgical resection and initiation of platinum-based adjuvant chemotherapy are ineligible for atezolizumab funding. 2. Patients treated with an immune checkpoint inhibitor in the curative setting who have a disease-free interval of 6 months or greater from the last dose may be eligible for one line of PD-1 or PD-L1 inhibitor therapy for advanced NSCLC provided all other eligibility criteria are met.
Atezolizumab (A-teh-zoh-LIZ-yoo-mab) Other Name: Tecentriq®	Advanced or Metastatic Non-Small Cell Lung Cancer	The patient must meet one of the following criteria: • Atezolizumab is used for the treatment of patients who have locally advanced or metastatic non-small cell lung cancer whose disease has progressed on or after cytotoxic chemotherapy. • Patients with EGFR or ALK mutations should be treated with targeted agents followed by cytotoxic chemotherapy prior to receiving atezolizumab.	Atezolizumab 840 mg as an intravenous (IV) infusion every 2 weeks, 1200 mg as an IV infusion every 3 weeks, or 1680 mg as an IV infusion every 4 weeks [ST-QBP regimen code: ATEZ]. Treatment with atezolizumab should be continued until unacceptable toxicity or confirmed disease progression.	1. Ontario Health (Cancer Care Ontario) will fund one line of atezolizumab, nivolumab, nivolumab plus ipilimumab, or pembrolizumab for advanced non-small cell lung cancer. Patients who were treated with durvalumab (or other anti-PD1/PD-L1 therapy) in the curative setting must have a disease free interval of 6 months or greater in order to be considered for funding under this policy. 2. Atezolizumab is funded for single agent use only. 3. It is recommended that atezolizumab be used after treatment with a platinum-based therapy. 4. Atezolizumab is not funded for patients who have confirmed disease progression after receiving a prior anti-PD-1 inhibitor in the advanced setting. 5. For patients who stop atezolizumab without disease progression, continuation of atezolizumab will be funded provided that no other treatment is given in between.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
Atezolizumab (A-teh-zoh-LIZ-yoo-mab) Other Name: Tecentriq®	In Combination with Etoposide and Platinum for Extensive-Stage Small Cell Lung Cancer	Atezolizumab is used in combination with platinum-based chemotherapy (carboplatin or cisplatin) and etoposide for the first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC). Treatment is only for patients who have not received previous treatment for ES-SCLC and have good performance status upon treatment initiation with atezolizumab.	Atezolizumab 1200 mg intravenously (IV), once every 3 weeks (in combination with etoposide and platinum (carboplatin or cisplatin)) for 4 cycles as induction, followed by atezolizumab 1200 mg once every 3 weeks as maintenance until disease progression or unacceptable toxicity. [ST-QBP regimen codes: One of CISPETOP+ATEZ, CISPETOP(PO)+ATEZ, CRBPETOP+ATEZ, or CRBPETOP(PO)+ATEZ as induction, followed by ATEZ(MNT) as maintenance]	1. Ontario Health (Cancer Care Ontario) will fund one of atezolizumab or durvalumab, in combination with platinum-etoposide followed by maintenance, for ES-SCLC. 2. Atezolizumab must be used in combination with etoposide and platinum chemotherapy, followed by atezolizumab maintenance. 3. Retreatment with atezolizumab, in combination with etoposide-platinum, followed by atezolizumab maintenance is not publicly funded.
Atezolizumab (A-teh-zoh-LIZ-yoo-mab) Other Name: Tecentriq®	Previously Untreated Unresectable or Metastatic Hepatocellular Carcinoma	Atezolizumab is used in combination with bevacizumab for the first-line treatment of adult patients with unresectable or metastatic hepatocellular carcinoma (HCC) who require systemic therapy and have had no prior systemic treatment. Treatment should be for patients with an Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1 and a Child-Pugh 'A' liver function classification.	Atezolizumab 1200 mg intravenously (IV) and bevacizumab 15 mg/kg IV on day 1 of each 21-day cycle. Treatment with atezolizumab and bevacizumab should be continued until loss of clinical benefit* or unacceptable toxicity, whichever comes first. [ST-QBP regimen code: ATEZBEVA] *In the pivotal trial, loss of clinical benefit was determined after an assessment of biochemical and radiographic data and of clinical status (e.g., symptomatic deterioration such as pain due to disease). Treatment beyond radiographic disease progression could continue if there is observed evidence of clinical benefit, and symptoms and signs indicating unequivocal disease progression are absent.	1. Patients with fibrolamellar HCC, sarcomatoid HCC, or mixed cholangiocarcinoma and HCC are not eligible for funding under this policy. 2. Patients who stop either atezolizumab or bevacizumab due to intolerance may continue treatment with the remaining agent in the absence of progression if the clinician determines there would be clinical benefit. Monotherapy with the remaining agent should stop if the patient develops intolerance or has progression.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
Avelumab (a-VEL-yoo-mab) Other Name: Bavencio®	Metastatic Merkel Cell Carcinoma	The patient must meet one of the following criteria: • Avelumab is used for the treatment of previously treated adult patients with metastatic Merkel cell carcinoma who have good performance status and have had prior cytotoxic chemotherapy. • Avelumab is used for the treatment of adult patients with metastatic Merkel cell carcinoma who have good performance status and are ineligible for treatment with cytotoxic chemotherapy (e.g., contraindications to treatment with cytotoxic chemotherapy).	Avelumab 10 mg/kg given as an intravenous infusion every 2 weeks (ST-QBP regimen code: AVEL). Treatment should continue until confirmed disease progression or unacceptable toxicity. For patients who achieve a complete response (CR), treatment should continue for a maximum of 12 months after confirmation of CR.	Avelumab funding is for single agent use only. Patients who have a confirmed CR and relapse after stopping treatment are allowed one re-initiation of treatment if the treating physician deems the patient eligible for retreatment. Claims should be submitted under the same form used for initial treatment.
Avelumab (a-VEL-yoo-mab) Other Name: Bavencio®	Maintenance Treatment for Unresectable, Locally Advanced or Metastatic Urothelial Carcinoma	Avelumab is used for the first-line maintenance treatment of patients with histologically confirmed, unresectable, locally advanced or metastatic urothelial carcinoma whose disease has not progressed with first-line platinum-based induction chemotherapy. Treatment should be for patients with good performance status.	Avelumab 10 mg/kg intravenously (IV), up to a maximum of 800 mg per dose, once every two weeks. Patients may continue to receive avelumab until confirmed disease progression or unacceptable toxicity, whichever comes first. [ST-QBP regimen code: AVEL(MNT)]	1. First-line chemotherapy should be platinum-based, and patients must have received 4 to 6 cycles of treatment with chemotherapy unless fewer cycles were necessary due to a documented intolerance. Patients must not have experienced disease progression (i.e., they must have had an ongoing complete response, partial response, or stable disease) prior to initiation of avelumab maintenance. 2. Patients who have disease progression within 12 months of neoadjuvant or adjuvant systemic therapy are not eligible for avelumab maintenance. Patients may be eligible for pembrolizumab if all other eligibility criteria are met. 3. Patients who have received prior PD-1 or PD-L1 inhibitors in the advanced setting are not eligible for avelumab maintenance. 4. Patients who are not able to tolerate platinum-based chemotherapy and receive non-platinum chemotherapy may be considered for funding under this policy provided all other eligibility criteria are met, and the patient has received a minimum of 12 weeks (4 to 6 cycles) of treatment with no evidence of progressive disease on or after treatment. Requests for patients who received alternative non-platinum chemotherapy should be submitted as prior approval requests.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
				5. For patients who require a treatment interruption of avelumab maintenance therapy, a restart of avelumab will only be considered if the disease is still in remission.
Azacitidine (ay-za-SYE-ti-deen) Other Name: Vidaza®	Acute Myeloid Leukemia (AML)	For the treatment of adult patients who are not eligible for hematopoietic stem cell transplantation with Acute Myeloid Leukemia (AML) with 20-30% blasts and multi-lineage dysplasia, according to World Health Organization (WHO) classification	Intended dosing schedule (repeated every 28 days; 1 cycle = every 28 days) 75 mg/m^2 sc daily for 7 consecutive days, or 75 mg/m^2 sc daily for 6 consecutive days, or 75 mg/m^2 sc 5-2-2 (5 consecutive days of treatment, followed by 2 consecutive days without treatment, and then 2 consecutive days of treatment every 28 days)	The NDFP will only fund the regimens listed on the form, as per Ministry criteria. An exception is the one-off situation that may occur (e.g. statutory holidays). Sites are encouraged to contact the NDFP should there be questions relating to the one-off scenarios. Evidence of eligibility must be demonstrated either with a bone marrow aspirate or biopsy, whichever report produces the worst percentage. The bone marrow aspirate or biopsy must be completed within 8 weeks of starting azacitidine. As part of reimbursement, sites are required to submit to the NDFP copies of the baseline bone marrow and cytogenetics report. If cytogenetics is inconclusive or not done, the patient may still meet criteria based on the IPSS score being intermediate-2 or higher by virtue of the percent blast count and the number of cytopenias. In certain situations, the provision of prior cytogenetics is sufficient if the MDS is confirmed by morphology and a) if IPSS score meets criteria without the need for cytogenetics, OR b) if blast count is 20-30%. Treatments will be funded as long as the patient continues to benefit or until disease progression.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
Azacitidine (ay-za-SYE-ti-deen) Other Name: Vidaza®	Acute Myeloid Leukemia (AML) Greater Than 30% Blasts	The patient must meet the following criteria: Azacitidine is used for the treatment of older adult patients with newly diagnosed acute myeloid leukemia (AML) with greater than 30% bone marrow blasts without immediate intent for hematopoietic stem cell transplant (HSCT) or who are unfit for induction chemotherapy.	Azacitidine subcutaneously (SC) according to one of these intended dosing schedules (repeated every 28 days; 1 cycle = every 28 days)[1] 75 mg/m^2 sc daily for 7 consecutive days, or 75 mg/m^2 sc daily for 6 consecutive days, or 75 mg/m^2 sc 5-2-2 (5 consecutive days of treatment, followed by 2 consecutive days without treatment, and then 2 consecutive days of treatment every 28 days) Treatments will be funded as long as the patient continues to benefit or until disease progression or unacceptable toxicity, whichever comes first. ST-QBP regimen code: AZCT	The NDFP will only fund the dosing schedules listed on the form, as per Ministry criteria. An exception is the one-off situation that may occur (e.g. statutory holidays). Sites are encouraged to contact their Reimbursement Analyst should there be questions relating to the one-off scenarios.
Azacitidine (ay-za-SYE-ti-deen) Other Name: Vidaza®	In Combination with Venetoclax (Outpatient) for Previously Untreated Acute Myeloid Leukemia	The patient must meet the following criteria: Venetoclax in combination with azacitidine is used in adult patients for the treatment of newly diagnosed acute myeloid leukemia (AML) who are 75 years of age or older, or who are 18 to 74 years of age and have comorbidities that preclude the use of intensive induction chemotherapy.	Cycle 1: Azacitidine 75 mg/m2 subcutaneously once daily for 6 or 7 doses (starting on day 1) in combination with venetoclax 100 mg once daily on day 1, 200 mg once daily on day 2, then 400 mg once daily on days 3 to 28. Cycle 2 and onwards: Azacitidine 75 mg/m2 subcutaneously once daily for 6 or 7 doses (starting on day 1) in combination with venetoclax 400 mg once daily on days 1 to 28. [repeated every 28 days; 1 cycle = every 28 days]	1. Enrolment in this policy is for funding of azacitidine in the outpatient setting only. Funding for outpatient use of venetoclax must be obtained through the Ministry's Exceptional Access Program. Please check that your patient will be eligible for benefits under the Ontario Drug Benefit Program. Some patients may require registration in the Trillium Drug Program. Please ensure all doses are submitted through eClaims using the respective enrolment forms for outpatient and inpatient administered doses. 2. For funding of doses administered in the inpatient setting, a separate enrolment form must be submitted. See the policy 'Azacitidine in combination with Venetoclax (Inpatient) - Previously Untreated Acute Myeloid Leukemia'. Inpatient administration of both azacitidine and venetoclax are funded though the High Cost Therapy Funding Program (HCTFP).

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
			Treatment should be continued until disease progression or unacceptable toxicity, whichever comes first. [ST-QBP regimen code: AZCTVENE]	3. The New Drug Funding Program (NDFP) will only fund the azacitidine dosing schedules listed on this form, as per Ministry criteria. Sites are encouraged to contact their Reimbursement Analyst if they have questions on eligible dosing schedules. 4. Patients previously treated with a hypomethylating agent, venetoclax, or chemotherapy for myelodysplastic syndrome (MDS) are not eligible for funding of azacitidine in combination with venetoclax. 5. Patients with high risk MDS who are not fit for intensive induction chemotherapy are not eligible for funding of azacitidine in combination with venetoclax. 6. Azacitidine in combination with venetoclax will be funded in patients with newly diagnosed AML, regardless of cytogenetic risk, providing the patient meets the eligibility criteria. 7. In the event azacitidine is discontinued due to toxicities or intolerance, venetoclax should also be discontinued. 8. For patients without unacceptable toxicity, it is recommended that patients be treated for a minimum of 6 cycles. 9. Patients 75 years of age or older with an ECOG performance status greater than 2 may be eligible for funding under this policy if their performance status is judged to be related to their AML, provided all other criteria are met. Please submit as a prior approval request including the most recent clinic note.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
Azacitidine (ay-za-SYE-ti-deen) Other Name: Vidaza®	Myelodysplastic Syndromes (MDS)	For treatment of adult patients who are not eligible for hematopoietic stem cell transplantation with Intermediate-2 and high-risk myelodysplastic syndrome (MDS) according to the International Prognostic Scoring System (IPSS)	Intended dosing schedule (repeated every 28 days; 1 cycle = every 28 days) 75 mg/m^2 scdaily for 7 consecutive days, or 75 mg/m^2 sc daily for 6 consecutive days, or 75 mg/m^2 sc 5-2-2 (5 consecutive days of treatment, followed by 2 consecutive days without treatment, and then 2 consecutive days of treatment every 28 days)	The NDFP will only fund the regimens listed on the form, as per Ministry criteria. An exception is the one-off situation that may occur (e.g. statutory holidays). Sites are encouraged to contact the NDFP should there be questions relating to the one-off scenarios. Evidence of eligibility must be demonstrated either with a bone marrow aspirate or biopsy, whichever report produces the worst percentage. The bone marrow aspirate or biopsy must be completed within 8 weeks of starting azacitidine. As part of reimbursement, sites are required to submit to the NDFP copies of the baseline bone marrow and cytogenetics report. If cytogenetics is inconclusive or not done, the patient may still meet criteria based on the IPSS score being intermediate-2 or higher by virtue of the percent blast count and the number of cytopenias. In certain situations, the provision of prior cytogenetics is sufficient if the MDS is confirmed by morphology and a) if IPSS score meets criteria without the need for cytogenetics, OR b) if blast count is 20-30%. Treatments will be funded as long as the patient continues to benefit or until disease progression.
Bendamustine (BEN-da-MUS-teen) Other Name: Treanda®	First line – Chronic Lymphocytic Leukemia	• Bendamustine is being used as first line therapy for the chronic lymphocytic leukemia • The patient has Binet Stage B or C and a WHO performance status of ≤ 2 at the recommended dose • The patient is not medically fit to tolerate fludarabine-based regimens and could be treat with other options such as chlorambucil	Bendamustine 100 mg/m^2 on Days 1 and 2 within each 28 day cycle to a maximum of 6 cycles	Bendamustine funding is for single agent use only.
Bendamustine (BEN-da-MUS-teen) Other Name: Treanda®	First Line - Indolent Non-Hodgkin's Lymphoma and Mantle Cell Lymphoma	• Bendamustine is used in combination with rituximab in the first line setting in patients with indolent CD20 positive non-Hodgkin's lymphoma or mantle cell lymphoma	Bendamustine 90 mg/m^2 on Days 1 and 2 of a 28-day cycle to a maximum of 6 cycles (combination therapy)	Bendamustine is not funded if used as a single agent. Patients who receive first line rituximab bendamustine would be eligible for rituximab maintenance provided that the maintenance rituximab funding criteria are met.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
		• The patient has an ECOG performance status of less than or equal to 2		
Bendamustine (BEN-da-MUS-teen) Other Name: Treanda®	Relapsed/Refractory - Indolent Non-Hodgkin's Lymphoma and Mantle Cell Lymphoma	• Bendamustine is used in the relapsed/refractory setting in patients with indolent CD20 positive non-Hodgkin's lymphoma or mantle cell lymphoma **when used in combination with rituximab**, where the combination of fludarabine-rituximab could previously have been a therapeutic option Patients with indolent CD20 positive non-Hodgkin's lymphoma (excluding mantle cell lymphoma) may use bendamustine in combination with obinutuzumab if the patient meets obinutuzumab criteria.	Bendamustine 90 mg/m^2 on Days 1 and 2 of a 28-day cycle to a maximum of 6 cycles (combination therapy)	a. Bendamustine is not funded if used as a single agent. b. A patient whose disease has relapsed from rituximab is eligible for rituximab funding provided that the funding criteria for rituximab retreatment are met (e.g., the patient has sustained a response and has remained treatment free for at least 6 months following the last dose of rituximab received). Please refer to the rituximab retreatment eligibility form for details.
Bendamustine (BEN-da-MUS-teen) Other Name: Treanda®	With polatuzumab vedotin and rituximab (biosimilar) - Relapsed or Refractory Diffuse Large B-cell Lymphoma	Polatuzumab vedotin is used in combination with bendamustine and rituximab (pola-BR) for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma, not otherwise specified, who are not eligible for autologous stem cell transplant (ASCT) and have received at least 1 prior therapy. Eligible patients should have good performance status and a life expectancy greater than or equal to 24 weeks.	Cycle 1: Rituximab 375mg/m2 intravenously (IV) on Day 1, Polatuzumab vedotin 1.8mg/kg IV on Day 2, Bendamustine 90mg/m2 IV on Days 2 and 3 Cycles 2 to 6: Rituximab 375mg/m2 IV on Day 1, Polatuzumab vedotin 1.8mg/kg IV on Day 1, Bendamustine 90mg/m2 IV on Days 1 and 2 Treatment with pola-BR should continue for a maximum of 6 cycles (21 days per cycle), or until unacceptable toxicity or disease progression, whichever occurs first. [ST-QBP regimen code: BEND+POLA+RITU]	1. NDFP will only fund polatuzumab vedotin in combination with bendamustine and rituximab (pola-BR). An exception is if pola-BR is being used as a bridge to CAR T-cell therapy, in which case bendamustine may be omitted if appropriate based on clinician judgement. 2. Enrolment in this policy will fulfill enrolment requirements for all drugs in this regimen (polatuzumab vedotin, rituximab biosimilar, and bendamustine) 3. Pola-BR is not funded: a. In patients with previously untreated diffuse large B-cell lymphoma (DLBCL); or b. In patients with active CNS lymphoma; or c. If used as salvage therapy for patients who are eligible for ASCT; or d. In patients with Burkitt lymphoma 4. Pola-BR may be considered in patients with transformed follicular lymphoma to DLBCL, HIV-related lymphoma, grey zone lymphoma, and mediastinal large B-cell lymphoma. 5. Pola-BR may be considered in patients who have progressed on prior CAR -T-cell therapy provided the patient is not eligible for ASCT.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes

Bevacizumab (Biosimilar)
(be-vuh-SIZ-uh-mab bye-oh-SIH-mih-lar)
Other names: Mvasi®, Zirabev®, Bambevi®, Abevmy®, Aybintio®, Vegzelma®
	Metastatic Colorectal, Small Bowel, or Appendiceal Cancer	• To be used as combination therapy with the FOLFIRI or FOLFOX or XELOX regimens for the first line treatment of metastatic colorectal, small bowel, or appendiceal cancer (or second-line treatment for patients who received pembrolizumab as first-line treatment); OR
		• To be used with fluoropyrimidine (AVEX) for the first-line treatment of patients with metastatic colorectal, small bowel, or appendiceal cancer for whom combination chemotherapy with oxaliplatin or irinotecan is unsuitable, and patient has an ECOG Performance Status < 2.
		• The patient must meet the following criteria:
		  ○ The patient has metastatic colon, rectal, small bowel or appendiceal cancer.
		  ○ The patient is being treated in the first line setting
		The patient is receiving one of the following regimens as per NDFP criteria: FOLFIRI, FOLFOX, XELOX, AVEX
			Bevacizumab 5 mg/kg q14 days (with FOLFIRI or FOLFOX), or
			Bevacizumab 7.5 mg/kg q21 days (with XELOX or AVEX)
				1. To be used in combination with FOLFIRI, FOLFOX, XELOX, or AVEX regimens only. Not reimbursed as a single agent. Not reimbursed if used in other lines of therapy or if used for other indications.
				2. Switches between bevacizumab and panitumumab will only be considered within the first 3 months of starting therapy with either agent, provided there is no disease progression on treatment. Patients will only be approved for one switch (i.e. from bevacizumab to panitumumab or vice versa). Please upload a clinic note indicating the reason(s) for switching. If chemotherapy with panitumumab is initiated and proximity to planned surgery is noted as the contraindication, subsequent treatment with bevacizumab will not be funded, regardless of the patient's final surgical status. In addition, in this setting, panitumumab as a single agent will not be funded as a subsequent line of therapy.
				3. Patients whose disease progresses on panitumumab in combination with chemotherapy are not eligible for subsequent treatment with bevacizumab.

Bevacizumab (Biosimilar) (be-vuh-SIZ-uh-mab bye-oh-SIH-mih-lar) Other names: Mvasi®, Zirabev®, Bambevi®, Abevmy®, Aybintio®, Vegzelma®	Metastatic (Stage IVB), Persistent, or Recurrent Carcinoma of the Cervix	• Bevacizumab will be used in combination with chemotherapy[1, 2, 3, 4] for the treatment of patients with metastatic (Stage IVB), persistent or recurrent carcinoma of the cervix of all histological subtypes (except small cell)[5]; and The patient has an Eastern Cooperative Performance Status (ECOG) of ≤ 1	Bevacizumab 15mg/kg IV every 21 days.	1. Single agent bevacizumab is not funded. Bevacizumab is only funded if used with the following chemotherapy regimens: paclitaxel-carboplatin, paclitaxel-cisplatin, paclitaxel-topotecan. For more information on the dosing schedules, please refer to the list of evidence informed regimens for cervical cancer at www.cancercareontario.ca/stqbp. 2. Bevacizumab is only funded in the first line setting. Funding will continue until disease progression. Continued use of bevacizumab in patients whose disease has progressed while on a first line regimen will not be funded. 3. In situations where a treatment break has been taken, bevacizumab is only funded if the continuation of the same first line regimen is considered clinically appropriate. 4. In situations where chemotherapy needs to be started first, the later addition of bevacizumab will be funded provided that funding criteria are met at the time of treatment initiation and the patient's disease has not yet progressed while on chemotherapy.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
				5. Bevacizumab funding is intended for patients who are not candidates for other curative treatments (e.g., radiation, surgery). 6. Paclitaxel, carboplatin, topotecan and cisplatin are funded through the Systemic Treatment Quality-Based Procedure (ST-QBP) and are included in the band level pricing.
Bevacizumab (Biosimilar) (be-vuh-SIZ-uh-mab bye-oh-SIH-mih-lar) Other names: Mvasi®, Zirabev®, Bambevi®, Abevmy®, Aybintio®, Vegzelma®	Front-line Treatment (Previously Untreated) Ovarian, Fallopian Tube, and Primary Peritoneal Cancer (with paclitaxel and carboplatin)	• Bevacizumab is given in combination with paclitaxel and carboplatin for the front-line treatment of epithelial ovarian, fallopian tube or primary peritoneal cancer patients with high risk of relapse (stage III sub-optimally debulked*, or stage III unresectable, or stage IV patients) • Patient has Eastern Cooperative Oncology Group performance status (ECOG) <= 2 *Sub-optimal debulking is defined as patients who have > 1 cm of residual disease after debulking surgery.	• Bevacizumab 7.5 mg/kg every 3 weeks as an intravenous infusion. Bevacizumab will be funded with cycles 2-6 of chemotherapy, and as maintenance treatment for up to 12 additional cycles or until disease progression, whichever comes first (i.e., a maximum of 17 bevacizumab cycles per patient [1 cycle = 1 dose]).	1. Bevacizumab is only funded if used in combination with carboplatin and paclitaxel given together once every 3 weeks (CRBPPACL+BEVA). 2. Funding is for a maximum of 17 cycles of bevacizumab or until disease progression, whichever comes first. 3. CCO will fund **one line** of bevacizumab therapy (i.e., **either** front-line bevacizumab **or** bevacizumab in the platinum-resistant recurrent setting, but not both). 4. As per the August 2, 2017 memo, please see below for the following policy clarifications: a. Patients who are receiving neoadjuvant chemotherapy (i.e., are receiving chemotherapy prior to a planned interval debulking) are not eligible to receive bevacizumab prior to surgery. b. If a patient has stage III disease and was initially deemed to be unresectable, but subsequently becomes optimally debulked, the patient is not eligible for bevacizumab post-surgery. c. After definitive surgery, patients are eligible for bevacizumab if the patient is rendered to be sub-optimally debulked (i.e., at least one nodule > 1 cm remaining after debulking) or deemed unresectable. d. Stage IV patients (at the time of primary diagnosis) who have planned interval debulking surgery are eligible for bevacizumab after surgery. e. The surgical assessment by a gynecological oncologist should be documented and may be requested by NDFP in the event of an audit. 5. When bevacizumab is used in combination with paclitaxel for front-line treatment (previously untreated) ovarian cancer, the cost of paclitaxel is funded through the Systemic Treatment Quality-Based Procedure (ST-QBP) and is included in the band level pricing.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes

Bevacizumab (Biosimilar)
(be-vuh-SIZ-uh-mab bye-oh-SIH-mih-lar)
Other names: Mvasi®, Zirabev®, Bambevi®, Abevmy®, Aybintio®, Vegzelma®
	Platinum-Resistant Recurrent Ovarian, Fallopian Tube, or Primary Peritoneal Cancer	The patient must meet the following criteria:
		• Bevacizumab is used in combination with paclitaxel, topotecan, or pegylated liposomal doxorubicin for the treatment of patients with platinum-resistant recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who have received no more than two prior anticancer regimens AND the patient has good performance status and no contraindications** to bevacizumab.
		• The patient's disease is NOT primary platinum refractory. (Primary platinum refractory refers to disease that has progressed while on front-line platinum-based chemotherapy.)
		
		**Contraindications to bevacizumab may include a history of bowel obstruction related to underlying disease; history of abdominal fistula, GI perforation or intra-abdominal abscess; evidence of tumour on the rectosigmoid; prior radiotherapy to the pelvis or abdomen; surgery within 4 weeks before starting treatment; untreated CNS disease or symptomatic CNS metastases; history or evidence of thrombotic or hemorrhagic disorders within 6 months of starting treatment; uncontrolled hypertension; active clinically significant cardiovascular disease; non-healing wound, ulcer, or bone fracture.
		
		On a time-limited basis (until October 5, 2018), CCO will fund bevacizumab for patients who had missed an opportunity to use bevacizumab under the platinum-resistant setting, provided that the patient continues to have good performance status, no contraindications to bevacizumab (that would make the patient more susceptible to GI perforation or other adverse events), and the disease is not primary
			Bevacizumab 10mg/kg every 2 weeks when given with pegylated liposomal doxorubicin, paclitaxel, or topotecan (as part of TOPO(W)+BEVA).
			Or
			Bevacizumab 15mg/kg every 3 weeks when given with topotecan (as part of TOPO+BEVA).
			
			Treatment is funded until disease progression or unacceptable toxicity.
				1. pCODR noted that the patients in the AURELIA trial were carefully selected to avoid the risk of GI perforations. Careful patient selection and appropriate informed consent for treatment are essential. pCODR also felt that it was very important that physicians provide their patients with a detailed description of the risk of GI perforations prior to commencing treatment with bevacizumab.
				
				2. CCO will fund one line of bevacizumab therapy (i.e., either front-line bevacizumab or bevacizumab in the platinum-resistant recurrent setting, but not both).
				
				3. CCO will fund bevacizumab with chemotherapy for patients with new platinum-resistant disease who may have received prior treatments during the platinum-sensitive stage of their disease, provided the patient has good performance status and no contraindications to bevacizumab.
				
				4. When bevacizumab is used in combination with paclitaxel or topotecan for platinum-resistant ovarian cancer, the costs of paclitaxel and topotecan are funded through the Systemic Treatment Quality-Based Procedure (ST-QBP) and are included in the band level pricing.
				
				5. Platinum resistance is defined as clinical or radiological disease progression within 6 months following platinum-based therapy.
				
				6. Bevacizumab must be initiated with chemotherapy. In the event of toxicity requiring discontinuation of an agent, CCO will fund continuation of therapy with the remaining agent(s).
				
				7. CCO will fund bevacizumab when used with one of the following regimens –
				a. bevacizumab 10mg/kg every 2 weeks with paclitaxel 80mg/m^2 on Days 1, 8, 15, 22 every 4 weeks [ST-QBP: PACL(W)+BEVA];
				b. bevacizumab 10mg/kg every 2 weeks with pegylated liposomal doxorubicin 40mg/m^2 Day 1 every 4 weeks [STQBP: PGLDX+BEVA];
				c. bevacizumab 10mg/kg every 2 weeks with topotecan 4mg/m^2 Days 1, 8, 15 every 4 weeks [ST-QBP: TOPO(W)+BEVA];

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
		platinum refractory. Patients who have received NDFP funding for frontline bevacizumab are not eligible for the time-limited funding. A clinic note confirming the above needs to be submitted to CCO as part of the enrolment.		d. bevacizumab 15mg/kg every 3 weeks with topotecan 1.25mg/m^2 Days 1 to 5 every 3 weeks [ST-QBP: TOPO+BEVA].
Bevacizumab (Biosimilar) (be-vuh-SIZ-uh-mab bye-oh-SIH-mih-lar) Other names: Mvasi®, Zirabev®, Bambevi®, Abevmy®, Aybintio®, Vegzelma®	Previously Untreated Unresectable or Metastatic Hepatocellular Carcinoma	Atezolizumab is used in combination with bevacizumab for the first-line treatment of adult patients with unresectable or metastatic hepatocellular carcinoma (HCC) who require systemic therapy and have had no prior systemic treatment. Treatment should be for patients with an Eastern Cooperative Oncology Group (ECOG) Performance Status of 0 or 1 and a Child-Pugh 'A' liver function classification.	Atezolizumab 1200 mg intravenously (IV) and bevacizumab 15 mg/kg IV on day 1 of each 21-day cycle. Treatment with atezolizumab and bevacizumab should be continued until loss of clinical benefit* or unacceptable toxicity, whichever comes first. [ST-QBP regimen code: ATEZBEVA] *In the pivotal trial, loss of clinical benefit was determined after an assessment of biochemical and radiographic data and of clinical status (e.g., symptomatic deterioration such as pain due to disease). Treatment beyond radiographic disease progression could continue if there is observed evidence of clinical benefit, and symptoms and signs indicating unequivocal disease progression are absent.	1. Patients with fibrolamellar HCC, sarcomatoid HCC, or mixed cholangiocarcinoma and HCC are not eligible for funding under this policy. 2. Patients who stop either atezolizumab or bevacizumab due to intolerance may continue treatment with the remaining agent in the absence of progression if the clinician determines there would be clinical benefit. Monotherapy with the remaining agent should stop if the patient develops intolerance or has progression.
Blinatumomab (blin-a-too-moo-mab) Other name: Blincyto®	Minimal Residual Disease (MRD)-Positive B-cell Precursor Acute Lymphoblastic Leukemia	The patient must meet the following criteria: Blinatumomab is used for the treatment of adult and pediatric patients with Philadelphia chromosome-negative (Ph-), CD19 positive (CD19+), B-cell precursor acute lymphoblastic leukemia (BCP-ALL) who are in first or second hematologic complete remission (CR) and are minimal residual disease positive (MRD+).	<u>Funded dose for patients 45 kg or over:</u> Blinatumomab 28 mcg/day for days 1-28, followed by a 14-day treatment-free interval. <u>Funded dose for patients under 45 kg:</u> Blinatumomab 15 mcg/m^2/day for 28 days, followed by a 14-day treatment-free interval. Treatment should be continued until unacceptable toxicity, hematologic relapse, MRD	1. Patients treated with 4 cycles of blinatumomab under this policy will not be eligible for blinatumomab retreatment for relapsed ALL. 2. Patients with Philadelphia chromosome-positive ALL, MRD negative or unknown status are not eligible for blinatumomab under this policy. 3. NDFP will provide coverage of blinatumomab in both the inpatient and outpatient settings, provided that funding criteria are met. 4. NDFP recognizes that the amount of drug used to prepare the IV solution for infusion exceeds the amount that is infused into the patient due to the unique preparation method (i.e., an "overfill" of drug is required to account for the priming of the IV line and to ensure that the

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
		MRD+ disease is defined as MRD detected at a level greater than or equal to 0.1% (i.e.,≥ 10^{-3}) Patients should have received, over the course of their treatment for BCP-ALL, a minimum of 3 intensive chemotherapy blocks of a treatment regimen that is age-appropriate and given with curative intent before proceeding to blinatumomab therapy.	relapse, treatment with hematopoietic stem cell transplant (HSCT), or up to the completion of 4 cycles. Maintenance or consolidation therapy after HSCT is not funded. [ST-QBP regimen code: BLIN]	patient will receive the prescribed dose of blinatumomab.). This "overfill" amount will be automatically captured in eClaims according to the treatment doses submitted.
Blinatumomab (blin-a-too-moo-mab) Other name: Blincyto®	Relapsed or Refractory Acute Lymphoblastic Leukemia (Ph- BCP-ALL)	The patient must meet the following criteria: Adult patients with Philadelphia chromosome-negative (Ph-) relapsed or refractory B precursor acute lymphoblastic leukemia (ALL). Treatment should be for patients with a good performance status.	Cycle 1: Blinatumomab 9 mcg/day for days 1-7, followed by blinatumomab 28 mcg/day for 21 days, followed by a 14-day treatment-free interval (ST-QBP regimen code: BLIN). Cycles 2-5: Blinatumomab 28 mcg/day for 28 days, followed by a 14-day treatment-free interval (ST-QBP regimen code: BLIN).	1. New Drug Funding Program (NDFP) will provide coverage of blinatumomab in both the inpatient and outpatient settings, provided that funding criteria are met. 2. NDFP recognizes that the amount of drug used to prepare the IV solution for infusion exceeds the amount that is infused into the patient due to the unique preparation method (i.e., an "overfill" of drug is required to account for the priming of the IV line and to ensure that the patient will receive the prescribed dose of blinatumomab.). This "overfill" amount will be automatically captured in eClaims according to the treatment doses submitted. 3. NDFP will provide funding for 2 cycles of induction and 3 cycles of consolidation. Maintenance blinatumomab is not funded by NDFP. 4. For patients currently enrolled on the third line blinatumomab policy, treatments can continue to be submitted on the existing policy. Please note, however, that the existing policy will be archived and no longer available for new patient enrolments. 5. Patients who completed 4 cycles of blinatumomab for minimal residual disease-positive BCP-ALL are not eligible for blinatumomab retreatment.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
Blinatumomab (blin-a-too-moo-mab) Other name: Blincyto®	Relapsed or Refractory Acute Lymphoblastic Leukemia (Ph+ BCP-ALL)	The patient must meet the following criteria: • Adult patients with Philadelphia chromosome-positive B-cell precursor acute lymphoblastic leukemia (Ph+ BCP-ALL) who have been treated with at least two prior tyrosine kinase inhibitors (TKIs) and have relapsed or refractory (R/R) disease. Treatment should be for patients with good performance status.	Cycle 1: Blinatumomab 9 mcg/day for days 1-7, followed by blinatumomab 28 mcg/day for 21 days, followed by a 14-day treatment-free interval (ST-QBP regimen code: BLIN). Cycles 2-5: Blinatumomab 28 mcg/day for 28 days, followed by a 14-day treatment-free interval (ST-QBP regimen code: BLIN). Continue treatment until unacceptable toxicity or disease progression to a maximum of 2 cycles for induction and 3 cycles for consolidation.	1. NDFP will provide coverage of blinatumomab in both the inpatient and outpatient settings, provided that funding criteria are met. 2. NDFP recognizes that the amount of drug used to prepare the IV solution for infusion exceeds the amount that is infused into the patient due to the unique preparation method (i.e., an "overfill" of drug is required to account for the priming of the IV line and to ensure that the patient will receive the prescribed dose of blinatumomab.). This "overfill" amount will be automatically captured in eClaims according to the treatment doses submitted.
Blinatumomab (blin-a-too-moo-mab) Other name: Blincyto®	Relapsed or Refractory Pediatric Acute Lymphoblastic Leukemia	The patient must meet the following criteria: For the treatment of pediatric patients with Philadelphia chromosome-negative (Ph-) relapsed or refractory B precursor acute lymphoblastic leukemia (ALL) who are in second or later relapse, or who relapsed after allogeneic hematopoietic stem cell transplant (alloHSCT), or who have refractory disease. Treatment should be in patients with a good performance status and no active central nervous system disease.	Cycle 1: Blinatumomab 5 mcg/m^2/day for days 1-7, followed by blinatumomab 15 mcg/m^2/day for 21 days, followed by a 14-day treatment-free interval Subsequent cycles (up to a maximum of 5 total cycles): Blinatumomab 15 mcg/m^2 /day for 28 days, followed by a 14-day treatment-free interval Patients achieving a complete response (CR) within the first two treatment cycles could receive up to three additional cycles of blinatumomab (5 cycles maximum).	1. NDFP will provide coverage of blinatumomab in both the inpatient and outpatient settings, provided that funding criteria are met. 2. NDFP recognizes that the amount of drug used to prepare the IV solution for infusion exceeds the amount that is infused into the patient due to the unique preparation method (i.e., an "overfill" of drug is required to account for the priming of the IV line and to ensure that the patient will receive the prescribed dose of blinatumomab.). This "overfill" amount will be automatically captured in eClaims according to the treatment doses submitted. 3. Patients who completed 4 cycles of blinatumomab for minimal residual disease-positive BCP-ALL are not eligible for blinatumomab retreatment.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
Bortezomib (bore-TEH-zo-mib) Other name: Velcade®	In Combination with Lenalidomide and Dexamethasone for Previously Untreated Multiple Myeloma Without Intent for Stem Cell Transplantation	The patient must meet the following criteria: Bortezomib is used in combination with lenalidomide and low-dose dexamethasone (RVd) in patients with newly diagnosed multiple myeloma, good performance status, and in whom stem cell transplantation is not intended.	Bortezomib 1.3 mg/m^2 or 1.5 mg/m^2 intravenously (IV) or subcutaneously (SC) days 1, 8, and 15, in combination with lenalidomide and dexamethasone, every 3 weeks for 8 cycles. Bortezomib can also be given at 1.3 mg/m^2 IV or SC on days 1, 4, 8, and 11 every 3 weeks. All cycles of bortezomib are given with lenalidomide and dexamethasone. Starting with cycle 9 onwards, lenalidomide and dexamethasone should be continued as maintenance until disease progression or unacceptable toxicity. ST-QBP regimen code: BORTDEXALENA	1. Please refer to the Ontario Drug Benefit Formulary for the Limited Use criteria for lenalidomide. 2. Regardless of the chosen administration schedule (i.e. once weekly or twice weekly), bortezomib will be funded for a total of eight 3-week cycles. 3. Patients who are refractory to lenalidomide will not be eligible for daratumumab or carfilzomib-based triplets that are used in combination with lenalidomide. 4. Patients who start treatment and are subsequently deemed transplant ineligible may complete induction therapy under this policy (up to 8 cycles of bortezomib-based therapy in total). 5. On a time-limited basis (until [3 months after effective date]), patients who initiated lenalidomide and dexamethasone therapy for previously untreated multiple myeloma in the previous 3 months may add bortezomib to their treatment regimen provided the patient's disease has not progressed on lenalidomide and dexamethasone. 6. Patients who require treatment interruptions, but have not progressed, may resume therapy at a later date to complete up to 8 cycles of bortezomib (in combination with lenalidomide and dexamethasone).
Bortezomib (bore-TEH-zo-mib) Other name: Velcade®	Previously Untreated Multiple Myeloma – Pre-Stem Cell Transplant	The patient has newly diagnosed multiple myeloma and is eligible for autologous stem cell transplantation[a] Bortezomib is used as a component of induction therapy pre-autologous stem cell transplantation (ASCT)[b]	Bortezomib must be used as part of combination therapy. Funded doses may include either of the following: Bortezomib 1.3 mg/m^2 IV or sc Days 1, 4, 8, and 11 of each cycle for 4 cycles[c] (1 cycle = 21 days), or Bortezomib 1.5 mg/m^2 IV or sc weekly on Days 1, 8, 15, and 22 of each cycle for 4 cycles[c] (1 cycle = 28 days)	[a]The patient must not have received prior therapy (e.g., dexamethasone, chemotherapy, or immunomodulator-based therapy) for multiple myeloma. [b]Bortezomib-based combination therapy can include the addition of dexamethasone, alkylator or anthracycline chemotherapy, or immunomodulator-based therapy to the bortezomib backbone. [c]For additional doses, prior authorization is required.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
Bortezomib (bore-TEH-zo-mib) Other name: Velcade®	Previously Untreated – Multiple Myeloma	The patient has previously untreated multiple myeloma and is unsuitable for stem cell transplantation Bortezomib will be given as part of a combination therapy	Bortezomib will be given as part of VMP or CyBorD. For VMP, the bortezomib dose is 1.3 mg/m2 IV or SC, given on days 1, 4, 8, 11, 22, 25, 29, 32 on a six week cycle for cycles 1 to 4; and given on days 1, 8, 22, 29 on a six week cycle for cycles 5 to 9. Patients who are not able to tolerate the twice weekly bortezomib schedule may be switched to (or initially offered) the once weekly bortezomib schedule (Blood. 2010; 116(23):4745-4743). The once weekly bortezomib dose is 1.3mg/m2 (as part of the VMP regimen) on days 1, 8, 15 and 22 every 35 days (cycles 1-9). For CyBorD, the bortezomib dose is 1.3 to 1.5mg/m2 IV or SC on Days 1, 8, 15, and 22 every 4 weeks for up to 8 or 9 cycles. A minimum of 72 hours is required between bortezomib doses.	N/A

