Genetic testing: oncology - molecular analysis of solid tumors and hematologic malignancies

These services may or may not be covered by your HealthPartners plan. Please see your plan documents for your specific coverage information. If there is a difference between this general information and your plan documents, your plan documents will be used to determine your coverage.

Administrative Process

Prior authorization is required for the following services:

- Molecular Profiling Panel Testing of Solid Tumors and Hematologic Malignancies
- Single Gene Testing of Solid Tumors and Hematologic Malignancies, unless stated below as prior authorization not required
- HLA Typing For Transplantation
- Red Blood Cell Genotyping in Multiple Myeloma
- Tumor Mutational Burden (TMB) Testing
- Measurable (Minimal) Residual Disease (MRD) Analysis
- Tumor-Type Agnostic Solid Tumor Molecular Profiling Panel Tests
- Testing that is associated with a procedure code listed in “Box A”, below.

Prior authorization is not required for the following services:

- Tumor Specific BCR/ABL Kinase Domain Analysis
- Myeloproliferative Neoplasms (MPNs) Panel Tests
- Tumor Specific MPL Variant Analysis
- Tumor Specific CEBPA Variant Analysis (81218)
- Tumor Specific FLT3 Variant Analysis
- Tumor Specific IGHV Variant Somatic Hypermutation Analysis
- Tumor Specific KIT Variant Analysis (81272, 81273)
- Tumor Specific MGMT Methylation Analysis
- Tumor Specific Microsatellite Instability (MSI) Analysis
- Tumor Specific PIK3CA Variant Analysis
- Tumor Specific NPM1 Variant Analysis
- Tumor Specific IDH1 and IDH2 Variant Analysis

The following genetic tests are considered investigational/experimental and, therefore, not covered:

- Cancer Exome and Genome Sequencing in Solid Tumors and Hematologic Malignancies
- Genetic Testing to Confirm the Identity of Laboratory Specimens

Prior authorization is sometimes required for certain codes. Refer to the list in Related Content to find out whether prior authorization is required for a specific indication. Prior authorization requirements are based on both the procedure code (CPT) and primary diagnosis code (ICD-10-CM) associated with the genetic testing.

Prior authorization is not required for Targeted testing related to solid tumors and hematological malignancies when it is associated with both:

- a primary diagnosis code from the list in related content, and
- a procedure code from the list in related content

Tests that require prior authorization will be reviewed for medical necessity of the testing as a whole. That is, a single coverage decision will apply to all of the tests, services, and/or procedure codes associated with the genetic test, whether they are requested/billed together or separately.

Box A: Genetic testing procedure codes that require prior authorization
Molecular pathology procedures, Tier 2 or unlisted (CPT 81400-81408, 81479)
Unlisted multianalyte assays (CPT 81599)
Any other listed or unlisted laboratory/pathology CPT code when it is used in association with a genetic test

Policy Reference Table

If available, codes are listed below for informational purposes only, and do not guarantee member coverage or provider reimbursement. The list may not be all-inclusive.

HealthPartners

Coverage Criteria Sections	Example Tests (Labs)	Common CPT Codes	Common ICD Codes
Molecular Profiling Panel Testing of Solid Tumors and Hematologic Malignancies			
Tumor-Type Agnostic Solid Tumor Molecular Profiling Panels	FoundationOne CDx (Foundation Medicine)	0037U	C00-D49, Z85
	MSK-IMPACT (Memorial Sloan Kettering Medical Center)	0048U	
	Oncomap ExTra (Exact Sciences Laboratories, LLC)	0329U	
	OnkoSight Advanced Solid Tumor NGS Panel (BioReference Labs)	81445, 81455, 81457, 81458	
	Precise Tumor (Myriad)		
	Tempus xT (Tempus)	0473U	
	Guardant360 TissueNext (Guardant)	0334U	
	PGDx elio tissue complete (Personal Genome Diagnostics, Inc)	0250U	
	OmniSeq INSIGHT (Labcorp)	81459	
	Tempus xT with PD-L1 IHC, MMR IHC (Tempus)		
	Solid Tumor Expanded Panel (Quest Diagnostics)	0379U	
	UW OncoPlex Cancer Gene Panel (University of Washington)	81459	
	Strata Select (Strata Oncology)	0391U	
Targeted RNA Fusion Panels	Targeted Solid Tumor NGS Fusion Panel (NeoGenomics)	81449	C91, C34, C71, C49, C96
Broad RNA Fusion Panel Tests	Tempus xR Whole Transcriptome RNA Sequencing (Tempus)	81456	C00-C80
	Aventa FusionPlus (Aventa Genomics)	0444U	
Broad Molecular Profiling Panels for Hematologic Malignancies and Myeloid Malignancy Panels	FoundationOne Heme (Foundation Medicine)	81450, 81455	C91, C92, D46.9
	Tempus xT Hematologic Malignancy (Tempus)		
	Neo Comprehensive - Myeloid Disorders (NeoGenomics Laboratories)		
	MayoComplete Myeloid Neoplasms Comprehensive OncoHeme Next-Generation Sequencing, Varies (Mayo Clinic Laboratories)	81450	
	Onkosight Advanced NGS Myeloid Panel (BioReference Laboratories)		
Colorectal Cancer Focused Molecular Profiling Panels	Colon Cancer Mutation Panel (Ohio State University Molecular Pathology Lab)	81445	C18-C20
	COLONSEQPlus Panel (MedFusion)	81457	
Lung Cancer Focused Molecular Profiling Panels	Oncomine Dx Target Test (Thermo Fisher Scientific)	0022U	C34
	OnkoSight Advanced Lung Cancer NGS Panel (Bioreference Laboratories)	81457	
	Lung HDPCR (Protean BioDiagnostics)	0478U	

Cutaneous Melanoma Focused Molecular Profiling Panels	MelanomaSeqPlus (Quest Diagnostics)	81445	C43, D03
	OnkoSight Advanced Melanoma Panel NGS (Bioreference Laboratories)	81457	
Acute Myeloid Leukemia (AML) Focused Molecular Profiling Panels	MyAML Gene Panel Assay (Laboratory for Personalized Molecular Medicine)	0050U	C92, D47
	NeoTYPE AML Prognostic Profile (NeoGenomics)	81450	
	LeukoVantage, Acute Myeloid Leukemia (AML) (Quest Diagnostics)		
Myeloproliferative Neoplasms (MPNs) Panel	Myeloproliferative Neoplasm, JAK2 V617F with Reflex to CALR and MPL, Varies (Mayo Medical Laboratories)	81206, 81207, 81208, 81219, 81270, 81279, 81338, 81339	D47
	OnkoSight Advanced NGS JAK2, MPL, CALR Panel (BioReference Laboratories)		
Single Gene Testing of Solid Tumors and Hematologic Malignancies			
Tumor Specific *BCR/ABL* Kinase Domain Analysis	ABL1 Kinase Domain Mutation Analysis (NeoGenomics)	81170	C91, C92
	Onkosight NGS ABL1 Sequencing (BioReference Laboratories)		
Tumor Specific *BCR/ABL* FISH, Qualitative and Quantitative Tests	BCR/ABL1 Gene Rearrangement, Quantitative, PCR (Quest Diagnostics)	81206, 81207, 81208	C83, C85, C91.00-C91.02, C92.0 – C92.12, D45, D47, D47.1, D47.3, D69.3
	BCR-ABL1 Transcript Detection for Chronic Myelogenous Leukemia (CML) and Acute Lymphocytic Leukemia (ALL), Quantitative (Labcorp)		
	BCR-ABL1 (t(9;22)) RNA Quantitative with Interpretation (University of Iowa Hospitals and Clinics – Department of Pathology)	0016U	
	MRDx BCR-ABL Test (MolecularMD)	0040U	
	Detection by FISH of t(9;22) BCR/ABL (CGC Genetics)		
	BCR/ABL t(9;22) (NeoGenomics Laboratories)	81479, 88271, 88274, 88275, 88291	
	BCR ABL Qualitative (Cincinnati Children's Hospital)		
Tumor Specific *BRAF* Variant Analysis	BRAF Mutation Analysis (NeoGenomics)	81210	C18-C21, C34, C43, C71, C73, C91.4
Tumor Specific *BRCA1/2* Variant Analysis	BRCA1/2 Mutation Analysis, NGS, Tumor (Mayo Clinic Laboratories)	81162, 81163, 81164, 81165, 81166, 81167, 81216	C56, C61
	BRCA1/2 Mutation Analysis for Tumors (NeoGenomics Laboratories)		
Tumor Specific *CALR* Variant Analysis	Calreticulin (CALR) Mutation Analysis (Quest Diagnostics)	81219	C94, D47.1
Tumor Specific *CEBPA* Variant Analysis	CEBPA Mutation Analysis (Labcorp)	81218	C92
Tumor Specific *EGFR* Variant Analysis	EGFR Mutation Analysis (NeoGenomics Laboratories)	81235	C34
Tumor Specific ESR1 Variant Analysis	ESR1 Mutations Analysis, NGS, Tumor (Mayo Clinic Laboratories)	81479	C50