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
Bortezomib (bore-TEH-zo-mib) Other name: Velcade®	Previously Untreated Transplant Ineligible Mantle Cell Lymphoma	Bortezomib (in combination with rituximab, cyclophosphamide, doxorubicin, and prednisone as part of VR-CAP) is used for the treatment of patients with previously untreated mantle cell lymphoma who are ineligible for an autologous stem cell transplant.	Bortezomib 1.3 mg/m2 intravenously (IV) or subcutaneously (SC) on days 1, 4, 8, and 11 every 21 days OR Bortezomib 1.3 to 1.5 mg/m2 IV or SC on days 1, 8, and 15 every 21 days. Treatment should be continued until disease progression, unacceptable toxicity or up to a maximum of 8 cycles, whichever occurs first. [ST-QBP regimen code: BORTCYCDOXPRED+R]	1. Enrolment in this policy is for the funding of bortezomib only. For rituximab funding, please complete the policy "Rituximab (Biosimilar IV) and Rituximab SC in Combination with Chemotherapy - Indolent B-cell Lymphoma."
Bortezomib (bore-TEH-zo-mib) Other name: Velcade®	Relapsed or Refractory Multiple Myeloma	Please select one of the following criteria: a. The patient has multiple myeloma that is refractory to or has relapsed within one year of the conclusion of initial or subsequent treatment(s) and is suitable for further chemotherapy b. The patient has relapsed at least one year after autologous stem cell transplantation c. Bortezomib is used, with or without dexamethasone, for the retreatment of patients with relapsed or refractory multiple myeloma who have not progressed on prior proteasome inhibitor therapy	Patient will receive Bortezomib: - 1.3 mg/m² IV or SC on days 1, 4, 8 and 11 every 3 weeks for eight cycles, followed by treatment on days 1, 8, 15, and 22 every 5 weeks - Weekly 1.3 mg/m² IV or SC	1. Funding does not extend to maintenance treatment for multiple myeloma patients post-autologous stem cell transplantation.
Brentuximab Vedotin (bren-tuk-see- mab veh-doe-tin) Other name: Adcertis®	Consolidation Post-Autologous Stem Cell Transplant (ASCT) for Hodgkin Lymphoma	Brentuximab vedotin will be used for the post-autologous stem cell transplant (ASCT) consolidation treatment of patients with Hodgkin lymphoma (HL) at increased risk of relapse or progression*. *Patients with increased risk of relapse or progression as defined in the pivotal trial: • Refractory to frontline therapy or;	Brentuximab vedotin 1.8 mg/kg intravenously (IV) once every 3 weeks until a maximum of 16 cycles, disease progression or unacceptable toxicity, whichever comes first [ST-QBP regimen code: BREN(CONS)].	1. Patients who are not ASCT candidates are not eligible for brentuximab vedotin funding under this policy. 2. The funding of brentuximab vedotin under this policy is not for pre-ASCT use. 3. As per the manufacturer's product monograph, the dose for patients weighing greater than 100 kg should be calculated based on a weight of 100 kg.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
		• Relapsed less than 12 months from frontline therapy or; • Relapse 12 months or greater after frontline therapy with extranodal disease.	Consolidation treatment should be initiated within four to six weeks post-ASCT or upon recovery from ASCT.	4. NDFP will fund brentuximab vedotin monotherapy in a subsequent line of therapy if the patient has had a disease-free interval (DFI) of 12 months or greater from completion of prior brentuximab vedotin.
Brentuximab Vedotin (bren-tuk-see-mab veh-doe-tin) Other name: Adcertis®	In Combination with Chemotherapy for Previously Untreated Peripheral T-cell Lymphoma (PTCL)	Brentuximab vedotin is used for the treatment of previously untreated adult patients with systemic anaplastic large cell lymphoma (sALCL), peripheral T-cell lymphoma not otherwise specified (PTCL-NOS) or angioimmunoblastic T-cell lymphoma (AITL), whose tumours express CD30, in combination with cyclophosphamide, doxorubicin, and prednisone (CHP). Patients with anaplastic lymphoma kinase (ALK) positive sALCL must have an International Prognostic Index (IPI) score of equal or greater than 2.	Brentuximab vedotin 1.8 mg/kg intravenously (IV) once on day 1 with each cycle of CHP, or in combination with cyclophosphamide, etoposide, and prednisone (CEP). Treatment should be continued for six to eight cycles, until disease progression or unacceptable toxicity, whichever comes first. [ST-QBP regimen codes: CHP+BREN or CEP+BREN]	1. As per the manufacturer's product monograph, the dose for patients weighing greater than 100 kg should be calculated based on a weight of 100 kg (i.e., a maximum single dose of 180 mg). 2. Brentuximab vedotin must be started with either CHP or CEP chemotherapy in order to be eligible for funding.
Brentuximab Vedotin (bren-tuk-see-mab veh-doe-tin) Other name: Adcertis®	In Combination with Chemotherapy for Previously Untreated Stage IV Hodgkin Lymphoma	The patient meets the following criteria: Brentuximab vedotin is used for the treatment of previously untreated patients with Stage IV Hodgkin lymphoma (HL) in combination with doxorubicin, vinblastine and dacarbazine (AVD).	Brentuximab vedotin 1.2 mg/kg intravenously (IV) once on day 1 and 15 of each 28 day-cycle with AVD. Treatment should be continued up to a maximum of six cycles, until disease progression or unacceptable toxicity, whichever comes first. [ST-QBP regimen code: AVD+BREN]	1. As per the manufacturer's product monograph, the dose for patients weighing greater than 100 kg should be calculated based on a weight of 100 kg (i.e., a maximum single dose of 120 mg). 2. Brentuximab vedotin must be used with AVD chemotherapy to be eligible for funding. 3. Patients with nodular lymphocyte-predominant Hodgkin lymphoma, or cerebral or meningeal disease (including signs and symptoms of progressive multifocal leukoencephalopathy) are not eligible for funding under this policy. 4. There is currently insufficient evidence to support funding under this policy for patients under 18 years of age based on the pivotal trial. 5. As the Health Canada approved indication is specific to patients with stage IV disease, patients with stage III (or earlier stage) HL will not be eligible for funding under this policy.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
Brentuximab Vedotin (bren-tuk-see-mab veh-doe-tin) Other name: Adcertis®	Previously Treated Primary Cutaneous Anaplastic Large Cell Lymphoma or Mycosis Fungoides	Brentuximab vedotin is used for the treatment of adult patients with CD30-positive primary cutaneous anaplastic large cell lymphoma (pcALCL) or mycosis fungoides (MF) who have had prior systemic therapy and have good performance status. Patients with MF must have received at least one prior systemic therapy and patients with pcALCL must have at least one prior systemic therapy or prior radiation therapy.	Brentuximab vedotin 1.8 mg/kg intravenously (IV) once on day 1 of each 21-day cycle. Treatment should be continued until disease progression, unacceptable toxicity, or up to a maximum of 16 cycles, whichever comes first. ST-QBP regimen code: [BREN]	1. As per the manufacturer's product monograph, the dose for patients weighing greater than 100 kg should be calculated based on a weight of 100 kg (i.e., a maximum single dose of 180 mg). 2. Patients with subtypes of cutaneous T-cell lymphoma that are not pcALCL or MF (including Sezary Syndrome) are not eligible for brentuximab vedotin funding under this policy. 3. Brentuximab vedotin is only funded as monotherapy under this policy. 4. Upon disease relapse, patients may be funded for up to an additional 16 cycles of brentuximab vedotin retreatment if there was no disease progression within 6 months of the last dose of brentuximab vedotin and all other funding criteria are met. Claims should be submitted under the same enrolment form used for initial treatment.
Brentuximab Vedotin (bren-tuk-see-mab veh-doe-tin) Other name: Adcertis®	Relapsed or Refractory Hodgkin Lymphoma	Brentuximab vedotin will be used in patients with Hodgkin's lymphoma who have relapsed disease following autologous stem cell transplant (ASCT) and who have an ECOG performance status of 0 or 1.	Brentuximab vedotin 1.8 mg/kg IV every 3 weeks until disease progression or unacceptable toxicity.	1. A clinic note confirming relapse post autologous stem cell transplantation and a pathology report confirming CD30+ve Hodgkin's lymphoma must be submitted to CCO prior to the start of treatment. 2. Treatments beyond 16 cycles require documentation showing continued evidence of benefit (i.e., a clinic note and CT scan confirming that there is no evidence of disease progression). The documentation can be submitted with the treatment claims. 3. Patients who are not candidates for ASCT and who have relapsed disease following at least two prior multi-agent chemotherapies are not eligible for brentuximab funding. 4. Use of brentuximab vedotin prior to ASCT or as maintenance after ASCT will not be funded. 5. As per the manufacturer's product monograph, the maximum dose that can be administered is based on a weight of 100kg. 6. NDFP will fund brentuximab vedotin monotherapy in a subsequent line of therapy if the patient has had a disease-free interval (DFI) of 12 months or greater from completion of prior brentuximab vedotin (in combination with chemotherapy) or brentuximab vedotin consolidation. Retreatment with brentuximab vedotin (in combination with chemotherapy) will not be funded.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
Brentuximab Vedotin (bren-tuk-see-mab veh-doe-tin) Other name: Adcertis®	Systemic Anaplastic Large Cell Lymphoma	Brentuximab vedotin will be used as monotherapy in patients with systemic anaplastic large cell lymphoma who have failed at least one prior multi-agent chemotherapy regimen and who have an ECOG performance status of 0 or 1.	Brentuximab vedotin 1.8 mg/kg IV every 3 weeks until disease progression or unacceptable toxicity.	1. A pathology report confirming CD30+ve systemic anaplastic large cell lymphoma and a clinic note outlining the patient's treatment history must be submitted to CCO prior to the start of treatment. 2. Treatments beyond 16 cycles require documentation showing continued evidence of benefit (i.e., a clinic note and CT scan confirming that there is no evidence of disease progression). The documentation can be submitted with the treatment claims. 3. Use of brentuximab vedotin in the first line setting or as a bridge to allogeneic stem cell transplant will not be funded. 4. As per the manufacturer's product monograph, the maximum dose that can be administered is based on a weight of 100kg. 5. Romidepsin (or pralatrexate) funding is also available for patients with the CD30+ systemic anaplastic large cell lymphoma subtype of peripheral T-cell lymphoma, provided funding criteria are met. No evidence exists to inform the optimal sequencing for brentuximab vedotin versus pralatrexate or romidepsin. The choice in sequencing should be based on a discussion between the treating hematologist and patient. 6. NDFP will fund brentuximab vedotin monotherapy in a subsequent line of therapy if the patient has had a disease-free interval (DFI) of six months or greater from completion of prior brentuximab vedotin (in combination with chemotherapy). Retreatment with brentuximab vedotin (in combination with chemotherapy) will not be funded.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
Cabazitaxel (ca-BA-zee-tax-el) Other name: Jevtana™	Metastatic Castration –Resistant Prostate Cancer	Cabazitaxel will be used in combination with prednisone for the treatment of metastatic castration-resistant prostate cancer (mCRPC) in patients who have received a prior docetaxel-containing regimen.	Cabazitaxel 20 mg/m2 or 25 mg/m2 IV every 3 weeks (with 10 mg oral prednisone daily) until disease progression.	1. Cabazitaxel is not funded if used in combination with abiraterone, or enzalutamide, or radium-223 for mCRPC. 2. Cabazitaxel is funded in the mCRPC setting in patients who have progressed on/after prior docetaxel-containing chemotherapy and an androgen-receptor-axis-targeted agent (ARAT), regardless of the order of treatment or treatment setting(s).
Carfilzomib (kar-FILZ-oh-mib) Other name: Kyprolis®	In combination with dexamethasone – relapsed multiple myeloma	Carfilzomib is used in combination with dexamethasone for patients with relapsed myeloma with a good performance status who have received one to three prior treatments.	Cycle 1 - carfilzomib 20 mg/m² days 1 and 2, followed by carfilzomib 56 mg/m² days 8, 9, 15, 16 Cycle 2 and beyond - carfilzomib 56 mg/m² days 1, 2, 8, 9, 15, 16 Carfilzomib is funded when used in combination with dexamethasone (ST-QBP regimen code: CARFDEXA).	1. Retreatment with carfilzomib is not publicly funded (i.e. if patients previously received carfilzomib, regardless of funding source, they are not eligible to receive carfilzomib under this policy). 2. Carfilzomib must be initiated with dexamethasone to be eligible for funding.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
Carfilzomib (kar-FILZ-oh-mib) Other name: Kyprolis®	In combination with dexamethasone and lenalidomide – relapsed multiple myeloma	• Carfilzomib is used in combination with lenalidomide and dexamethasone for patients with multiple myeloma who have received at least one prior treatment. • Treatment should be in patients who have good performance status and are deemed to have adequate renal function. • The patient's disease did not progress during treatment with bortezomib. • If previously treated with lenalidomide, the patient did not discontinue due to adverse events or had disease progression during the first 3 months of treatment. • If the patient was most recently treated with lenalidomide, the patient's disease has not progressed at any time during treatment.	Cycle 1 - carfilzomib 20 mg/m² days 1 and 2, followed by carfilzomib 27 mg/m² days 8, 9, 15, 16 Cycle 2-12 - carfilzomib 27 mg/m² days 1, 2, 8, 9, 15, 16 Cycle 13-18 - carfilzomib 27 mg/m² days 1, 2, 15, 16 Carfilzomib is funded when used in combination with lenalidomide and dexamethasone (ST-QBP regimen code: CARFDEXALENA). Treatment with carfilzomib should continue until disease progression or unacceptable toxicity, up to a maximum of 18 cycles.	1. Retreatment with carfilzomib is not publicly funded (i.e. if patients previously received carfilzomib, regardless of funding source, they are not eligible to receive carfilzomib under this policy). 2. Patients transitioning from a private payer or compassionate program will be eligible for a total of 18 cycles of carfilzomib. 3. Carfilzomib must be initiated with lenalidomide and dexamethasone to be eligible for funding. 4. Patients who start with lenalidomide/dexamethasone for relapsed multiple myeloma may add carfilzomib to the treatment regimen provided the patient meets all criteria at the point of carfilzomib addition.
Cemiplimab (seh-MIP-lih-mab) Other name: Libtayo™	Metastatic or Locally Advanced Cutaneous Squamous Cell Carcinoma	• Cemiplimab is used for patients with metastatic or locally advanced cutaneous squamous cell carcinoma (CSCC) who are not candidates for curative surgery or curative radiation. • Treatment should be for previously treated (prior radiation and/or surgery) or treatment naive patients who are not amenable to curative surgery or curative radiation with good performance status.	Cemiplimab 350 mg as a fixed dose intravenously (IV) every 3 weeks. Alternatively, a weight-based dose of 3 mg/kg IV every 2 weeks for patients with low body weight (i.e., a body mass index (BMI) of < 18.5 kg/m^2) may be considered. Treatment with cemiplimab should continue up to 96 weeks or until symptomatic disease progression or unacceptable toxicity, whichever occurs first. ST-QBP regimen code: CEMI	1. Patients may be retreated with cemiplimab provided they did not experience disease progression while being treated with cemiplimab, and are otherwise eligible for this therapy. Claims for retreatment should be submitted under the same enrolment form used for initial treatment. Retreatment may be funded for up to 96 weeks of therapy. 2. Patients with CSCC who have previously received anti-PD-1 or anti-PD-L1 therapy will not be eligible for funding under this policy. 3. Cemiplimab will not be eligible for funding under this policy if used in a neoadjuvant or adjuvant setting.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
Cetuximab (se-TUX-i-mab) Other name: Erbitux®	In Combination with Encorafenib for Previously Treated Metastatic Colorectal Cancer	Cetuximab is used in combination with encorafenib for patients with previously treated BRAF V600E-mutated metastatic colorectal cancer (mCRC). Treatment is only for patients who have received at least one previous systemic treatment for mCRC, have good performance status, adequate organ function, and have not received prior EGFR or BRAF inhibitors.	Cetuximab intravenously (IV) once weekly or every 2 weeks in combination with encorafenib*. Treatment should continue until confirmed disease progression or unacceptable toxicity, whichever comes first. *The recommended dose of encorafenib for this indication is 300 mg orally once daily. [ST-QBP regimen code: ENCO+CETU] Approved dosing schedules: (in combination with encorafenib): • Loading dose of 400 mg/m2 IV, followed by 250 mg/m2 IV once weekly • 500 mg/m2 IV every 2 weeks (no loading dose)	1. Please refer to the Ministry of Health's Exceptional Access Program for full reimbursement criteria for encorafenib when used in combination with cetuximab for mCRC. 2. Patients are eligible for one line of EGFR inhibitor-based therapy guided by biomarker findings (e.g., panitumumab with multi-agent chemotherapy, panitumumab in combination with encorafenib, cetuximab in combination with encorafenib, single agent panitumumab, or cetuximab in combination with irinotecan). 3. In the event encorafenib or cetuximab is discontinued due to unacceptable toxicity, the other drug must also be discontinued.
Cetuximab (se-TUX-i-mab) Other name: Erbitux®	With Irinotecan - Metastatic Colorectal, Small Bowel, or Appendiceal Cancer	a. The patient has metastatic colon, rectal, small bowel, or appendiceal cancer b. The patient has failed chemotherapy regimens containing oxaliplatin and irinotecan c. The tumour has non-mutated (wild-type) RAS oncogene d. Cetuximab will be used in combination with irinotecan	One of the following regimens for cetuximab: • Loading dose of 400 mg/m^2 IV, followed by weekly 250 mg/m^2 IV until disease progression, or • 500 mg/m^2 every 2 weeks (no loading dose) One of the following regimens for irinotecan: • 350 mg/m^2 IV every 3 weeks, or • 180 mg/m^2 every 2 weeks, or • 125 mg/m^2 on days 1, 8, 15 and 22 every 6 weeks	1. Treatments administered prior to RAS testing will not be reimbursed. 2. A copy of the RAS test result must be provided to the NDFP. 3. If the patient experiences intolerance to this regimen and the physician would like to use panitumumab, please submit a Prior Approval request for panitumumab in eClaims along with relevant documentation for review. 4. Patients are eligible for one line of EGFR inhibitor-based therapy guided by biomarker findings (e.g., panitumumab with multi-agent chemotherapy, panitumumab in combination with encorafenib, cetuximab in combination with encorafenib, single agent panitumumab, or cetuximab in combination with irinotecan). 5. Irinotecan is funded through the Systemic Treatment Quality-Based Procedure (ST-QBP) and is included in the band level pricing.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
Cetuximab (se-TUX-i-mab) Other name: Erbitux®	Locally Advanced Squamous Cell Carcinoma of the Head and Neck (and radiation)	a. The patient has locally or regionally advanced squamous cell carcinoma of the head and neck without distant metastases b. The patient is unable to use cisplatin or carboplatin/5FU due to a medical contraindication (i.e., true platinum allergy or where the use of myelosuppressive drugs is contraindicated) c. Cetuximab use must be with curative radical radiotherapy.	Cetuximab 400 mg/m^2 IV loading dose, followed by 250 mg/m^2 IV weekly for 6 to 7 weeks. [ST-QBP regimen code: CETU(RT)] Treatment is limited to the duration of radiation therapy	N/A
Cetuximab (se-TUX-i-mab) Other name: Erbitux®	Previously Treated Metastatic Colorectal Cancer (with encorafenib)	• Cetuximab is used in combination with encorafenib for patients with previously treated BRAF V600E-mutated metastatic colorectal cancer (mCRC). • Treatment is only for patients who have received at least one previous systemic treatment for mCRC, have good performance status, adequate organ function, and have not received prior EGFR or BRAF inhibitors.	Cetuximab intravenously (IV) once weekly or every 2 weeks in combination with encorafenib*. Treatment should continue until confirmed disease progression or unacceptable toxicity, whichever comes first. *The recommended dose of encorafenib for this indication is 300 mg orally once daily. [ST-QBP regimen code: ENCO+CETU]. Please select the approved dosing schedule for cetuximab (used in combination with encorafenib): • Loading dose of 400 mg/m2 IV, followed by 250 mg/m2 IV once weekly; • 500 mg/m2 IV every 2 weeks (no loading dose).	1. Please refer to the Ministry of Health's Exceptional Access Program for full reimbursement criteria for encorafenib when used in combination with cetuximab for mCRC. 2. Patients are eligible for one line of EGFR inhibitor-based therapy guided by biomarker findings (e.g., panitumumab with multi-agent chemotherapy, panitumumab in combination with encorafenib, cetuximab in combination with encorafenib, single agent panitumumab, or cetuximab in combination with irinotecan). 3. In the event encorafenib or cetuximab is discontinued due to unacceptable toxicity, the other drug must also be discontinued.
Clodronate (CLOE-dron-ate) Other names: Bonefos®, Ostac®, Clasteon®	Metastatic Breast Cancer	The patient must meet criteria a, b and one of c: a. The patient has metastatic breast cancer b. The patient has bone metastases c. The patient:	Maximum dose: clodronate 1500 mg every 3 to 4 weeks	N/A

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
		• was given oral clodronate and is unable to tolerate it • is likely to be unable to tolerate oral clodronate (e.g. the patient is on IV chemotherapy or has pre-existing nausea related to medications or disease)		
Crisantaspase Recombinant ( ) Other name: Rylaze®	Acute Lymphoblastic Leukemia, Lymphoblastic Lymphoma, Mixed or Biphenotypic Leukemia	Crisantaspase recombinant is used for the treatment of pediatric and adult patients with acute lymphoblastic leukemia, lymphoblastic lymphoma, or mixed/biphenotypic leukemia with a documented hypersensitivity reaction or silent inactivation to an Escherichia coli (E.coli)-derived asparaginase.	Crisantaspase recombinant intramuscularly (IM) three times per week (25 mg/m2 on Monday and Wednesday, then 50 mg/m2 on Friday) for a total of 6 doses to replace each planned dose of pegaspargase. Treatment should be discontinued in patients who experience a hypersensitivity reaction, silent inactivation, high grade toxicities, or evidence of disease progression.	1. Patients with a history of a hypersensitivity reaction to an E. coli-derived asparaginase should have experienced a grade 3 (or higher) allergic reaction as per the Common Terminology Criteria for Adverse Events (version 5.0). 2. There is a risk of medication errors between the available asparaginase products. Please note that crisantaspase recombinant is dosed using milligrams per meter squared and not by units per meter squared. 3. Patients should not be treated with crisantaspase recombinant if they have a history of grade 3 or higher pancreatitis (per the Common Terminology Criteria for Adverse Events, version 5.0). 4. In the literature, a nadir serum asparaginase activity (NSAA) level of greater than or equal to 0.1 IU/mL was considered to be the minimum threshold for adequate asparaginase activity. 5. Crisantaspase recombinant will be reimbursed on a per vial basis.
Daratumumab (da-ra-TOO-moo-mab) Other Names: Darzalex®	And Bortezomib in combination with Cyclophosphamide and Dexamethasone – Previously Untreated Light Chain (AL) Amyloidosis	Daratumumab and bortezomib (in combination with cyclophosphamide and dexamethasone) is used for the treatment of adult patients with previously untreated light chain (AL) amyloidosis and who have a good performance status.	• Cycles 1 to 2: Daratumumab 1800 mg subcutaneously (SC) on day 1, 8, 15, and 22 Bortezomib 1.3 mg/m^2 SC on day 1, 8, 15, and 22 • Cycles 3 to 6: Daratumumab 1800 mg SC on day 1 and 15 Bortezomib 1.3 mg/m^2 SC on day 1, 8, 15, and 22 • Cycles 7 to 24: Daratumumab 1800 mg SC on day 1 (1 cycle = every 28 days) For cycles 1 to 6, daratumumab and bortezomib are administered in combination with cyclophosphamide and dexamethasone. For	1. Completion of this form will enroll the patient in both daratumumab and bortezomib. 2. The patient should demonstrate the following: a. Histopathologic diagnosis of systemic AL amyloidosis based on detection by immunohistochemistry and polarizing light microscopy of green birefringent in Congo red-stained tissue specimens or characteristic electron microscopy appearance; b. Measurable disease by serum M protein greater than or equal to 5 g/L OR abnormal serum free light chain ratio OR difference between involved and uninvolved free light chains (dFLC) greater than or equal to 50 mg/L; c. Involvement of at least one organ system; d. Adequate hematologic, hepatic, and renal function.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
			cycles 7 to 24, daratumumab monotherapy is administered as maintenance. Treatments will be funded until evidence of hematologic progression or organ decompensation while on treatment, unacceptable toxicity, or up to a maximum of 24 cycles (whichever occurs first). [ST-QBP regimen codes: CYBORD+DARA(SC) then DARA(MNT-SC)]	3. Patients previously treated for AL amyloidosis will not be eligible for funding under this policy. 4. Patients with a previous history or current diagnosis of multiple myeloma (including the presence of lytic bone disease, plasmacytomas, greater than or equal to 60% plasma cells in bone marrow, or hypercalcemia) will not be eligible for funding under this policy. In addition, patients previously treated for multiple myeloma (including medications that target CD38) will not be eligible for funding. 5. Patients with a planned autologous stem cell transplant (ASCT) during the first 6 cycles of this treatment regimen will not be eligible for funding. 6. Patients with non-AL amyloidosis will not be eligible for funding. 7. Patients with advanced cardiac disease (Mayo Cardiac Stage IIIB or NYHA Classification IIIB or IV heart failure) are eligible for funding at the discretion of the treating clinician.
Daratumumab (da-ra-TOO-moo-mab) Other Names: Darzalex®	In Combination with Bortezomib-Based Regimen for Newly Diagnosed Transplant Ineligible Multiple Myeloma	The patient must meet the following criteria: Daratumumab is used in combination with either bortezomib, melphalan and prednisone (DVMP) or cyclophosphamide, bortezomib and dexamethasone (DCyBorD) for the treatment of patients with newly diagnosed multiple myeloma who are not suitable for autologous stem cell transplant and have good performance status.	Daratumumab if used in combination with CyBorD (1 cycle = 4 weeks) Subcutaneous (SC) Cycles 1 and 2 – daratumumab 1800mg SC on Days 1, 8, 15, 22; Cycles 3 to 6 – daratumumab 1800mg SC on Days 1 and 15; Cycles 7 and beyond – daratumumab 1800mg SC on Day 1 Or Intravenous (IV) Cycles 1 and 2 – daratumumab 16mg/kg on Days 1, 8, 15, 22; Cycles 3 to 6 – daratumumab 16mg/kg on Days 1 and 15; Cycles 7 and beyond – daratumumab 16mg/kg on Day 1 Daratumumab if used in combination with VMP Subcutaneous (SC)	1. Daratumumab must be used with either VMP or CyBorD to be eligible for funding. No additional anti-myeloma therapies are permitted other than those listed above. 2. Daratumumab is not funded if used • for the treatment of monoclonal gammopathy of undetermined significance (MGUS), or smoldering multiple myeloma, or amyloidosis without evidence of concomitant myeloma; • as maintenance or consolidation post autologous stem cell transplant. 3. Slow gradual biochemical changes, that otherwise would qualify as progression, may not be a reason to change therapy in clinical practice, unless coupled with signs of clinical evidence of progression (such as increased pain, or increased need for supportive measures, or renal failure). The decision to continue daratumumab or move to the next line of therapy is at the discretion of the treating physician. 4. Sites must complete a separate enrolment form for NDFP funding of bortezomib (eClaims form title: Bortezomib - Previously Untreated - Multiple Myeloma).

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
			Cycle 1 – daratumumab 1800mg SC on Days 1, 8, 15, 22, 29, and 36 of a 6-week cycle Cycles 2 to 9 – daratumumab 1800mg SC on Days 1 and 22 every 6 weeks Cycles 10 and beyond – daratumumab 1800mg SC on Day 1 every 4 weeks Intravenous (IV) Cycles 1 – Daratumumab 16mg/kg IV on Days 1, 8, 15, 22, 29, and 36 of a 6-week cycle; Cycles 2 to 9 – Daratumumab 16mg/kg IV on Days 1 and 22 every 6 weeks; Cycles 10 and beyond – Daratumumab 16mg/kg IV on Day 1 every 4 weeks Daratumumab may continue as a single agent following completion of the bortezomib-based regimen, until unacceptable toxicity or disease progression. ST-QBP regimen codes: Daratumumab in combination with VMP (or BMP) [DVMP] – ST-QBP codes - (BMP+DARA, DARA(MNT), BMP+DARA(SC), DARA(MNT-SC)) Daratumumab in combination with CyBorD [DCyBorD] – ST-QBP codes CYBORD+DARA, DARA(MNT), CYBORD+DARA(SC), DARA(MNT-SC))	
Daratumumab (da-ra-TOO-moo-mab) Other Names: Darzalex®	In Combination with Bortezomib and Dexamethasone for Relapsed Multiple Myeloma	Daratumumab is used in combination with bortezomib and dexamethasone for the treatment of patients with multiple myeloma with good performance status who have received at least one prior therapy.	Subcutaneous (SC) Cycles 1 to 3 – daratumumab 1800mg SC once per week for a total of 9 doses; Cycles 4 to 8 – daratumumab 1800mg SC once every 3 weeks for a total of 5 doses; Cycle 9 and onwards – daratumumab 1800mg SC once every 4 weeks. Or Intravenous (IV)	1. Daratumumab must be initiated with bortezomib and dexamethasone to be eligible for funding. No additional anti-myeloma therapies are permitted other than those used as part of this triplet. 2. Patients who start with bortezomib/dexamethasone for relapsed multiple myeloma may add daratumumab to the treatment regimen at a later date, provided the patient meets all criteria at the point of daratumumab addition and there has been no disease progression

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
			Cycles 1 to 3 – daratumumab 16 mg/kg IV once per week for a total of 9 doses; Cycles 4 to 8 – daratumumab 16 mg/kg IV once every 3 weeks for a total of 5 doses; Cycle 9 and onwards – daratumumab 16 mg/kg IV once every 4 weeks. Daratumumab is funded when used in combination with bortezomib and dexamethasone. Cycles 1-8 are given in combination with bortezomib and dexamethasone as part of an every 3-week treatment cycle. Treatment with daratumumab should be continued until disease progression or unacceptable toxicity. ST-QBP regimen codes: BORTDEXADARA or BORTDEXADARA(SC) for cycles 1-8, DARA(MNT) or DARA(MNT-SC)for cycle 9 and beyond.	while on treatment. for cycles 1-8, DARA(MNT) or DARA(MNT-SC)for cycle 9 and beyond. 3. Patients who were previously treated with bortezomib or are currently on bortezomib must meet all of the following criteria to be eligible for the addition of daratumumab: • Bortezomib was not discontinued due to adverse events • The patient's disease is not refractory* to bortezomib *Refractory disease is defined as: 1. Disease progression within 60 days of any dose of bortezomib, or 2. Disease progression while on bortezomib, or 3. Failure to achieve at least a minimal response while on bortezomib 4. Patients whose disease is refractory to both lenalidomide and bortezomib are not eligible for publicly funded daratumumab. 5. Sites must complete a separate enrolment form for NDFP funding of bortezomib (eClaims form title: Bortezomib – Relapsed or Refractory Multiple Myeloma). 6. The use of daratumumab as maintenance or consolidation post-autologous stem cell transplantation is not eligible for NDFP funding under this policy.
Daratumumab (da-ra-TOO-moo-mab) Other Names: Darzalex®	In Combination with Lenalidomide and Dexamethasone for Newly Diagnosed Transplant Ineligible Multiple Myeloma	Daratumumab is used in combination with lenalidomide and dexamethasone (DRd) for the treatment of patients with newly diagnosed multiple myeloma who are not suitable for autologous stem cell transplant and have good performance status.	Subcutaneous (SC) Cycles 1 and 2 – daratumumab 1800mg SC on Days 1, 8, 15, 22; Cycles 3 to 6 – daratumumab 1800mg SC on Days 1 and 15; Cycles 7 and beyond – daratumumab 1800mg SC on Day 1; Or Intravenous (IV) Cycles 1 and 2 – daratumumab 16mg/kg IV on Days 1, 8, 15, 22; Cycles 3 to 6 – daratumumab 16mg/kg IV on Days 1 and 15;	1. Daratumumab must be used with lenalidomide and dexamethasone to be eligible for funding. No additional anti-myeloma therapies are permitted other than those used as part of this regimen. 2. Daratumumab is not funded if used • for the treatment of monoclonal gammopathy of undetermined significance (MGUS), or smoldering multiple myeloma, or amyloidosis without evidence of concomitant myeloma; • as maintenance or consolidation post autologous stem cell transplant. 3. Slow gradual biochemical changes, that otherwise would qualify as progression, may not be a reason to change therapy in clinical practice, unless coupled with signs of clinical evidence of progression (such as increased pain, or increased need for supportive measures, or renal failure). The decision to continue

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
			Cycles 7 and beyond – daratumumab 16mg/kg IV on Day 1 All cycles are given in combination with lenalidomide and dexamethasone as part of an every 4-week treatment cycle. Treatment should continue until unacceptable toxicity or disease progression. (ST-QBP regimen codes: DARADEXALENA, DARADEXALENA(SC))	daratumumab or move to the next line of therapy is at the discretion of the treating physician.
Daratumumab (da-ra-TOO-moo-mab) Other Names: Darzalex®	In Combination with Lenalidomide and Dexamethasone for Relapsed Multiple Myeloma	Daratumumab is used in combination with lenalidomide and dexamethasone for the treatment of patients with multiple myeloma with good performance status who have received at least one prior therapy.	Subcutaneous (SC) Cycles 1 to 2 – daratumumab 1800mg SC once per week for a total of 8 doses; Cycles 3 to 6 – daratumumab 1800mg SC once every 2 weeks for a total of 8 doses; Cycle 7 and beyond – daratumumab 1800mg SC once every 4 weeks. Or Intravenous (IV) Cycles 1 to 2 – daratumumab 16 mg/kg IV once per week for a total of 8 doses; Cycles 3 to 6 – daratumumab 16 mg/kg IV once every 2 weeks for a total of 8 doses; Cycle 7 and beyond – daratumumab 16 mg/kg IV once every 4 weeks. Daratumumab is funded when used in combination with lenalidomide and dexamethasone. All cycles are given in combination with lenalidomide and dexamethasone as part of an every 4-week treatment cycle. Treatment with daratumumab should be continued until disease progression or unacceptable toxicity. ST-QBP regimen codes: DARADEXALENA or DARADEXALEN(SC)	1. Daratumumab must be initiated with lenalidomide and dexamethasone to be eligible for funding. No additional anti-myeloma therapies are permitted other than those used as part of this triplet. 2. CCO will fund one novel triplet therapy for relapsed multiple myeloma (either daratumumab-based or carfilzomib-based). Patients who experience toxicity to one of these triplets may switch once to another triplet within the first 3 months of starting treatment. 3. Patients who were previously treated with lenalidomide or are currently on lenalidomide must meet all of the following criteria to be eligible for the addition of daratumumab: • Lenalidomide was not discontinued due to adverse events • The patient's disease is not refractory* to lenalidomide. *Refractory disease is defined as: • Disease progression within 60 days of any dose of lenalidomide, or • Disease progression while on lenalidomide, or • Failure to achieve at least a minimal response while on lenalidomide. 4. Patients whose disease is refractory to both lenalidomide and bortezomib are not eligible for publicly funded daratumumab. 5. The use of daratumumab as maintenance or consolidation post-autologous stem cell transplantation is not eligible for NDFP funding under this policy

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
Denosumab (den-OH-sue-mab) Other name: Xgeva®	Hormone Refractory Prostate Cancer	Denosumab will be used for the treatment of bony metastases for patients with hormone refractory prostate cancer as determined by an elevated PSA level, or evidence of progressive bony disease, despite castrate serum testosterone levels (<1.7 nmol/L or 50ng/dL)	Denosumab 120 mg SC every 4 weeks	Evidence of progressive bony disease can be demonstrated by progressive changes in radionucleotide bone scan or clinical signs of disease progression (e.g., pathologic fracture or increasing bone pain) Serum testosterone level does not apply for patients who have undergone orchidectomy
Durvalumab (dur-VAL-ue-mab) Other name: Imfinzi®	In Combination with Etoposide and Platinum for Extensive-Stage Small Cell Lung Cancer	Durvalumab is used in combination with etoposide and platinum (EP) chemotherapy (cisplatin or carboplatin), for the treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC) who have not received previous treatment for ES-SCLC, and have good performance status upon treatment initiation with durvalumab.	Durvalumab 1500mg* intravenously (IV), once every 3 weeks (in combination with etoposide and platinum (carboplatin or cisplatin)) for 4 cycles, followed by durvalumab 1500mg once every 4 weeks as monotherapy until disease progression or unacceptable toxicity. *For patients weighing less than or equal to 30kg, a weight-based durvalumab dose of 20mg/kg is used until weight increases to greater than 30kg. [ST-QBP regimen code: Either one of CISPETOP+DURV, or CISPETOP(PO)+DURV, or CRBPETOP+DURV, or CRBPETOP(PO)+DURV, followed by DURV(MNT) for use as monotherapy]	1. Durvalumab must be used in combination with etoposide and platinum chemotherapy, followed by durvalumab maintenance.
Durvalumab (dur-VAL-ue-mab) Other name: Imfinzi®	Locally Advanced Unresectable Stage III Non-Small Cell Lung Cancer Following Concurrent Chemoradiation	Durvalumab is used for the treatment of patients with locally advanced, unresectable stage III non-small cell lung cancer (NSCLC) following curative intent platinum-based concurrent chemoradiation therapy.	Durvalumab 10 mg/kg intravenously (IV) once every 2 weeks up to a maximum of 12 months (or equivalent therapy), or until disease progression or unacceptable toxicity, whichever occurs first (ST-QBP regimen code: DURV). Treatment with durvalumab should be initiated within 6 weeks of completion of concurrent chemoradiation.	2. Patients who progress while on durvalumab are not eligible for anti-PD-1/anti-PD-L1 funding for advanced non-small cell lung cancer. 3. Patients who require a temporary treatment interruption may complete the remaining doses (up to the maximum of 26) as long as the disease has not progressed.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
Enfortumab Vedotin (en-FOR-too-mab veh-DOH-tin) Other name: Padcev®	Previously Treated Advanced or Metastatic Urothelial Cancer	Enfortumab vedotin is used for the treatment of adult patients with locally advanced unresectable or metastatic urothelial cancer (mUC) who have previously received platinum-containing chemotherapy and a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor therapy and have a good performance status.	Enfortumab vedotin 1.25 mg/kg (maximum single dose of 125 mg) given intravenously (IV) on days 1, 8, and 15 of each 28-day cycle until disease progression or unacceptable toxicity, whichever comes first. [ST-QBP regimen code: ENFO]	1. Enfortumab vedotin funding is for single agent use only. 2. Treatment with enfortumab vedotin should not be initiated in patients with pre-existing grade 2 or higher neuropathy or ongoing clinically significant toxicity from previous treatment, active central nervous system (CNS) metastases, uncontrolled diabetes, or active keratitis or corneal ulcerations.
Eribulin (ER-i-BUE-lin) Other name: Halaven®	Metastatic or Incurable Locally Advanced – Breast Cancer	The patient meets all of the following criteria: • Eribulin is used for the treatment of a patient with metastatic or incurable locally advanced breast cancer who has had previous treatment with a taxane and an anthracycline, whose disease has progressed following at least two chemotherapy regimens for metastatic or locally recurrent disease, and whose disease has progressed after the last therapy; and • The patient has good performance status (ECOG ≤ 2)	Eribulin 1.4 mg/m^2 IV on Days 1 and 8 of a 21 day cycle.	N/A
Erwinia Asparaginase (er-WIH-nee-uh as-PAR-a-jin-ase) Other name: Erwinase®	Newly Diagnosed Pediatric Acute Lymphoblastic Leukemia, Lymphoblastic Lymphoma, or Mixed/Biphenotypic Leukemia	The patient must meet the following criteria: Erwinia asparaginase is used in the treatment of front line pediatric[1,2] acute lymphoblastic leukemia, lymphoblastic lymphoma or mixed/biphenotypic leukemia in the event of documented clinical allergy or silent inactivation to pegaspargase. 1. The patient is eligible for Erwinia asparaginase if the diagnosis occurred prior to 18 years of age. 2. If the diagnosis occurred at 18 or 19 years of age, the patient is eligible for CCO funding if Erwinia asparaginase is administered at a POGO-affiliated pediatric cancer centre or satellite site and the patient's care is managed by a pediatric oncology service.	Erwinia asparaginase up to 25,000U/m^2/dose IV or IM	1. Erwinia asparaginase will be reimbursed on a per vial basis. 2. If the diagnosis changes from standard risk to high risk, please send a secure communication to your CCO Reimbursement Analyst to notify them of the change.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
Erwinia Asparaginase (er-WIH-nee-uh as-PAR-a-jin-ase) Other name: Erwinase®	Relapsed or Refractory Pediatric Acute Lymphoblastic Leukemia, Lymphoblastic Lymphoma, or Mixed/Biphenotypic Leukemia	The patient must meet the following criteria: Erwinia asparaginase is used in the treatment of relapsed or refractory pediatric[1,2] acute lymphoblastic leukemia, lymphoblastic lymphoma or mixed/biphenotypic leukemia. 1. The patient is eligible for Erwinia asparaginase if the diagnosis occurred prior to 18 years of age. 2. If the diagnosis occurred at 18 or 19 years of age, the patient is eligible for CCO funding if Erwinia asparaginase is administered at a POGO-affiliated pediatric cancer centre or satellite site and the patient's care is managed by a pediatric oncology service.	Erwinia asparaginase up to 25,000U/m²/dose IV or IM	1. Erwinia asparaginase will be reimbursed on a per vial basis.
Gemcitabine (jem-SITE-a-been) Other name: Gemzar®	Advanced Pancreatic Cancer (with Nab-Paclitaxel)	The patient must meet the following criteria: • The gemcitabine and nab-paclitaxel regimen will be used to treat first-line Advanced Pancreatic Cancer (Locally Advanced Unresectable Pancreatic Cancer or Metastatic Pancreatic Cancer) • Patient's ECOG is less than or equal to 2 at the time of enrolment	Gemcitabine 1000 mg/m^2 and nab-paclitaxel 125 mg/m^2 Days 1, 8, 15 every 28 days	1. Nab-paclitaxel must be administered in combination with gemcitabine, and not as a single-agent. 2. When nab-paclitaxel is used in combination with gemcitabine for advanced pancreatic cancer, the cost of gemcitabine is funded through the Systemic Treatment Quality-Based Procedure (ST-QBP) and is included in the band level pricing.
Gemtuzumab Ozogamicin (djem-TOOZ-ue-mab oh-zoe-ga-MYE-sin) Other name: Mylotarg®	Previously Untreated Acute Myeloid Leukemia (Outpatient) – *see HCTFP for inpatient policy version*	The patient must meet the following criteria: Gemtuzumab ozogamicin is used in combination with daunorubicin and cytarabine for the treatment of adult patients with previously untreated, de novo CD33-positive acute myeloid leukemia (AML), except acute promyelocytic leukemia (APL). Treatment should be for patients with good performance status, and who have favourable, intermediate, or unknown cytogenetics (using the European LeukemiaNet (ELN) 2017 risk classification).	**Induction**: Gemtuzumab ozogamicin 3 mg/m^2 (up to a maximum single dose of 4.5 mg) intravenously (IV) on days 1, 4, and 7 in combination with cytarabine and daunorubicin. Treatment with gemtuzumab ozogamicin, in combination with daunorubicin and cytarabine, is funded for one induction cycle only. **Consolidation**: Gemtuzumab ozogamicin 3 mg/m^2 (up to a maximum single dose of 4.5 mg)	1. In the event where the cytogenetic status is unknown (that is, because the test was unsuccessful) or when the cytogenetic test result is not yet available, gemtuzumab ozogamicin could be initiated during induction therapy. 2. Once a patient's cytogenetic status is confirmed as being adverse risk, gemtuzumab ozogamicin is no longer eligible for funding. 3. Gemtuzumab ozogamicin is not funded for use in patients with adverse cytogenetics, therapy-related AML or in combination with midostaurin for FMS-like tyrosine kinase 3 (FLT3)-mutated acute myeloid leukemia (AML).

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
			IV on day 1 in combination with cytarabine, or cytarabine and daunorubicin. For those achieving complete remission following induction, gemtuzumab ozogamicin is funded for up to two cycles, in combination with standard cytarabine consolidation or cytarabine and daunorubicin consolidation. [ST-QBP regimen codes for outpatient use only: CYTA(HD)+GEMT or CYTADAUN+GEMT]	4. Gemtuzumab ozogamicin may be funded if idarubicin is used as an alternative anthracycline to daunorubicin, in combination with cytarabine. 5. Gemtuzumab ozogamicin is not funded if used in combination with other treatments (e.g., FLAG-IDA or azacitidine). Gemtuzumab ozogamicin may be used with an anthracycline and high-dose cytarabine (or high-dose cytarabine alone) as consolidative therapy based on institutional best practice. 6. Gemtuzumab ozogamicin is not funded for relapsed or refractory AML or when used as a single-agent. 7. Patients with de novo CD33-positive, FLT3-positive AML with favourable, intermediate, or unknown cytogenetics may use one of either gemtuzumab ozogamicin or midostaurin (assuming other eligibility criteria are met). 8. All doses (induction and consolidation) are to be submitted through eClaims using separate enrolment forms for inpatient and outpatient use. This policy is only for doses administered in the outpatient setting.
Inotuzumab Ozogamicin (in-oh-TOOZ-ue-mab oh-zoe-ga-MYE-sin) Other name: Besponsa®	Relapsed or Refractory Acute Lymphoblastic Leukemia (Outpatient) – *see HCTFP for inpatient policy version*	The patient must meet the following criteria: • For the treatment of Philadelphia chromosome (Ph)-positive and Ph-negative patients with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL) who have good performance status. • [For patients with Ph-positive ALL, failure with at least one second-generation or third-generation tyrosine kinase inhibitor (TKI) and standard multi-drug induction chemotherapy is required before treatment with inotuzumab ozogamicin.]	Cycle 1: Inotuzumab ozogamicin 0.8 mg/m^2 intravenously (IV) on day 1 followed by inotuzumab ozogamicin 0.5 mg/m^2 IV on days 8 and 15 [total dose per cycle = 1.8 mg/m^2]. Cycle 1 is 21 days (ST-QBP regimen code: INOT). Subsequent cycles: For patients who achieve a complete response or complete response with incomplete count recovery (CR/CRi): Inotuzumab ozogamicin 0.5 mg/m^2 IV on days 1, 8 and 15 [total dose per cycle = 1.5 mg/m^2]. For patients who have not achieved a CR/CRi: Inotuzumab ozogamicin 0.8 mg/m^2 IV on day 1 followed by 0.5 mg/m^2 IV on days 8 and 15 [total dose per cycle = 1.8 mg/m^2].	N/A

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
			Subsequent cycles are 28 days (ST-QBP regimen code: INOT). Treatment should be continued until unacceptable toxicity or disease progression, up to a maximum of three cycles, for those patients proceeding to hematopoietic stem cell transplant (HSCT). For patients not proceeding to HSCT who achieve CR/CRi and minimal residual disease (MRD) negativity, treatment may be continued for a maximum of six total cycles.	
Ipilimumab (IP-i-LIM-ue-mab) Other name: Yervoy®	Previously Treated Advanced Unresectable Melanoma (Formerly Unresectable Stage III or IV Melanoma)	• **Initial Treatment:** Patient has unresectable Stage III or IV melanoma and has received at least one systemic therapy for advanced melanoma; the patient has an ECOG performance score ≤ 1; • **Re-induction:** At the time of disease progression, the patient has had stable disease for at least three months or has previously experienced a complete or partial response to ipilimumab; the patient has an ECOG performance score ≤ 1	Induction/Re-induction: Ipilimumab 3mg/kg every 3 weeks for 4 doses	1. Patients who have received ipilimumab before the effective funding date of pembrolizumab (i.e., received at least one treatment of ipilimumab prior to June 2, 2016) will be eligible to receive pembrolizumab upon disease progression. 2. If patient has received ipilimumab funding in the first-line setting, they will not be eligible for ipilimumab funding for re-induction or in subsequent lines of therapy. 3. Ipilimumab is not funded if the patient has an ECOG ≥ 2. 4. For patients treated with anti-PD-1 monotherapy (instead of combination nivolumab plus ipilimumab) in the metastatic setting, ipilimumab monotherapy will be funded as a subsequent line of therapy provided that funding criteria are met. 5. Patients with BRAF mutation may be initiated on BRAF targeted therapy or immunotherapy. Upon disease progression, the patient may be switched to the other treatment modality as a subsequent line of therapy.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
Ipilimumab (IP-i-LIM-ue-mab) Other name: Yervoy®	Previously Untreated Advanced Unresectable Melanoma	• For the first-line treatment of patients who are at least 18 years old with advanced melanoma (i.e. primary cutaneous unresectable Stage IIIC or IV melanoma or metastatic melanoma), regardless of BRAF mutation status, who have an ECOG Performance Status less than or equal to 1, and are not currently receiving immunosuppressive therapy. • If a patient has brain metastasis, then they must be asymptomatic or stable.	Ipilimumab 3mg/kg every 3 weeks for 4 doses	1. Patients who have received ipilimumab before the effective funding date of pembrolizumab (i.e., received at least one treatment of ipilimumab prior to June 2, 2016) will be eligible to receive pembrolizumab upon disease progression. 2. If patient has received ipilimumab in the first-line setting, they will not be eligible for ipilimumab funding for re-induction or in subsequent lines of therapy (NDFP Policy: Previously Treated Advanced Unresectable Melanoma). 3. Requests for dose escalation up to 10 mg/kg will not be considered. 4. Maintenance or re-induction requests in the first line setting will not be considered.
Isatuximab (EYE-sa-TUX-i-mab) Other name: Sarclisa®	And Carfilzomib - In Combination with Dexamethasone for Relapsed or Refractory Multiple Myeloma	Isatuximab and carfilzomib are used in combination with dexamethasone (IsaKd) in adult patients* with relapsed or refractory multiple myeloma (MM) who have received at least one prior line of therapy. *Patients should have evaluable disease and a good performance status. *Patients must <u>not</u>: • Be refractory to an anti-CD38 monoclonal antibody, OR • Be refractory to carfilzomib, OR • Have a left ventricular ejection fraction less than 40%.	Isatuximab Cycle 1: 10 mg/kg intravenously (IV) on days 1, 8, 15, and 22 Cycle 2 and onwards: 10 mg/kg IV on days 1 and 15 Carfilzomib Cycle 1: 20 mg/m² IV on days 1 and 2, then 56 mg/m² IV on days 8, 9, 15 and 16 Cycle 2 and onwards: 56 mg/m² IV on days 1, 2, 8, 9, 15, and 16 <u>OR</u> Cycle 1: 20 mg/m² IV on day 1, then 70 mg/m² IV on days 8 and 15 Cycle 2 and onwards: 70 mg/m² IV on days 1, 8, and 15 [1 cycle = 28 days] Treatment should continue until disease progression or unacceptable toxicity, whichever occurs first.	1. Completion of this form will enroll the patient in both isatuximab and carfilzomib. 2. Refractory disease is defined as: • Disease progression within 60 days of any dose of therapy, OR • Disease progression while on therapy, OR • Failure to achieve at least a minimal response while on therapy. 3. The following patients are eligible for funding, provided all other eligibility criteria are met: • Patients who only have measurable disease using serum free light chains; • Patients who have primary refractory multiple myeloma; • Patients who have amyloidosis concomitant with multiple myeloma. 4. Patients will only be eligible for one line of isatuximab-based therapy (in combination with carfilzomib and dexamethasone <u>or</u> in combination with pomalidomide and dexamethasone) provided all other eligibility criteria are met.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
			[ST-QBP regimen code: CARFDEXA+ISAT, CARFDEXA(W)+ISAT]	
Isatuximab (EYE-sa-TUX-i-mab) Other name: Sarclisa®	In Combination with Pomalidomide and Dexamethasone for Relapsed or Refractory Multiple Myeloma	Isatuximab is used in combination with pomalidomide and dexamethasone (IsaPd) in adult patients with relapsed or refractory multiple myeloma (MM) who have received at least two prior lines of therapy including lenalidomide and a proteasome inhibitor*. Patients must: • Be refractory to the last line of therapy AND • Have a good performance status. Patients must not: • Be refractory to an anti-CD38 monoclonal antibody. *Lenalidomide and a proteasome inhibitor may be given as monotherapy or in combination with any prior therapy	Cycle 1: Isatuximab 10 mg/kg intravenously (IV) on days 1, 8, 15, and 22 Cycle 2 and onwards: Isatuximab 10 mg/kg IV on days 1 and 15 [1 cycle = 28 days] Isatuximab is given in combination with pomalidomide and dexamethasone. Treatment should continue until disease progression or unacceptable toxicity whichever comes first. [ST-QBP regimen code(s): DEXAPOMA+ISAT]	1. Enrolment in this policy is for isatuximab only. Please refer to the Ministry of Health for the full reimbursement criteria of pomalidomide. 2. Refractory disease is defined as: • Disease progression within 60 days of any dose of therapy, OR • Disease progression while on therapy, OR • Failure to achieve at least a minimal response while on therapy. 3. The following patients are eligible for funding, provided all other eligibility criteria are met: • Patients who have primary refractory myeloma; • Patients with free light chain measurable disease only; • Patients with known high risk cytogenetics [del(17p), t(4;14), or t(14;16) by fluorescence in situ hybridization (FISH)]. 4. Patients with primary amyloidosis are not eligible. 5. Patients will only be eligible for one line of an isatuximab-based therapy (in combination with carfilzomib and dexamethasone or in combination with pomalidomide and dexamethasone) provided all other eligibility criteria are met.
Liposomal Daunorubicin and Cytarabine (lip-o-SO-mal DAW-no-RUE-bih-sin (and) SITE-ah-rah-been) Other name: Vyxeos®	Previously Untreated Acute Myeloid Leukemia (Outpatient) – *see HCTFP for inpatient policy version*	Liposomal daunorubicin and liposomal cytarabine will be used in adult patients with newly diagnosed therapy-related acute myeloid leukemia (t-AML) or AML with myelodysplasia-related changes (AML-MRC) who are deemed fit for intensive chemotherapy.	First Induction: Liposomal daunorubicin 44 mg/m^2 and liposomal cytarabine 100 mg/m^2 intravenously (IV) on days 1, 3, and 5. Second Induction (if required): Liposomal daunorubicin 44 mg/m^2 and liposomal cytarabine 100 mg/m^2 IV on days 1 and 3. Consolidation: Liposomal daunorubicin 29 mg/m^2 and liposomal cytarabine 65 mg/m^2 IV on days 1 and 3.	1. Vyxeos® is a product containing two drugs (liposomal daunorubicin and liposomal cytarabine) in one IV dosage form. 2. t-AML is defined as a pathological diagnosis of AML as per the World Health Organization (WHO) criteria and documented history of prior cytotoxic or radiation therapy for an unrelated disease. 3. AML-MRC is defined as a pathological diagnosis of AML as per the WHO criteria and one of the documented antecedent hematologic disorders: • bone marrow documentation of myelodysplastic syndrome (MDS) before diagnosis of AML with or without prior use of a hypomethylating agent, OR • bone marrow documentation of chronic myelomonocytic leukemia (CMMoL) before diagnosis of AML, OR

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
			Liposomal daunorubicin and liposomal cytarabine is funded for up to 2 cycles of induction therapy. Patients who achieve complete remission (CR) or CR with incomplete neutrophil or platelet recovery (CRi) during induction cycles are eligible for up to an additional 2 cycles of consolidation therapy using liposomal daunorubicin and liposomal cytarabine. [ST-QBP regimen code: LIPOCYTADAUN(CONS)]	• de novo AML with fluorescence in situ hybridization or cytogenetic changes linked to MDS as per WHO criteria. 4. Liposomal daunorubicin and liposomal cytarabine is not funded if used in combination with other anti-cancer therapies. 5. All doses (induction and consolidation) are to be submitted through eClaims using the corresponding enrolment forms for inpatient and outpatient use. This policy is only for doses administered in the inpatient setting.
Liposomal Doxorubicin (lip-o-SO-mal docs-oh-RUBE-i-sin) Other name: Caelyx®	Platinum – Resistant Ovarian, Fallopian Tube, or Primary Peritoneal Cancer	a. Patient has previously been treated with platinum-containing chemotherapy: with paclitaxel or without paclitaxel (please specify) b. One of the following: • disease has relapsed less than 6 months following therapy • tumour has progressed during therapy or not responding to therapy c. Patient has reasonable performance status with symptoms that are likely to be alleviated if response is achieved	Liposomal doxorubicin 50 mg/m^2 every 4 weeks Or Liposomal doxorubicin 40 mg/m^2 every 4 weeks (if used with bevacizumab 10 mg/kg every 2 weeks)	1. Patients with primary platinum refractory disease (i.e., disease that has progressed while on front-line platinum-based chemotherapy) are not eligible for bevacizumab in the platinum-resistant setting. 2. Liposomal doxorubicin is only funded once (i.e., as one line of therapy, either as a single agent or as part of a combination regimen) for the treatment of recurrent ovarian, fallopian tube, or primary peritoneal cancer.
Liposomal Doxorubicin (lip-o-SO-mal docs-oh-RUBE-i-sin) Other name: Caelyx®	Single Agent Treatment of Platinum Sensitive Ovarian, Fallopian Tube, or Primary Peritoneal Cancer for Patients Unable to Receive Platinum Therapy	a. The patient: is platinum sensitive (Patients are considered platinum sensitive if they have had a response of 6 months or longer from the date of their last platinum containing therapy) or, has had a response of 6 months or longer from the date of the last single agent therapy b. The patient is not able to receive treatment with a platinum agent (e.g. allergy)	Liposomal Doxorubicin 50 mg/m^2 IV q28 days	1. Platinum sensitive patients are eligible to receive single agent paclitaxel. 2. Liposomal doxorubicin is only funded once (i.e., as one line of therapy, either as a single agent or as part of a combination regimen) for the treatment of recurrent ovarian, fallopian tube, or primary peritoneal cancer.
Liposomal Doxorubicin	HIV-positive Kaposi's Sarcoma	a. Patient has HIV-positive Kaposi's sarcoma b. Patient has either: • visceral Kaposi's sarcoma	Liposomal doxorubicin 20 mg/m^2 every 2 weeks	N/A

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
(lip-o-SO-mal docs-oh-RUBE-i-sin) Other name: Caelyx®		• progressive disease despite prior therapy with vinblastine or interferon c. Patient has either : • signs of peripheral neuropathy or is believed to be at high risk of neuropathy • other medical condition that makes it inappropriate to use standard combination chemotherapy. Please specify the nature of the condition d. ECOG performance status is 0-2		
Liposomal Doxorubicin (lip-o-SO-mal docs-oh-RUBE-i-sin) Other name: Caelyx®	Platinum-sensitive recurrent ovarian, fallopian tube, or primary peritoneal cancer (with carboplatin)	The patient must meet the following criteria: • Pegylated liposomal doxorubicin is used in combination with carboplatin for the treatment of platinum-sensitive recurrent ovarian, fallopian tube, or primary peritoneal cancer	Pegylated liposomal doxorubicin 30mg/m^2 IV on Day 1 every 4 weeks until disease progression or unacceptable toxicity. ST-QBP will fund carboplatin AUC 4-6 IV Day 1 every 4 weeks (regimen CRBPPGLDX).	1. Platinum-sensitive is defined as having a disease which recurs or progresses 6 months or longer from the date of the last dose of platinum-containing therapy. 2. Pegylated liposomal doxorubicin is only funded once (i.e., as one line of therapy, either as a single agent or as part of a combination regimen) for the treatment of recurrent ovarian, fallopian tube, or primary peritoneal cancer. 3. Retreatment with this regimen (or a pegylated liposomal doxorubicin-based regimen) is not funded by NDFP.
		The patient must meet the following criteria: • Midostaurin is used for the treatment of adult patients with newly diagnosed FMS-like tyrosine kinase 3 (FLT3)-mutated acute myeloid leukemia (AML). Patients should be deemed to be fit to receive standard induction and consolidation chemotherapy.	**Induction**: Midostaurin 50mg orally twice daily on days 8 to 21 with each cycle, up to a maximum of 2 induction cycles, regardless of the funding source. Patients who have residual AML after a second induction cycle should be discontinued from midostaurin therapy. **Consolidation**: Midostaurin 50mg orally twice daily on days 8 to 21 of each cycle of consolidation, up to a maximum of 4 cycles, regardless of the funding source.	1. Funding is for doses administered in the inpatient setting only. Please refer to the Ontario Drug Benefit Exceptional Access Program for funding of doses administered in the outpatient setting. Patients requiring outpatient treatment will need to apply to the Ontario Drug Benefit Program's Exceptional Access Program. At the initiation of therapy, please check that your patient will be eligible for benefits under the Ontario Drug Benefit Program. Some patients may require registration in the Trillium Drug Program. 2. Midostaurin is used in combination with standard induction chemotherapy with cytarabine and daunorubicin followed by standard cytarabine consolidation chemotherapy, OR any 7+3 induction regimen containing idarubicin followed by standard consolidation chemotherapy with cytarabine. 3. Midostaurin is not funded if used for a. maintenance therapy for AML;

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
				b. therapy-related AML after prior radiation therapy or chemotherapy for another cancer or disorder; c. re-induction and/or re-consolidation.
Nab-Paclitaxel (nab pack-li-TAX-ell) Other name: Abraxane®	Metastatic Breast Cancer	The patient must meet criteria a, b OR c, and d: a. The patient has metastatic breast cancer. b. Has had acute infusion reactions with paclitaxel or docetaxel considered by treating physicians to be due to the vehicle of the taxanes (Cremophor and polysorbate 80) c. Has experienced severe toxicity from previous administration of other taxanes (Severe toxicity could be due to pre-medications for the administration of the taxane or due to the taxane itself)[a] d. Specify previous taxane: docetaxel or paclitaxel	No specified funded dose. For recommended dose, see **CCO Drug Formulary**	[a]excludes glycemic effects of steroids Nab-paclitaxel may be used in place of paclitaxel or docetaxel provided that the patient meets nab-paclitaxel eligibility criteria. The cost of paclitaxel or docetaxel is funded through the Systemic Treatment Quality-Based Procedure (ST-QBP) and is included in the band level pricing.
Nab-Paclitaxel (nab pack-li-TAX-ell) Other name: Abraxane®	Advanced Pancreatic Cancer (with Gemcitabine)	The patient must meet the following criteria: • The gemcitabine and nab-paclitaxel regimen will be used to treat first-line Advanced Pancreatic Cancer (Locally Advanced **Unresectable** Pancreatic Cancer or Metastatic Pancreatic Cancer) • Patient's ECOG must be less than or equal to 2 at the time of enrolment	Gemcitabine 1000 mg/m^2 and nab-paclitaxel 125 mg/m^2 Days 1, 8, 15 every 28 days	Patients who are funded for this gemcitabine-nab-paclitaxel combination for the treatment of either locally advanced unresectable or metastatic pancreatic cancer will not be eligible for the funding of oxaliplatin and irinotecan under the FOLFIRINOX regimen and gemcitabine single agent. Nab-paclitaxel must be administered in combination with gemcitabine, and not as a single-agent Completion of this form will fulfill the enrolment requirements for both gemcitabine and nab-paclitaxel.
Nivolumab (nye-VOL-ue-mab) Other name: Opdivo®	Adjuvant Treatment for Completely Resected Stage III or IV Melanoma	The patient must meet the following criteria: • Nivolumab is used for the adjuvant treatment of adult patients with completely resected stage IIIA (with node metastases >1mm), IIIB, IIIC, IIID or stage IV melanoma and; • Disease must be completely resected including in-transit metastases; however, presence of regional lymph nodes with micrometastases after sentinel lymph node biopsy alone is allowed.	Nivolumab 3 mg/kg intravenously (IV) once every 2 weeks up to a maximum dose of 240 mg until disease progression or a maximum of one year of equivalent therapy, whichever comes first. OR Nivolumab 6 mg/kg intravenously (IV) once every 4 weeks up to a maximum dose of 480 mg	1. Staging is based on the 8th edition of the American Joint Committee on Cancer (AJCC) melanoma staging system. 2. Patients with stage IIIA melanoma must have node metastases >1mm to be eligible for funding. 3. In-transit, satellite or distant metastases must be completely resected. 4. Patients with BRAF mutated melanoma who initiated treatment with adjuvant immunotherapy or adjuvant dabrafenib and trametinib may switch once between adjuvant therapies within 3 months of initiation of therapy. Funded therapy will be limited to a total of 12 months of adjuvant treatment, regardless of funding source.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
			until disease progression or a maximum of one year of equivalent therapy, whichever comes first. ST-QBP regimen code: NIVL	5. Patients who initiated adjuvant therapy with interferon may switch once to adjuvant immunotherapy or adjuvant dabrafenib and trametinib, provided all eligibility criteria are met. 6. Patients with ocular melanoma will not be eligible for adjuvant nivolumab. 7. Nivolumab is funded for single agent use only. 8. Patients who have confirmed disease progression on adjuvant nivolumab will not be eligible for anti-PD-1/anti-PD-L-1 immunotherapy (e.g. pembrolizumab or nivolumab) in the metastatic setting. 9. Patients whose disease relapses at least 6 months after completing adjuvant nivolumab may be eligible for combination ipilimumab & nivolumab in the metastatic setting. If the patient is unfit for combination immunotherapy, single agent immunotherapy.
Nivolumab (nye-VOL-ue-mab) Other name: Opdivo®	Adjuvant Treatment of Urothelial Carcinoma	Nivolumab monotherapy is used as adjuvant therapy in adult patients* with urothelial carcinoma (UC) who are at high risk of recurrence after radical resection of UC. Treatment is only for patients who have no evidence of recurrence confirmed prior to initiating therapy, no metastatic disease or active autoimmune disease, and with good performance status. Treatment should be initiated within 120 days of surgical resection. *Eligible patients include those who have: • muscle invasive urothelial carcinoma at diagnosis **AND** • received cisplatin-based neoadjuvant chemotherapy (ypT2-pT4a or ypN+) OR have not received neoadjuvant cisplatin chemotherapy (pT3-pT4a or pN+) and are ineligible or have declined adjuvant cisplatin-based chemotherapy.	Nivolumab 3 mg/kg intravenously (IV) every 2 weeks (up to a maximum of 240 mg) or nivolumab 6 mg/kg IV every 4 weeks (up to a maximum of 480 mg). Treatment should continue until disease recurrence or unacceptable toxicity up to a maximum of 1 year (i.e., 26 doses of nivolumab if given every 2 weeks or 13 doses if given every 4 weeks), whichever comes first. [ST-QBP regimen code: NIVL]	1. As per the pivotal trial, patients deemed ineligible for adjuvant cisplatin-based chemotherapy (as per the Galsky criteria) include those with: • Creatinine clearance (using the Cockcroft-Gault formula) less than 60 mL/min. • Common Terminology Criteria for Adverse Events (CTCAE) version 4, grade 2 or above audiometric hearing loss. • CTCAE version 4, grade 2 peripheral neuropathy. • New York Heart Association (NYHA) Class III or IV Heart Failure. 2. Patients with urethral tumors who are at high risk of recurrence after radical resection are eligible.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
Nivolumab (nye-VOL-ue-mab) Other name: Opdivo®	Advanced Melanoma (Unresectable or Metastatic Melanoma)	The patient must meet the following criteria: • Nivolumab is used as a treatment for patients with unresectable or metastatic melanoma, regardless of BRAF status, who are previously untreated or may have received prior treatment with BRAF targeted therapy, with good performance status and who have stable brain metastases (if present).	Nivolumab 3 mg/kg IV, up to a maximum dose of 240 mg, every 2 weeks as an intravenous infusion, or nivolumab 6 mg/kg IV, up to a maximum dose of 480 mg, every 4 weeks as an intravenous infusion.	1. The patient is no longer eligible for nivolumab once there is confirmed disease progression. 2. Nivolumab is not funded for patients who have confirmed disease progression while receiving a prior anti-PD-1 inhibitor. 3. For patients treated with anti-PD-1 monotherapy (instead of combination nivolumab plus ipilimumab) in the metastatic setting, ipilimumab monotherapy will be funded as a subsequent line of therapy provided that funding criteria are met. 4. Nivolumab funding is for single agent use only. 5. For patients completing or stopping single agent nivolumab without disease progression, resumption of treatment will be funded provided no other treatment is given in between. 6. Patients with BRAF mutation may be initiated on BRAF targeted therapy or immunotherapy. Upon disease progression, the patient may be switched to the other treatment modality as a subsequent line of therapy.
Nivolumab (nye-VOL-ue-mab) Other name: Opdivo®	Advanced or Metastatic Non-Small Cell Lung Cancer	The patient must meet the following criteria: • Nivolumab is used as a treatment for adult patients with advanced or metastatic non-small cell lung cancer (NSCLC) with disease progression on or after cytotoxic chemotherapy for advanced disease and who have a good performance status.	Nivolumab 3 mg/kg IV, up to a maximum dose of 240 mg, every 2 weeks as an intravenous infusion, or nivolumab 6 mg/kg IV, up to a maximum dose of 480 mg, every 4 weeks as an intravenous infusion.	1. Ontario Health (Cancer Care Ontario) will fund one line of atezolizumab, nivolumab, nivolumab plus ipilimumab, or pembrolizumab for advanced non-small cell lung cancer. Patients who were treated with durvalumab (or other anti-PD1/PD-L1 therapy) in the curative setting must have a disease free interval of 6 months or greater in order to be considered for funding under this policy. 2. It is recommended that nivolumab be used after treatment with a platinum-based therapy. 3. The patient is no longer eligible for nivolumab once there is confirmed disease progression. 4. If the patient previously received non-NDFP funded chemotherapy for NSCLC, clarification (documented in a clinic note) may be requested to confirm the patient's prior chemotherapy treatments. 5. Nivolumab funding is for single agent use only.
Nivolumab (nye-VOL-ue-mab) Other name:	Advanced or Metastatic Renal Cell Carcinoma and No Prior mTOR Inhibitor	The patient must meet the following criteria: • Nivolumab is used as a treatment for patients with advanced or metastatic renal cell carcinoma with disease progression after at least one prior	Nivolumab 3 mg/kg IV, up to a maximum dose of 240 mg, every 2 weeks as an intravenous infusion, or nivolumab 6 mg/kg IV, up to a	1. Nivolumab is funded as a second line treatment for patients that have received one prior tyrosine kinase inhibitor (e.g., first line sunitinib or pazopanib), OR as a third line treatment for patients that have received

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
Opdivo®		anti-angiogenic systemic treatment and who have good performance status.	maximum dose of 480 mg, every 4 weeks as an intravenous infusion.	two prior tyrosine kinase inhibitors (e.g., first line sunitinib or pazopanib, second line axitinib). 2. Patients previously treated with an mTOR inhibitor (e.g., everolimus or temsirolimus), will not be eligible for coverage for nivolumab. However, patients previously treated with an mTOR inhibitor, prior to the public listing of nivolumab, will be eligible to receive coverage for nivolumab upon disease progression 3. Patients who have a disease-free interval of 6 months or greater after completion of adjuvant therapy may be eligible for one line of immune checkpoint inhibitor-based therapy for advanced or metastatic renal cell carcinoma provided all other eligibility criteria are met. 4. The patient is no longer eligible for nivolumab once there is confirmed disease progression. 5. Nivolumab funding is for single agent use only. 6. Patients who progress on treatment with combination nivolumab plus ipilimumab (or nivolumab maintenance) will not be eligible for single agent nivolumab in subsequent lines of therapy.
Nivolumab (nye-VOL-ue-mab) Other name: Opdivo®	Advanced or Metastatic Renal Cell Carcinoma and Prior mTOR Inhibitor	The patient must meet the following criteria: • Nivolumab is used as a treatment for patients with advanced or metastatic renal cell carcinoma with disease progression after at least one prior anti-angiogenic systemic treatment and who have good performance status.	Nivolumab 3 mg/kg IV, up to a maximum dose of 240 mg, every 2 weeks as an intravenous infusion, or nivolumab 6 mg/kg IV, up to a maximum dose of 480 mg, every 4 weeks as an intravenous infusion.	1. Nivolumab is funded as a second line treatment for patients that have received one prior tyrosine kinase inhibitor (e.g., first line sunitinib or pazopanib), OR as a third line treatment for patients that have received two prior tyrosine kinase inhibitors (e.g., first line sunitinib or pazopanib, second line axitinib). 2. Patients previously treated with an mTOR inhibitor (e.g., everolimus or temsirolimus), will not be eligible for coverage for nivolumab. However, patients previously treated with an mTOR inhibitor, prior to the public listing of nivolumab, will be eligible to receive coverage for nivolumab upon disease progression. 3. Patients who have a disease-free interval of 6 months or greater after completion of adjuvant therapy may be eligible for one line of immune checkpoint inhibitor-based therapy for advanced or metastatic renal cell carcinoma provided all other eligibility criteria are met. 4. The patient is no longer eligible for nivolumab once there is confirmed disease progression. 5. Nivolumab funding is for single agent use only.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
				6. Patients who progress on treatment with combination nivolumab plus ipilimumab (or nivolumab maintenance) will not be eligible for single agent nivolumab in subsequent lines of therapy.
Nivolumab (nye-VOL-ue-mab) Other name: **Opdivo®**	Esophageal and Esophagogastric Junction - Adjuvant	The patient must meet the following criteria: • Nivolumab is used for the adjuvant treatment of completely resected esophageal or esophagogastric junction (EGJ) cancer in patients who have residual pathologic disease following prior neoadjuvant chemoradiotherapy (CRT).	Nivolumab 3 mg/kg intravenously (IV) every 2 weeks (up to a maximum dose of 240 mg); or nivolumab 6 mg/kg IV every 4 weeks (up to a maximum dose of 480 mg). Treatment with nivolumab should be initiated within 4 to 16 weeks of complete resection. Treatment should continue until disease progression or unacceptable toxicity to a maximum of 1 year, whichever comes first. [ST-QBP regimen code: NIVL]	1. Nivolumab should not be used in combination with other adjuvant anti-cancer drugs. 2. Patients who receive adjuvant therapy with an immune checkpoint inhibitor, may be eligible for nivolumab or pembrolizumab in combination with chemotherapy in the advanced setting provided there was a disease-free interval (DFI) of 6 months or greater after the completion of adjuvant therapy, and all other eligibility criteria are met.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
Nivolumab (nye-VOL-ue-mab) Other name: **Opdivo®**	Gastric, Esophageal and Esophagogastric Junction - Advanced	The patient must meet the following criteria: • Nivolumab is used in combination with fluoropyrimidine- and platinum-based chemotherapy for the first-line treatment of adult patients with human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic gastric, esophagogastric junction (EGJ), or esophageal adenocarcinoma.	Nivolumab 3 mg/kg given intravenously (IV) (up to a maximum of 240 mg) every 2 weeks; or Nivolumab 4.5 mg/kg given IV (up to a maximum of 360 mg) every 3 weeks. Treatment should continue until confirmed disease progression or unacceptable toxicity to a maximum of 2 years, whichever comes first. [ST-QBP regimen codes: CISPFU+NIVL, CRBPFU+NIVL, CAPECISP+NIVL, CAPECRBP+NIVL, MFOLFOX6+NIVL, or XELOX+NIVL, NIVL(MNT)].	1. NDFP will only fund one of nivolumab or pembrolizumab for the first-line treatment of gastric, EGJ, or esophageal cancer in the advanced setting. Please note the following: - Only pembrolizumab can be funded for squamous cell carcinoma of the esophagus. • Only nivolumab can be funded for gastric adenocarcinoma. • For patients who are a candidate for either therapy (esophageal or EGJ adenocarcinoma), the decision is up to the treating physician. 2. Patients who complete 2 years' worth of treatment without disease progression may receive up to an additional 1 years' worth of treatment with nivolumab, with or without chemotherapy, at the point of confirmed disease progression if the treating physician deems the patient eligible for retreatment and provided that no other systemic treatment is given in between. Claims should be submitted under the same form used for the initial course of treatment. 3. At least 1 cycle of chemotherapy must be given concurrently with nivolumab before changing to nivolumab maintenance due to intolerance. 4. Patients who received prior adjuvant therapy with an immune checkpoint inhibitor may be eligible for nivolumab in combination with chemotherapy in the advanced setting provided there was a disease-free interval (DFI) of 6 months or greater after completing adjuvant therapy.
Nivolumab (nye-VOL-ue-mab) Other name: Opdivo®	Recurrent or Metastatic Squamous Cell Carcinoma of the Head and Neck, which is Platinum Resistant or Refractory	The patient must meet the following criteria: Nivolumab is used for the treatment of patients with squamous cell cancer of the head and neck (SCCHN) who either: have a recurrence within 6 months of potentially curative neoadjuvant/adjuvant platinum-based therapy; or, have a recurrence after receiving platinum-based therapy in a non-curative setting; and have good performance status.	Nivolumab 3 mg/kg IV, up to a maximum dose of 240 mg, every 2 weeks as an intravenous infusion, or nivolumab 6 mg/kg IV, up to a maximum dose of 480 mg, every 4 weeks as an intravenous infusion.	1. Patients who have disease progression more than 6 months following platinum-based chemotherapy should be retreated with a platinum-based therapy* (unless there is a documented intolerance or contraindication [see Note 2]), and then qualify for nivolumab upon disease progression. (*funded by ST-QBP if evidence-informed) 2. Patients with a documented intolerance or contraindication to platinum-based therapy and being treated with palliative intent will be eligible to receive coverage for nivolumab. 3. The patient is no longer eligible for nivolumab once there is confirmed disease progression.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
		Treatment should continue until confirmed disease progression or unacceptable toxicity.		4. Nivolumab is not funded for patients who have confirmed disease progression after receiving a prior anti-PD-1 inhibitor in the metastatic setting. 5. Nivolumab funding is for single agent use only. 6. Ontario Health will fund one line of pembrolizumab or nivolumab for recurrent or metastatic squamous cell carcinoma of the head and neck.
Nivolumab (nye-VOL-ue-mab) Other name: Opdivo®	Relapsed Classical Hodgkin Lymphoma (cHL) Post-Autologous Stem Cell Transplant (ASCT) or ASCT Ineligible	The patient must meet the following criteria: • For the treatment of patients with classical Hodgkin Lymphoma (cHL) who have relapsed or progressed after autologous stem cell transplantation (ASCT) and brentuximab vedotin (BV), or who are not candidates for ASCT and have failed BV.	Nivolumab 3 mg/kg IV, up to a maximum of 240 mg, every two weeks as an intravenous (IV) infusion, or nivolumab 6 mg/kg IV, up to a maximum of 480 mg, every four weeks as an IV infusion. Treatment should continue until confirmed disease progression or unacceptable toxicity. [ST-QBP regimen code: NIVL]	1. Patients will be eligible for either pembrolizumab or nivolumab for refractory or relapsed classical Hodgkin lymphoma (cHL), but not both. 2. For patients stopping nivolumab without disease progression, resumption of treatment will be funded provided no other treatment is given in between. 3. Nivolumab is not funded for patients who have confirmed disease progression while receiving a prior anti-PD-1 inhibitor.
Nivolumab (nye-VOL-ue-mab) Other name: Opdivo®	Plus Ipilimumab - Advanced Malignant Pleural Mesothelioma	Combination nivolumab plus ipilimumab is used for the treatment of adult patients with unresectable malignant pleural mesothelioma (MPM) who have not received prior systemic therapy for MPM, and who have good performance status.	Nivolumab 4.5 mg/kg intravenously (IV), up to a maximum dose of 360 mg, once every 3 weeks plus ipilimumab 1 mg/kg IV once every 6 weeks. Treatment with combination nivolumab plus ipilimumab should continue until confirmed disease progression or unacceptable toxicity to a maximum of two years, whichever comes first. [ST-QBP regimen code: NIVL+IPIL]	1. Patients who stop ipilimumab, in the absence of disease progression, may continue treatment with nivolumab monotherapy. Nivolumab monotherapy should stop if the patient experiences serious adverse effects, has disease progression, or after completion of two years of therapy. 2. Completion of this form will automatically enroll the patient for both nivolumab and ipilimumab. 3. Patients who complete 2 years' worth of nivolumab plus ipilimumab without disease progression may receive an additional 1 years' worth of nivolumab plus ipilimumab at the point of confirmed disease progression if the treating physician deems the patient eligible for retreatment and