Tumor Specific *FLT3* Variant Analysis	FLT3 ITD and TKD Mutation (PCR) (PathGroup)	81245, 81246	C92
	LeukoStrat CDx FLT3 Mutation Assay (Versiti)	0023U	
	FLT3 ITD MRD Assay (Laboratory for Personalized Molecular Medicine)	0046U	
Tumor Specific *IDH1* and *IDH2* Variant Analysis	IDH1/IDH2 Mutation Analysis by PCR (NeoGenomics)	81120, 81121	C71, C92, D49.6
	IDH1, IDH2, and TERT Mutation Analysis, Next Generation Sequencing, Tumor (IDTRT) (Mayo Clinic)	0481U	
Tumor Specific *IGHV* Somatic Hypermutation Analysis	IgHV Mutation Analysis (NeoGenomics)	81261, 81262, 81263	C83, C91, D47.Z1
Tumor Specific *JAK2* Variant Analysis	JAK2 Exon 12 to 15 Sequencing, Polycythemia Vera Reflex, Varies (Mayo Clinic Laboratories)	0027U	C91, C92, C94, D45, D47.1, D47.3, D75.81
	JAK2 Mutation (University of Iowa)	0017U	
	JAK2 V617F Mutation Analysis (Quest Diagnostics)	81270	
Tumor Specific *KIT* Variant Analysis	KIT Mutation Analysis (ProPath)	81272, 81273	C43, C49.A, C92, D47.1, D47.02
	KIT (D816V) Digital PCR in Systemic Mastocystosis (Labcorp)		
Tumor Specific *KRAS* Variant Analysis	KRAS Mutation Analysis (NeoGenomics)	81275, 81276	C18-21, C34
Tumor Specific *MGMT* Methylation Analysis	MGMT Promoter Methylation - Tumor (Ohio State University Molecular Laboratory)	81287	C71
Tumor Specific *MLH1* Methylation Analysis	MLH1 Promoter Methylation Analysis (NeoGenomics)	81288	C18-C21, C54.1
Tumor Specific *MPL* Variant Analysis	MPL Mutation Analysis (Quest Diagnostics)	81338, 81339	D45, D47.1, D47.3, D75.81
Tumor Specific Microsatellite Instability (MSI) Analysis	Microsatellite Instability (MSI) by PCR (NeoGenomics)	81301	C15-C23, C50, C53, C54.1, C62, C80
	Microsatellite Instability (MSI) (Quest Diagnostics)		
Tumor Specific *NPM1* Variant Analysis	NPM1 MRD Assay (Laboratory for Personalized Molecular Medicine	0049U	C92
	Onkosight NGS NPM1 Sequencing (BioReference Laboratories)	81310	
Tumor Specific *NRAS* Variant Analysis	NRAS Mutation Analysis (NeoGenomics)	81311	C18-C21
Tumor Specific *PIK3CA* Variant Analysis	PIK3CA Mutation Analysis (Quest Diagnostics)	81309	C50, C55
	PIK3CA Mutation Analysis, therascreen - QIAGEN (Labcorp)	0155U	
Tumor Specific *TP53* Variant Analysis	TP53 Mutation Analysis (NeoGenomics Laboratories)	81352	C92, R71, R79
HLA Typing for Transplantation			
	HLA-A,B Intermediate Resolution (Versiti)		