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
				no other systemic treatment is given in between. Claims should be submitted under the same enrolment form used for initial treatment. 4. Patients receiving funding for systemic treatment from WSIB are not eligible for funding through the New Drug Funding Program (NDFP). For patients currently receiving WSIB benefits, please contact WSIB directly to discuss any claim-related issues.
Nivolumab (nye-VOL-ue-mab) Other name: Opdivo®	Plus Ipilimumab - Advanced Melanoma (Unresectable or Metastatic Melanoma)	The patient must meet the following criteria: • Combination nivolumab plus ipilimumab is used for the treatment of unresectable or metastatic melanoma regardless of BRAF status, who are treatment naïve or may have received prior treatment with BRAF-targeted therapy, with ECOG performance status of 0 or 1 and with stable brain metastases (if present).	Nivolumab 1mg/kg and ipilimumab 3mg/kg every three weeks for up to four doses, (ST-QBP regimen code: NIVL+IPIL), followed by • Nivolumab maintenance at 3mg/kg up to a maximum of 240mg every two weeks or • Nivolumab maintenance at 6mg/kg up to a maximum of 480mg every four weeks. (ST-QBP regimen code: NIVL(MNT)). Patients enrolling in this policy must be able to initiate treatment with nivolumab and ipilimumab at the same time. Treatment with combination nivolumab plus ipilimumab (followed by nivolumab maintenance) should be continued until unacceptable toxicity or confirmed disease progression.	1. Patients with BRAF mutation may be initiated on BRAF targeted therapy or immunotherapy. Upon disease progression, the patient may be switched to the other treatment modality as a subsequent line of therapy. 2. For patients who stop nivolumab maintenance without disease progression, continuation of maintenance nivolumab will be funded provided that no other treatment is given in between. 3. Completion of this form will automatically enroll the patient for both nivolumab and ipilimumab. 4. Combination nivolumab plus ipilimumab is not funded for patients who have confirmed disease progression while receiving a prior anti-PD-1 inhibitor.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
Nivolumab (nye-VOL-ue-mab) Other name: Opdivo®	Plus Ipilimumab - In Combination with Platinum Doublet Chemotherapy for First Line Metastatic or Recurrent Non-Small Cell Lung Cancer	Nivolumab plus ipilimumab is used in combination with two cycles of platinum doublet chemotherapy (PDC) for the first line treatment of adult patients with metastatic or recurrent non-small cell lung cancer (NSCLC) with no known epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumour aberrations, and who have good performance status.	Nivolumab 4.5 mg/kg intravenously (IV), up to a maximum of 360 mg, every 3 weeks plus ipilimumab 1 mg/kg IV every 6 weeks. Nivolumab plus ipilimumab must be given in combination with 2 cycles of platinum doublet chemotherapy, followed by maintenance nivolumab plus ipilimumab until confirmed disease progression or unacceptable toxicity up to a maximum of 2 years, whichever comes first. (ST-QBP regimen codes: One of CISPPEME+NIVL+IPIL, CRBPPACL+NIVL+IPIL, CRBPPEME+NIVL+IPIL, CRBPGEMC+NIVL+IPIL or CISPGEMC+NIVL+IPIL for the induction phase, followed by NIVL+IPIL(MNT) for the maintenance phase.)	1. Ontario Health (Cancer Care Ontario) will fund one line of atezolizumab, nivolumab, nivolumab plus ipilimumab, or pembrolizumab for advanced non-small cell lung cancer. 2. Patients who were treated with durvalumab (or other anti-PD1/PD-L1 therapy) in the curative setting must have a disease free interval of 6 months or greater in order to be considered for funding under this policy. 3. For patients who stop nivolumab plus ipilimumab without disease progression, continuation of nivolumab plus ipilimumab (to complete 2 years' worth of treatment) will be funded provided that no other treatment is given in between. 4. Patients who complete 2 years' worth of treatment without disease progression may receive up to an additional 1 years' worth of nivolumab plus ipilimumab treatment at the point of confirmed disease progression if the treating physician deems the patient eligible for retreatment. Claims should be submitted under the same enrolment form used for initial treatment. 5. Nivolumab plus ipilimumab will not be funded if the patient has a typical or atypical carcinoid tumour.
Nivolumab (nye-VOL-ue-mab) Other name: Opdivo®	Plus Ipilimumab - Metastatic Renal Cell Carcinoma	Combination nivolumab plus ipilimumab is used for the treatment of previously untreated patients with intermediate or poor-risk advanced renal cell carcinoma based on the International Metastatic Renal Cell Carcinoma Database Consortium (IMDC) criteria.	Nivolumab 3mg/kg and ipilimumab 1mg/kg every three weeks for up to four doses (ST-QBP regimen code: NIVL+IPIL), followed by • Nivolumab maintenance at 3mg/kg up to a maximum of 240mg every two weeks (ST-QBP regimen code: NIVL(MNT)) or • Nivolumab maintenance at 6mg/kg up to a maximum of 480mg every four weeks (ST-QBP regimen code: NIVL(MNT)). Patients enrolling in this policy must be able to initiate treatment with nivolumab and ipilimumab at the same time.	1. Patients who have progressed on prior therapies in the metastatic setting (e.g. tyrosine kinase inhibitors) are not eligible for combination nivolumab plus ipilimumab. 2. For patients who stop nivolumab maintenance without disease progression, continuation of maintenance nivolumab will be funded provided that no other treatment is given in between. 3. Patients who have a disease-free interval of 6 months or greater after completion of adjuvant therapy may be eligible for one line of immune checkpoint inhibitor-based therapy for advanced or metastatic renal cell carcinoma provided all other eligibility criteria are met. 4. Completion of this form will automatically enroll the patient for both nivolumab and ipilimumab.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
			Treatment with combination nivolumab plus ipilimumab (followed by nivolumab maintenance) should be continued until unacceptable toxicity or confirmed disease progression.	
Obinutuzumab (oh-bi-nue-tooz-ue-mab) Other name: Gazyva®	Previously Untreated Chronic Lymphocytic Leukemia	a. Patient has previously untreated chronic lymphocytic leukemia (CLL) b. Patient has adequate renal function c. Fludarabine-based treatment is considered inappropriate for this patient d. Obinutuzumab will be used in combination with chlorambucil	Cycle 1: 100 mg intravenously on day 1, 900 mg intravenously on day 2, 1000 mg intravenously on days 8 and 15. Cycles 2 to 6: 1000 mg intravenously on day 1 only. Cycles are 28 days. Obinutuzumab will be used in combination with chlorambucil.	1. On a time limited basis (6 months), patients who initiated chlorambucil for previously untreated CLL in the three months prior to July 17, 2015 and whose disease has not progressed will have the option of adding obinutuzumab. 2. To be eligible for funding, patients must be able to start obinutuzumab in combination with chlorambucil. During the course of treatment, chlorambucil may be temporarily held due to toxicity or intolerance. 3. Screening for Hepatitis B virus with HbsAg and HbcAb has been completed or is in progress

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
Obinutuzumab (oh-bi-nue-tooz-ue-mab) Other name: Gazyva®	In Combination with Chemotherapy for Refractory Follicular Lymphoma	The patient must meet the following criteria: • Obinutuzumab, in combination with chemotherapy, is used in adults with follicular lymphoma whose disease is refractory to a rituximab containing regimen and has a good performance status. Rituximab refractory disease is defined as having no response to or progression during or within 6 months after treatment with rituximab or a rituximab-containing regimen. Patients with non-follicular indolent lymphoma histologies (excluding chronic lymphocytic leukemia (CLL) and mantle cell lymphoma) may be eligible for obinutuzumab funding provided all other funding criteria are met.	Cycle 1: Obinutuzumab 1000 mg intravenously days 1, 8, 15. Cycles 2 to 6: Obinutuzumab 1000 mg intravenously day 1 only. Obinutuzumab is only funded when used in combination with chemotherapy.	Patients being treated with bendamustine in combination with obinutuzumab must complete a separate enrolment form for bendamustine (eClaims form title: Bendamustine - Relapsed/Refractory - Indolent Non-Hodgkin's Lymphoma and Mantle Cell Lymphoma).
Obinutuzumab (oh-bi-nue-tooz-ue-mab) Other name: Gazyva®	In Combination with Venetoclax for Previously Untreated Chronic Lymphocytic Leukemia	Obinutuzumab is used in combination with venetoclax for the treatment of adult patients with previously untreated chronic lymphocytic leukemia (CLL) who are ineligible for fludarabine-based regimens, require treatment, and have good performance status.	Cycle 1: 100 mg Intravenously (IV) on day 1 followed by 900 mg IV on day 2 (or 1000 mg IV on day 1), followed by 1000 mg IV on days 8 and 15, in combination with venetoclax. Cycles 2 through 6: 1000 mg IV on day 1, in combination with venetoclax. Treatment should be given for a total of 12 months as a finite treatment (i.e., six 28-day cycles of obinutuzumab in combination with venetoclax, followed by six months of single agent venetoclax). ST-QBP regimen code: [VENE+OBIN]	1. Please refer to the Ontario Drug Benefit (ODB) Exceptional Access Program (EAP) for full funding criteria of venetoclax used in combination with obinutuzumab. 2. Patients with small lymphocytic lymphoma (SLL) who otherwise meet funding criteria may be considered for obinutuzumab funding under this policy. 3. Patients who complete treatment with obinutuzumab in combination with venetoclax will not be eligible for retreatment with the same regimen upon disease progression. 4. Retreatment with venetoclax, either in combination with rituximab or as monotherapy, may be funded for patients who did not experience disease progression during treatment or within 12 months of completing treatment with obinutuzumab with venetoclax. 5. Other rituximab-based regimens for relapsed CLL may be funded for patients with a progression-free interval of at least 6 months after prior CD20-targeting therapy. 6. Patients with central nervous system (CNS) lymphoma, CNS leukemia, known prolymphocytic leukemia, or history of (or currently suspected)

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
				Richter syndrome are not eligible for obinutuzumab in combination with venetoclax. 7. Patients who require a treatment interruption prior to completing 6 cycles of obinutuzumab may resume treatment to complete 6 cycles provided there has been no disease progression during the treatment interruption and no systemic therapy for CLL is given during that time.
Obinutuzumab (oh-bi-nue-tooz-ue-mab) Other name: Gazyva®	Maintenance Treatment for Refractory Follicular Lymphoma	The patient must meet the following criteria: • Obinutuzumab is used as maintenance treatment in patients with disease response to or who have stable disease after induction treatment with obinutuzumab plus chemotherapy (i.e. the initial 6 treatment cycles).	Obinutuzumab 1000 mg given intravenously every 2 months until disease progression or for up to 2 years (maximum 12 doses), whichever occurs first.	Obinutuzumab maintenance should be initiated within 4 months of the last dose of obinutuzumab induction therapy.
Panitumumab (PAN-i-TOOM-ue-mab) Other name: Vectibix®	In Combination with Chemotherapy for Metastatic Colorectal, Small Bowel, or Appendiceal Cancer	The patient must meet the following criteria: • Panitumumab is used in addition to combination chemotherapy for the treatment of patients with wild-type RAS metastatic colorectal, small bowel, or appendiceal cancer in the first line treatment setting (or second line for patients who received pembrolizumab as first line treatment) who have a contraindication or intolerance to bevacizumab and who would otherwise be treated only with combination chemotherapy. • Patients should have good performance status.	6 mg/kg every 2 weeks in combination with FOLFOX or FOLFIRI (ST-QBP regimen codes: MFOLFOX6+PNTM or FOLFIRI+PNTM). The cost of oxaliplatin as part of FOLFOX or irinotecan as part of FOLFIRI are funded through the Systemic Treatment Quality-Based Procedure (ST-QBP) and are included in the band level pricing. Treatment is funded until disease progression or unacceptable toxicity.	1. Examples of contraindications or intolerance to bevacizumab include: • High risk of bleeding or wound healing issues due to temporal proximity to surgery – recently received or planned for resectable/potentially resectable liver metastases. • A history of cardiovascular disease, or established class-specific side effects to bevacizumab such as hypertension, thromboembolic events, atrial fibrillation, as well as, proteinuria, risk of or presence of fistulae, risk of or current GI perforation, primary tumour in place, active bleeding, non-healing wound, ulcer, recent trauma, etc. 2. Treatments administered prior to RAS testing will not be reimbursed. 3. Patients who use panitumumab under this policy will not be eligible for bevacizumab in later lines of therapy. 4. Switches between bevacizumab and panitumumab will only be considered within the first 3 months of starting therapy with either agent, provided there is no disease progression on treatment. Patients will only be approved for one switch (i.e., from bevacizumab to panitumumab or vice versa). Please upload a clinic note indicating the reason(s) for switching and contraindication(s) to bevacizumab. If chemotherapy with panitumumab is initiated and proximity to planned surgery is noted as the contraindication, subsequent treatment with

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
				bevacizumab will not be funded, regardless of the patient's final surgical status. In addition, in this setting, panitumumab as a single agent will not be funded as a subsequent line of therapy. 5. Panitumumab must be used in addition to combination chemotherapy. Single agent treatments will not be funded under this policy.
Panitumumab (PAN-i-TOOM-ue-mab) Other name: Vectibix®	In Combination with Encorafenib for Previously Treated Metastatic Colorectal Cancer	Panitumumab is used in combination with encorafenib for patients with previously treated BRAF V600E-mutated metastatic colorectal cancer (mCRC). Treatment is only for patients who have received at least one previous systemic treatment for mCRC, have good performance status, adequate organ function, and have not received prior EGFR or BRAF inhibitors.	Panitumumab 6 mg/kg intravenously every 2 weeks in combination with encorafenib*. Treatment should continue until confirmed disease progression or unacceptable toxicity, whichever comes first. *The recommended dose of encorafenib for this indication is 300 mg orally once daily. [ST-QBP regimen code: ENCO+PNTM].	1. Please refer to the Ministry of Health's Exceptional Access Program for full reimbursement criteria for encorafenib when used in combination with panitumumab for mCRC. 2. Patients are eligible for one line of EGFR inhibitor-based therapy guided by biomarker findings (e.g., panitumumab with multi-agent chemotherapy, panitumumab in combination with encorafenib, cetuximab in combination with encorafenib, single agent panitumumab, or cetuximab in combination with irinotecan). 3. In the event encorafenib or panitumumab is discontinued due to unacceptable toxicity, the other drug must also be discontinued.
Panitumumab (PAN-i-TOOM-ue-mab) Other name: Vectibix®	Metastatic Colorectal, Small Bowel, or Appendiceal Cancer	a. The patient has metastatic colon, rectal, small bowel, or appendiceal cancer b. The patient has failed chemotherapy regimens containing oxaliplatin and irinotecan c. The tumour has non-mutated (wild-type) RAS oncogene d. The patient will be treated with single agent panitumumab	6 mg/kg every 2 weeks until disease progression	1. Treatments administered prior to RAS testing will not be reimbursed. 2. A copy of the RAS test result must be provided to Ontario Health (Cancer Care Ontario). 3. Panitumumab will only be funded if given as a single agent. 4. Patients are eligible for one line of EGFR inhibitor-based therapy guided by biomarker findings (e.g., panitumumab with multi-agent chemotherapy, panitumumab in combination with encorafenib, cetuximab in combination with encorafenib, single agent panitumumab, or cetuximab in combination with irinotecan).

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
Panitumumab (PAN-i-TOOM-ue-mab) Other name: Vectibix	Previously Treated Metastatic Colorectal Cancer (with encorafenib)	• Panitumumab is used in combination with encorafenib for patients with previously treated BRAF V600E-mutated metastatic colorectal cancer (mCRC). • Treatment is only for patients who have received at least one previous systemic treatment for mCRC, have good performance status, adequate organ function, and have not received prior EGFR or BRAF inhibitors.	Panitumumab 6 mg/kg intravenously every 2 weeks in combination with encorafenib*. Treatment should continue until confirmed disease progression or unacceptable toxicity, whichever comes first. *The recommended dose of encorafenib for this indication is 300 mg orally once daily. [ST-QBP regimen code: ENCO+PNTM].	1. Please refer to the Ministry of Health's Exceptional Access Program for full reimbursement criteria for encorafenib when used in combination with panitumumab for mCRC. 2. Patients are eligible for one line of EGFR inhibitor-based therapy guided by biomarker findings (e.g., panitumumab with multi-agent chemotherapy, panitumumab in combination with encorafenib, cetuximab in combination with encorafenib, single agent panitumumab, or cetuximab in combination with irinotecan). 3. In the event encorafenib or panitumumab is discontinued due to unacceptable toxicity, the other drug must also be discontinued.
Pegaspargase (peg-ah-SPAR-jase) Other name: Oncaspar®	Adult Acute Lymphoblastic Leukemia (ALL), Lymphoblastic Lymphoma, Mixed or Biphenotypic Leukemia (Outpatient) – *see HCTFP for inpatient version*	The patient must meet the following criteria: • Pegaspargase is used as part of a multi-agent chemotherapy regimen, given with curative intent, for the treatment of adult patients with acute lymphoblastic leukemia (ALL), lymphoblastic lymphoma or mixed/biphenotypic leukemia.	**Adults under 60 years of age (as part of a modified Dana-Farber Cancer Institute (DFCI)-based or alternate clinician-informed regimen):** Pegaspargase 1000-2000 units/m2 intravenously (IV) or by intramuscular (IM) injection once every cycle during induction and intensification, to a maximum of 11 total doses. **Adults 60 years of age or older (as part of a modified DFCI-based or alternate clinician-informed regimen):** Pegaspargase 1000-1250 units/m2 intravenously (IV) or by intramuscular (IM) injection once every cycle during induction and intensification, to a maximum of 8 total doses. Maximum single dose of 3750 units irrespective of age. [ST-QBP regimen codes for outpatient use only: DANAFARBER(INT-PEG) or HYPERCVAD+PEG].	1. Pegaspargase will be reimbursed on a per vial basis to a maximum of one vial per dose. 2. All doses (induction and intensification) are to be submitted through eClaims using separate enrolment forms for inpatient and outpatient use. This policy is only for doses administered in the outpatient setting.
Pegaspargase (peg-ah-SPAR-jase) Other name: Oncaspar®	Extranodal Natural Killer/T-cell Lymphoma	The patient must meet the following criteria: • Pegaspargase is used as part of a multi-agent chemotherapy regimen for the curative treatment of adult patients with extranodal natural killer/T-cell lymphoma (ENKTL).	Pegaspargase up to 2500 units/m2 intravenously (IV) or by intramuscular (IM) injection once every cycle of multi-agent chemotherapy (e.g., DDGP or modified SMILE), up to a maximum of six total cycles.	1. Pegaspargase will be reimbursed on a per vial basis. 2. Pegaspargase as part of upfront chemotherapy may be given concurrently or sequentially with radiation therapy based on the extent of disease at diagnosis.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
			[ST-QBP regimen codes: DDGP or SMILE(PEG)]	
Pegaspargase (peg-ah-SPAR-jase) Other name: Oncaspar®	Newly Diagnosed Pediatric Acute Lymphoblastic Leukemia, Lymphoblastic Lymphoma, or Mixed/Biphenotypic Leukemia	The patient must meet the following criteria: • Pegaspargase is used as part of a multi-agent regimen for the treatment of newly diagnosed pediatric[1,2] acute lymphoblastic leukemia, lymphoblastic lymphoma or mixed/biphenotypic leukemia. 1. The patient is eligible for pegaspargase if the diagnosis occurred prior to 18 years of age. 2. If the diagnosis occurred at 18 or 19 years of age, the patient is eligible for CCO funding if pegaspargase is administered at a POGO-affiliated pediatric cancer centre or satellite site and the patient's care is managed by a pediatric oncology service.	Pegaspargase up to 2,500U/m²/dose IV or IM	1. Pegaspargase will be reimbursed on a per vial basis. 2. If the diagnosis changes from standard risk to high risk, please send a secure communication to your CCO Reimbursement Analyst to notify them of the change.
Pegaspargase (peg-ah-SPAR-jase) Other name: Oncaspar®	Relapsed or Refractory Pediatric Acute Lymphoblastic Leukemia, Lymphoblastic Lymphoma, or Mixed/Biphenotypic Leukemia	The patient must meet the following criteria: • Pegaspargase is used as part of a multi-agent regimen for the treatment of relapsed or refractory pediatric[1,2] acute lymphoblastic leukemia, lymphoblastic lymphoma or mixed/biphenotypic leukemia. 1. The patient is eligible for pegaspargase if the diagnosis occurred prior to 18 years of age. 2. If the diagnosis occurred at 18 or 19 years of age, the patient is eligible for CCO funding if pegaspargase is administered at a POGO-affiliated pediatric cancer centre or satellite site and the patient's care is managed by a pediatric oncology service.	Pegaspargase up to 2,500U/m²/dose IV or IM	1. Pegaspargase will be reimbursed on a per vial basis.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
Pembrolizumab (PEM-broe-LIZ-ue-mab) Other name: Keytruda®	(Adult and Pediatric) – Adjuvant Treatment for Completely Resected Stage IIB or IIC Melanoma	Pembrolizumab is used in the adjuvant treatment of adult and pediatric (12 years and older) patients with stage IIB or IIC* melanoma following complete resection. Treatment is only for patients who have not received previous systemic treatment for melanoma and have good performance status (PS). Treatment with pembrolizumab should be initiated within 12 weeks of surgery. *As defined by the American Joint Committee on Cancer 2017 classification, eighth edition.	Pembrolizumab 2 mg/kg given intravenously (IV) (up to a maximum of 200 mg) every 3 weeks (adult and pediatric), or Pembrolizumab 4 mg/kg IV (up to a maximum of 400 mg) every 6 weeks (adult patients only). Treatment should continue until disease progression, or unacceptable toxicity, up to a maximum of 12 months (or equivalent therapy*), whichever comes first. *17 cycles if administered every 3 weeks, or 9 cycles administered every 6 weeks. [ST-QBP regimen code(s): PEMB]	1.Pembrolizumab funding is for single agent use only. 2.Patients with ocular melanoma will not be eligible for adjuvant pembrolizumab. 3.Patients who have confirmed disease progression on adjuvant pembrolizumab will not be eligible for anti-PD-1 or anti-PD-L1 immunotherapy in the metastatic setting. However, these patients may be eligible for single agent ipilimumab. 4.Patients whose disease relapses at least 6 months after their last dose of adjuvant pembrolizumab may be eligible for combination ipilimumab and nivolumab in the metastatic setting. If the patient is unfit for combination immunotherapy, they may be eligible for single agent immunotherapy.
Pembrolizumab (PEM-broe-LIZ-ue-mab) Other name: Keytruda®	Adjuvant Treatment for Completely Resected Stage III or IV Melanoma	Pembrolizumab is used for the adjuvant treatment of adult patients with completely resected stage IIIA (with node metastases >1mm), IIIB, IIIC, IIID or stage IV melanoma and; Disease must be completely resected including in-transit metastases; however, presence of regional lymph nodes with micrometastases after sentinel lymph node biopsy alone is allowed.	Pembrolizumab 2 mg/kg given intravenously (IV) (up to a maximum of 200 mg) every 21 days; or Pembrolizumab 4 mg/kg IV (up to a maximum of 400 mg) every 42 days. Treatment should be continued until disease progression or unacceptable toxicity up to a maximum of 12 months (or equivalent therapy), whichever comes first. [ST-QBP regimen code: PEMB]	1. Staging is based on the 8th edition of the American Joint Committee on Cancer (AJCC) melanoma staging system. 2. Patients with stage IIIA melanoma must have node metastases >1mm to be eligible for funding. 3. In-transit, satellite or distant metastases must be completely resected. 4. Patients with BRAF mutated melanoma who initiated treatment with adjuvant immunotherapy or adjuvant dabrafenib and trametinib may switch once between adjuvant therapies within 3 months of initiation of therapy. Funded therapy will be limited to a total of 12 months of adjuvant treatment, regardless of funding source. 5. Patients who initiated adjuvant therapy with interferon may switch once to adjuvant immunotherapy or adjuvant dabrafenib and trametinib, provided all eligibility criteria were met at the time of treatment initiation. 6. Patients with ocular melanoma will not be eligible for adjuvant pembrolizumab. 7. Pembrolizumab is funded for single agent use only. 8. Patients who have confirmed disease progression on adjuvant pembrolizumab will not be eligible for anti-PD-1/anti-PD-L1

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
				immunotherapy (e.g. pembrolizumab or nivolumab) in the metastatic setting. 9. Patients whose disease relapses at least 6 months after completing adjuvant pembrolizumab may be eligible for combination ipilimumab & nivolumab in the metastatic setting. If the patient is unfit for combination immunotherapy, they may be eligible for single agent immunotherapy.
Pembrolizumab (PEM-broe-LIZ-ue-mab) Other name: Keytruda®	Pembrolizumab - Adjuvant Treatment for Renal Cell Carcinoma	Pembrolizumab is used for the adjuvant treatment of adult patients* with renal cell carcinoma (RCC) at intermediate-high or high risk of recurrence post-nephrectomy, or following nephrectomy and resection of metastatic lesions. Treatment is only for patients who have not received previous systemic treatment for advanced RCC and have good performance status. Treatment with pembrolizumab should be initiated within 12 weeks of complete resection. *Eligible patients include those who have: ○ Histologically confirmed RCC with a clear cell component, with or without sarcomatoid features; ○ Intermediate-high or high-risk recurrence post-nephrectomy, or M1 with no evidence of disease (M1 NED) following nephrectomy and metastasectomy; and ○ Partial or radical nephrectomy (and complete metastasectomy in M1 NED patients) with negative surgical margins 4 weeks or more before the initiation of treatment.	Pembrolizumab 2 mg/kg given intravenously (IV) (up to a maximum of 200 mg) every 3 weeks, or pembrolizumab 4 mg/kg IV (up to a maximum of 400 mg) every 6 weeks. Treatment should continue until disease recurrence, or unacceptable toxicity, up to a maximum of 12 months (or equivalent therapy*), whichever comes first. *17 cycles if administered every 3 weeks, or 9 cycles administered every 6 weeks. [ST-QBP regimen code: PEMB]	1. Pembrolizumab is funded for single agent use only. 2. Intermediate-high risk RCC is defined as: • pT2, grade 4 or sarcomatoid, N0, M0 • pT3, any grade, N0, M0 3. High risk RCC is defined as: • pT4, any grade, N0, M0 • pT any stage, any grade, N+, M0 4. M1 NED is defined as a primary tumour and solid, isolated, soft-tissue metastases that could be completely resected at the time of nephrectomy (synchronous) or 1 year or less from date of nephrectomy (metachronous). 5. Patients who progress while on or within 6 months of adjuvant pembrolizumab are not eligible for immune checkpoint inhibitor-based therapy for advanced or metastatic RCC. 6. Patients with a histology other than clear cell are not eligible for funding under this policy.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
Pembrolizumab (PEM-broe-LIZ-ue-mab) Other name: Keytruda®	(Adult and Pediatric) - Relapsed Classical Hodgkin Lymphoma Post-Autologous Stem Cell Transplant or ASCT Ineligible	Pembrolizumab is used as monotherapy in adult and pediatric patients* with refractory or relapsed classical Hodgkin lymphoma (cHL) who have failed autologous stem cell transplant (ASCT) or who are not candidates for multi-agent salvage chemotherapy and ASCT. Treatment is for patients with good performance status. *Eligible patients include those who: 1. have failed to achieve a response or progressed after ASCT; 2. are not eligible to receive an ASCT due to chemotherapy-resistant disease, advanced age, or any significant coexisting medical condition that may have a negative impact on tolerability of ASCT.	Pembrolizumab 2 mg/kg, up to a maximum of 200 mg, every three weeks as an intravenous (IV) infusion (adult and pediatric), or Pembrolizumab 4 mg/kg, up to a maximum of 400 mg, every six weeks as an IV infusion (adult patients only). Treatment should be continued until disease progression or unacceptable toxicity, or to a maximum of 2 years (or equivalent therapy), whichever comes first. [ST-QBP regimen code: PEMB]	1. Patients will be eligible for either pembrolizumab or nivolumab for refractory or relapsed classical Hodgkin lymphoma (cHL), but not both. 2. For patients who stop pembrolizumab without disease progression, resumption of treatment (to complete two total years) will be funded provided no other treatment is given in between. 3. Pembrolizumab is not funded for patients who have progressed on a prior PD-1 or PD-L1 inhibitor. 4. Patients who complete 2 years' worth of treatment without disease progression may receive up to an additional 1 years' worth of treatment with pembrolizumab at the point of confirmed disease progression if the treating physician deems the patient eligible for retreatment and provided that no other systemic treatment is given in between. Claims should be submitted under the same enrolment form used for initial treatment.
Pembrolizumab (PEM-broe-LIZ-ue-mab) Other name: Keytruda®	(Adult Who Failed Prior Brentuximab Vedotin) - Relapsed Classical Hodgkin Lymphoma Post-Autologous Stem Cell Transplant or ASCT Ineligible	Pembrolizumab is used as monotherapy for the treatment of adult patients with refractory or relapsed classical Hodgkin Lymphoma (cHL) who have failed autologous stem cell transplant (ASCT) and brentuximab vedotin (BV), or who are not candidates for ASCT and have failed BV.	Pembrolizumab 2 mg/kg given intravenously (IV) (up to a maximum of 200 mg) every 21 days; or Pembrolizumab 4 mg/kg IV (up to a maximum of 400 mg) every 42 days. Treatment should continue until confirmed disease progression or unacceptable toxicity to a maximum of 2 years (up to 35 doses given every 3 weeks or 18 doses given every 6 weeks), whichever comes first. [ST-QBP regimen code: PEMB]	1. Patients will be eligible for either pembrolizumab or nivolumab for refractory or relapsed classical Hodgkin lymphoma (cHL), but not both. Please enroll in the policy entitled Pembrolizumab (Adult and Pediatric) - Relapsed Classical Hodgkin Lymphoma Post-Autologous Stem Cell Transplant or ASCT Ineligible for patients with relapsed cHL who are brentuximab vedotin naïve if criteria are met. 2. For patients who stop pembrolizumab without disease progression, resumption of treatment (to complete two total years) will be funded provided no other treatment is given in between. 3. Pembrolizumab is not funded for patients who have confirmed disease progression while receiving a prior anti-PD-1 inhibitor. 4. Patients who complete up to 2 years' worth of treatment without disease progression may receive up to an additional 1 year of treatment at the point of confirmed disease progression if the treating physician deems the patient eligible for retreatment. Claims should be submitted under the same enrolment form used for initial treatment.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
Pembrolizumab (PEM-broe-LIZ-ue-mab) Other name: Keytruda®	Advanced Melanoma (Unresectable or Metastatic Melanoma) and no prior ipilimumab	The patient must meet the following criteria: • Pembrolizumab is used for the treatment of adult patients with advanced melanoma (unresectable or metastatic melanoma). • Patients are naïve to ipilimumab treatment (patients with BRAF mutation positive may or may not have received BRAF targeted therapy). • Treatment should be for patients with an ECOG performance status of 0 or 1, and who have stable brain metastases (if present).	Pembrolizumab 2 mg/kg given intravenously (IV) (up to a maximum of 200 mg) every 21 days; or Pembrolizumab 4 mg/kg IV (up to a maximum of 400 mg) every 42 days. Treatment should continue until confirmed disease progression or unacceptable toxicity to a maximum of 2 years (up to 35 doses given every 3 weeks or 18 doses given every 6 weeks), whichever comes first. [ST-QBP regimen code: PEMB]	1. Patients who have received ipilimumab before the effective funding date of pembrolizumab (i.e., received at least one treatment of ipilimumab prior to June 2, 2016) will be eligible to receive pembrolizumab upon disease progression. 2. Pembrolizumab funding is for single agent use only. 3. Pembrolizumab is not funded for patients who have confirmed disease progression while receiving a prior anti-PD-1 inhibitor in the metastatic setting. 4. Patients whose disease relapses at least 6 months after completing adjuvant anti-PD-1 inhibitor may be eligible for combination ipilimumab and nivolumab in the metastatic setting or, if the patient is unfit for combination immunotherapy, single agent immunotherapy. 5. For patients completing or stopping single agent pembrolizumab without disease progression, resumption of treatment will be funded provided no other treatment is given in between. Pembrolizumab funding is for a total of 24 months' worth of therapy or until confirmed disease progression, whichever occurs first. Pembrolizumab retreatment, for up to an additional 12 months' worth of therapy, can be considered at the point of confirmed disease progression (see FAQ #7). Claims should be submitted under the same form used for initial treatment. 6. For patients treated with anti-PD-1 monotherapy (instead of combination nivolumab plus ipilimumab) in the metastatic setting, ipilimumab monotherapy will be funded as a subsequent line of therapy provided that funding criteria are met. 7. Patients with BRAF mutation may be initiated on BRAF targeted therapy or immunotherapy. Upon disease progression, the patient may be switched to the other treatment modality as a subsequent line of therapy.
Pembrolizumab (PEM-broe-LIZ-ue-mab) Other name: Keytruda®	Advanced Melanoma (Unresectable or Metastatic Melanoma) and prior ipilimumab	The patient must meet the following criteria: • Pembrolizumab is used in the treatment of adult patients with advanced melanoma (unresectable or metastatic melanoma). • Patients have failed ipilimumab, and if BRAF mutation positive, have also failed BRAF mutation therapy.	Pembrolizumab 2 mg/kg given intravenously (IV) (up to a maximum of 200 mg) every 21 days; or Pembrolizumab 4 mg/kg IV (up to a maximum of 400 mg) every 42 days. Treatment should continue until confirmed disease progression or unacceptable toxicity to a	1. Patients who have received ipilimumab before the effective funding date of pembrolizumab (i.e., received at least one treatment of ipilimumab prior to June 2, 2016) will be eligible to receive pembrolizumab upon disease progression. 2. Pembrolizumab funding is for single agent use only. 3. Pembrolizumab is not funded for patients who have confirmed disease progression while receiving a prior anti-PD-1 inhibitor in the metastatic

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
		• Treatment should be for patients with an ECOG performance status of 0 or 1, and who have stable brain metastases (if present).	maximum of 2 years (up to 35 doses given every 3 weeks or 18 doses given every 6 weeks), whichever comes first. [ST-QBP regimen code: PEMB]	setting. 4. Patients whose disease relapses at least 6 months after completing adjuvant anti-PD-1 inhibitor may be eligible for combination ipilimumab and nivolumab in the metastatic setting or, if the patient is unfit for combination immunotherapy, single agent immunotherapy. 5. For patients completing or stopping single agent pembrolizumab without disease progression, resumption of treatment will be funded provided no other treatment is given in between. Pembrolizumab funding is for a total of 24 months' worth of therapy or until confirmed disease progression, whichever occurs first. Pembrolizumab retreatment, for up to an additional 12 months' worth of therapy, can be considered at the point of confirmed disease progression (see FAQ #6). Claims should be submitted under the same form used for initial treatment. 6. Patients with BRAF mutation may be initiated on BRAF targeted therapy or immunotherapy. Upon disease progression, the patient may be switched to the other treatment modality as a subsequent line of therapy.
Pembrolizumab (PEM-broe-LIZ-ue-mab) Other name: Keytruda®	Advanced or Metastatic Non-Small Cell Lung Cancer (Second or Subsequent Line)	The patient must meet the following criteria: • Pembrolizumab is used for the treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumours express PD-L1 with Tumour Proportion Score (TPS) ≥ 1% (as determined by a validated test) and who have good performance status, and who have disease progression on or after cytotoxic chemotherapy. • Patients with epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genetic tumour aberrations should have disease progression on authorized therapy for these aberrations and cytotoxic chemotherapy prior to receiving pembrolizumab.	Pembrolizumab 2 mg/kg given intravenously (IV) (up to a maximum of 200 mg) every 21 days; or Pembrolizumab 4 mg/kg IV (up to a maximum of 400 mg) every 42 days. Treatment should continue until confirmed disease progression or unacceptable toxicity to a maximum of 2 years (up to 35 doses given every 3 weeks or 18 doses given every 6 weeks), whichever comes first. [ST-QBP regimen code: PEMB]	1. Ontario Health (Cancer Care Ontario) will fund one line of atezolizumab, nivolumab, nivolumab plus ipilimumab, or pembrolizumab for advanced non-small cell lung cancer. Patients who were treated with durvalumab (or other anti-PD1/PD-L1 therapy) in the curative setting must have a disease free interval of 6 months or greater in order to be considered for funding under this policy. 2. Patients who complete 35 cycles without disease progression may receive up to additional 17 cycles at the point of confirmed disease progression if the treating physician deems the patient eligible for retreatment. Claims should be submitted under the same form used for initial treatment. 3. It is recommended that pembrolizumab be used after treatment with a platinum-based therapy. 4. Patients switching from other therapies for second or subsequent line NSCLC must provide PD-L1 testing results and a clinic note indicating the reason for switching when submitting the enrolment form.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
				5. Pembrolizumab is not funded for patients who have confirmed disease progression after receiving a prior anti-PD-1 inhibitor in the metastatic setting. 6. Pembrolizumab funding is for single agent use only.
Pembrolizumab (PEM-broe-LIZ-ue-mab) Other name: Keytruda®	First Line Treatment of Advanced Esophageal and Esophagogastric Junction Carcinoma	The patient must meet the following criteria: • Pembrolizumab is used in combination with platinum and fluoropyrimidine-based chemotherapy for the first-line treatment of locally advanced unresectable or metastatic esophageal adenocarcinoma or squamous cell carcinoma, or human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic adenocarcinoma of the esophagogastric junction (EGJ) in patients with good performance status.	Pembrolizumab 2 mg/kg given intravenously (IV) (up to a maximum of 200 mg) every 21 days; or Pembrolizumab 4 mg/kg IV (up to a maximum of 400 mg) every 42 days. Treatment should continue until confirmed disease progression or unacceptable toxicity to a maximum of 2 years (up to 35 doses given every 3 weeks or 18 doses given every 6 weeks), whichever comes first. When used as combination therapy, pembrolizumab must be given with a fluoropyrimidine and a platinum for up to 6 cycles, followed by pembrolizumab maintenance. [ST-QBP regimen codes: CISPFU+PEMB, CRBPFU+PEMB, CAPECISP+PEMB, CAPECRBP+PEMB, MFOLFOX6+PEMB, or XELOX+PEMB for the induction phase, followed by PEMB(MNT) for the maintenance phase].	1. NDFP will only fund one of nivolumab or pembrolizumab for the first-line treatment of gastric, EGJ, or esophageal cancer in the advanced setting. Please note the following: • Only pembrolizumab can be funded for squamous cell carcinoma of the esophagus. • Only nivolumab can be funded for gastric adenocarcinoma. • For patients who are a candidate for either therapy (esophageal or EGJ adenocarcinoma), the decision is up to the treating physician. 2. For patients who temporarily stop pembrolizumab without disease progression, continuation of pembrolizumab (to complete 2 years' worth of treatment) will be funded provided that no other systemic treatment is given in between. 3. Patients who complete 2 years' worth of treatment without disease progression may receive up to an additional 1 years' worth of treatment with pembrolizumab, with or without chemotherapy, at the point of confirmed disease progression if the treating physician deems the patient eligible for retreatment and provided that no other systemic treatment is given in between. Claims should be submitted under the same form used for the initial course of treatment. 4. At least 1 cycle of chemotherapy must be given concurrently with pembrolizumab before changing to pembrolizumab maintenance due to intolerance. 5. Patients who received prior adjuvant therapy with an immune checkpoint inhibitor may be eligible for pembrolizumab in combination with chemotherapy in the advanced setting provided there was a

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
				disease-free interval (DFI) of 6 months or greater after completing adjuvant therapy.
Pembrolizumab (PEM-broe-LIZ-ue-mab) Other name: Keytruda®	First Line Treatment of MSI-H/dMMR Metastatic Colorectal Cancer	The patient must meet the following criteria: • Pembrolizumab is used as monotherapy for the first-line treatment of metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) colorectal cancer in patients with good performance status.	Pembrolizumab 2 mg/kg given intravenously (IV) (up to a maximum of 200 mg) every 21 days; or Pembrolizumab 4 mg/kg IV (up to a maximum of 400 mg) every 42 days. Treatment should continue until confirmed disease progression or unacceptable toxicity to a maximum of 2 years (up to 35 doses given every 3 weeks or 18 doses given every 6 weeks), whichever comes first. [ST-QBP regimen code: PEMB]	1. On a time-limited basis, the NDFP can consider requests for patients who missed the opportunity to access pembrolizumab as first-line treatment for MSI-H/dMMR metastatic colorectal cancer provided all other eligibility criteria are met. Please submit as a prior approval request including the most recent clinic note summarizing the patient's treatment history and the pathology report confirming MSI-H/dMMR status. 2. Patients with metastatic small bowel and appendiceal cancers who meet all other funding criteria may be considered for pembrolizumab funding under this policy. 3. For patients who temporarily stop pembrolizumab without disease progression, continuation of pembrolizumab (to complete 2 years' worth of treatment) will be funded provided that no other systemic treatment is given in between. 4. Patients who complete 2 years' worth of treatment without disease progression may receive up to an additional 1 years' worth of treatment with pembrolizumab monotherapy at the point of confirmed disease progression if the treating physician deems the patient eligible for retreatment and provided that no other systemic treatment is given in between. Claims should be submitted under the same form used for the initial course of treatment.
Pembrolizumab (PEM-broe-LIZ-ue-mab) Other name: Keytruda®	In Combination with Axitinib for First Line Advanced or Metastatic Renal Cell Carcinoma	The patient must meet the following criteria: • Pembrolizumab is used in combination with axitinib for the first line treatment of patients with advanced or metastatic renal cell carcinoma (RCC) who have good performance status.	Pembrolizumab 2 mg/kg given intravenously (IV) (up to a maximum of 200 mg) every 21 days; or Pembrolizumab 4 mg/kg IV (up to a maximum of 400 mg) every 42 days. Treatment should continue until confirmed disease progression or unacceptable toxicity to a maximum of 2 years (up to 35 doses given every 3 weeks or 18 doses given every 6 weeks), whichever comes first. Axitinib should be	1. Please refer to the Ontario Drug Benefit Exceptional Access Program for full funding criteria for axitinib. 2. Patients who have a disease-free interval of 6 months or greater after completion of adjuvant therapy may be eligible for one line of immune checkpoint inhibitor-based therapy for advanced or metastatic renal cell carcinoma provided all other eligibility criteria are met. 3. For patients who stop pembrolizumab without disease progression, continuation of pembrolizumab (to complete 2 years' worth of treatment) will be funded provided that no other treatment is given in between.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
			continued until disease progression or unacceptable toxicity. [ST-QBP regimen code: AXIT+PEMB for combination therapy, AXIT(MNT) for axitinib maintenance portion]	4. Patients who complete 35 cycles without disease progression may receive up to an additional 17 cycles of pembrolizumab monotherapy at the point of confirmed disease progression if the treating physician deems the patient eligible for retreatment. Claims should be submitted under the same form used for initial treatment.
Pembrolizumab (PEM-broe-LIZ-ue-mab) Other name: Keytruda®	In Combination with Carboplatin and Paclitaxel for First-Line Metastatic Squamous Non-Small Cell Lung Cancer (NSCLC)	The patient must meet the following criteria: • Pembrolizumab is used in combination with carboplatin and paclitaxel for the treatment of adult patients with metastatic squamous non-small cell lung cancer (NSCLC) who have not had prior systemic chemotherapy for metastatic NSCLC. • Treatment should be for patients with good performance status.	Pembrolizumab 2 mg/kg given intravenously (IV) (up to a maximum of 200 mg) every 21 days; or Pembrolizumab 4 mg/kg IV (up to a maximum of 400 mg) every 42 days. Treatment should continue until confirmed disease progression or unacceptable toxicity to a maximum of 2 years (up to 35 doses given every 3 weeks or 18 doses given every 6 weeks), whichever comes first. Pembrolizumab should be given in combination with carboplatin and paclitaxel for the first 4-6 cycles, followed by pembrolizumab as a single agent for the maintenance phase. [ST-QBP regimen code: CRBPPACL+PEMB for induction phase, PEMB(MNT) for maintenance phase]	1. The cost of paclitaxel as part of this regimen for metastatic squamous non-small cell lung cancer (NSCLC) is funded through the Systemic Treatment Quality-Based Procedure (ST-QBP) and is included in the band level pricing. 2. Ontario Health (Cancer Care Ontario) will fund one line of atezolizumab, nivolumab, nivolumab plus ipilimumab, or pembrolizumab for advanced non-small cell lung cancer. Patients who were treated with durvalumab (or other anti-PD1/PD-L1 therapy) in the curative setting must have a disease free interval of 6 months or greater in order to be considered for funding under this policy. 3. Patients who are not able to tolerate platinum doublet therapy with paclitaxel may be considered for funding under this policy if an alternate platinum doublet therapy can be used with pembrolizumab. Requests for pembrolizumab to be used with alternate platinum doublets should be submitted as Prior Approvals. 4. For patients who stop pembrolizumab without disease progression, continuation of pembrolizumab (to complete 2 years' worth of treatment) will be funded provided that no other treatment is given in between. 5. Patients who complete 2 years' worth of treatment without disease progression may receive up to an additional 1 year's worth of treatment at the point of confirmed disease progression if the treating physician deems the patient eligible for retreatment. Claims should be submitted under the same form used for initial treatment.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
Pembrolizumab (PEM-broe-LIZ-ue-mab) Other name: Keytruda®	In Combination with Platinum and Pemetrexed for First Line Metastatic Non-Squamous Non-Small Cell Lung Cancer (NSCLC)	The patient must meet the following criteria: • Pembrolizumab is used in combination with pemetrexed and platinum chemotherapy for the treatment of metastatic non-squamous, non-small cell lung cancer (NSCLC), in adult patients with no EGFR or ALK genomic tumour aberrations, and no prior systemic chemotherapy treatment for metastatic NSCLC. • Treatment should be for patients with good performance status.	Pembrolizumab 2 mg/kg given intravenously (IV) (up to a maximum of 200 mg) every 21 days; or Pembrolizumab 4 mg/kg IV (up to a maximum of 400 mg) every 42 days. Treatment should continue until confirmed disease progression or unacceptable toxicity to a maximum of 2 years (up to 35 doses given every 3 weeks or 18 doses given every 6 weeks), whichever comes first. Pembrolizumab must be given in combination with pemetrexed and platinum (cisplatin or carboplatin) for the first 4-6 cycles, followed by pemetrexed only for the maintenance phase. [ST-QBP regimen code: CISPPEME+PEMB or CRBPPEME+PEMB for induction phase, PEME+PEMB(MNT) for maintenance phase]	1. The cost of pemetrexed-based induction and pemetrexed maintenance as part of this regimen for non-squamous non-small cell lung cancer (NSCLC) is funded through the Systemic Treatment Quality-Based Procedure (ST-QBP) and is included in the band level pricing. 2. Ontario Health (Cancer Care Ontario) will fund one line of atezolizumab, nivolumab, nivolumab plus ipilimumab, or pembrolizumab for advanced non-small cell lung cancer. Patients who were treated with durvalumab (or other anti-PD1/PD-L1 therapy) in the curative setting must have a disease free interval of 6 months or greater in order to be considered for funding under this policy. 3. For patients who stop pembrolizumab without disease progression, continuation of pembrolizumab (to complete 2 years' worth of treatment) will be funded provided that no other treatment is given in between. 4. Patients who complete 2 years' worth of treatment without disease progression may receive up to an additional 1 year's worth of treatment at the point of confirmed disease progression if the treating physician deems the patient eligible for retreatment. Claims should be submitted under the same enrolment form used for initial treatment.
Pembrolizumab (PEM-broe-LIZ-ue-mab) Other name: Keytruda®	Locally Recurrent Unresectable or Metastatic Triple Negative Breast Cancer	Pembrolizumab is used in combination with chemotherapy for the treatment of adult patients with locally recurrent unresectable or metastatic triple negative breast cancer (TNBC).* Patients must have: • Tumour(s) expressing PD-L1 with a combined positive score (CPS) of ≥ 10 (as determined by a validated test); AND • A good performance status; AND • If applicable, a minimum 6-month interval from completion of treatment with curative intent to recurrence of local or distant disease. Patients must not have:	Pembrolizumab 2 mg/kg given intravenously (IV) (up to a maximum of 200 mg) every 3 weeks, or pembrolizumab 4 mg/kg IV (up to a maximum of 400 mg) every 6 weeks, given in combination with chemotherapy. Treatment should continue until disease progression or unacceptable toxicity up to a maximum of 2 years (i.e., 35 doses given every 3 weeks, or 18 doses given every 6 weeks), whichever occurs first. [ST-QBP regimen code(s): CRBPGEMC(W)+PEMB, PACL(W)+PEMB]	1. Patients who complete 2 years of pembrolizumab may continue with chemotherapy in the presence of clinical benefit as per physician discretion.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
		• Received prior chemotherapy for metastatic or incurable locally advanced disease; OR • Contraindications to immunotherapy; OR • Unstable central nervous system metastases. *Refers to lack of expression of the estrogen receptor (ER), progesterone receptor (PR), and human epidermal growth factor receptor 2 (HER2) as per the American Society of Clinical Oncology (ASCO)/College of American Pathologists (CAP) guidelines.		
Pembrolizumab (PEM-broe-LIZ-ue-mab) Other name: Keytruda®	Metastatic, Persistent, or Recurrent Carcinoma of the Cervix	Pembrolizumab is used for the treatment of adult patients with persistent, recurrent, or metastatic cervical cancer whose tumours express PD-L1 (combined positive score [CPS] ≥ 1) as determined by a validated test, in combination with standard of chemotherapy, with or without bevacizumab. Treatment is only for patients who have not received prior systemic chemotherapy for metastatic or advanced disease, have a good performance status, and whose disease is not amenable to curative treatment. Patients must also not have active central nervous system (CNS) metastases or significant autoimmune disease.	Pembrolizumab 2 mg/kg given intravenously (IV) (up to a maximum of 200 mg) every 3 weeks or Pembrolizumab 4 mg/kg IV (up to a maximum of 400 mg) every 6 weeks. Treatment should continue until disease progression or unacceptable toxicity, up to a maximum of 2 years (up to 35 doses given every 3 weeks or 18 doses given every 6 weeks), whichever comes first. Pembrolizumab should be given in combination with platinum-based chemotherapy, with or without bevacizumab, followed by pembrolizumab maintenance. [ST-QBP regimen code(s): CISPPACL+PEMB, CISPPACL+BEVA+PEMB, CRBPPACL+PEMB, CRBPPACL+BEVA+PEMB for the induction phase, followed by PEMB(MNT), BEVA+PEMB(MNT) for the maintenance phase]	1. At least 1 cycle of chemotherapy must be given concurrently with pembrolizumab (with or without bevacizumab) before changing to pembrolizumab maintenance, with or without bevacizumab. 2. Patients who received cisplatin as part of chemoradiotherapy in the curative setting may still be eligible for pembrolizumab, provided all other eligibility criteria are met. 3. Patients who complete 2 years' worth of treatment without disease progression or recurrence on pembrolizumab may receive up to an additional 1 year's worth of treatment at the point of confirmed disease progression if the treating physician deems the patient eligible for retreatment. Please refer to FAQ viii for additional information. 4. If bevacizumab will be added to the patient's regimen and provided all eligibility criteria are met, please complete a separate enrolment for 'Bevacizumab (Biosimilar) – Metastatic (Stage IVB) Persistent or Recurrent Carcinoma of the Cervix'.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
Pembrolizumab (PEM-broe-LIZ-ue-mab) Other name: Keytruda®	Previously Treated Locally Advanced or Metastatic Urothelial Carcinoma	The patient must meet the following criteria: • Pembrolizumab is used for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma (MUC) who have disease progression during or following platinum-containing chemotherapy or within 12 months of completing neoadjuvant or adjuvant platinum-containing chemotherapy. • Treatment should be for patients with good performance status.	Pembrolizumab 2 mg/kg given intravenously (IV) (up to a maximum of 200 mg) every 21 days; or Pembrolizumab 4 mg/kg IV (up to a maximum of 400 mg) every 42 days. Treatment should continue until confirmed disease progression or unacceptable toxicity to a maximum of 2 years (up to 35 doses given every 3 weeks or 18 doses given every 6 weeks), whichever comes first. [ST-QBP regimen code: PEMB]	1. Ontario Health (Cancer Care Ontario) will fund one line of immunotherapy for locally advanced or metastatic urothelial carcinoma. 2. Patients who complete 2 years' worth of treatment without disease progression may receive up to an additional 1 year's worth of treatment at the point of confirmed disease progression if the treating physician deems the patient eligible for retreatment. Claims should be submitted under the same enrolment form used for initial treatment. 3. Pembrolizumab is not funded for patients who have confirmed disease progression after receiving a prior anti-PD-1/anti-PD-L1 inhibitor in the locally advanced or metastatic setting. 4. Pembrolizumab funding is for single agent use only.
Pembrolizumab (PEM-broe-LIZ-ue-mab) Other name: Keytruda®	Previously Treated MSI-H/dMMR Advanced Endometrial Cancer	Pembrolizumab is used as monotherapy for the treatment of adult patients with unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) endometrial carcinoma whose tumours have progressed following prior chemotherapy. Treatment is only for patients who have not received prior therapy with a programmed cell death 1 protein (PD-1) or programmed cell death ligand 1 (PD-L1) inhibitor, do not have active central nervous system (CNS) metastases or active autoimmune disease, and who have a good performance status.	Pembrolizumab 2 mg/kg given intravenously (IV) (up to a maximum of 200 mg) every 3 weeks, or pembrolizumab 4 mg/kg IV (up to a maximum of 400 mg) every 6 weeks. Treatment should continue until disease progression or unacceptable toxicity, up to a maximum of 2 years (up to 35 doses given every 3 weeks or 18 doses given every 6 weeks), whichever comes first. [ST-QBP regimen code(s): PEMB]	1. Patients who complete 2 years' worth of treatment without disease progression or recurrence on pembrolizumab may receive up to an additional 1 year's worth of treatment at the point of confirmed disease progression if the treating physician deems the patient eligible for retreatment.
Pembrolizumab (PEM-broe-LIZ-ue-mab) Other name: Keytruda®	Previously Untreated High-Risk Early-Stage Triple Negative Breast Cancer	Pembrolizumab is used for the treatment of adult patients with high-risk early-stage triple negative breast cancer (TNBC*) in combination with chemotherapy as neoadjuvant therapy, and then continued as monotherapy in the adjuvant setting. Treatment is only for patients with good performance status who have not received prior systemic therapy	Pembrolizumab 2 mg/kg given intravenously (IV) (up to a maximum of 200 mg) every 21 days, or Pembrolizumab 4 mg/kg IV (up to a maximum of 400 mg) every 42 days. Pembrolizumab is given in combination with neoadjuvant chemotherapy then as a single agent in the adjuvant setting.	1. Patients with T1a/T1bN0 (determined by radiographic and/or clinical assessment) disease are not eligible.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
		for non-metastatic TNBC and with no clinical contraindication to immunotherapy. Eligible non-metastatic patients include those with T1c, N1-2 or T2-4, N0-2 as per the American Joint Committee on Cancer (AJCC). Staging is based on radiological and/or clinical assessment. *Refers to lack of expression of the estrogen receptor (ER), progesterone receptor (PR), and human epidermal growth factor receptor 2 (HER2) as per the American Society of Clinical Oncology (ASCO)/ College of American Pathologists (CAP) guidelines.	Treatment should be continued until confirmed disease progression or recurrence or unacceptable toxicity up to a maximum of 1 year (i.e., 17 doses given every 3 weeks, or 9 doses given every 6 weeks), whichever occurs first. [ST-QBP regimen codes: AC+PEMB, AC(DD)+PEMB, CRBPPACL(W)+PEMB, PACL+PEMB, PACL(W)+PEMB, PACL(DD)+PEMB, FEC+PEMB, DOCE+PEMB, CYCLDOCE+PEMB followed by PEMB for the monotherapy phase]	
Pembrolizumab (PEM-broe-LIZ-ue-mab) Other name: Keytruda®	Previously Untreated Locally Advanced or Metastatic Non-Small Cell Lung Cancer	The patient must meet the following criteria: • Pembrolizumab is used for the treatment of locally advanced or previously untreated metastatic non-small cell lung cancer (NSCLC) in adult patients whose tumours express PD-L1 (Tumour Proportion Score [TPS] ≥ 50%) as determined by a validated test and who do not harbour a sensitizing epidermal growth factor receptor (EGFR) mutation or anaplastic lymphoma kinase (ALK) translocation. Patients should have good performance status. • Patients who have locally advanced (stage IIIB) disease cannot be eligible for potentially curative concurrent chemoradiotherapy. On a time-limited basis (ending July 17, 2018), CCO will fund pembrolizumab for patients who have not progressed on first-line therapy (platinum doublet and/or maintenance pemetrexed).	Pembrolizumab 2 mg/kg given intravenously (IV) (up to a maximum of 200 mg) every 21 days; or Pembrolizumab 4 mg/kg IV (up to a maximum of 400 mg) every 42 days. Treatment should continue until confirmed disease progression or unacceptable toxicity to a maximum of 2 years (up to 35 doses given every 3 weeks or 18 doses given every 6 weeks), whichever comes first. [ST-QBP regimen code: PEMB]	1. Ontario Health (Cancer Care Ontario) will fund one line of atezolizumab, nivolumab, nivolumab plus ipilimumab, or pembrolizumab for advanced non-small cell lung cancer. Patients who were treated with durvalumab (or other anti-PD1/PD-L1 therapy) in the curative setting must have a disease free interval of 6 months or greater in order to be considered for funding under this policy. 2. Patients who complete 35 cycles without disease progression may receive up to an additional 17 cycles at the point of confirmed disease progression if the treating physician deems the patient eligible for retreatment. Claims should be submitted under the same form used for initial treatment. 3. Patients switching from other first-line therapies must provide PD-L1 testing results and a clinic note indicating the reason for switching when submitting the enrolment form. 4. Pembrolizumab funding is for single agent use only.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
Pembrolizumab (PEM-broe-LIZ-ue-mab) Other name: Keytruda®	Recurrent or Metastatic Squamous Cell Carcinoma of the Head and Neck	Pembrolizumab is used for the first-line treatment of metastatic or unresectable recurrent head & neck squamous cell carcinoma (HNSCC): As monotherapy for patients whose tumours have PD-L1 expression combined positive score (CPS) greater than or equal to 1, or in combination with platinum and 5-fluorouracil (5-FU) chemotherapy regardless of PD-L1 expression level.	Pembrolizumab 2 mg/kg given intravenously (IV) (up to a maximum of 200 mg) every 21 days; or Pembrolizumab 4 mg/kg IV (up to a maximum of 400 mg) every 42 days. Treatment should continue until confirmed disease progression or unacceptable toxicity to a maximum of 2 years (up to 35 doses given every 3 weeks or 18 doses given every 6 weeks), whichever comes first. When used as combination therapy, pembrolizumab must be given with 5-FU and platinum (cisplatin or carboplatin) for up to 6 cycles, followed by pembrolizumab maintenance [ST-QBP regimen codes: CISPFU+PEMB, CRBPFU+PEMB or CRBPPACL+PEMB for the induction phase, PEMB(MNT) for the maintenance phase]. When used as monotherapy, the ST-QBP regimen code is PEMB.	1. Patients will also be considered for funding under this policy if carboplatin and paclitaxel is used as the chemotherapy backbone with pembrolizumab as outlined in the 'Funded Dose' section. 2. Ontario Health will fund one line of pembrolizumab or nivolumab for recurrent or metastatic squamous cell carcinoma of the head and neck. 3. Patients with a primary cutaneous squamous cell carcinoma are not eligible for pembrolizumab. 4. For patients who temporarily stop pembrolizumab without disease progression, continuation of pembrolizumab (to complete 2 years' worth of treatment) will be funded provided that no other systemic treatment is given in between. 5. Patients who complete 2 years' worth of treatment without disease progression may receive up to an additional 1 years' worth of treatment with pembrolizumab monotherapy at the point of confirmed disease progression if the treating physician deems the patient eligible for retreatment and provided that no other systemic treatment is given in between. Claims should be submitted under the same form used for the initial course of treatment.
Pertuzumab (per-TOO-zoo-mab) Other names: Perjeta®	With Trastuzumab (Biosimilar) - Unresectable Locally Recurrent or Metastatic Breast Cancer	For use in combination with a taxane for the treatment of patients with HER2-positive unresectable locally recurrent or metastatic breast cancer with an ECOG status of 0 or 1, who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease.	Loading dose of pertuzumab 840 mg and trastuzumab 8 mg/kg, followed every 3 weeks thereafter by a dose of pertuzumab 420 mg and trastuzumab 6 mg/kg, until disease progression or unmanageable toxicity. [ST-QBP regimen codes: DOCE+PERT+TRAS, NPAC+PERT+TRAS, NPAC(W)+PERT+TRAS, PACL+PERT+TRAS, PACL(W)+PERT+TRAS, PERT+TRAS]	1. Existing patients with an enrolment and treatment claim(s) submitted in eClaims prior to December 15, 2022 will be eligible for continued funding of trastuzumab (Herceptin) in combination with pertuzumab until their treatment course has completed. Sites are required to use the Perjeta-Herceptin combo packs in order to be reimbursed. As of September 15, 2022, sites may start using a trastuzumab biosimilar in combination with pertuzumab for new and existing patients. As of December 15, 2022, all new starts must use a trastuzumab biosimilar in combination with pertuzumab. Perjeta is available as single vials. 2. HER2 positive tumour status is confirmed either by IHC (score of 3+) and/or FISH/SISH/ISH (ratio of ≥ 2). A copy of the pathology report must be uploaded in eClaims. The results of the FISH/SISH/ISH test must also be provided if the IHC test result is equivocal.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
				3. The patient must have a baseline left ventricular ejection fraction (LVEF) of ≥ 50% (as determined by a MUGA scan or ECHO). It is recommended that a MUGA scan or ECHO be repeated every 3 months during treatment to ensure that the LVEF is within the institution's normal limits. 4. Pertuzumab is funded when given in combination with trastuzumab and a taxane. If the taxane is discontinued (e.g., after 6-8 cycles or due to unmanageable toxicity), continued treatment with pertuzumab-trastuzumab will be funded provided there is no evidence of disease progression while on treatment. 5. If the time between two sequential infusions is 6 weeks or more, re-load with an initial dose of 840 mg pertuzumab and 8 mg/kg trastuzumab, followed every 3 weeks thereafter by a dose of 420 mg pertuzumab and 6 mg/kg trastuzumab.
Polatuzumab Vedotin (pol-a-TOOZ-ue-mab ve-doe-tin) Other name: Polivy®	With bendamustine and rituximab (biosimilar) - Relapsed or Refractory Diffuse Large B-cell Lymphoma	Polatuzumab vedotin is used in combination with bendamustine and rituximab (pola-BR) for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma, not otherwise specified, who are not eligible for autologous stem cell transplant (ASCT) and have received at least 1 prior therapy. Eligible patients should have good performance status and a life expectancy greater than or equal to 24 weeks.	Cycle 1: Rituximab 375mg/m2 intravenously (IV) on Day 1, Polatuzumab vedotin 1.8mg/kg IV on Day 2, Bendamustine 90mg/m2 IV on Days 2 and 3 Cycles 2 to 6: Rituximab 375mg/m2 IV on Day 1, Polatuzumab vedotin 1.8mg/kg IV on Day 1, Bendamustine 90mg/m2 IV on Days 1 and 2 Treatment with pola-BR should continue for a maximum of 6 cycles (21 days per cycle), or until unacceptable toxicity or disease progression, whichever occurs first. [ST-QBP regimen code: BEND+POLA+RITU]	1. NDFP will only fund polatuzumab vedotin in combination with bendamustine and rituximab (pola-BR). An exception is if pola-BR is being used as a bridge to CAR T-cell therapy, in which case bendamustine may be omitted if appropriate based on clinician judgement. 2. Enrolment in this policy will fulfill enrolment requirements for all drugs in this regimen (polatuzumab vedotin, rituximab biosimilar, and bendamustine) 3. Pola-BR is not funded: a. In patients with previously untreated diffuse large B-cell lymphoma (DLBCL); or b. In patients with active CNS lymphoma; or c. If used as salvage therapy for patients who are eligible for ASCT; or d. In patients with Burkitt lymphoma 4. Pola-BR may be considered in patients with transformed follicular lymphoma to DLBCL, HIV-related lymphoma, grey zone lymphoma, and mediastinal large B-cell lymphoma. 5. Pola-BR may be considered in patients who have progressed on prior CAR -T-cell therapy provided the patient is not eligible for ASCT.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
Plerixafor (pleh-RIKS-ah-for) Other name: Mozobil®	Stem Cell Mobilization in non-Hodgkin's Lymphoma or Multiple Myeloma	a) Non-Hodgkin's Lymphoma, or b) Multiple Myeloma Plerixafor will be used in combination with filgrastim to mobilize hematopoietic stem cells for subsequent autologous transplantation; AND One of the following: a) The patient has a PBCD34+ count of less than 10 cells/µL after 4 days of filgrastim; OR b) Less than 50% of the target CD34 yield is achieved on the first day of apheresis (after being mobilized by filgrastim alone or following chemotherapy); OR c) If a patient has failed a previous stem cell mobilization with filgrastim alone or following chemotherapy	Plerixafor 0.24 mg/kg sc is given daily for a single mobilization attempt (maximum of 4 doses). The daily dose must not exceed 40 mg.	No Supporting documentation required for this policy. In the absence of collecting supporting documentation: • CCO reserves the right to perform an audit on the patient's eligibility to receive reimbursement for this policy • In the event of an audit, CCO may request a clinic note demonstrating: • Peripheral blood CD34+ count of less than 10 cells/ µL after 4 days of filgrastim (e.g., a clinic note and flow cytometry report); OR • Less than 50% of the target CD34 yield is achieved on the first day of apheresis (after being mobilized with filgrastim alone or chemotherapy, (e.g., a clinic note and flow cytometry report.) Please specify the drug(s) used in the previous attempt and indicate the target CD34 yield; OR • A clinic note documenting failure of a previous attempt at stem cell mobilization with filgrastim alone or following chemotherapy. The drug(s) used in the previous attempt must be specified. CCO reserves the right to recover the cost of treatment claims if the requested documentation is not provided.
Pralatrexate (PRAL-a-TREX-ate) Other name: Folotyn®	Relapsed or Refractory Peripheral T-Cell Lymphoma	Pralatrexate is used for the treatment of patients with relapsed or refractory peripheral T-cell lymphoma (PTCL) who have undergone previous systemic treatment, none of which include romidepsin. Treatment should be for patients with a good performance status.	Pralatrexate 30 mg/m^2 intravenously (IV) once weekly for six weeks followed by one week off treatment (a seven week cycle) [ST-QBP regimen code: PRAL]. Treatment should continue until disease progression or unacceptable toxicity.	1. Patients will be eligible for either pralatrexate or romidepsin, but not both. 2. Vitamin supplementation is mandatory prior to the first dose of pralatrexate: i. Folic acid 1 to 1.25 mg orally once daily beginning 10 days prior to the first dose of pralatrexate and continuing for 30 days after the last dose; ii. Vitamin B12 1000 mcg intramuscularly within 10 weeks prior to the first dose of pralatrexate and continuing every 8 to 10 weeks thereafter during therapy.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
Porfimer Sodium – Photodynamic Therapy (POR-fimm-er) Other name: Photofrin®	Advanced non-small cell lung cancer	a. The patient has advanced non-small cell lung cancer b. The patient has symptomatic bronchial obstruction	Porfimer sodium 2 mg/kg IV	N/A
Radium-223 Dichloride (REY-dee-um DYE-klor-ide) Other name: Xofigo®	Castration-Resistant Prostate Cancer	Patient has castration-resistant prostate cancer (CRPC) with symptomatic bone metastases and no known visceral metastatic disease	**Effective as of April 18, 2016:** Administered pre- or post-docetaxel, funded dose regimen is 55 kBq (1.49 microcurie) per kg body weight, given at 4 week intervals for a total of 6 injections. If used in the pre-docetaxel setting, no subsequent funding will be considered in the post-docetaxel setting.	Please check the following to confirm and acknowledge that: • A consult with a medical or radiation oncologist has been done before starting radium • This enrolment will not be combined with cabazitaxel or enzalutamide or abiraterone for mCRPC • If radium is funded in the pre-docetaxel setting, no subsequent funding will be considered in the post-docetaxel setting
Raltitrexed (rall-tee-TREX-edd) Other name: Tomudex®	Adjuvant Colorectal, Small Bowel, or Appendiceal Cancer	The patient must meet criteria "a" and at least one of criteria "b" or "c": a. Raltitrexed will be used as adjuvant therapy in patients with colorectal, small bowel, or appendiceal cancer b. The patient has complete dihydropyrimidine dehydrogenase (DPD) deficiency c. The patient also i. has experienced unacceptable toxicity with fluorouracil chemotherapy, and/or ii. lives more than 60 km from the treatment centre/hospital, and/or iii. has special transportation needs (e.g., ambulance or special vehicle)	Raltitrexed 3 mg/m^2 intravenously (IV) every 21 days. Treatment should continue until disease progression, unacceptable toxicity or up to a maximum of 8 cycles, whichever comes first. [ST-QBP regimen codes: RALT, OXALRALT]	As per the Clinical Pharmacogenetics Implementation Consortium (CPIC) Guideline (2017), *DPYD* poor metabolizers are defined as a patient carrying two no function alleles OR a patient carrying one no function allele plus one decreased function allele. Patients with a *DPYD* poor metabolizer phenotype have complete DPD deficiency.
Raltitrexed (rall-tee-TREX-edd) Other name: Tomudex®	Adjuvant Esophageal, Gastroesophageal Junction, or Gastric Cancer	The patient must meet criteria "a" and at least one of criteria "b" or "c": a. Raltitrexed will be used as adjuvant therapy in patients with esophageal, gastroesophageal junction, or gastric cancer	Raltitrexed 3 mg/m^2 intravenously (IV) every 21 days	As per the Clinical Pharmacogenetics Implementation Consortium (CPIC) Guideline (2017), *DPYD* poor metabolizers are defined as a patient carrying two no function alleles OR a patient carrying one no function allele plus one decreased function allele. Patients with a *DPYD* poor metabolizer phenotype have complete DPD deficiency.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
		b. The patient has complete dihydropyrimidine dehydrogenase (DPD) deficiency c. The patient also i. has experienced unacceptable toxicity with fluorouracil chemotherapy, and/or ii. lives more than 60 km from the treatment centre/hospital, and/or iii. has special transportation needs (e.g., ambulance or special vehicle)	Treatment should continue until disease progression, unacceptable toxicity or up to a maximum of 8 cycles, whichever comes first. [ST-QBP regimen codes: RALT, OXALRALT]	
Raltitrexed (rall-tee-TREX-edd) Other name: Tomudex®	Advanced Malignant Pleural Mesothelioma (MPM)	a. The patient has advanced, symptomatic MPM b. The patient has good performance status (ECOG 0-1) c. The patient is not suitable for surgical resection	Raltitrexed 3 mg/m^2 IV combined with cisplatin 80 mg/m^2 IV on day 1 q3 weeks until disease progression Cisplatin is not funded by NDFP.	N/A
Raltitrexed (rall-tee-TREX-edd) Other name: Tomudex®	Metastatic Colorectal, Small Bowel, or Appendiceal Cancer	The patient must meet criteria "a" and at least one of criteria "b" or "c": a. Raltitrexed will be used to treat patients with metastatic colorectal, small bowel, or appendiceal cancer b. The patient has complete dihydropyrimidine dehydrogenase (DPD) deficiency c. The patient also i. has experienced unacceptable toxicity with fluorouracil chemotherapy, and/or ii. lives more than 60 km from the treatment centre/hospital, and/or iii. has special transportation needs (e.g., ambulance or special vehicle)	Raltitrexed 3 mg/m^2 intravenously (IV) every 21 days Treatment should continue until disease progression or unacceptable toxicity, whichever comes first. [ST-QBP regimen codes: RALT, OXALRALT, IRINRALT]	As per the Clinical Pharmacogenetics Implementation Consortium (CPIC) Guideline (2017), *DPYD* poor metabolizers are defined as a patient carrying two no function alleles OR a patient carrying one no function allele plus one decreased function allele. Patients with a *DPYD* poor metabolizer phenotype have complete DPD deficiency.
Raltitrexed (rall-tee-TREX-edd) Other name: Tomudex®	Metastatic Esophageal, Gastroesophageal Junction, or Gastric Cancer	The patient must meet criteria "a" and at least one of criteria "b" or "c": a. Raltitrexed will be used to treat patients with metastatic esophageal, gastroesophageal junction, or gastric cancer b. The patient has complete dihydropyrimidine dehydrogenase (DPD) deficiency	Raltitrexed 3 mg/m^2 intravenously (IV) every 21 days Treatment should continue until disease progression or unacceptable toxicity, whichever comes first.	As per the Clinical Pharmacogenetics Implementation Consortium (CPIC) Guideline (2017), *DPYD* poor metabolizers are defined as a patient carrying two no function alleles OR a patient carrying one no function allele plus one decreased function allele. Patients with a *DPYD* poor metabolizer phenotype have complete DPD deficiency.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
		c. The patient also i. has experienced unacceptable toxicity with fluorouracil chemotherapy, and/or ii. lives more than 60 km from the treatment centre/hospital, and/or iii. has special transportation needs (e.g., ambulance or special vehicle)	[ST-QBP regimen codes: RALT, OXALRALT, IRINRALT]	
Ramucirumab (RA-mue-SIR-ue-mab) Other name: Cyramza®	Advanced or metastatic gastric cancer or gastro-esophageal junction adenocarcinoma	The patient must meet the following criteria: a. Ramucirumab is used in combination with paclitaxel for the treatment of advanced or metastatic gastric cancer or gastro-esophageal junction (GEJ) adenocarcinoma with disease progression following first-line chemotherapy. b. Treatment should be for patients with an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1.	Ramucirumab 8 mg/kg IV on days 1, 15 every 28 days until disease progression (to be used in combination with paclitaxel).	• To be eligible for funding, patients must be able to start ramucirumab in combination with paclitaxel. Paclitaxel may be temporarily held due to toxicity or intolerance. • In the event that a patient has to discontinue paclitaxel due to toxicity or intolerance, ramucirumab will continue to be funded. Relevant documentation (e.g., clinic note) is required. If disease progresses while on single agent ramucirumab, further funding of ramucirumab will be discontinued. • The paclitaxel component (i.e., paclitaxel IV on days 1, 8, and 15) of this regimen is funded through the Systemic Treatment Quality-Based Program (ST-QBP). The regimen is evidence-informed in the palliative setting and is known by regimen code PACL(W)+RAMU. ST-QBP funds the drug cost and the delivery cost of paclitaxel plus the delivery cost of ramucirumab. NDFP funds the drug cost of ramucirumab provided the patient meets the eligibility criteria. There is no NDFP enrolment form for paclitaxel for this indication.
Rituximab (Biosimilar IV) (rit-TUCKS-ee-mab bye-oh-SIH-mih-lar) Other names: Truxima®, Riximyo®, Ruxience®, Riabni®	Aggressive Histology Lymphoma	The patient must meet criteria a, b, and c: a. Patient has aggressive histology lymphoma - diffuse large B-cell lymphoma (DLBCL) or a variant of DLBCL (e.g., mediastinal sclerosing B-cell lymphoma, T-cell rich B-cell lymphoma, Burkitt-like lymphoma, intravascular lymphoma) b. Patient has not received previous treatment for aggressive histology lymphoma c. Patient is not known to be seropositive for HIV	Rituximab 375 mg/m² IV (See Note 3) or 1400 mg SC (fixed dose) on day one of a standard CHOP (or CHOP-like) regimen for 6 to 8 cycles All patients must receive their first dose of rituximab by IV administration prior to initiating rituximab SC	1. Patients previously treated with rituximab for indolent histology lymphoma are eligible if the interval from the last dose of rituximab is greater than 6 months. Please provide a copy of pathology report. 2. The IV and SC formulations of rituximab are not interchangeable. 3. All patients must receive their first dose of rituximab by IV administration. Subsequent doses may be given subcutaneously if the patient tolerated the first IV dose.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
Rituximab (Biosimilar IV) (rit-TUCKS-ee-mab bye-oh-SIH-mih-lar) Other names: Truxima®, Riximyo®, Ruxience®, Riabni®	HIV-Related, Aggressive Histology B-Cell Lymphoma	The patient has HIV-related, aggressive-histology, CD20+ve B-cell lymphoma with CD4 counts that are greater than 50/mm³ and has not received previous treatment for aggressive histology lymphoma	Rituximab 375 mg/m² IV (See Note 2) or 1400 mg SC (fixed dose) on day one of a standard CHOP, CHOP-like, or similar dose intense regimens for 6 to 8 cycles All patients must receive their first dose of rituximab by IV administration prior to initiating rituximab SC	1. The IV and SC formulations of rituximab are not interchangeable. 2. All patients must receive their first dose of rituximab by IV administration. Subsequent doses may be given subcutaneously if the patient tolerated the first IV dose.
Rituximab (Biosimilar IV) (rit-TUCKS-ee-mab bye-oh-SIH-mih-lar) Other names: Truxima®, Riximyo®, Ruxience®, Riabni®	Maintenance Treatment – Lymphoma	The patient must meet criteria a, b, c, and d: a. Patient has follicular lymphoma or other indolent B-cell histology lymphoma (e.g., mantle cell lymphoma, marginal zone lymphoma, lymphoplasmacytoid lymphoma (Waldenstrom's macroglobulinemia), hairy cell leukemia, mucosa-associated lymphoid tissue (MALT) lymphoma but excluding diffuse small lymphocytic lymphoma/chronic lymphocytic leukemia) b. Patient has received and responded to induction therapy with one of the following: • Rituximab in combination with chemotherapy • Rituximab alone • Chemotherapy alone c. Patient was rituximab naïve prior to induction therapy for indolent histology lymphoma d. Maintenance rituximab will be initiated within 6 months of the last dose of induction therapy	Rituximab 375 mg/m² IV (See Note 3) or 1400 mg SC (fixed dose) for a maximum of 8 doses over a 2-year period All patients must receive their first dose of rituximab by IV administration prior to initiating rituximab SC	1. Patients who present with concurrent aggressive and indolent histology lymphomas and are treated with rituximab induction therapy are eligible if maintenance rituximab is initiated within 6 months of the last dose of induction therapy. Please provide a copy of the pathology report. 2. The IV and SC formulations of rituximab are not interchangeable. 3. All patients must receive their first dose of rituximab by IV administration. Subsequent doses may be given subcutaneously if the patient tolerated the first IV dose.
Rituximab (Biosimilar IV) (rit-TUCKS-ee-mab bye-oh-SIH-mih-lar) Other names: Truxima®, Riximyo®, Ruxience®, Riabni®	Previously Untreated Chronic Lymphocytic Leukemia	The patient must meet criterion a: a. Patient has previously untreated chronic lymphocytic leukemia where fludarabine-based therapy is considered appropriate	Cycle 1 – rituximab 375 mg/m² Cycles 2 through 6 – rituximab 500 mg/m²	For patients with high tumour load, consider a slower infusion rate or split dosing over 2 days during the first cycle. Rituximab must be used with fludarabine-based chemotherapy. Patients on current fludarabine-based therapy may receive rituximab provided they have not progressed on therapy. Screening for Hepatitis B virus with HbsAg and HbcAb has been completed or is in progress.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
Rituximab (Biosimilar IV) (rit-TUCKS-ee-mab bye-oh-SIH-mih-lar) Other names: Truxima®, Riximyo®, Ruxience®, Riabni®	Retreatment – Indolent Lymphoma	The patient must meet criteria a and b: a. Rituximab will be used in combination with chemotherapy for the treatment of follicular or other indolent lymphoma b. The patient has previously received rituximab (including combination rituximab-chemotherapy, rituximab monotherapy, or maintenance rituximab) and has sustained a response and remained treatment free for at least 6 months following the last dose of rituximab received.	Rituximab 375 mg/m² IV (See Note 4) or 1400 mg SC (fixed dose) in combination with chemotherapy, up to a maximum of 8 cycles All patients must receive their first dose of rituximab by IV administration prior to initiating rituximab SC	1. NDFP funding of rituximab retreatment does not apply to: a. Indolent lymphoma patients who have remained treatment free for less than 6 months following the last rituximab dose used in the treatment of indolent lymphoma. b. Patients with chronic lymphocytic leukemia/small lymphocytic lymphoma. 2. NDFP funding does not extend to use of maintenance rituximab after rituximab retreatment. 3. The IV and SC formulations of rituximab are not interchangeable. 4. All patients must receive their first dose of rituximab by IV administration. Subsequent doses may be given subcutaneously if the patient tolerated the first IV dose.
Rituximab (Biosimilar IV) (rit-TUCKS-ee-mab bye-oh-SIH-mih-lar) Other names: Truxima®, Riximyo®, Ruxience®, Riabni®	Second Line – Chronic Lymphocytic Leukemia	The patient meets criteria a and b: a. Rituximab is being used in the second line setting for relapsed or refractory chronic lymphocytic leukemia, in combination with a fludarabine-based treatment (i.e., the patient is a suitable candidate for fludarabine-based therapy). b. The patient is anti-CD20 antibody naïve (i.e., the patient has never been treated with an anti-CD20 antibody (rituximab or obinutuzumab) for chronic lymphocytic leukemia).	Cycle 1 – Rituximab 375 mg/m^2 Cycles 2 to 6 – Rituximab 500 mg/m^2	For patients with a high tumour load, consider a slower infusion rate or split dosing over 2 days. Rituximab must be used with fludarabine-based chemotherapy. Screening for Hepatitis B virus with HbsAg and HbcAb has been completed or is in progress.
Rituximab (Biosimilar IV) (rit-TUCKS-ee-mab bye-oh-SIH-mih-lar) Other names: Truxima®, Riximyo®, Ruxience®, Riabni®	In combination with idelalisib – relapsed chronic lymphocytic leukemia	The patient must meet the following criteria: Rituximab is used in combination with idelalisib for the treatment of patients with relapsed chronic lymphocytic leukemia (CLL).	Rituximab 375mg/m^2 Day 1, Week 1, then 500mg/m^2 Day 1 on weeks 3, 5, 7, 9, 13, 17, and 21. The number of cycles funded equals 8.	• Rituximab-idelalisib is not funded as a sequential treatment option for patients whose disease has progressed on ibrutinib in the relapsed setting (and vice versa). • Patients who have experienced intolerance but not disease progression to ibrutinib in the relapsed setting may switch to rituximab-idelalisib (and vice versa). Documentation on the nature of the intolerance is required. • Rituximab is only funded if used in combination with idelalisib. • For patients with a high tumour load, consider a slower infusion rate or split dosing over 2 days during the first cycle.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
				• The recommended dose of idelalisib is 150mg twice daily. The product monograph for idelalisib notes that idelalisib is contraindicated in first line CLL outside of a clinical trial. • Idelalisib is not funded by CCO. For patients who are eligible for Ontario Drug Benefit funding, refer to the Ministry's Exceptional Access Program for details.
Rituximab (Biosimilar IV) (rit-TUCKS-ee-mab bye-oh-SIH-mih-lar) Other names: Truxima®, Riximyo®, Ruxience®, Riabni®	Single Agent – Indolent Lymphoma	The patient must meet one of criteria a, b, c, d, and e: a. Follicular lymphoma and is unable to tolerate further chemotherapy due to hematologic toxicity b. Follicular lymphoma and has failed anthracycline or purine analog chemotherapy c. Mantle cell lymphoma • Is unable to tolerate further chemotherapy • Is resistant or refractory to 2 or more lines of chemotherapy • Has failed anthracycline or purine analog chemotherapy • Other CD20 positive low grade lymphoma (e.g., marginal zone lymphoma, lymphoplasmacytoid lymphoma (Waldenstrom's macroglobulinemia), hairy cell leukemia, mucosa associated lymphoid tissue (MALT) lymphoma but excluding diffuse small lymphocytic lymphoma/chronic lymphocytic leukemia) • Is unable to tolerate further chemotherapy • Is resistant or refractory to 2 or more lines of chemotherapy • Has failed anthracycline or purine analog chemotherapy e. Post-transplant lymphoproliferative disorder	Single agent rituximab 375 mg/m^2 weekly for 4 weeks. After treatment with single agent rituximab, patients are eligible for retreatment with single agent rituximab if a durable response lasting a minimum of 6 months is achieved. Patients who have previously received rituximab in combination with chemotherapy and/or rituximab maintenance are not eligible for single agent rituximab retreatment.	Screening for Hepatitis B virus with HbsAg and HbcAb has been completed or is in progress.
Rituximab (Biosimilar IV) (rit-TUCKS-ee-mab bye-oh-SIH-mih-lar)	In Combination with Chemotherapy – Indolent B-cell Lymphoma	The patient must meet criteria a, b, c, and d: a. Patient has follicular lymphoma or other indolent B-cell histology lymphoma (e.g., mantle cell lymphoma, marginal zone lymphoma, lymphoplasmacytoid	Rituximab 375 mg/m^2 IV (See Note 3) or 1400 mg SC (fixed dose) given with chemotherapy for 4 – 8 cycles	1. Patients previously treated with rituximab for **aggressive histology lymphoma** are eligible if the interval from the last dose of rituximab is greater than 1 year. Please provide a copy of pathology report. 2. The IV and SC formulations of rituximab are not interchangeable.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
Other names: Truxima®, Riximyo®, Ruxience®, Riabni®		lymphoma (Waldenstrom's macroglobulinemia), hairy cell leukemia, mucosa-associated lymphoid tissue (MALT) lymphoma but excluding diffuse small lymphocytic lymphoma/chronic lymphocytic leukemia) b. Patient is: • untreated, OR • has been previously treated c. Patient has not received previous treatment with rituximab for indolent B-cell lymphoma d. Patient will receive rituximab in combination with chemotherapy	All patients must receive their first dose of rituximab by IV administration prior to initiating rituximab SC	3. All patients must receive their first dose of rituximab by IV administration. Subsequent doses may be given subcutaneously if the patient tolerated the first IV dose.
Rituximab (Biosimilar IV) (rit-TUCKS-ee-mab bye-oh-SIH-mih-lar) Other names: Truxima®, Riximyo®, Ruxience®, Riabni®	As Part of the MATRix Regimen in Newly Diagnosed, Previously Untreated Primary Central Nervous System Lymphoma	The patient must meet the following criteria: Rituximab is used in combination with high-dose methotrexate, cytarabine and thiotepa (MATRix regimen) as induction therapy in patients with newly diagnosed, previously untreated primary central nervous system (CNS) lymphoma.	Rituximab 375 mg/m^2 intravenously on Day -5 and Day 0 of the MATRix regimen for up to 4 cycles. Rituximab is funded when used in combination with high-dose methotrexate, cytarabine and thiotepa (ST-QBP regimen code: MATRIX).	Patients previously treated with rituximab for indolent or aggressive histology lymphoma are eligible if the patient has sustained a response and remained disease free for at least 6 months following the last dose of rituximab received. Please provide a copy of pathology report.
Rituximab (Biosimilar IV) (rit-TUCKS-ee-mab bye-oh-SIH-mih-lar) Other names: Truxima®, Riximyo®, Ruxience®, Riabni®	Retreatment - Aggressive Histology Lymphoma	Rituximab retreatment in combination with salvage chemotherapy for relapsed aggressive histology CD20+ lymphoma with intent to proceed to autologous stem cell transplantation. • To be used with salvage chemotherapy (e.g., DHAP (dexamethasone, cytarabine, cisplatin), GDP (gemcitabine, dexamethasone, cisplatin)) • The patient was previously treated with rituximab-based chemoimmunotherapy (e.g., R-CHOP) for aggressive histology lymphoma and had a best response of at least partial response (PR)	Rituximab 375mg/m^2 intravenously (IV) or rituximab 1400 mg subcutaneously (SC) as a fixed dose on day 1 of each cycle of salvage chemotherapy for up to 3 cycles. All patients must receive their first dose of rituximab by IV administration prior to initiating rituximab SC	1. The IV and SC formulations of rituximab are not interchangeable. 2. All patients must receive their first dose of rituximab by IV administration. Subsequent doses may be given subcutaneously if the patient tolerated the first IV dose. 3. For IV administration, only rituximab (Biosimilar IV) is funded for this indication.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
Rituximab (Biosimilar IV) (rit-TUCKS-ee-mab bye-oh-SIH-mih-lar) Other names: Truxima®, Riximyo®, Ruxience®, Riabni®	In Combination with Venetoclax - Relapsed Chronic Lymphocytic Leukemia	Rituximab is used in combination with venetoclax for the treatment of adult patients with chronic lymphocytic leukemia (CLL) who have received at least one prior therapy, irrespective of their 17p deletion status.	After completion of the dose ramp-up period for venetoclax, rituximab is initiated on an every 28-day schedule for a total of six cycles while daily venetoclax continues. Cycle 1 – rituximab 375 mg/m^2 intravenously (IV), in combination with venetoclax (See Note 3). Cycles 2 through 6 – rituximab 500 mg/m^2 IV or 1600 mg subcutaneously (SC) as a fixed dose, in combination with venetoclax. Treatment with venetoclax monotherapy should be continued until disease progression or unacceptable toxicity, up to a maximum of two years from the start of rituximab therapy, whichever comes first [ST-QBP regimen code: VENE+RITU]. All patients must receive their first dose of rituximab by IV administration prior to initiating rituximab SC.	1. For patients with a high tumour load, consider a slower infusion rate or split the dose of rituximab over 2 days during the first cycle. 2. The IV and SC formulations of rituximab are not interchangeable. 3. All patients must receive their first dose of rituximab by IV administration. Subsequent doses may be given SC if the patient tolerated the first IV dose. 4. Venetoclax is not funded by Ontario Health (Cancer Care Ontario). For patients who are eligible for Ontario Drug Benefit (ODB) funding, refer to the Ministry of Health's Exceptional Access Program for details. 5. Patients previously treated with an anti-CD20-containing therapy (rituximab or obinutuzumab) and who had a treatment-free interval of 12 months or longer since the last dose of anti-CD20 therapy may be treated with venetoclax and rituximab for relapsed CLL.
Rituximab (Biosimilar IV) (rit-TUCKS-ee-mab bye-oh-SIH-mih-lar) Other names: Truxima®, Riximyo®, Ruxience®, Riabni®	With polatuzumab vedotin and bendamustine - Relapsed or Refractory Diffuse Large B-cell Lymphoma	Polatuzumab vedotin is used in combination with bendamustine and rituximab (pola-BR) for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma, not otherwise specified, who are not eligible for autologous stem cell transplant (ASCT) and have received at least 1 prior therapy. Eligible patients should have good performance status and a life expectancy greater than or equal to 24 weeks.	Cycle 1: Rituximab 375mg/m2 intravenously (IV) on Day 1, Polatuzumab vedotin 1.8mg/kg IV on Day 2, Bendamustine 90mg/m2 IV on Days 2 and 3 Cycles 2 to 6: Rituximab 375mg/m2 IV on Day 1, Polatuzumab vedotin 1.8mg/kg IV on Day 1, Bendamustine 90mg/m2 IV on Days 1 and 2	1. NDFP will only fund polatuzumab vedotin in combination with bendamustine and rituximab (pola-BR). An exception is if pola-BR is being used as a bridge to CAR T-cell therapy, in which case bendamustine may be omitted if appropriate based on clinician judgement. 2. Enrolment in this policy will fulfill enrolment requirements for all drugs in this regimen (polatuzumab vedotin, rituximab biosimilar, and bendamustine) 3. Pola-BR is not funded: a. In patients with previously untreated diffuse large B-cell lymphoma (DLBCL); or b. In patients with active CNS lymphoma; or c. If used as salvage therapy for patients who are eligible for ASCT; or

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
			Treatment with pola-BR should continue for a maximum of 6 cycles (21 days per cycle), or until unacceptable toxicity or disease progression, whichever occurs first. [ST-QBP regimen code: BEND+POLA+RITU]	d. In patients with Burkitt lymphoma 4. Pola-BR may be considered in patients with transformed follicular lymphoma to DLBCL, HIV-related lymphoma, grey zone lymphoma, and mediastinal large B-cell lymphoma. 5. Pola-BR may be considered in patients who have progressed on prior CAR -T-cell therapy provided the patient is not eligible for ASCT.
Rituximab Subcut (rit-TUCKS-ee-mab) Other name: Rituxan® SC	Aggressive Histology Lymphoma	The patient must meet criteria a, b, and c: a. Patient has aggressive histology lymphoma – diffuse large B-cell lymphoma (DLBCL) or a variant of DLBCL (e.g., mediastinal sclerosing B-cell lymphoma, T-cell rich B-cell lymphoma, Burkitt-like lymphoma, intravascular lymphoma) b. Patient has not received previous treatment for aggressive histology lymphoma c. Patient is not known to be seropositive for HIV	Rituximab 375 mg/m² IV (See Note 3) or 1400 mg SC (fixed dose) on day one of a standard CHOP (or CHOP-like) regimen for 6 to 8 cycles All patients must receive their first dose of rituximab by IV administration prior to initiating rituximab SC	1. Patients previously treated with rituximab for indolent histology lymphoma are eligible if the interval from the last dose of rituximab is greater than 6 months. Please provide a copy of pathology report. 2. The IV and SC formulations of rituximab are not interchangeable. 3. All patients must receive their first dose of rituximab by IV administration. Subsequent doses may be given subcutaneously if the patient tolerated the first IV dose.
Rituximab Subcut (rit-TUCKS-ee-mab) Other name: Rituxan® SC	HIV-Related, Aggressive Histology B-Cell Lymphoma	The patient has HIV-related, aggressive-histology, CD20+ve B-cell lymphoma with CD4 counts that are greater than 50/mm³ and has not received previous treatment for aggressive histology lymphoma	Rituximab 375 mg/m² IV (See Note 2) or 1400 mg SC (fixed dose) on day one of a standard CHOP, CHOP-like, or similar dose intense regimens for 6 to 8 cycles All patients must receive their first dose of rituximab by IV administration prior to initiating rituximab SC	1. The IV and SC formulations of rituximab are not interchangeable. 2. All patients must receive their first dose of rituximab by IV administration. Subsequent doses may be given subcutaneously if the patient tolerated the first IV dose.
Rituximab Subcut (rit-TUCKS-ee-mab) Other name: Rituxan® SC	Maintenance Treatment – Lymphoma	The patient must meet criteria a, b, c, and d: a. Patient has follicular lymphoma or other indolent B-cell histology lymphoma (e.g., mantle cell lymphoma, marginal zone lymphoma, lymphoplasmacytoid lymphoma (Waldenstrom's macroglobulinemia), hairy cell leukemia, mucosa-associated lymphoid tissue (MALT) lymphoma but excluding diffuse small lymphocytic lymphoma/chronic lymphocytic leukemia) b. Patient has received and responded to induction therapy with one of the following:	Rituximab 375 mg/m² IV (See Note 3) or 1400 mg SC (fixed dose) for a maximum of 8 doses over a 2-year period All patients must receive their first dose of rituximab by IV administration prior to initiating rituximab SC	1. Patients who present with concurrent aggressive and indolent histology lymphomas and are treated with rituximab induction therapy are eligible if maintenance rituximab is initiated within 6 months of the last dose of induction therapy. Please provide a copy of the pathology report. 2. The IV and SC formulations of rituximab are not interchangeable. 3. All patients must receive their first dose of rituximab by IV administration. Subsequent doses may be given subcutaneously if the patient tolerated the first IV dose.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
		• Rituximab in combination with chemotherapy • Rituximab alone • Chemotherapy alone c. Patient was rituximab naïve prior to induction therapy for indolent histology lymphoma d. Maintenance rituximab will be initiated within 6 months of the last dose of induction therapy		
Rituximab Subcut (rit-TUCKS-ee-mab) Other name: Rituxan® SC	Previously Untreated – Chronic Lymphocytic Leukemia	The patient must meet the following criteria: a. Patient has previously untreated chronic lymphocytic leukemia where fludarabine-based therapy is considered appropriate	Cycle 1 – Rituximab 375 mg/m^2 IV (See Note 5) Cycles 2 to 6 – Rituximab 500 mg/m^2 IV or 1600 mg subcutaneously (SC) (fixed dose) All patients must receive their first dose of rituximab by IV administration prior to initiating rituximab SC	1. For patients with a high tumour load, consider a slower infusion rate or split dosing over 2 days. 2. Rituximab must be used with fludarabine-based chemotherapy. Patients who are receiving rituximab by subcutaneous administration must use fludarabine and cyclophosphamide. 3. Patients on current fludarabine-based therapy may receive rituximab provided they have not progressed on therapy. 4. The IV and SC formulations are not interchangeable. 5. All patients must receive their first dose of rituximab by IV administration. Subsequent doses may be given SC if the patient tolerated the first IV dose.
Rituximab Subcut (rit-TUCKS-ee-mab) Other name: Rituxan® SC	Retreatment – Indolent Lymphoma	The patient must meet criteria a and b: a. Rituximab will be used in combination with chemotherapy for the treatment of follicular or other indolent lymphoma b. The patient has previously received rituximab (including combination rituximab-chemotherapy, rituximab monotherapy, or maintenance rituximab) and has sustained a response and remained treatment free for at least 6 months following the last dose of rituximab received	Rituximab 375 mg/m² IV (See Note 4) or 1400 mg SC (fixed dose) in combination with chemotherapy, up to a maximum of 8 cycles All patients must receive their first dose of rituximab by IV administration prior to initiating rituximab SC	1. NDFP funding of rituximab retreatment does not apply to: a. Indolent lymphoma patients who have remained treatment free for less than 12 months following the last rituximab dose used in the treatment of indolent lymphoma. b. Patients with chronic lymphocytic leukemia/small lymphocytic lymphoma. 2. NDFP funding does not extend to use of maintenance rituximab after rituximab retreatment. 3. The IV and SC formulations of rituximab are not interchangeable. 4. All patients must receive their first dose of rituximab by IV administration. Subsequent doses may be given subcutaneously if the patient tolerated the first IV dose.
Rituximab Subcut (rit-TUCKS-ee-mab)	Second Line – Chronic Lymphocytic Leukemia	The patient meets criteria a and b: a. Rituximab is being used in the second line setting for relapsed or refractory chronic lymphocytic	Cycle 1 – Rituximab 375 mg/m^2 IV (See Note 4) Cycles 2 to 6 – Rituximab 500 mg/m^2 IV or 1600 mg subcutaneously (SC) (fixed dose)	1. For patients with a high tumour load, consider a slower infusion rate or split dosing over 2 days.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
Other name: Rituxan® SC		leukemia, in combination with a fludarabine-based treatment (i.e., the patient is a suitable candidate for fludarabine-based therapy). b. The patient is anti-CD20 antibody naïve (i.e., the patient has never been treated with an anti-CD20 antibody (rituximab or obinutuzumab) for chronic lymphocytic leukemia).	All patients must receive their first dose of rituximab by IV administration prior to initiating rituximab SC	2. Rituximab must be used with fludarabine-based chemotherapy. Patients who are receiving rituximab by subcutaneous administration must use fludarabine and cyclophosphamide. 3. The IV and SC formulations are not interchangeable. 4. All patients must receive their first dose of rituximab by IV administration. Subsequent doses may be given SC if the patient tolerated the first IV dose.
Rituximab Subcut (rit-TUCKS-ee-mab) Other name: Rituxan® SC	Rituximab in Combination with Chemotherapy – Indolent B-cell Lymphoma	The patient must meet criteria a, b, c, and d: a. Patient has follicular lymphoma or other indolent B-cell histology lymphoma (e.g., mantle cell lymphoma, marginal zone lymphoma, lymphoplasmacytoid lymphoma (Waldenstrom's macroglobulinemia), hairy cell leukemia, mucosa-associated lymphoid tissue (MALT) lymphoma but excluding diffuse small lymphocytic lymphoma/chronic lymphocytic leukemia) b. Patient is: • untreated, OR • has been previously treated c. Patient has <u>not</u> received previous treatment with rituximab for indolent B-cell lymphoma d. Patient will receive rituximab in combination with chemotherapy	Rituximab 375 mg/m² IV (See Note 3) or 1400 mg SC (fixed dose) given with chemotherapy for 4 – 8 cycles All patients must receive their first dose of rituximab by IV administration prior to initiating rituximab SC	1. Patients previously treated with rituximab for **aggressive histology lymphoma** are eligible if the interval from the last dose of rituximab is greater than 1 year. Please provide a copy of pathology report. 2. The IV and SC formulations of rituximab are not interchangeable. 3. All patients must receive their first dose of rituximab by IV administration. Subsequent doses may be given subcutaneously if the patient tolerated the first IV dose.
Romidepsin (ROE-mi-DEP-sin) Other name: Istadax®	Relapsed or Refractory Peripheral T-Cell Lymphoma	For patients with relapsed or refractory peripheral T-cell lymphoma (PTCL) who: • are ineligible for transplant; • have undergone previous systemic therapy; and • have an Eastern Cooperative Performance Status (ECOG) of 0 to 2.	Romidepsin 14 mg/m² intravenously on days 1, 8, and 15 (cycle length is 28 days), until disease progression or unacceptable toxicity.	1. The following subtypes are eligible for romidepsin funding: PTCL (unspecified or NOS), angioimmunoblastic T-cell lymphoma (AITL), anaplastic large T-cell lymphoma, cutaneous gamma/delta T-cell lymphoma, hepatosplenic PTCL, enteropathy associated, T-cell lymphoma, extranodal natural killer/TCL nasal type, subcutaneous panniculitis like TCL, transformed mycosis fungoides. 2. Romidepsin funding does not apply to patients with non-transformed mycosis fungoides type of cutaneous T-cell lymphoma, Sezary syndrome, or patients with known CNS lymphoma.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
				3. The romidepsin eligibility criteria also applies to patients who have had prior stem cell transplant. 4. Brentuximab vedotin funding is also available for patients with the CD30+ systemic anaplastic large cell lymphoma subtype of peripheral T-cell lymphoma, provided funding criteria are met. No evidence exists to inform the optimal sequencing for brentuximab vedotin versus pralatrexate or romidepsin. The choice in sequencing should be based on a discussion between the treating hematologist and patient. 5. Patients will be eligible for either pralatrexate or romidepsin, but not both.
Sacituzumab Govitecan (SAK-i-TOOZ-ue-mab GOE-vi-TEE-kan) Other name: Trodelvy®	Unresectable Locally Advanced or Metastatic Triple Negative Breast Cancer	Sacituzumab govitecan is used for the treatment of adult patients with unresectable locally advanced or metastatic triple negative breast cancer (TNBC*) who have received two or more therapies, with at least one therapy used to treat metastatic disease, and have a good performance status. Eligible patients must have adequate blood counts and organ function, stable or no brain metastases. *Refers to lack of expression of the estrogen receptor (ER), progesterone receptor (PR), and human epidermal growth factor receptor 2 (HER2) as per the American Society of Clinical Oncology (ASCO)/College of American Pathologists (CAP) guidelines.	Sacituzumab govitecan 10 mg/kg intravenously (IV) on days 1 and 8 of each 21-day cycle. Treatment should continue until documented radiographic disease progression, unacceptable toxicity, or clinical deterioration, whichever comes first. [ST-QBP regimen code: SACI]	None.
Siltuximab (sil-TUCKS-ee-mab) Other name: Sylvant®	Multicentric Castleman's Disease	The patient must meet the following criteria: • Siltuximab is used for the treatment of patients with multicentric Castleman's disease (MCD) previously treated or untreated • Patients are human immunodeficiency virus (HIV) negative • Patients are human herpes virus-8 (HHV8) negative	Siltuximab 11mg/kg IV once every three weeks until treatment failure.	1. Siltuximab is not funded for patients with HIV-positive and/or HHV8-positive multicentric Castleman's disease. 2. A clinic note should be submitted every 18 cycles, demonstrating at least stable disease and good tolerability to treatment.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
		• Treatment should be for patients with an ECOG performance status of ≤2		
Strontium 89 (STRON-tee-um) Other name: Metastron®	Palliative Bone Seeking Radiopharmaceuticals	The patient meets all of the following criteria: • Prostate, breast or lung cancer histology • Pain poorly controlled with conventional analgesic regimens • Multiple sites of uncomplicated, painful bone metastases on both sides of the diaphragm • No impending or established pathological fracture, spinal cord compression or hypercalcemia • Bone scan demonstrates activity (uptake) at the sites of painful bone metastases • Stable or absent soft tissue or visceral (liver, lung) disease • Adequate performance status (Karnofsky ≥ 60) • Adequate bone marrow reserve (WBC > 4.0 x 10^9/L; platelets > 100 x 10^9/L • Adequate renal function (BUN < 10 mmol/L; creatinine < 150 µmol/L • Adequate hepatic function (no elevation of liver enzymes) • No recent (< 4 weeks) chemotherapy or wide field radiotherapy off study • Life expectancy > 4 months, and b. A multidisciplinary assessment has been conducted by at least 2 of the 3 following specialists: radiation oncology, medical oncology, nuclear medicine	Strontium 89: 148 mBq (4 mCi) by slow IV injection (1-2 minutes) accompanied by IV or PO hydration (at least 500 mL)	Patients with a partial response or complete response following radiopharmaceutical therapy may be considered for repeat administration for persistent or recurrent bone pain. In order to avoid the risk of severe, cumulative myelosuppression, the interval between radiopharmaceutical administrations should be at least 12 weeks. For bone pain refractory to initial therapy, retreatment may be undertaken if the following is ruled out: rapid systemic disease progression, mechanical component to bone pain, underlying other bone pathology, impending or established fracture or spinal cord compression.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
Temsirolimus (TEM-sir-RO-li-mus) Other name: Torisel®	Metastatic Renal Cell Carcinoma	Patient has poor risk[1] metastatic renal cell carcinoma, independent of histology, and is being treated with temsirolimus in the first line setting	Temsirolimus 25mg IV weekly until disease progression	1. Poor risk is defined using a modification of criteria from Mekhail et al (J Clin Oncol. 2005; 23:832-41). Patients must have at least 3 of the following features: a. high lactate dehydrogenase (> 1.5 times upper limit of normal); b. low hemoglobin (< lower limit of normal); c. high corrected serum calcium (> 10mg/dL); d. time from initial diagnosis to first treatment is less than 12 months; e. poor performance status (Karnofsky performance status < 80); f. metastases in multiple organ sites (e.g. lung, liver, retroperitoneal lymph nodes, etc.)
Trastuzumab (Biosimilar) (trass-TOO-zoo-mab bye-oh-SIH-mih-lar) Other name: Ogivri®, Trazimera®, Herzuma®, Kanjinti®, Ontruzant®	Adjuvant Treatment for HER2/neu-Overexpressing Primary Breast Cancer	The patient has tested positive for Her2/neu as per Ontario Health (Cancer Care Ontario) criteria: • IHC 3+ • FISH/SISH ≥2 One of the following: • Node-positive disease • Node-negative tumor (with size > 1 cm) The patient has received either: • adjuvant chemotherapy • neoadjuvant chemotherapy If the patient has received adjuvant or neoadjuvant chemotherapy not funded by NDFP, indicate the chemotherapy regimen	One of the following schedules: 4 mg/kg x 1 IV followed by 2 mg/kg IV weekly, OR 8 mg/kg x 1 IV followed by 6 mg/kg IV q3 weeks Trastuzumab loading dose of 4 mg/kg x 1, followed by 2 mg/kg IV weekly funded for a maximum of 54 q1 week treatments over a maximum period of 14 months. Trastuzumab loading dose of 8 mg/kg x 1, followed by 6 mg/kg IV q3 weeks funded for a maximum of 18 q3 week treatments over a maximum period of 14 months. Switching from q1 week regimen to q3 week regimen (and vice versa) is allowed assuming that the actual amount of drug is not exceeded and the 14 month period remains the same.	Trastuzumab should not be given concurrently with an anthracycline. A copy of the complete surgical pathology report must be provided to NDFP, stating at minimum: the date of the biopsy; the name of the hospital where the test occurred; the hospital pathology specimen number of the original materials used for the Her2/neu test; the size of the HER2 positive tumour. The results of a FISH/SISH test must be provided if the IHC test result is equivocal. The patient has a normal cardiac ejection fraction (MUGA Scan or Echocardiogram)
Trastuzumab (Biosimilar)	Advanced Gastric, Gastroesophageal, or Esophageal Cancer	The patient must meet the following criteria: • Trastuzumab will be used in combination with intravenous 5-fluorouracil (or capecitabine) and cisplatin or with an oxaliplatin-based regimen for	Trastuzumab loading dose of 8mg/kg IV on Day 1 of the first cycle, followed by 6 mg/kg every 3 weeks until disease progression or unacceptable toxicity.	Chemotherapy may be started and trastuzumab added later provided that there has been no disease progression. Trastuzumab may be continued as a single agent until disease progression following six cycles of trastuzumab-chemotherapy.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
(trass-TOO-zoo-mab bye-oh-SIH-mih-lar) Other name: Ogivri®, Trazimera®, Herzuma®, Kanjinti®, Ontruzant®		the treatment of patients with HER2-positive advanced (non-resectable; either locally advanced, recurrent, or metastatic) adenocarcinoma of the esophagus, stomach or gastroesophageal junction who have not received prior systemic therapy treatment for their metastatic disease • Trastuzumab should only be administered to patients with advanced esophageal, gastroesophageal junction or gastric cancer (non-resectable; either locally advanced, recurrent, or metastatic) whose tumours have HER2 overexpression (by IHC2+ [and confirmed by FISH+], or IHC3+, as determined by an accurate and validated assay)	Alternative dosing schedule for FOLFOX: trastuzumab 6 mg/kg IV on Day 1 of the first cycle, followed by 4 mg/kg every 2 weeks until disease progression or unacceptable toxicity. [ST-QBP regimen codes: CAPECISP+TRAS, CISPFU+TRAS, MFOLFOX6+TRAS, XELOX+TRAS for the chemotherapy plus trastuzumab portion followed by TRAS as monotherapy]	A photocopy of pathology report demonstrating HER2 overexpression (by IHC2+ [and confirmed by FISH+], or IHC3+) must be submitted to Ontario Health (Cancer Care Ontario). The report must state clearly the hospital, date of biopsy and the hospital pathology specimen of the original material used for the test. The patient must have a normal cardiac ejection fraction. Trastuzumab should not be given concurrently with an anthracycline.
Trastuzumab (Biosimilar) (trass-TOO-zoo-mab bye-oh-SIH-mih-lar) **Other name: Ogivri®, Trazimera®, Herzuma®, Kanjinti®, Ontruzant®**	Advanced or Recurrent Endometrial Cancer	• Trastuzumab is used as a primary or subsequent-line of treatment for patients with advanced (stage III-IV) or recurrent (any previous stage) human epidermal growth factor receptor 2 (HER2)-positive serous endometrial cancer.	Trastuzumab at a loading dose of 8 mg/kg intravenously (IV) on Day 1 of the first cycle followed by 6 mg/kg IV every 3 weeks until disease progression or unacceptable toxicity. The first six cycles are given in combination with carboplatin and paclitaxel followed by trastuzumab monotherapy as maintenance therapy. [ST-QBP regimen codes: CRBPPACL+TRAS for the induction portion followed by TRAS maintenance]	1. Trastuzumab, in combination with carboplatin and paclitaxel, followed by trastuzumab maintenance is funded in patients with advanced (stage III-IV) or recurrent (any previous stage) HER2-positive serous endometrial cancer, not both.
Trastuzumab (Biosimilar) (trass-TOO-zoo-mab bye-oh-SIH-mih-lar)	Second Line – Metastatic Breast Cancer	• Trastuzumab will be used for the treatment of second line HER2 positive metastatic breast cancer when given in combination with chemotherapy after previous exposure to trastuzumab based treatments in the metastatic setting	One of the following regimens: Trastuzumab loading dose of 8 mg/kg IV on Day 1 of the first cycle, followed by 6 mg/kg every 3 weeks until disease progression, unacceptable toxicity or withdrawal of consent, or	Trastuzumab will not be funded: in combination with lapatinib for the second line treatment of HER2 positive metastatic breast cancer, and/or if the patient has progressed on lapatinib for the second line treatment of HER2 positive metastatic breast cancer.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
Other name: Ogivri®, Trazimera®, Herzuma®, Kanjinti®, Ontruzant®			Trastuzumab loading dose of 4 mg/kg IV on Day 1 of the first cycle, followed by 2 mg/kg every week until disease progression, unacceptable toxicity or withdrawal of consent	Funding of second line trastuzumab for HER2-positive metastatic breast cancer will be discontinued upon evidence of further disease progression. Trastuzumab will continue to be funded if a patient had to discontinue their chemo treatment due to toxicity or intolerance. If disease progresses while on single agent trastuzumab, then further funding of trastuzumab will be discontinued. The patient must have normal cardiac ejection fraction. Trastuzumab should not be given concurrently with an anthracycline. For patients who have not received trastuzumab (adjuvant/metastatic) through the New Drug Funding Program, a photocopy of pathology report demonstrating HER2 overexpression must be submitted to Ontario Health (Cancer Care Ontario). The report must state clearly the hospital, date of biopsy and the hospital pathology specimen of the original material used for the test.
Trastuzumab (Biosimilar) (trass-TOO-zoo-mab bye-oh-SIH-mih-lar) Other name: Ogivri®, Trazimera®, Herzuma®, Kanjinti®, Ontruzant®	Single Agent – Metastatic Breast Cancer	• Her2/neu Status Patient must test positive for Her2/neu as per Ontario Health (Cancer Care Ontario) criteria. A photocopy of the pathology report of the Her2/neu test must be submitted to Ontario Health (Cancer Care Ontario). The report must state clearly the hospital, date of biopsy and the hospital pathology specimen number of the original material used for the Her2/neu test. Specify tests used for detection of Her2/neu: • IHC 3+ • FISH/ SISH ≥ 2 Patient has metastatic breast cancer, and has received: • at least 2 chemotherapy regimens for metastatic breast cancer • anthracycline as adjuvant therapy and had 1 chemotherapy regimen as first line therapy for metastatic breast cancer • an anthracycline/taxane combination as adjuvant therapy	Therapy should be initiated with a loading dose of 4 mg/kg, followed by 2 mg/kg IV weekly Patients may be switched to 6 mg/kg IV q3 weeks after they are adequately loaded over a reasonable period of time with weekly dosing	The patient has a normal cardiac ejection fraction. There is no evidence of extensive lung involvement. Reimbursement will be discontinued for patients whose disease progresses while being treated with trastuzumab in the metastatic setting.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
		Specify previous chemotherapy		
Trastuzumab (Biosimilar) (trass-TOO-zoo-mba bye-oh-SIH-mih-lar) Other name: Ogivri®, Trazimera®, Herzuma®, Kanjinti®, Ontruzant®	In combination with Docetaxel – Metastatic Breast Cancer	• Her2/neu Status: Patient must test positive for Her2/neu as per Ontario Health (Cancer Care Ontario) criteria. A photocopy of the pathology report of the Her2/neu test must be submitted to Ontario Health (Cancer Care Ontario). The report must state clearly the hospital, date of biopsy and the hospital pathology specimen number of the original material used for the Her2/neu test. Please specify tests used for detection of Her2/neu: • IHC 3+ • FISH/ SISH ≥ 2. Combination treatment for patients receiving trastuzumab and docetaxel. (NDFP funds trastuzumab provided the patient meets funding criteria. The cost of docetaxel as part of this regimen is funded through the Systemic Treatment Quality-Based Procedure (ST-QBP) and is included in the band level pricing.) i. Patient has metastatic breast cancer. AND ii. cannot tolerate anthracyclines or has failed anthracycline therapy for metastatic disease or has received an anthracycline as adjuvant therapy.	Therapy should be initiated with a loading dose of 4 mg/kg, followed by 2 mg/kg IV weekly. Patients may be switched to 6 mg/kg IV q3 weeks after they are adequately loaded over a reasonable period of time with weekly dosing.	The patient has a normal cardiac ejection fraction. There is no evidence of extensive lung involvement. Reimbursement will be discontinued for patients whose disease progresses while being treated with trastuzumab in the metastatic setting.
Trastuzumab (Biosimilar) (trass-TOO-zoo-mab bye-oh-SIH-mih-lar) Other name: Ogivri®, Trazimera®, Herzuma®, Kanjinti®, Ontruzant®	In combination with Paclitaxel – Metastatic Breast Cancer	• Her2/neu Status: Patient must test positive for Her2/neu as per Ontario Health (Cancer Care Ontario) criteria. A photocopy of the pathology report of the Her2/neu test must be submitted to Ontario Health (Cancer Care Ontario). The report must state clearly the hospital, date of biopsy and the hospital pathology specimen number of the original material used for the Her2/neu test. Please specify tests used for detection of Her2/neu:	Therapy should be initiated with a loading dose of 4 mg/kg, followed by 2 mg/kg IV weekly. Patients may be switched to 6 mg/kg IV q3 weeks after they are adequately loaded over a reasonable period of time with weekly dosing.	The patient has a normal cardiac ejection fraction. There is no evidence of extensive lung involvement. Reimbursement will be discontinued for patients whose disease progresses while being treated with trastuzumab in the metastatic setting.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
		• IHC 3+ • FISH/ SISH ≥ 2. Patient has metastatic breast cancer and (one of the following): • Cannot tolerate anthracyclines • Has failed anthracycline therapy for metastatic disease • Has received an anthracycline as adjuvant therapy Note: NDFP funds trastuzumab provided the patient meets funding criteria. The cost of docetaxel as part of this regimen is funded through the Systemic Treatment Quality-Based Procedure (ST-QBP) and is included in the band level pricing.		
Trastuzumab (Biosimilar) (trass-TOO-zoo-mab bye-oh-SIH-mih-lar) Other name: Ogivri®, Trazimera®, Herzuma®, Kanjinti®, Ontruzant®	In combination with Vinorelbine – Metastatic Breast Cancer	• Her2/neu Status: Patient must test positive for Her2/neu as per Ontario Health (Cancer Care Ontario) criteria. A photocopy of the pathology report of the Her2/neu test must be submitted to Ontario Health (Cancer Care Ontario). The report must state clearly the hospital, date of biopsy and the hospital pathology specimen number of the original material used for the Her2/neu test. Please specify tests used for detection of Her2/neu: • IHC 3+ • FISH/SISH ≥ 2 Patient has metastatic breast cancer Patient has progressed with anthracycline or taxane therapy in the adjuvant or metastatic setting Note: NDFP funds trastuzumab provided the patient meets funding criteria. The cost of docetaxel as part of this regimen is funded through the Systemic Treatment Quality-Based Procedure (ST-QBP) and is included in the band level pricing.	Therapy should be initiated with a loading dose of 4 mg/kg, followed by 2 mg/kg IV weekly. Patients may be switched to 6 mg/kg IV q3 weeks after they are adequately loaded over a reasonable period of time with weekly dosing.	The patient has a normal cardiac ejection fraction. There is no evidence of extensive lung involvement. Reimbursement will be discontinued for patients whose disease progresses while being treated with trastuzumab in the metastatic setting.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
Trastuzumab (Biosimilar) (trass-TOO-zoo-mab bye-oh-SIH-mih-lar) Other name: Ogivri®, Trazimera®, Herzuma®, Kanjinti®, Ontruzant®	With First Line Docetaxel – Metastatic Breast Cancer	The patient must meet the following criteria: a. Her2/neu Status: Patient must test positive for Her2/neu as per Ontario Health (Cancer Care Ontario) criteria. A photocopy of the pathology report of the Her2/neu test must be submitted to Ontario Health (Cancer Care Ontario). The report must state clearly the hospital, date of biopsy and the hospital pathology specimen number of the original material used for the Her2/neu test. Please specify tests used for detection of Her2/neu: • IHC 3+ • FISH/SISH ≥ 2 Patient has metastatic breast cancer Patient will not be receiving an anthracycline Note: NDFP funds trastuzumab provided the patient meets funding criteria. The cost of docetaxel as part of this regimen is funded through the Systemic Treatment Quality-Based Procedure (ST-QBP) and is included in the band level pricing.	Therapy should be initiated with a loading dose of 4 mg/kg, followed by 2 mg/kg IV weekly. Patients may be switched to 6 mg/kg IV q3 weeks after they are adequately loaded over a reasonable period of time with weekly dosing.	Precautions: • The patient has a normal cardiac ejection fraction • There is no evidence of extensive lung involvement Reimbursement will be discontinued for patients whose disease progresses while being treated with trastuzumab in the metastatic setting.
Trastuzumab (Biosimilar) (trass-TOO-zoo-mab bye-oh-SIH-mih-lar) Other name: Ogivri®, Trazimera®, Herzuma®, Kanjinti®, Ontruzant®	With Tucatinib and Capecitabine - Metastatic Breast Cancer	Trastuzumab (biosimilar) is used in combination with tucatinib and capecitabine for the treatment of patients with locally advanced unresectable or metastatic human epidermal growth factor receptor 2 (HER2)-positive breast cancer, including patients with brain metastases. Patients must have received prior treatment with trastuzumab, pertuzumab, and trastuzumab emtansine (T-DM1), separately or in combination, and have a good performance status.	Trastuzumab* 8 mg/kg as a loading dose intravenously (IV) on day 1 of the first cycle, followed by 6 mg/kg IV every 21 days until disease progression or unacceptable toxicity, whichever comes first. [ST-QBP regimen code: CAPETUCA + TRAS] *Trastuzumab is funded in combination with tucatinib and capecitabine, with the recommended doses as follows: • Tucatinib 300 mg orally twice daily; • Capecitabine 1000 mg/m2 orally twice daily on days 1 to 14 of every 21-day cycle.	1. Please refer to the Ministry of Health's Exceptional Access Program (EAP) for full reimbursement criteria for tucatinib when used in combination with trastuzumab and capecitabine for advanced breast cancer. Please check that your patient will be eligible for benefits under the Ontario Drug Benefit Program. Some patients may require registration in the Trillium Drug Program. 2. Treatment with trastuzumab can continue if tucatinib or capecitabine are discontinued due to unacceptable toxicity. 3. Prior treatment with trastuzumab deruxtecan may be considered as an alternative to trastuzumab emtansine (T-DM1) for funding purposes. If applicable, please submit as a prior approval request in eClaims including a clinic note(s) or documentation outlining the patient's treatment history.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
Trastuzumab Deruxtecan (trass-TOO-zoo-mab de RUX teh can) Other name: Enhertu®	Unresectable Locally Advanced or Metastatic Breast Cancer	Trastuzumab deruxtecan is used for the treatment of adult patients with unresectable locally advanced or metastatic human epidermal growth factor receptor 2 (HER2)-positive breast cancer who have a good performance status. Patients must have either: • Been treated with at least one prior anti-HER2-based regimen for unresectable locally advanced or metastatic disease, OR • Experienced disease recurrence during or within 6 months of completing neoadjuvant or adjuvant therapy with an anti-HER2-based regimen. Patients must have not been treated with an anti-HER2 antibody-drug conjugate in the unresectable locally advanced or metastatic setting.	Trastuzumab deruxtecan 5.4 mg/kg intravenously (IV) every 21 days. Treatment should continue until disease progression or unacceptable toxicity, whichever comes first. [ST-QBP regimen code(s): ENHE]	1. Trastuzumab deruxtecan is used as monotherapy. 2. Patients will be eligible for only one of either trastuzumab deruxtecan OR trastuzumab emtansine in the unresectable locally advanced or metastatic setting. 3. There is a risk of medication errors between trastuzumab deruxtecan, trastuzumab emtansine, and trastuzumab. Do not substitute or interchange any of the three medications for each other.
Trastuzumab Emtansine (trass-TOO-zoo-mab em TAN seen) Other name: Kadcyla®	Adjuvant Treatment for Early Breast Cancer	• Trastuzumab emtansine is used for the adjuvant treatment of patients with human epidermal growth factor receptor 2 (HER2)-positive early breast cancer, who have residual disease after preoperative systemic treatment including trastuzumab.	Trastuzumab emtansine 3.6 mg/kg intravenously (IV) once every 21 days. Treatment should be continued for a maximum of 14 cycles to complete one year (18 cycles total) of anti-HER2 therapy, or until disease progression or unacceptable toxicity, whichever comes first. [ST-QBP regimen code: KADC]	1. Patients who have not had surgery or neoadjuvant trastuzumab are not eligible to use trastuzumab emtansine under this policy. 2. Patients who progress on or within 6 months of completing trastuzumab emtansine therapy for early breast cancer will not be eligible for trastuzumab emtansine for advanced breast cancer. 3. NDFP will fund a total of 18 cycles of trastuzumab and trastuzumab emtansine combined for early breast cancer.
Trastuzumab Emtansine (trass-TOO-zoo- mab em TAN seen) Other name: Kadcyla®	Unresectable Locally Advanced or Metastatic Breast Cancer	• Trastuzumab emtansine is used for the **second line treatment** of HER2-positive, unresectable locally advanced or metastatic breast cancer. • The patient has an ECOG performance status of 0 or 1, and,	Trastuzumab emtansine 3.6 mg/kg IV every 3 weeks until disease progression or unacceptable toxicity	1. A complete pathology report (with the date of biopsy, staging information, positive HER2 test results) must be submitted if no prior documentation has been submitted to Ontario Health (Cancer Care Ontario) for trastuzumab funding.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
		• has either received prior treatment with trastuzumab plus chemotherapy in the metastatic setting or had disease recurrence during or within 6 months of completing adjuvant therapy with trastuzumab plus chemotherapy.		2. There is a risk of medication errors between trastuzumab deruxtecan, trastuzumab emtansine, and trastuzumab. Do not substitute or interchange any of the three medications for each other. 3. The trastuzumab emtansine dose should not be re-escalated after a dose reduction is made. 4. It is recommended that the left ventricular ejection fraction (LVEF) be greater than or equal to 50% prior to initiation of therapy. It is also recommended that LVEF be assessed (via MUGA or ECHO) prior to the initiation of trastuzumab emtansine and at regular intervals (e.g., every 3 months) during treatment. If, at routine monitoring, the LVEF is ≤ 40%, or is 40-45% with a 10% or greater absolute decrease below the pre-treatment value, withhold the trastuzumab emtansine and repeat the LVEF assessment within approximately 3 weeks.Trastuzumab emtansine should be permanently discontinued if the LVEF has not improved or has declined further. 5. Patients will be eligible for only one of either trastuzumab deruxtecan OR trastuzumab emtansine in the unresectable locally advanced or metastatic setting.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
Trastuzumab Emtansine (trass-TOO-zoo- mab em TAN seen) Other name: Kadcyla®	Unresectable Locally Advanced or Metastatic Breast Cancer as Third or Subsequent Line of Treatment (Time-Limited*) *For patients who have initiated or completed at least two lines of HER2 targeted therapy prior to the implementation of this temporary funding (October 17, 2014)	• Trastuzumab emtansine is used for patients with HER2-positive, unresectable locally advanced or metastatic breast cancer with an ECOG performance status of 0 or 1, and • Who have initiated or completed at least two lines of HER2 targeted therapy prior to the implementation of this temporary trastuzumab emtansine funding (October 17, 2014), and who have not received trastuzumab emtansine in any prior line of therapy	Trastuzumab emtansine 3.6 mg/kg IV every 3 weeks until disease progression or unacceptable toxicity	Reimbursement of trastuzumab emtansine under the NDFP, according to the clinical criterion outlined above, is effective on October 17, 2014 and ends on October 16, 2017. Patients enrolled prior to the end date may continue to receive funding for treatments beyond October 16, 2017, until disease progression or unacceptable toxicity. Enrolments submitted on October 17, 2017 and later will not be considered. For this policy, the following documents may be requested: • Pathology report confirming date of biopsy, Tumour Node Metastases (TNM) staging information and positive HER2 test results There is a risk of medication errors between trastuzumab emtansine and trastuzumab. Do not substitute trastuzumab emtansine for or with trastuzumab. Do not exceed the recommended trastuzumab emtansine dose (i.e., 3.6 mg/kg IV every 3 weeks). The trastuzumab emtansine dose should not be re-escalated after a dose reduction is made. It is recommended that the left ventricular ejection fraction (LVEF) be greater than or equal to 50% prior to initiation of therapy. It is also recommended that LVEF be assessed (via MUGA or ECHO) prior to the initiation of trastuzumab emtansine and at regular intervals (e.g., every 3 months) during treatment. If, at routine monitoring, the LVEF is ≤ 40%, or is 40-45% with a 10% or greater absolute decrease below the pretreatment value, withhold the trastuzumab emtansine and repeat the LVEF assessment within approximately 3 weeks. Trastuzumab emtansine should be permanently discontinued if the LVEF has not improved or has declined further.

Funded Drugs and Eligibility Criteria under EBP

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
No current indications				

Funded Drugs and Eligibility Criteria under HCTFP

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
Azacitidine (ay-za-SYE-ti-deen) Other Name: Vidaza®	In Combination with Venetoclax (Inpatient) for Previously Untreated Acute Myeloid Leukemia	The patient must meet the following criteria: Venetoclax in combination with azacitidine is used in adult patients for the treatment of newly diagnosed acute myeloid leukemia (AML) who are 75 years of age or older, or who are 18 to 74 years of age and have comorbidities that preclude the use of intensive induction chemotherapy.	Cycle 1: Azacitidine 75 mg/m2 subcutaneously once daily for 6 or 7 doses (starting on day 1) in combination with venetoclax 100 mg once daily on day 1, 200 mg once daily on day 2, then 400 mg once daily on days 3 to 28. Cycle 2 and onwards: Azacitidine 75 mg/m2 subcutaneously once daily for 6 or 7 doses (starting on day 1) in combination with venetoclax 400 mg once daily on days 1 to 28. [repeated every 28 days; 1 cycle = every 28 days] Treatment should be continued until disease progression or unacceptable toxicity, whichever comes first.	1. Enrolment in this policy is for funding of azacitidine and venetoclax doses administered in the inpatient setting only. Please ensure all claims are submitted through eClaims under the appropriate policies for inpatient and outpatient administered doses. 2. For funding of doses administered in the outpatient setting, a separate enrolment form must be submitted. See the policy 'Azacitidine in combination with Venetoclax (Inpatient) - Previously Untreated Acute Myeloid Leukemia'. Outpatient azacitidine is funded through the New Drug Funding Program whereas outpatient venetoclax funding is obtained through the Ministry's Exceptional Access Program. At the initiation of therapy, please check that your patient is eligible for benefits under the Ontario Drug Benefit Program. Some patients may require registration in the Trillium Drug Program. 3. The High Cost Therapy Funding Program (HCTFP) will only fund the azacitidine dosing schedules listed on this form. Sites are encouraged to contact their Reimbursement Analyst if they have questions on eligible dosing schedules. 4. Patients previously treated with a hypomethylating agent, venetoclax, or chemotherapy for myelodysplastic syndrome (MDS) are not eligible for funding of azacitidine in combination with venetoclax. 5. Patients with high risk MDS who are not fit for intensive induction chemotherapy are not eligible for funding of azacitidine in combination with venetoclax. 6. Azacitidine in combination with venetoclax will be funded in patients with newly diagnosed AML, regardless of cytogenetic risk, providing the patient meets the eligibility criteria. 7. In the event azacitidine is discontinued due to toxicities or intolerance, venetoclax should also be discontinued. 8. For patients without unacceptable toxicity, it is recommended that patients be treated for a minimum of 6 cycles.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
				9. Patients 75 years of age or older with an ECOG performance status greater than 2 may be eligible for funding under this policy if their performance status is judged to be related to their AML, provided all other criteria are met. Please submit as a prior approval request including the most recent clinic note.
Dinutuximab (din-ue-TUX-i-mab) Other name: Unituxin®	Pediatric High-Risk Neuroblastoma	In combination with granulocyte-macrophage colony-stimulating factor (GM-CSF), interleukin-2 (IL-2) and retinoic acid (RA) for the treatment of pediatric patients who achieve a response to prior pediatric protocol first-line multi-agent, multimodal therapy.	Dinutuximab Cycles 1-5 17.5 mg/m^2 per day intravenously (IV) for 4 days during each of the cycles. GM-CSF Cycles 1, 3, 5 250 mcg/m^2/day subcutaneously (SC) for 14 days during each of the cycles, starting 3 days before the start of dinutuximab. Treatment should be continued until unacceptable toxicity or disease progression to a maximum of six cycles of dinutuximab in combination with GM-CSF, IL-2 and RA. (I.e., for clarification, a maximum of five cycles of dinutuximab are administered. The sixth treatment cycle only includes RA.)	1. The High Cost Therapy Funding Program (HCTFP) will provide coverage of dinutuximab and GM-CSF in both the inpatient and outpatient settings, provided that funding criteria are met. 2. The HCTFP will allow funding of dinutuximab and GM-CSF when used in an adapted regimen where IL-2 is removed from Cycles 2 and 4 and GM-CSF is administered with all dinutuximab-containing cycles (i.e., up to 5 cycles (70 doses) of GM-CSF will be allowed). 3. Dinutuximab and GM-CSF will be reimbursed on a per vial basis.
Dinutuximab (din-ue-TUX-i-mab) Other name: Unituxin®	Pediatric Relapsed or Refractory High-Risk Neuroblastoma	Dinutuximab is used in combination with granulocyte-macrophage colony-stimulating factor (GM-CSF), irinotecan and temozolomide for the treatment of patients with high-risk neuroblastoma in first relapse or with refractory disease.	• Dinutuximab 17.5 mg/m^2/day intravenously (IV) for 4 days during each cycle • GM-CSF 250 mcg/m^2/day subcutaneously (SC) for 7 days during each cycle • All cycles are given in combination with temozolomide and irinotecan as part of an every 21-day cycle. • Treatment should be continued until unacceptable toxicity or disease progression to a maximum of 17 cycles of dinutuximab in	1. The High-Cost Therapy Funding Program (HCTFP) will provide coverage of dinutuximab and GM-CSF in both the inpatient and outpatient settings, provided that funding criteria are met. 2. Dinutuximab and GM-CSF will be reimbursed on a per vial basis. 3. Patients with high-risk neuroblastoma who were previously treated for refractory or relapsed disease will not be eligible for funding under this policy. 4. Refractory disease is defined as inadequate response to treatment that included at least 4 cycles of 2 or more chemotherapy agents, including an alkylator and a platinum agent. 5. Treatment with dinutuximab should only be delivered in specialized pediatric cancer centers with experience and knowledge of managing neuroblastoma.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
			combination with GM-CSF, irinotecan and temozolomide.	6. Treatment beyond 6 cycles requires documentation showing continued evidence of benefit (i.e., a clinic note and CT scan confirming that there is no evidence of disease progression). The documentation must be submitted with the treatment claims.
Gemtuzumab Ozogamicin (djem-TOOZ-ue-mab oh-zoe-ga-MYE-sin) Other name: Mylotarg®	Previously Untreated Acute Myeloid Leukemia (Inpatient) – *see NDFP for outpatient policy version*	Gemtuzumab ozogamicin is used in combination with daunorubicin and cytarabine for the treatment of adult patients with previously untreated, de novo CD33-positive acute myeloid leukemia (AML), except acute promyelocytic leukemia (APL). Treatment should be for patients with good performance status, and who have favourable, intermediate, or unknown cytogenetics (using the European LeukemiaNet (ELN) 2017 risk classification).	**Induction**: Gemtuzumab ozogamicin 3 mg/m^2 (up to a maximum single dose of 4.5 mg) intravenously (IV) on days 1, 4, and 7 in combination with cytarabine and daunorubicin. Treatment with gemtuzumab ozogamicin, in combination with daunorubicin and cytarabine, is funded for one induction cycle only. **Consolidation**: Gemtuzumab ozogamicin 3 mg/m^2 (up to a maximum single dose of 4.5 mg) IV on day 1 in combination with cytarabine, or cytarabine and daunorubicin. For those achieving complete remission following induction, gemtuzumab ozogamicin is funded for up to two cycles, in combination with standard cytarabine consolidation or cytarabine and daunorubicin consolidation. [ST-QBP regimen codes for outpatient use only: CYTA(HD)+GEMT or CYTADAUN+GEMT]	1. In the event where the cytogenetic status is unknown (that is, because the test was unsuccessful) or when the cytogenetic test result is not yet available, gemtuzumab ozogamicin could be initiated during induction therapy. 2. Once a patient's cytogenetic status is confirmed as being adverse risk, gemtuzumab ozogamicin is no longer eligible for funding. 3. Gemtuzumab ozogamicin is not funded for use in patients with adverse cytogenetics, therapy-related AML or in combination with midostaurin for FMS-like tyrosine kinase 3 (FLT3)-mutated acute myeloid leukemia (AML). 4. Gemtuzumab ozogamicin may be funded if idarubicin is used as an alternative anthracycline to daunorubicin, in combination with cytarabine. 5. Gemtuzumab ozogamicin is not funded if used in combination with other treatments (e.g., FLAG-IDA or azacitidine). Gemtuzumab ozogamicin may be used with an anthracycline and high-dose cytarabine (or high-dose cytarabine alone) as consolidative therapy based on institutional best practice. 6. Gemtuzumab ozogamicin is not funded for relapsed or refractory AML or when used as a single-agent. 7. Patients with de novo CD33-positive, FLT3-positive AML with favourable, intermediate, or unknown cytogenetics may use one of either gemtuzumab ozogamicin or midostaurin (assuming other eligibility criteria are met). 8. All doses (induction and consolidation) are to be submitted through eClaims using separate enrolment forms for inpatient and outpatient use. This policy is only for doses administered in the inpatient setting.
Gilteritinib (GIL-te-RI-ti-nib) Other name: Xospata®	Relapsed or Refractory FLT3-mutated Acute Myeloid Leukemia (Inpatient)	Gilteritinib is used for the treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) whose FLT3 mutation status is confirmed by a validated test and who have a good performance status.	Gilteritinib 120mg (three 40mg tablets) orally once daily in continuous 28-day cycles. Treatment should continue as long as clinical benefit is observed or until unacceptable toxicity occurs.	1. Funding is for doses administered in the inpatient setting only. Please refer to the Ministry of Health's Exceptional Access Program for funding of doses administered in the outpatient setting. 2. Gilteritinib funding is for single agent use only. 3. Patients who initiate treatment with gilteritinib in the relapsed or refractory AML setting who then proceed to a hematopoietic stem cell transplant (HSCT) would be able to resume gilteritinib following the HSCT. Claims should be submitted under the same form used for the initial course of treatment.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
			In the absence of disease progression or unacceptable toxicity, treatment may be given for a minimum of six months to determine clinical benefit as a delay in clinical response can occur.	4. Gilteritinib is not funded if used for a. therapy-related AML; b. patients who have had a prior relapse while being treated with gilteritinib or another tyrosine kinase inhibitor (TKI) specific to FLT3-mutated AML in the relapsed or refractory AML setting; c. earlier lines of treatment prior to refractory or relapsed disease; d. AML with FLT3 mutations outside of FLT3-ITD, FLT3-TKD/D835, FLT3-TKD/I836. 5. After 1 cycle, dose escalations of up to 200mg once daily to achieve complete remission will be permitted but the dose should not be escalated after achieving complete remission.
Inotuzumab Ozogamicin (in-oh-TOOZ-ue-mab oh-zoe-ga-MYE-sin) Other name: Besponsa®	Relapsed or Refractory Acute Lymphoblastic Leukemia (Inpatient) *see NDFP for outpatient policy version*	For the treatment of Philadelphia chromosome (Ph)-positive and Ph-negative patients with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL) who have good performance status. [For patients with Ph-positive ALL, failure with at least one second-generation or third-generation tyrosine kinase inhibitor (TKI) and standard multi-drug induction chemotherapy is required before treatment with inotuzumab ozogamicin.]	Cycle 1: Inotuzumab ozogamicin 0.8 mg/m2 intravenously (IV) on day 1 followed by inotuzumab ozogamicin 0.5 mg/m2 IV on days 8 and 15 [total dose per cycle = 1.8 mg/m2]. Cycle 1 is 21 days. Subsequent cycles: For patients who achieve a complete response or complete response with incomplete count recovery (CR/CRi): Inotuzumab ozogamicin 0.5 mg/m2 IV on days 1, 8 and 15 [total dose per cycle = 1.5 mg/m2]. For patients who have not achieved a CR/CRi: Inotuzumab ozogamicin 0.8 mg/m2 IV on day 1 followed by 0.5 mg/m2 IV on days 8 and 15 [total dose per cycle = 1.8 mg/m2]. Subsequent cycles are 28 days. Treatment should be continued until unacceptable toxicity or disease	1. Enrolment in this policy is for funding of inotuzumab ozogamicin doses administered in the inpatient setting only. Please ensure all claims are submitted through eClaims under the appropriate policies for inpatient and outpatient use. 2. For funding of doses administered in the outpatient setting, a separate enrolment form must be submitted. Refer to the New Drug Funding Program (NDFP) policy entitled 'Inotuzumab Ozogamicin (Outpatient) - Relapsed or Refractory Acute Lymphoblastic Leukemia'.

Drug Name	Indication	Eligibility Criteria	Funded Dose	Notes
			progression, up to a maximum of three cycles, for those patients proceeding to hematopoietic stem cell transplant (HSCT). For patients not proceeding to HSCT who achieve CR/CRi and minimal residual disease (MRD) negativity, treatment may be continued for a maximum of six total cycles.	
Liposomal Daunorubicin and Cytarabine (lip-o-SO-mal DAW-no-RUE-bih-sin (and) SITE-ah-rah-been) Other name: Vyxeos®	Previously Untreated Acute Myeloid Leukemia (Inpatient) – *see NDFP for outpatient policy version*	Liposomal daunorubicin and liposomal cytarabine will be used in adult patients with newly diagnosed therapy-related acute myeloid leukemia (t-AML) or AML with myelodysplasia-related changes (AML-MRC) who are deemed fit for intensive chemotherapy.	First Induction: Liposomal daunorubicin 44 mg/m^2 and liposomal cytarabine 100 mg/m^2 intravenously (IV) on days 1, 3, and 5. Second Induction (if required): Liposomal daunorubicin 44 mg/m^2 and liposomal cytarabine 100 mg/m^2 IV on days 1 and 3. Consolidation: Liposomal daunorubicin 29 mg/m^2 and liposomal cytarabine 65 mg/m^2 IV on days 1 and 3. Liposomal daunorubicin and liposomal cytarabine is funded for up to 2 cycles of induction therapy. Patients who achieve complete remission (CR) or CR with incomplete neutrophil or platelet recovery (CRi) during induction cycles are eligible for up to an additional 2 cycles of consolidation therapy using liposomal daunorubicin and liposomal cytarabine.	1. Vyxeos® is a product containing two drugs (liposomal daunorubicin and liposomal cytarabine) in one IV dosage form. 2. t-AML is defined as a pathological diagnosis of AML as per the World Health Organization (WHO) criteria and documented history of prior cytotoxic or radiation therapy for an unrelated disease. 3. AML-MRC is defined as a pathological diagnosis of AML as per the WHO criteria and one of the documented antecedent hematologic disorders: • bone marrow documentation of myelodysplastic syndrome (MDS) before diagnosis of AML with or without prior use of a hypomethylating agent, OR • bone marrow documentation of chronic myelomonocytic leukemia (CMMoL) before diagnosis of AML, OR • de novo AML with fluorescence in situ hybridization or cytogenetic changes linked to MDS as per WHO criteria. 4. Liposomal daunorubicin and liposomal cytarabine is not funded if used in combination with other anti-cancer therapies. 5. All doses (induction and consolidation) are to be submitted through eClaims using the corresponding enrolment forms for inpatient and outpatient use. This policy is only for doses administered in the inpatient setting.
Midostaurin (MYE-doe-STAW-rin)	FLT3-mutated Acute Myeloid Leukemia (Inpatient)	The patient must meet the following criteria:	**Induction**: Midostaurin 50mg orally twice daily on days 8 to 21 with each cycle, up to a maximum of 2 induction cycles, regardless	1. Funding is for doses administered in the inpatient setting only. Please refer to the Ontario Drug Benefit Exceptional Access Program for funding of doses administered in the outpatient setting. Patients requiring outpatient treatment will need to apply to the

Other name: Rydapt®		Midostaurin is used for the treatment of adult patients with newly diagnosed FMS-like tyrosine kinase 3 (FLT3)-mutated acute myeloid leukemia (AML). Patients should be deemed to be fit to receive standard induction and consolidation chemotherapy.	of the funding source. Patients who have residual AML after a second induction cycle should be discontinued from midostaurin therapy. **Consolidation**: Midostaurin 50mg orally twice daily on days 8 to 21 of each cycle of consolidation, up to a maximum of 4 cycles, regardless of the funding source.	Ontario Drug Benefit Program's Exceptional Access Program. At the initiation of therapy, please check that your patient will be eligible for benefits under the Ontario Drug Benefit Program. Some patients may require registration in the Trillium Drug Program. 2. Midostaurin is used in combination with standard induction chemotherapy with cytarabine and daunorubicin followed by standard cytarabine consolidation chemotherapy, OR any 7+3 induction regimen containing idarubicin followed by standard consolidation chemotherapy with cytarabine. 3. Midostaurin is not funded if used for a. maintenance therapy for AML; b. therapy-related AML after prior radiation therapy or chemotherapy for another cancer or disorder; c. re-induction and/or re-consolidation.
Pegaspargase (peg-ah-SPAR-jase) Other name: Oncaspar®	Adult Acute Lymphoblastic Leukemia (ALL), Lymphoblastic Lymphoma, Mixed or Biphenotypic Leukemia (Inpatient) – *see NDFP for outpatient policy version*	Pegaspargase is used as part of a multi-agent chemotherapy regimen, given with curative intent, for the treatment of adult patients with acute lymphoblastic leukemia (ALL), lymphoblastic lymphoma or mixed/biphenotypic leukemia.	**Adults under 60 years of age (as part of a modified Dana-Farber Cancer Institute (DFCI)-based or alternate clinician-informed regimen):** Pegaspargase 1000-2000 units/m2 intravenously (IV) or by intramuscular (IM) injection once every cycle during induction and intensification, to a maximum of 11 total doses. **Adults 60 years of age or older (as part of a modified DFCI-based or alternate clinician-informed regimen):** Pegaspargase 1000-1250 units/m2 intravenously (IV) or by intram**uscu**lar (IM) injection once every cycle during induction and intensification, to a maximum of 8 total doses. Maximum single dose of 3750 units irrespective of age.	1. Pegaspargase will be reimbursed on a per vial basis to a maximum of one vial per dose. 2. All doses (induction and intensification) are to be submitted through eClaims using separate enrolment forms for inpatient and outpatient use. This policy is only for doses administered in the inpatient setting.

Thiotepa (THY-oh-TEH-puh) Other name: Tepadina®	As Part of the MATRix Regimen in Newly Diagnosed, Previously Untreated Primary Central Nervous System Lymphoma	Thiotepa is used in combination with high-dose methotrexate, cytarabine and rituximab (MATRix regimen) as induction therapy in patients with newly diagnosed, previously untreated primary central nervous system (CNS) lymphoma.	Thiotepa 30 mg/m² intravenously on Day 4 of the MATRix regimen. [1 cycle = 21 days] Thiotepa is funded when used in combination with high-dose methotrexate, cytarabine and rituximab. Thiotepa is funded up to a maximum of 4 cycles or until disease progression or occurrence of unacceptable toxicities (whichever occurs first).	1. Enrolment in this policy is for thiotepa only. Any thiotepa doses given as part of the MATRix regimen will only be funded for inpatient use. 2. Rituximab doses given as part of the MATRix regimen are only funded in the outpatient setting. Please enroll separately in the New Drug Funding Program (NDFP) policy entitled 'Rituximab (Biosimilar IV) – As Part of the MATRix Regimen in Newly Diagnosed, Previously Untreated Primary Central Nervous System Lymphoma' for reimbursement of outpatient rituximab.
Venetoclax (veh-NEH-toh-klax) Other name: Venclexta®	In Combination with Azacitidine (Inpatient) for Previously Untreated Acute Myeloid Leukemia	The patient must meet the following criteria: Venetoclax in combination with azacitidine is used in adult patients for the treatment of newly diagnosed acute myeloid leukemia (AML) who are 75 years of age or older, or who are 18 to 74 years of age and have comorbidities that preclude the use of intensive induction chemotherapy.	Cycle 1: Azacitidine 75 mg/m2 subcutaneously once daily for 6 or 7 doses (starting on day 1) in combination with venetoclax 100 mg once daily on day 1, 200 mg once daily on day 2, then 400 mg once daily on days 3 to 28. Cycle 2 and onwards: Azacitidine 75 mg/m2 subcutaneously once daily for 6 or 7 doses (starting on day 1) in combination with venetoclax 400 mg once daily on days 1 to 28. [repeated every 28 days; 1 cycle = every 28 days] Treatment should be continued until disease progression or unacceptable toxicity, whichever comes first.	1. Enrolment in this policy is for funding of azacitidine and venetoclax doses administered in the inpatient setting only. Please ensure all claims are submitted through eClaims under the appropriate policies for inpatient and outpatient administered doses. 2. For funding of doses administered in the outpatient setting, a separate enrolment form must be submitted. See the policy 'Azacitidine in combination with Venetoclax (Inpatient) - Previously Untreated Acute Myeloid Leukemia'. Outpatient azacitidine is funded through the New Drug Funding Program whereas outpatient venetoclax funding is obtained through the Ministry's Exceptional Access Program. At the initiation of therapy, please check that your patient is eligible for benefits under the Ontario Drug Benefit Program. Some patients may require registration in the Trillium Drug Program. 3. The High Cost Therapy Funding Program (HCTFP) will only fund the azacitidine dosing schedules listed on this form. Sites are encouraged to contact their Reimbursement Analyst if they have questions on eligible dosing schedules. 4. Patients previously treated with a hypomethylating agent, venetoclax, or chemotherapy for myelodysplastic syndrome (MDS) are not eligible for funding of azacitidine in combination with venetoclax. 5. Patients with high risk MDS who are not fit for intensive induction chemotherapy are not eligible for funding of azacitidine in combination with venetoclax.

				6. Azacitidine in combination with venetoclax will be funded in patients with newly diagnosed AML, regardless of cytogenetic risk, providing the patient meets the eligibility criteria. 7. In the event azacitidine is discontinued due to toxicities or intolerance, venetoclax should also be discontinued. 8. For patients without unacceptable toxicity, it is recommended that patients be treated for a minimum of 6 cycles. 9. Patients 75 years of age or older with an ECOG performance status greater than 2 may be eligible for funding under this policy if their performance status is judged to be related to their AML, provided all other criteria are met. Please submit as a prior approval request including the most recent clinic note.
Voretigene neparvovec (voe RET i jeen ne PAR voe vek) Other name: Luxturna®	Previously Untreated Inherited Retinal Dystrophy	Voretigene neparvovec is used for the treatment of patients with vision loss due to inherited retinal dystrophy caused by biallelic retinal pigment epithelium 65 kDa protein (RPE65) mutations. The patient must meet the following criteria: • Biallelic retinal pigment epithelium 65 kDa protein (RPE65) mutations, as confirmed by an accredited laboratory using validated assay methods and discussed with the medical/clinical geneticist. • Possess sufficient viable retinal cells in each eye to be treated, as determined by an inherited retinal disease specialist through non-invasive means such as optical coherence tomography (OCT) and/or ophthalmoscopy and by at least 1 of the following: o Retinal thickness within the posterior pole of greater than 100 µm as shown on OCT, or	Voretigene neparvovec 1.5 x 1011 vector genomes (vg), administered by subretinal injection in each eye. Each dose will be delivered into the subretinal space in a total volume of 0.3 mL. Administration procedure to each eye is performed on separate days within a close interval but no fewer than 6 days apart. Reimbursement process: each eye to be submitted as a separate treatment claim. Only one enrolment form is required to confirm eligibility for both eyes.	1. Treatment is limited to one treatment per eye per patient lifetime. 2. Treatment with voretigene neparvovec should be administered within 12 months of initial patient assessment. 3. Patient selection and the pre- and post-surgical evaluation should be carried out by a physician who specializes in inherited retinal diseases. 4. Treatment with voretigene neparvovec should be administered by a retinal surgeon experienced in performing subretinal surgery, submacular injection and management of associated complications. 5. Prior to initiation of the immunomodulatory regimen and prior to administration of voretigene neparvovec, the patient must be checked for symptoms of active infectious disease of any nature, and in case of such infection the start of treatment must be postponed until after the patient has recovered.

		o 3 or more disc areas of the retina without atrophy or pigmentary degeneration within the posterior pole, or o a remaining visual field within 30 degrees of fixation as measured by III4e isopter or equivalent, or o measurable full-field stimulus testing (FST) • At least 4 years and under 65 years of age. • Visual acuity worse than 20/60 (both eyes) and/or visual field less than 20 degrees and/or measurable FST. 3 • Has not received a previous treatment course of voretigene neparvovec.		

Version Control Tracking

Old version no.	Date changed	New version no.	Revision
N/A	January 9, 2015	1.0	• Implemented and posted document on the Ontario Health (Cancer Care Ontario) website, replacing all NDFP and EBP web forms. All eligibility criteria are consistent with CCO eClaims as of January 9, 2015.
1.0	January 26, 2015	1.1	• Implemented Radium-223-Dichloride – Castration-Resistant Prostate Cancer and Rituximab-HIV-Related Aggressive Histology B-cell Lymphoma. All eligibility criteria are consistent with CCO eClaims as of January 9, 2015.
1.1	February 4, 2015	1.2	• Revised language in Eligibility – NDFP and Eligibility – EBP on pages 2 and 3.
1.2	February 19, 2015	1.3	• Removed notes section for *Eribulin – Metastatic or Incurable Locally Advanced – Breast Cancer*. As of February 19, 2015, supporting documentation is no longer required for the policy enrolment.
1.3	March 31, 2015	1.4	• Revised policy title of *Ipilimumab – Unresectable Melanoma* to *Ipilimumab – Previously Treated Advanced Unresectable Melanoma*, where supporting documentation is no longer required for enrolment as of April 1, 2015. • Implemented new policy Ipilimumab – Previously Untreated Advanced Unresectable Melanoma, effective date April 1, 2015.
1.4	April 17, 2015	1.5	• Implemented new policy Gemcitabine and Nab-Paclitaxel – Advanced Pancreatic Cancer, effective date April 17, 2015. • Revised policy title from *Gemcitabine – Pancreatic Cancer* to *Gemcitabine – Advanced Pancreatic Cancer*. Revised eligibility criteria, updated notes on eligibility for related policies, effective date April 17, 2015.

Old version no.	Date changed	New version no.	Revision
			• Revised policy titles from Oxaliplatin and Irinotecan – Metastatic Pancreatic Adenocarcinoma to Oxaliplatin and Irinotecan – Advanced Pancreatic Cancer to Advanced Pancreatic Cancer (FOLFIRINOX). Revised eligibility criteria, updated notes on eligibility for related policies, effective date April 17, 2015.
1.5	May 29, 2015	1.5	• Revised policy for docetaxel for second or subsequent line treatment of non-small cell lung cancer (NSCLC) • Implemented new policy Docetaxel – Hormone Sensitive Prostate Cancer
1.6	June 1, 2015	1.6	• Updated Notes section in the azacitidine policies, where supplemental form submissions have been revised to every 6 cycles, at disease progression, and when patient has discontinued treatment, effective June 1, 2015.
1.7	July 17, 2015	1.7	• Formatting and minor editing changes on various policies. These changes do not impact eligibility criteria or funding criteria. • Link to CCO Drug Formulary was added when there is no specified funded dose • Implemented new policy Obinutuzumab – Previously Untreated Chronic Lymphocytic Leukemia
1.7	January 6, 2016	1.8	• Added Paclitaxel – Non-Small Cell Lung Cancer (NSCLC) • Implemented new policy Bevacizumab – Metastatic (Stage 4B), Persistent or Recurrent Carcinoma of the Cervix • Implemented new policy Romidepsin – Relapsed or Refractory Peripheral T-Cell Lymphoma • Policy revision for Rituximab – Second Line Chronic Lymphocytic Leukemia • Policy revision for Pemetrexed – Combination with Platinum for Non-Small Cell Lung Cancer • Policy revision for Plerixafor - Stem Cell Mobilization in Non-Hodgkin's Lymphoma or Multiple Myeloma
1.8	March 30, 2016	1.9	• Policy revision for Radium-223 Dichloride – Castration-Resistant Prostate Cancer • Implemented new policy Bevacizumab – Front-line Treatment (Previously Untreated) Ovarian, Fallopian Tube, and Primary Peritoneal Cancer (with paclitaxel and carboplatin)
1.9	June 2, 2016	1.10	• Policy revision for Oxaliplatin – Adjuvant High Risk Stage II or Stage III Colon or Rectal Cancer • Implemented new policy Pembrolizumab – Advanced Melanoma (Unresectable or Metastatic Melanoma) and no prior ipilimumab • Implemented new policy Pembrolizumab – Advanced Melanoma (Unresectable or Metastatic Melanoma) and prior ipilimumab
1.10	September 9, 2016	1.11	• Implemented new policy Aldesleukin (interleukin-2) – In-Transit Metastases from Melanoma • Policy revision for Liposomal Doxorubicin – Platinum – Resistant Ovarian, Fallopian Tube, or Primary Peritoneal Cancer • Policy revision for Liposomal Doxorubicin – Single Agent Treatment of Platinum Sensitive Ovarian, Fallopian Tube, or Primary Peritoneal Cancer for Patients Unable to Receive Platinum Therapy • Policy revision for Paclitaxel – Single Agent Treatment of Platinum Sensitive Ovarian, Fallopian Tube, or Primary Peritoneal Cancer for Patients Unable to Receive Platinum Therapy • Policy revision for Paclitaxel in Combination with Platinum – First Line – Advanced Ovarian, Fallopian Tube, or Primary Peritoneal Carcinoma • Policy revision for Paclitaxel in Combination with Platinum – Recurrent – Advanced Ovarian, Fallopian Tube, or Primary Peritoneal Carcinoma • Policy revision for Topotecan – Platinum – Resistant Ovarian, Fallopian Tube, or Primary Peritoneal Cancer • Policy revision for Topotecan – Single Agent Treatment of Platinum Sensitive Ovarian, Fallopian Tube, or Primary Peritoneal Cancer for Patients Unable to Receive Platinum Therapy
1.11	October 19, 2016	1.12	• Implemented new policy Rituximab – In combination with idelalisib – relapsed chronic lymphocytic leukemia

Old version no.	Date changed	New version no.	Revision
			• Policy revision for Trastuzumab (EBP) – Adjuvant Trastuzumab with Chemotherapy for HER2/neu-Overexpressing Breast Cancer Tumours Less than or Equal to 1 cm in Diameter
1.12	December 22, 2016	1.13	• Implemented new policy Siltuximab – Multicentric Castleman's Disease
1.13	February 28, 2017	1.14	• Implemented new policy Ramucirumab – Advanced or metastatic gastric cancer or gastro-esophageal junction adenocarcinoma • Policy revision for Docetaxel – Early Operable Breast Cancer (eligibility criteria) • Policy revision for Trastuzumab (EBP) – Adjuvant Trastuzumab with Chemotherapy for HER2/neu-Overexpressing Breast Cancer Tumours Less than or Equal to 1 cm in Diameter (note 'e')
1.14	March 21, 2017	1.15	• Implemented new policy Nivolumab – Advanced Melanoma (Unresectable or Metastatic Melanoma) • Implemented new policy Nivolumab – Advanced or Metastatic Non-Small Cell Lung Cancer • Implemented new policy Nivolumab – Advanced or Metastatic Renal Cell Carcinoma and No Prior mTOR Inhibitor • Implemented new policy Nivolumab – Advanced or Metastatic Renal Cell Carcinoma and Prior mTOR Inhibitor
1.15	April 24, 2017	1.16	• Implemented new policy Blinatumomab – Acute Lymphoblastic Leukemia
1.16	May 31, 2017	1.17	• Fixed typographical error in Blinatumomab – Acute Lymphoblastic Leukemia
1.17	June 29, 2017	1.18	• Policy revision for Bevacizumab – First Line – Metastatic Colorectal, Small Bowel, or Appendiceal Cancer • Policy revision for Cetuximab with Irinotecan – Third Line – Metastatic Colorectal, Small Bowel, or Appendiceal Cancer • Policy revision for Irinotecan – First Line – Metastatic Colorectal, Small Bowel, or Appendiceal Cancer • Policy revision for Irinotecan – Second Line – Metastatic Colorectal, Small Bowel, or Appendiceal Cancer • Policy revision for Oxaliplatin – Adjuvant Colorectal, Small Bowel, or Appendiceal Cancer • Policy revision for Oxaliplatin – First Line – Metastatic Colorectal, Small Bowel, or Appendiceal Cancer • Policy revision for Oxaliplatin – Second Line – Metastatic Colorectal, Small Bowel, or Appendiceal Cancer • Policy revision for Oxaliplatin – With Surgery for Curative Intent for Colorectal, Small Bowel, or Appendiceal Cancer Patients with Resectable or Potentially Resectable Liver Mets • Policy revision for Panitumumab – Metastatic Colorectal, Small Bowel, or Appendiceal Cancer • Policy revision for Raltitrexed – Metastatic Colorectal, Small Bowel, or Appendiceal Cancer
1.18	August 8, 2017	1.19	• Policy revision for *Azacitidine – Acute Myeloid Leukemia (AML)* (removal of requirement for supplemental forms) • Policy revision for *Azacitidine – Myelodysplastic Syndromes (MDS)* (removal of requirement for supplemental forms) • Policy revision for Pertuzumab – In combination with trastuzumab-taxane for HER2 positive unresectable locally recurrent or metastatic cancer (removal of requirement for supplemental forms) • Policy revision for *Trastuzumab – Single Agent Metastatic Breast Cancer* (removal of requirement for supplemental forms) • Policy revision for Trastuzumab – In combination with Docetaxel – Metastatic Breast Cancer (removal of requirement for supplemental forms) • Policy revision for Trastuzumab – In combination with Paclitaxel – Metastatic Breast Cancer (removal of requirement for supplemental forms)

Old version no.	Date changed	New version no.	Revision
			• Policy revision for Trastuzumab – In combination with Vinorelbine – Metastatic Breast Cancer (removal of requirement for supplemental forms) • Implemented new policy Liposomal Doxorubicin ("Caelyx") Platinum-sensitive recurrent ovarian, fallopian tube, or primary peritoneal cancer
1.19	September 1, 2017	1.20	• Implemented new policy Panitumumab – In Combination with Chemotherapy for First Line Metastatic Colorectal, Small Bowel, or Appendiceal Cancer • Policy revision for Panitumumab – Metastatic Colorectal, Small Bowel, or Appendiceal Cancer • Policy revision for Cetuximab – Third Line – Metastatic Colorectal, Small Bowel, or Appendiceal Cancer (with irinotecan) • Policy revision for Bevacizumab – First Line – Metastatic Colorectal, Small Bowel, or Appendiceal Cancer
1.20	September 8, 2017	1.21	• Policy revision for Pemetrexed – Combination with Platinum for Non-Small Cell Lung Cancer • Policy revision for Pemetrexed – Non-Small Cell Lung Cancer (following Crizotinib) • Policy revision for Pemetrexed – Non-Small Cell Lung Cancer (Second or Subsequent Line)
1.21	October 5, 2017	1.22	• Implemented new policy Bevacizumab – Platinum-Resistant Recurrent Ovarian, Fallopian Tube, or Primary Peritoneal Cancer • Policy revision for Bevacizumab – Front-line Treatment (Previously Untreated) Ovarian, Fallopian Tube, and Primary Peritoneal Cancer (with paclitaxel and carboplatin) • Policy revision for Liposomal Doxorubicin – Platinum – Resistant Ovarian, Fallopian Tube, or Primary Peritoneal Cancer • Policy revision for Topotecan – Platinum – Resistant Ovarian, Fallopian Tube, or Primary Peritoneal Cancer
1.22	October 20, 2017	1.23	• Policy revision for Bevacizumab – First Line – Metastatic Colorectal, Small Bowel, or Appendiceal Cancer
1.23	January 17, 2018	1.24	• Implemented new policy Nivolumab – Recurrent or Metastatic Squamous Cell Carcinoma of the Head and Neck, which is Platinum Resistant or Refractory • Implemented new policy Pembrolizumab – Previously Untreated Locally Advanced or Metastatic Non-Small Cell Lung Cancer • Implemented new policy Pembrolizumab – Advanced or Metastatic Non-Small Cell Lung Cancer (Second or Subsequent Line)
1.24	February 2, 2018	1.25	• Policy revision for Pembrolizumab – Previously Untreated Locally Advanced or Metastatic Non-Small Cell Lung Cancer
1.25	April 1, 2018	1.26	• Implemented new policy Pegaspargase – Newly Diagnosed Pediatric Acute Lymphoblastic Leukemia, Lymphoblastic Lymphoma, or Mixed/Biphenotypic Leukemia • Implemented new policy Pegaspargase – Relapsed or Refractory Pediatric Acute Lymphoblastic Leukemia, Lymphoblastic Lymphoma, or Mixed/Biphenotypic Leukemia • Implemented new policy Erwinia Asparaginase – Newly Diagnosed Pediatric Acute Lymphoblastic Leukemia, Lymphoblastic Lymphoma, or Mixed/Biphenotypic Leukemia • Implemented new policy Erwinia Asparaginase – Relapsed or Refractory Pediatric Acute Lymphoblastic Leukemia, Lymphoblastic Lymphoma, or Mixed/Biphenotypic Leukemia
1.26	May 1, 2018	1.27	• Implemented new policy Carfilzomib (Doublet Therapy) – In Combination with Dexamethasone for Relapsed Multiple Myeloma • Implemented new policy Carfilzomib (Triplet Therapy) – In Combination with Lenalidomide and Dexamethasone for Relapsed Multiple Myeloma
1.27	May 3, 2018	1.28	• Policy revision for Carfilzomib (Triplet Therapy) – In Combination with Lenalidomide and Dexamethasone for Relapsed Multiple Myeloma

Old version no.	Date changed	New version no.	Revision
1.28	June 1, 2018	1.29	• Policy revision for Bortezomib – Relapsed or Refractory Multiple Myeloma
1.29	August 1, 2018	1.30	• Policy revision for Rituximab – Aggressive Histology Lymphoma (added rituximab SC) • Policy revision for Rituximab – HIV-Related, Aggressive Histology, B-cell Lymphoma (added rituximab SC) • Policy revision for Rituximab – Maintenance Treatment – Lymphoma (added rituximab SC) • Policy revision for Rituximab – Retreatment – Indolent Lymphoma (added rituximab SC) • Policy revision for Rituximab in Combination with Chemotherapy – Indolent B-cell Lymphoma (added rituximab SC)
1.30	September 7, 2018	1.31	• Policy revision for Nivolumab – Advanced Melanoma (Unresectable or Metastatic Melanoma) • Policy revision for Nivolumab – Advanced or Metastatic Non-Small Cell Lung Cancer • Policy revision for Nivolumab – Advanced or Metastatic Renal Cell Carcinoma and No Prior mTOR Inhibitor • Policy revision for Nivolumab – Advanced or Metastatic Renal Cell Carcinoma and Prior mTOR Inhibitor • Policy revision for Nivolumab – Recurrent or Metastatic Squamous Cell Carcinoma of the Head and Neck, which is Platinum Resistant or Refractory
1.31	October 17, 2018	1.32	• Implemented new policy Obinutuzumab - In Combination with Chemotherapy for Relapsed/Refractory Follicular Lymphoma • Implemented new policy Obinutuzumab - Maintenance Treatment for Relapsed/Refractory Follicular Lymphoma • Policy revision for Bendamustine - Relapsed/Refractory - Indolent Non-Hodgkin's Lymphoma and Mantle Cell Lymphoma • Policy revision for Rituximab - Retreatment – Indolent Lymphoma
1.31	November 7, 2018	1.33	• Implemented new policy Rituximab - As Part of the MATRix Regimen in Newly Diagnosed, Previously Untreated Primary Central Nervous System Lymphoma • Policy revision for Rituximab – Single Agent Indolent Lymphoma • Policy revision for Rituximab – Aggressive Histology Lymphoma • Policy title revision for Obinutuzumab - In Combination with Chemotherapy for Refractory Follicular Lymphoma • Policy title revision for Obinutuzumab - Maintenance Treatment for Refractory Follicular Lymphoma
1.33	January 17, 2019	1.34	• Policy revision for Rituximab – Previously Untreated Chronic Lymphocytic Leukemia (added rituximab SC) • Policy revision for Rituximab – Second Line – Chronic Lymphocytic Leukemia (added rituximab SC) • Policy revision for Rituximab – Retreatment – Indolent Lymphoma
1.34	March 13, 2019	1.35	• Implemented new policy Daratumumab – In Combination with Bortezomib and Dexamethasone for Relapsed Multiple Myeloma • Implemented new policy Daratumumab – In Combination with Lenalidomide and Dexamethasone for Relapsed Multiple Myeloma
1.35	March 15, 2019	1.36	• Formatting and date change in Daratumumab – In Combination with Bortezomib and Dexamethasone for Relapsed Multiple Myeloma • Formatting and date change in Daratumumab – In Combination with Lenalidomide and Dexamethasone for Relapsed Multiple Myeloma
1.36	April 16, 2019	1.37	• Implemented new policy Avelumab • Implemented new policy Nivolumab plus Ipilimumab - Advanced Melanoma (Unresectable or Metastatic Melanoma) • Policy revision for Nivolumab - Advanced Melanoma (Unresectable or Metastatic Melanoma) • Policy revision for Ipilimumab - Previously Treated Advanced Unresectable Melanoma • Policy revision for Ipilimumab - Previously Untreated Advanced Unresectable Melanoma

Old version no.	Date changed	New version no.	Revision
			• Policy revision for Pembrolizumab - Advanced Melanoma (Unresectable or Metastatic Melanoma) and no prior ipilimumab • Policy revision for Pembrolizumab - Advanced Melanoma (Unresectable or Metastatic Melanoma) and prior ipilimumab
1.37	May 15, 2019	1.38	• Implemented new Policy - Nivolumab plus Ipilimumab – Metastatic Renal Cell Carcinoma • Policy clarification for Nivolumab - Advanced or Metastatic Renal Cell Carcinoma and Prior mTOR Inhibitor • Policy clarification for Nivolumab - Advanced or Metastatic Renal Cell Carcinoma and No Prior mTOR Inhibitor
1.38	June 12, 2019	1.39	• Revised criteria and policy name from Blinatumumab – Acute Lymphoblastic Leukemia to Blinatumomab - Relapsed or Refractory Pediatric Acute Lymphoblastic Leukemia • Implemented new policy Blinatumomab - Relapsed or Refractory Acute Lymphoblastic Leukemia
1.39	July 18, 2019	1.40	• Implemented new policy Inotuzumab Ozogamicin - Relapsed or Refractory Acute Lymphoblastic Leukemia
1.40	Aug 12, 2019	1.41	• Implemented new policy Bevacizumab (Biosimilar) - First Line - Metastatic Colorectal, Small Bowel, or Appendiceal Cancer • Implemented new policy Bevacizumab (Biosimilar) - Metastatic (Stage IVB), Persistent, or Recurrent Carcinoma of the Cervix • Implemented new policy Bevacizumab (Biosimilar) with Paclitaxel and Carboplatin - Front-line Treatment (Previously Untreated) Ovarian, Fallopian Tube, and Primary Peritoneal Cancer

1.41	Oct 03, 2019	1.42	• Implemented new policy Bevacizumab (Biosimilar) for Platinum-Resistant Recurrent Ovarian, Fallopian Tube, or Primary Peritoneal Cancer
			• Removed non-biosimilar bevacizumab policies no longer funded for new enrolments:
			  ○ First Line – Metastatic Colorectal, Small Bowel, or Appendiceal Cancer
			  ○ Metastatic (Stage IVB), Persistent, or Recurrent Carcinoma of the Cervix
			  ○ Front-line Treatment (Previously Untreated) Ovarian, Fallopian Tube, and Primary Peritoneal Cancer (with paclitaxel and carboplatin)
			• Updated notes for melanoma policies to clarify funding scenarios
			• EBP policies no longer require prior approval by CCO

1.42	Nov 15, 2019	1.43	• Implemented new policy Trastuzumab (Biosimilar) - Adjuvant Treatment for Breast Cancer • Implemented new policy Trastuzumab (Biosimilar) - Advanced Gastric, Gastroesophageal, or Esophageal Cancer • Implemented new policy Trastuzumab (Biosimilar) - Second Line - Metastatic Breast Cancer • Implemented new policy Trastuzumab (Biosimilar) - Single Agent - Metastatic Breast Cancer • Implemented new policy Trastuzumab (Biosimilar) in combination with Docetaxel - Metastatic Breast Cancer • Implemented new policy Trastuzumab (Biosimilar) in combination with Paclitaxel - Metastatic Breast Cancer • Implemented new policy Trastuzumab (Biosimilar) in combination with Vinorelbine - Metastatic Breast Cancer • Implemented new policy Trastuzumab (Biosimilar) with First Line Docetaxel - Metastatic Breast Cancer • Removed non-biosimilar bevacizumab policy no longer funded for enrolment: Platinum-Resistant Recurrent Ovarian, Fallopian Tube, or Primary Peritoneal Cancer
1.43	Dec 6, 2019	1.44	• Implemented new policy Atezolizumab – Advanced or Metastatic Non-Small Cell Lung Cancer

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1.44	Dec 17, 2019	1.45	• Renamed brentuximab to brentuximab vedotin • Renamed Brentuximab - Hodgkin's Lymphoma to Brentuximab Vedotin – Relapsed or Refractory Hodgkin Lymphoma • Renamed Brentuximab - Systemic Anaplastic Large Cell Lymphoma to Brentuximab Vedotin – Systemic Anaplastic Large Cell Lymphoma • Implemented new policy Brentuximab Vedotin – Consolidation Post-Autologous Stem Cell Transplant (ASCT) for Hodgkin Lymphoma • Removed non-biosimilar trastuzumab policies no longer funded for new enrolments: ○ Adjuvant Treatment for Breast Cancer ○ Gastric Cancer ○ Second Line - Metastatic Breast Cancer ○ Single Agent - Metastatic Breast Cancer ○ In combination with Docetaxel - Metastatic Breast Cancer ○ In combination with Paclitaxel - Metastatic Breast Cancer ○ In combination with Vinorelbine - Metastatic Breast Cancer ○ With First Line Docetaxel - Metastatic Breast Cancer
1.45	Jan 22, 2020	1.46	• Added Herzuma® to trastuzumab biosimilar policies • Implemented new policy Durvalumab - Locally Advanced Unresectable Stage III Non-Small Cell Lung Cancer Following Concurrent Chemoradiation
1.46	Jan 29, 2020	2.00 (1.47)	• Updated document from Cancer Care Ontario to Ontario Health (Cancer Care Ontario) • Added High Cost Therapy Funding Program (HCTFP) • Implemented new policy Dinutuximab Pediatric High-Risk Neuroblastoma • Implemented new policy Nivolumab - Adjuvant Treatment for Completely Resected Stage III or IV Melanoma • Implemented new policy Nivolumab - Relapsed Classical Hodgkin Lymphoma (cHL) Post-Autologous Stem Cell Transplant (ASCT)
2.00	Feb 25, 2020	2.01	• Implemented new policy Blinatumomab - Relapsed or Refractory Acute Lymphoblastic Leukemia (Ph+ BCP-ALL) • Renamed policy Blinatumomab - Relapsed or Refractory Acute Lymphoblastic Leukemia to Blinatumomab - Relapsed or Refractory Acute Lymphoblastic Leukemia (Ph- BCP-ALL); FAQ updated on enrolment form • Revised policy Inotuzumab Ozogamicin - Relapsed or Refractory Acute Lymphoblastic Leukemia
2.01	Mar 16, 2020	2.02	• Edited Note 8 of Nivolumab – Adjuvant Treatment of Completely Resected Stage III or IV Melanoma for clarification • Implemented new policy Rituximab (Biosimilar IV) and Rituximab SC - In Combination with Venetoclax - Relapsed Chronic Lymphocytic Leukemia • Implemented new policy Rituximab (Biosimilar IV) and Rituximab SC - Retreatment - Aggressive Histology Lymphoma • Implemented new policy Rituximab (Biosimilar IV) and Rituximab SC - Aggressive Histology Lymphoma • Implemented new policy Rituximab (Biosimilar IV) - As Part of the MATRix Regimen in Newly Diagnosed, Previously Untreated Primary Central Nervous System Lymphoma • Implemented new policy Rituximab (Biosimilar IV) and Rituximab SC - HIV-Related, Aggressive Histology, B-cell Lymphoma • Implemented new policy Rituximab (Biosimilar IV) - In Combination with Idelalisib - Relapsed Chronic Lymphocytic Leukemia • Implemented new policy Rituximab (Biosimilar IV) and Rituximab SC - Maintenance Treatment - Lymphoma • Implemented new policy Rituximab (Biosimilar IV) and Rituximab SC - Previously Untreated Chronic Lymphocytic Leukemia • Implemented new policy Rituximab (Biosimilar IV) and Rituximab SC - Retreatment - Indolent Lymphoma

Old version no.	Date changed	New version no.	Revision
			• Implemented new policy Rituximab (Biosimilar IV) and Rituximab SC - Second Line - Chronic Lymphocytic Leukemia • Implemented new policy Rituximab (Biosimilar IV) - Single Agent - Indolent Lymphoma • Implemented new policy Rituximab (Biosimilar IV) and Rituximab SC in Combination with Chemotherapy - Indolent B-cell Lymphoma
2.02	Apr 24, 2020	2.03	• Updated eligibility criteria for Cetuximab and Radiation – Locally Advanced Squamous Cell Carcinoma of the Head and Neck • Added Mvasi® to Bevacizumab (Biosimilar) for Platinum-Resistant Recurrent Ovarian, Fallopian Tube, or Primary Peritoneal Cancer • Implemented new policy Pembrolizumab - In Combination with Platinum and Pemetrexed for First Line Metastatic Non-Squamous Non-Small Cell Lung Cancer (NSCLC) • Implemented new policy Pembrolizumab - Previously Treated Locally Advanced or Metastatic Urothelial Carcinoma

2.03	Jun 10, 2020	2.04	• Added note to Pertuzumab-Trastuzumab - Unresectable Locally Recurrent or Metastatic - Breast Cancer
			• Aligned eligibility criteria wording for Paclitaxel - Non-Small Cell Lung Cancer (NSCLC) to related policies
			• Aligned note wording between these policies:
			  ○ Atezolizumab - Advanced or Metastatic Non-Small Cell Lung Cancer
			  ○ Nivolumab - Advanced or Metastatic Non-Small Cell Lung Cancer
			  ○ Pembrolizumab - Previously Untreated Locally Advanced or Metastatic Non-Small Cell Lung Cancer
			  ○ Pembrolizumab - Advanced or Metastatic Non-Small Cell Lung Cancer (Second or Subsequent Line)
			• Implemented new policy Pembrolizumab - In Combination with Carboplatin and Paclitaxel for First-Line Metastatic Squamous Non-Small Cell Lung Cancer (NSCLC)
			• Updated eligibility criteria and notes for retreatment:
			  ○ Pembrolizumab - Advanced Melanoma (Unresectable or Metastatic Melanoma) and No Prior Ipilimumab
			  ○ Pembrolizumab - Advanced Melanoma (Unresectable or Metastatic Melanoma) and Prior Ipilimumab

2.04	Jul 31, 2020	2.05	• Implemented new policy Pralatrexate - Relapsed or Refractory Peripheral T-cell Lymphoma (PTCL) • Implemented new policy Pembrolizumab - Adjuvant Treatment for Completely Resected Stage III or IV Melanoma • Implemented new policy Pembrolizumab - Relapsed Classical Hodgkin Lymphoma (cHL) Post-Autologous Stem Cell Transplant (ASCT) or ASCT Ineligible • Updated notes in Nivolumab - Adjuvant Treatment for Completely Resected Stage III or IV Melanoma • Updated notes in Romidepsin - Relapsed or Refractory Peripheral T-Cell Lymphoma • Updated notes in Brentuximab Vedotin – Systemic Anaplastic Large Cell Lymphoma • Added Kanjinti® to trastuzumab biosimilar policies • Added Riximyo® and Ruxience® to rituximab biosimilar policies • Updated eligibility criteria in all pembrolizumab policies to specify adult patients

2.05	Aug 15, 2020	2.06	• Removed non-biosimilar rituximab policies no longer funded for new enrolments:
			  ○ Aggressive Histology Lymphoma
			  ○ As Part of the MATRix Regimen in Newly Diagnosed, Previously Untreated Primary Central Nervous System Lymphoma
			  ○ HIV-Related, Aggressive Histology, B-cell Lymphoma
			  ○ In Combination with Chemotherapy - Indolent B-cell Lymphoma
			  ○ In Combination with Idelalisib - Relapsed Chronic Lymphocytic Leukemia

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			○ In Combination with Venetoclax - Relapsed Chronic Lymphocytic Leukemia ○ Maintenance Treatment - Lymphoma ○ Previously Untreated Chronic Lymphocytic Leukemia ○ Retreatment - Aggressive Histology Lymphoma ○ Retreatment - Indolent Lymphoma ○ Second Line - Chronic Lymphocytic Leukemia ○ Single Agent - Indolent Lymphoma
2.06	Nov 10, 2020	2.07	• Renamed Nivolumab - Relapsed Classical Hodgkin Lymphoma (cHL) Post-Autologous Stem Cell Transplant (ASCT) to Nivolumab - Relapsed Classical Hodgkin Lymphoma (cHL) Post-Autologous Stem Cell Transplant (ASCT) or ASCT Ineligible, aligned eligibility criteria and notes to pembrolizumab policy • Implemented new policy Brentuximab Vedotin - In Combination with Chemotherapy for Previously Untreated Peripheral T-cell Lymphoma (PTCL) • Updated note in Brentuximab Vedotin – Systemic Anaplastic Large Cell Lymphoma
2.07	Dec 15, 2020	2.08	• Implemented Bortezomib - In Combination with Lenalidomide and Dexamethasone for Previously Untreated Multiple Myeloma Without Intent for Stem Cell Transplantation • Implemented Azacitidine - Acute Myeloid Leukemia (AML) Greater Than 30% Blasts
2.08	Feb 3, 2021	2.09	• Implemented Trastuzumab Emtansine - Adjuvant Treatment for Early Breast Cancer • Implemented Cemiplimab - Metastatic or Locally Advanced Cutaneous Squamous Cell Carcinoma
2.09	Mar 16, 2021em	2.10	• Implemented Pembrolizumab - In Combination with Axitinib for First Line Advanced or Metastatic Renal Cell Carcinoma • Updated notes in Nivolumab - Advanced or Metastatic Renal Cell Carcinoma and No Prior mTOR Inhibitor • Updated notes in Nivolumab - Advanced or Metastatic Renal Cell Carcinoma and Prior mTOR Inhibitor • Updated note in Nivolumab plus Ipilimumab - Metastatic Renal Cell Carcinoma • Updated gendered pronouns in notes for: ○ Ipilimumab - Previously Treated Advanced Unresectable Melanoma ○ Ipilimumab - Previously Untreated Advanced Unresectable Melanoma

2.10	Aug 9, 2021	2.11	• Implemented Pembrolizumab – Recurrent or Metastatic Squamous Cell Carcinoma of the Head and Neck
			• Updated notes in Nivolumab – Recurrent or Metastatic Squamous Cell Carcinoma of the Head and Neck, which is Platinum Resistant or Refractory
			• Updated funded dose in:
			  ○ Arsenic Trioxide - Relapsed/Refractory Induction of Acute Promyelocytic Leukemia (APL)
			  ○ Arsenic Trioxide - First Line Consolidation of Acute Promyelocytic Leukemia (APL)
			  ○ Arsenic Trioxide - Relapsed/Refractory Consolidation of Acute Promyelocytic Leukemia (APL)
			• Removed Interferon - Melanoma
			• Removed policies for drugs now funded by ST-QBP as of April 1, 2021:
			  ○ Docetaxel - Metastatic Castration-Resistant Prostate Cancer
			  ○ Docetaxel - Hormone Sensitive Prostate Cancer
			  ○ Docetaxel - Adjuvant Treatment for Breast Cancer
			  ○ Docetaxel - Early Operable Breast Cancer
			  ○ Docetaxel - Metastatic Breast Cancer
			  ○ Docetaxel - Neoadjuvant treatment for Non-Metastatic Breast Cancer
			  ○ Docetaxel - Non-Small Cell Lung Cancer (NSCLC)
			  ○ Docetaxel - Non-Small Cell Lung Cancer (Second or Subsequent Line)
			  ○ Epirubicin - Adjuvant Treatment for Breast Cancer
			  ○ Epirubicin - Neoadjuvant treatment for Non – Metastatic Breast Cancer
			  ○ Fludarabine - Indolent Lymphoma
			  ○ Gemcitabine - Carcinoma of Bladder or Urothelium
			  ○ Gemcitabine - Non-Small Cell Lung Cancer (NSCLC)
			  ○ Gemcitabine - Advanced Pancreatic Cancer
			  ○ Gemcitabine - Advanced Pancreatic Cancer (with Nab-Paclitaxel)
			  ○ Irinotecan - First Line – Metastatic Colorectal, Small Bowel, or Appendiceal Cancer
			  ○ Irinotecan - Second Line – Metastatic Colorectal, Small Bowel, or Appendiceal Cancer
			  ○ Irinotecan - Third Line – Metastatic Colorectal, Small Bowel, or Appendiceal Cancer (with Cetuximab)
			  ○ Irinotecan - Advanced Pancreatic Cancer (FOLFIRINOX with Oxaliplatin)
			  ○ Oxaliplatin - Adjuvant Colorectal, Small Bowel, or Appendiceal Cancer
			  ○ Oxaliplatin - First Line – Metastatic Colorectal, Small Bowel, or Appendiceal Cancer
			  ○ Oxaliplatin - Second Line – Metastatic Colorectal, Small Bowel, or Appendiceal Cancer
			  ○ Oxaliplatin - With Surgery for Curative Intent for Colorectal, Small Bowel, or Appendiceal Cancer Patients with Resectable or Potentially Resectable Liver Metastases
			  ○ Oxaliplatin - Advanced Pancreatic Cancer (FOLFIRINOX with irinotecan)
			  ○ Paclitaxel - Adjuvant Treatment for Breast Cancer
			  ○ Paclitaxel - Metastatic Breast Cancer
			  ○ Paclitaxel - Neoadjuvant treatment for Non-Metastatic Breast Cancer
			  ○ Paclitaxel - First Line or Recurrent – Advanced Ovarian Carcinoma
			  ○ Paclitaxel - First Line or Recurrent – Fallopian Tube Cancer

			○ Paclitaxel - First Line or Recurrent – Primary Peritoneal Cancer ○ Paclitaxel - First Line or Recurrent – Uterine Papillary Serous Carcinoma (UPSC) ○ Paclitaxel - Non-Small Cell Lung Cancer (NSCLC) ○ Paclitaxel - Single Agent Treatment of Platinum Sensitive Ovarian, Fallopian Tube or Primary Peritoneal Cancer for Patients Unable to Receive Platinum Therapy ○ Pamidronate - Metastatic Breast Cancer ○ Pamidronate - Plasma Cell Myeloma (with or without Bone Disease) ○ Pemetrexed - Advanced Malignant Pleural Mesothelioma (MPM) ○ Pemetrexed - Combination with Platinum for Non-Small Cell Lung Cancer ○ Pemetrexed - Maintenance Treatment of Nonsquamous Non-Small Cell Lung Cancer (NSCLC) ○ Pemetrexed - Non-Small Cell Lung Cancer (following Crizotinib) ○ Pemetrexed - Non-Small Cell Lung Cancer (Second or Subsequent Line) ○ Topotecan - Platinum – Resistant Ovarian, Fallopian Tube, or Primary Peritoneal Cancer ○ Topotecan - Single Agent Treatment of Platinum Sensitive Ovarian, Fallopian Tube, or Primary Peritoneal Cancer for Patients Unable to Receive Platinum Therapy ○ Vinorelbine - Metastatic Breast Cancer ○ Vinorelbine - Adjuvant Treatment of Completely Resected Stage II or IIIa Non-Small Cell Lung Cancer ○ Vinorelbine - Non-Small Cell Lung Cancer (NSCLC) ○ Zoledronic Acid - Hormone-Refractory Prostate Cancer • Updated notes in Bevacizumab - Metastatic (Stage IVB), Persistent, or Recurrent Carcinoma of the Cervix • Updated notes in Bevacizumab for Platinum-Resistant Recurrent Ovarian, Fallopian Tube, or Primary Peritoneal Cancer • Updated funded dose and notes in Bevacizumab in combination with Paclitaxel and Carboplatin - Front-line Treatment (Previously Untreated) Ovarian, Fallopian Tube, and Primary Peritoneal Cancer • Updated eligibility criteria and notes in Cabazitaxel - Metastatic Castration Resistant Prostate Cancer • Updated notes in Cetuximab with Irinotecan - Third Line - Metastatic Colorectal, Small Bowel, or Appendiceal Cancer • Updated notes in Gemcitabine and Nab-Paclitaxel - Advanced Pancreatic Cancer • Updated notes in Liposomal Doxorubicin - Platinum - Resistant Ovarian, Fallopian Tube, or Primary Peritoneal Cancer • Updated notes in Liposomal DOXorubicin - Single Agent Treatment of Platinum Sensitive Ovarian, Fallopian Tube, or Primary Peritoneal Cancer for Patients Unable to Receive Platinum Therapy • Updated notes in Liposomal Doxorubicin with Carboplatin - Platinum-Sensitive Recurrent Ovarian, Fallopian Tube, and Primary Peritoneal Cancer • Updated note in Nab-Paclitaxel - Metastatic Breast Cancer • Updated funded dose in Panitumumab - In Combination with Chemotherapy for First Line Metastatic Colorectal, Small Bowel, or Appendiceal Cancer • Updated notes in Pembrolizumab - In Combination with Carboplatin and Paclitaxel for First-Line Metastatic Squamous Non-Small Cell Lung Cancer (NSCLC) • Updated notes in Pembrolizumab - In Combination with Platinum and Pemetrexed for First Line Metastatic Non-Squamous Non-Small Cell Lung Cancer (NSCLC) • Updated funded dose notes in Radium-223 Dichloride - Castration-Resistant Prostate Cancer

			• Updated eligibility criteria note in Trastuzumab in combination with Docetaxel - Metastatic Breast Cancer • Updated eligibility criteria note in Trastuzumab in combination with Paclitaxel - Metastatic Breast Cancer • Updated eligibility criteria note in Trastuzumab in combination with Vinorelbine - Metastatic Breast Cancer • Updated eligibility criteria note in Trastuzumab with First Line Docetaxel - Metastatic Breast Cancer
2.11	Aug 23, 2021	2.12	• Implemented Blinatumomab - Minimal Residual Disease (MRD)-Positive B-cell Precursor Acute Lymphoblastic Leukemia • Updated notes in Blinatumomab - Relapsed or Refractory Acute Lymphoblastic Leukemia (Ph- BCP-ALL) • Updated notes in Blinatumomab - Relapsed or Refractory Pediatric Acute Lymphoblastic Leukemia
2.12	Nov 04, 2021	2.13	• Implemented Brentuximab Vedotin – In Combination with Chemotherapy for Previously Untreated Stage IV Hodgkin Lymphoma • Updated notes in Brentuximab Vedotin - Relapsed or Refractory Hodgkin Lymphoma • Updated notes in Brentuximab Vedotin - Consolidation Post-Autologous Stem Cell Transplant (ASCT) for Hodgkin Lymphoma
2.13	Nov 15, 2021	2.14	• Implemented Gemtuzumab Ozogamicin (Inpatient) – Previously Untreated Acute Myeloid Leukemia • Implemented Gemtuzumab Ozogamicin (Outpatient) – Previously Untreated Acute Myeloid Leukemia
2.14	Nov 30, 2021	2.15	• Moved gemtuzumab ozogamicin inpatient policy to HCFTP table
2.15	Dec 9, 2021	2.16	• Implemented Brentuximab Vedotin - Previously Treated Primary Cutaneous Anaplastic Large Cell Lymphoma or Mycosis Fungoides • Updated note 5 in Gemtuzumab Ozogamicin (Inpatient) – Previously Untreated Acute Myeloid Leukemia • Updated note 5 in Gemtuzumab Ozogamicin (Outpatient) – Previously Untreated Acute Myeloid Leukemia
2.16	Dec 15, 2021	2.17	• Implemented Pegaspargase - Extranodal Natural Killer/T-cell Lymphoma • Implemented Pegaspargase (Inpatient) - Adult Acute Lymphoblastic Leukemia (ALL), Lymphoblastic Lymphoma, Mixed or Biphenotypic Leukemia • Implemented Pegaspargase (Outpatient) - Adult Acute Lymphoblastic Leukemia (ALL), Lymphoblastic Lymphoma, Mixed or Biphenotypic Leukemia • Added Bambevi® to bevacizumab biosimilar policies
2.17	Jan 12, 2022	2.18	• Updated dosing section in Atezolizumab - Advanced or Metastatic Non-Small Cell Lung Cancer with extended dosing details
2.18	Jan 31, 2022	2.19	• Removed Trastuzumab (EBP) – Adjuvant Trastuzumab with Chemotherapy for HER2/neu-Overexpressing Breast Cancer Tumours Less than or Equal to 1 cm in Diameter • Added ST-QBP code to Pegaspargase (Outpatient) - Adult Acute Lymphoblastic Leukemia (ALL), Lymphoblastic Lymphoma, Mixed or Biphenotypic Leukemia
2.19	Feb 15, 2022	2.20	• Pembrolizumab - First Line Treatment of MSI-H/dMMR Metastatic Colorectal Cancer
2.20	Mar 1, 2022	2.21	• Implemented Gilteritinib (Inpatient) - Relapsed or Refractory FLT3-mutated Acute Myeloid Leukemia • Renamed "Bevacizumab (Biosimilar) - First Line - Metastatic Colorectal, Small Bowel, or Appendiceal Cancer" to "Bevacizumab (Biosimilar) - Metastatic Colorectal, Small Bowel, or Appendiceal Cancer", updated eligibility criteria and notes • Renamed "Cetuximab with Irinotecan - Third Line - Metastatic Colorectal, Small Bowel, or Appendiceal Cancer" to "Cetuximab and Irinotecan - Metastatic Colorectal, Small Bowel, or Appendiceal Cancer", updated eligibility criteria and notes

			• Renamed "Panitumumab - In Combination with Chemotherapy for First Line Metastatic Colorectal, Small Bowel, or Appendiceal Cancer" to "Panitumumab - In Combination with Chemotherapy for Metastatic Colorectal, Small Bowel, or Appendiceal Cancer", updated eligibility criteria and notes • Updated Panitumumab - Metastatic Colorectal, Small Bowel, or Appendiceal Cancer note section
2.21	Mar 15, 2022	2.22	• Added Riabni to rituximab biosimilar policies • Implemented Atezolizumab with Bevacizumab (Biosimilar) - Previously Untreated Unresectable or Metastatic Hepatocellular Carcinoma
2.22	Mar 31, 2022	2.23	• Implemented Midostaurin (Inpatient) - FLT3-mutated Acute Myeloid Leukemia
2.23	May 6, 2022	2.24	• Implemented Polatuzumab Vedotin with Bendamustine and Rituximab (Biosimilar) - Relapsed or Refractory Diffuse Large B-cell Lymphoma • Implemented Obinutuzumab - in Combination with Venetoclax for Previously Untreated Chronic Lymphocytic Leukemia
2.24	May 12, 2022	2.25	• Implemented Avelumab - Maintenance Treatment for Unresectable, Locally Advanced or Metastatic Urothelial Carcinoma • Implemented Pembrolizumab (Adult and Pediatric) - Relapsed Classical Hodgkin Lymphoma Post-Autologous Stem Cell Transplant or ASCT Ineligible • Renamed "Pembrolizumab (Adult Who Failed Prior Brentuximab Vedotin) - Relapsed Classical Hodgkin Lymphoma Post-Autologous Stem Cell Transplant or ASCT Ineligible" from "Pembrolizumab - Relapsed Classical Hodgkin Lymphoma (cHL) Post-Autologous Stem Cell Transplant (ASCT) or ASCT Ineligible" • Updated Nivolumab - Relapsed Classical Hodgkin Lymphoma (cHL) Post-Autologous Stem Cell Transplant (ASCT) or ASCT Ineligible notes
2.25	June 7, 2022	2.26	• Implemented Nivolumab plus Ipilimumab - Advanced Malignant Pleural Mesothelioma
2.26	June 15, 2022	2.27	• Implemented Nivolumab plus Ipilimumab - In Combination with Platinum Doublet Chemotherapy for First Line Metastatic or Recurrent Non-Small Cell Lung Cancer • Updated note 1 in Atezolizumab - Advanced or Metastatic Non-Small Cell Lung Cancer • Updated note 1 in Nivolumab - Advanced or Metastatic Non-Small Cell Lung Cancer • Updated note 1 in Pembrolizumab - Advanced or Metastatic Non-Small Cell Lung Cancer (Second or Subsequent Line) • Updated note 2 in Pembrolizumab - In Combination with Carboplatin and Paclitaxel for First-Line Metastatic Squamous Non-Small Cell Lung Cancer (NSCLC) • Updated note 2 in Pembrolizumab - In Combination with Platinum and Pemetrexed for First Line Metastatic Non-Squamous Non-Small Cell Lung Cancer (NSCLC) • Updated note 1 in Pembrolizumab - Previously Untreated Locally Advanced or Metastatic Non-Small Cell Lung Cancer
2.27	July 15, 2022	2.28	• Implemented Pembrolizumab - First-line Treatment of Advanced Esophageal and Esophagogastric Junction Carcinoma • Added Aybintio® to bevacizumab policies
2.28	July 22, 2022	2.29	• Implemented Durvalumab - In Combination with Etoposide and Platinum for Extensive-Stage Small Cell Lung Cancer • Removed Oxaliplatin (EBP) - With Surgery for Curative Intent for Colorectal Cancer Patients with Resectable or Potentially Resectable Extrahepatic Metastases
2.29	Aug 10, 2022	2.30	• Updated funded dose in Pembrolizumab - Adjuvant Treatment for Completely Resected Stage III or IV Melanoma • Updated funded dose in Pembrolizumab - (Adult and Pediatric) - Relapsed Classical Hodgkin Lymphoma Post-Autologous Stem Cell Transplant or ASCT Ineligible • Updated funded dose in Pembrolizumab - Advanced Melanoma (Unresectable or Metastatic Melanoma) and no prior ipilimumab

			• Updated funded dose in Pembrolizumab - Advanced Melanoma (Unresectable or Metastatic Melanoma) and no prior ipilimumab • Updated funded dose in Pembrolizumab - Advanced or Metastatic Non-Small Cell Lung Cancer (Second or Subsequent Line) • Updated funded dose in Pembrolizumab - In Combination with Axitinib for First Line Advanced or Metastatic Renal Cell Carcinoma • Updated funded dose in Pembrolizumab - In Combination with Carboplatin and Paclitaxel for First-Line Metastatic Squamous Non-Small Cell Lung Cancer (NSCLC) • Updated funded dose in Pembrolizumab - In Combination with Platinum and Pemetrexed for First Line Metastatic Non-Squamous Non-Small Cell Lung Cancer (NSCLC) • Updated funded dose in Pembrolizumab - Previously Untreated Locally Advanced or Metastatic Non-Small Cell Lung Cancer • Updated funded dose in Pembrolizumab - Previously Treated Locally Advanced or Metastatic Urothelial Carcinoma • Updated funded dose in Pembrolizumab - Recurrent or Metastatic Squamous Cell Carcinoma of the Head and Neck
2.30	August 19, 2022	2.31	• Implemented Azacitidine In Combination with Venetoclax (Inpatient) for Previously Untreated Acute Myeloid Leukemia • Implemented Azacitidine In Combination with Venetoclax (Outpatient) for Previously Untreated Acute Myeloid Leukemia • Implemented Daratumumab in Combination with Lenalidomide and Dexamethasone for Newly Diagnosed Transplant Ineligible Multiple Myeloma • Implemented Daratumumab in Combination with Bortezomib-Based Regimen for Newly Diagnosed Transplant Ineligible Multiple Myeloma • Updated funded dose in Bortezomib – Previously Untreated - Multiple Myeloma • Removed note 3 (time limited) from Daratumumab in Combination with Lenalidomide and Dexamethasone for Relapsed Multiple Myeloma • Removed note 3 (time limited) from Daratumumab in Combination with Bortezomib and Dexamethasone for Relapsed Multiple Myeloma
2.31	Aug 22, 2022	2.32	• Implemented Dinutuximab – Pediatric Relapsed or Refractory High-Risk Neuroblastoma
2.32	September 15, 2022	2.33	• Implemented Daratumumab and Bortezomib in combination with Cyclophosphamide and Dexamethasone – Previously Untreated Light Chain (AL) Amyloidosis • Renamed and updated "Pertuzumab in combination with trastuzumab-taxane for HER2 positive unresectable locally recurrent or metastatic cancer" to "Pertuzumab with Trastuzumab (Biosimilar) – Unresectable Locally Recurrent or Metastatic Breast Cancer" • Updated Daratumumab - In Combination with Lenalidomide and Dexamethasone for Relapsed Multiple Myeloma • Updated Daratumumab - In Combination with Bortezomib and Dexamethasone for Relapsed Multiple Myeloma • Updated note 2 in Trastuzumab Emtansine - Adjuvant Treatment for Early Breast Cancer • Added Ontruzant® to trastuzumab biosimilar policies
2.33	October 21, 2022	2.34	• Implemented Liposomal Daunorubicin and Liposomal Cytarabine (Inpatient) – Previously Untreated Acute Myeloid Leukemia • Implemented Liposomal Daunorubicin and Liposomal Cytarabine (Outpatient) – Previously Untreated Acute Myeloid Leukemia
2.34	November 10, 2022	2.35	• Implemented Nivolumab – Adjuvant Treatment of Completely Resected Esophageal or Esophagogastric Junction Cancer • Implemented Nivolumab – First-line Treatment of Advanced Gastric, Esophageal, and Esophagogastric Junction Adenocarcinoma
2.35	November 30, 2022	2.36	• Implemented Cetuximab - In Combination with Encorafenib for Previously Treated Metastatic Colorectal Cancer • Implemented Panitumumab - In Combination with Encorafenib for Previously Treated Metastatic Colorectal Cancer
2.36	December 6, 2022	2.37	• Implemented Cetuximab - In Combination with Encorafenib for Previously Treated Metastatic Colorectal Cancer • Implemented Panitumumab - In Combination with Encorafenib for Previously Treated Metastatic Colorectal Cancer • Added new note 1 to Pembrolizumab - First Line Treatment of Advanced Esophageal and Esophagogastric Junction Carcinoma

			• Updated note 4 in Panitumumab - Metastatic Colorectal, Small Bowel, or Appendiceal Cancer • Updated note 3 in Panitumumab - In Combination with Chemotherapy for Metastatic Colorectal, Small Bowel, or Appendiceal Cancer • Updated note 4 in Cetuximab with Irinotecan - Metastatic Colorectal, Small Bowel, or Appendiceal Cancer
2.37	January 18, 2023	2.38	• Implemented Thiotepa (Inpatient) – As Part of the MATRix Regimen in Newly Diagnosed, Previously Untreated Primary Central Nervous System Lymphoma • Updated eligibility criteria, funded dose and notes in Cabazitaxel – Metastatic Castration Resistant Prostate Cancer • Updated note 2 in Rituximab (Biosimilar IV) - As Part of the MATRix Regimen in Newly Diagnosed, Previously Untreated Primary Central Nervous System Lymphoma
2.38	February 17, 2023	2.39	• Implemented Trastuzumab (Biosimilar) with Tucatinib and Capecitabine - Metastatic Breast Cancer • Updated notes in Trastuzumab Emtansine - Unresectable Locally Advanced or Metastatic Breast Cancer • Updated eligibility criteria and funded dose for Trastuzumab (Biosimilar) - Advanced Gastric, Gastroesophageal, or Esophageal Cancer
2.39	February 21, 2023	2.40	• Implemented Voretigene Neparvovec - Previously Untreated Inherited Retinal Dystrophy
2.40	February 23, 2023	2.41	• Implemented Pembrolizumab – Previously Untreated High-Risk Early-Stage Triple Negative Breast Cancer • Implemented Bortezomib – Previously Untreated Transplant Ineligible Mantle Cell Lymphoma
2.41	March 9, 2023	2.42	• Implemented Atezolizumab – In Combination with Etoposide and Platinum for Extensive-Stage Small Cell Lung Cancer

2.42	March 30, 2023	2.43	• Implemented Pembrolizumab - Adjuvant Treatment for Renal Cell Carcinoma
			• Added a new note 1 in Pembrolizumab - First Line Treatment of MSI-H/dMMR Metastatic Colorectal Cancer
			• Replaced note 2 in Pembrolizumab - In Combination with Axitinib for First Line Advanced or Metastatic Renal Cell Carcinoma
			• Replaced note 3:
			  ○ Nivolumab plus Ipilimumab - Metastatic Renal Cell Carcinoma
			  ○ Nivolumab - Advanced or Metastatic Renal Cell Carcinoma and No Prior mTOR Inhibitor
			  ○ Nivolumab - Advanced or Metastatic Renal Cell Carcinoma and Prior mTOR Inhibitor

2.43	April 5, 2023	2.44	• Implemented Trastuzumab (Biosimilar) – Advanced or Recurrent Endometrial Cancer • Added a footnote in Pembrolizumab – Previously Untreated High-Risk Early-Stage Triple Negative Breast Cancer eligibility criteria

2.44	April 18, 2023	2.45	• Updated Raltitrexed - Metastatic Colorectal, Small Bowel, or Appendiceal Cancer
			• Implemented:
			  ○ Raltitrexed - Adjuvant Colorectal, Small Bowel, or Appendiceal Cancer
			  ○ Raltitrexed - Metastatic Esophageal, Gastroesophageal Junction, or Gastric Cancer
			  ○ Raltitrexed - Adjuvant Esophageal, Gastroesophageal Junction, or Gastric Cancer
			  ○ Enfortumab Vedotin - Previously Treated Advanced or Metastatic Urothelial Cancer

2.45	April 27, 2023	2.46	• Implemented Nivolumab – Adjuvant Treatment of Urothelial Carcinoma • Updated note 2 in Avelumab - Maintenance Treatment for Unresectable, Locally Advanced or Metastatic Urothelial Carcinoma
2.46	May 10, 2023	2.47	• Implemented Pembrolizumab (Adult and Pediatric) – Adjuvant Treatment for Completely Resected Stage IIB or IIC Melanoma

2.47	May 31, 2023	2.48	• Implemented:
			  ○ Isatuximab and Carfilzomib - In Combination with Dexamethasone for Relapsed or Refractory Multiple Myeloma
			  ○ Isatuximab - In Combination with Pomalidomide and Dexamethasone for Relapsed or Refractory Multiple Myeloma
			• Updated note 1 and deleted note 3 in Bortezomib - In Combination with Lenalidomide and Dexamethasone for Previously Untreated Multiple Myeloma Without Intent for Stem Cell Transplantation

2.48	June 12, 2023	2.49	• Implemented Pembrolizumab - Metastatic, Persistent, or Recurrent Carcinoma of the Cervix • Updated note, deleted FAQs ii, iii, iv and note 6 in Bevacizumab (Biosimilar) - Metastatic (Stage IVB), Persistent, or Recurrent Carcinoma of the Cervix
2.49	June 30, 2023	2.50	• Implemented Sacituzumab Govitecan - Unresectable Locally Advanced or Metastatic Triple Negative Breast Cancer
2.50	July 5, 2023	2.51	• Implemented Atezolizumab – Adjuvant Treatment for Non-Small Cell Lung Cancer

2.51	July 18, 2023	2.52	• Implemented:
			  ○ Pembrolizumab - Locally Recurrent Unresectable or Metastatic Triple Negative Breast Cancer
			  ○ Pembrolizumab - Previously Treated MSI-H/dMMR Advanced Endometrial Cancer
			  ○ Inotuzumab Ozogamicin (Inpatient) – Relapsed or Refractory Acute Lymphoblastic Leukemia
			• Renamed “Inotuzumab Ozogamicin - Relapsed or Refractory Acute Lymphoblastic Leukemia” to “Inotuzumab Ozogamicin (Outpatient) - Relapsed or Refractory Acute Lymphoblastic Leukemia”

2.52	Aug 1, 2023	2.53	• Implemented Trastuzumab Deruxtecan - Unresectable Locally Advanced or Metastatic Breast Cancer
			• Updated notes in Trastuzumab Emtansine - Unresectable Locally Advanced or Metastatic Breast Cancer
			• Corrected eligibility criteria from April 2023 implementation in:
			  ○ Metastatic Colorectal, Small Bowel, or Appendiceal Cancer
			  ○ Raltitrexed - Adjuvant Colorectal, Small Bowel, or Appendiceal Cancer
			  ○ Raltitrexed - Metastatic Esophageal, Gastroesophageal Junction, or Gastric Cancer
			  ○ Raltitrexed - Adjuvant Esophageal, Gastroesophageal Junction, or Gastric Cancer

2.53	Aug 15, 2023	2.54	• Implemented Crisantaspase Recombinant – Acute Lymphoblastic Leukemia, Lymphoblastic Lymphoma, Mixed or Biphenotypic Leukemia • Added Vegzelma® to bevacizumab biosimilar policies