HLA Typing for Transplantation	HLA-B Low Resolution (Versiti)	81370, 81371, 81372, 81373	C25, C81-C96, D46, D61, Z52.20, Z52.3, Z52.4 Z52.89, N17, N18, N19, I12, E08-E13
	HLA-DQB1,DQA1 Intermediate Resolution (Versiti)	81376	
	HLA-A, B, C, DRB1 and DQ High Resolution (Quest)	81378	
	HLA A,B,C Profile (High Resolution) (Labcorp)	81379	
	HLA-A High Resolution (Versiti)	81380	
	HLA High Resolution Panel by NGS (Versiti)	81378, 81382	
Measurable (Minimal) Residual Disease (MRD) Analysis			
Hematologic (Minimal) Residual Disease (MRD) Testing	MyMRD NGS Panel Assay (Laboratory for Personalized Molecular Medicine)	0171U	C91, R71, R79
	ClonoSEQ Assay (Adaptive Biotechnologies)	0364U	
Evidence-Based Solid Tumor Minimal Residual Disease (MRD) Testing	Signatera - Residual Disease Test (MRD) - (Natera)	0340U	C00-D49, Z85
	Guardant Reveal (Guardant Health)	81479	
	Guardant360 Response (Guardant Health)	0422U	
Emerging Evidence Solid Tumor Minimal Residual Disease (MRD) Testing	COLVERA (Clinical Genomics Pathology, Inc.)	0229U	
	Invitae Personalized Cancer Monitoring - Baseline Test and Monitoring Test (Invitae)	0306U, 0307U	
	Northstar Response (BillionToOne)	0486U	
	OptiSeq Colorectal Cancer NGS Panel (DiaCarta Inc.)	0498U	
	QuantiDNA Colorectal Cancer Triage Test (DiaCarta Inc.)	0501U	
HPV-Related Solid Tumor Minimal Residual Disease (MRD) Testing	NavDx (Naveris)	0356U	C10.9
Tumor Mutational Burden (TMB)			
Tumor Mutational Burden (TMB)	Tumor Mutational Burden (MedFusion)	81479	C00-D49, Z85
Red Blood Cell Genotyping in Multiple Myeloma			
Red Blood Cell Genotyping in Multiple Myeloma	PreciseType HEA (Immucor)	0001U	C90.0, R71, R79
	Navigator ABO Sequencing (Grifols Immunohematology Center)	0180U	
	Navigator ABO Blood Group NGS (Grifols Immunohematology Center)	0221U	
Cancer Exome and Genome Sequencing			
Cancer Exome and Genome Sequencing	Praxis Somatic Whole Genome Sequencing (Praxis Genomics)	0297U	C00-D49, Z85
	Cancer Whole Exome Sequencing with Transcriptome (Columbia University - Personalized Genomic Medicine)	81415, 81416, 81425, 81426	
	Tempus xE (Tempus)		

	EXaCT-1 Whole Exome Testing (Weill Cornell Medicine)	0036U	
Genetic Testing to Confirm the Identity of Laboratory Specimens			
Genetic Testing to Confirm the Identity of Laboratory Specimens	know error DNA Specimen Provenance Assay (DSPA) (Strand Diagnostics, LLC)	81265, 81266, 81479	C00.0-D49

Coverage

Molecular Profiling Panel Testing of Solid Tumors and Hematologic Malignancies

Tumor-Type Agnostic Solid Tumor Molecular Profiling Panels

1. Tumor-type agnostic solid tumor molecular profiling panels are considered **medically necessary** when:
   - A. The member meets both of the following:
     - i. The member has a diagnosis of:
       - a) Recurrent, relapsed, refractory, metastatic, or advanced stages III or IV cancer, **or**
       - b) Histiocytosis, **or**
       - c) Non-small cell lung cancer (NSCLC) regardless of stage, **or**
       - d) Resectable or borderline resectable pancreatic adenocarcinoma, **or**
       - e) Central nervous system tumor**, and**
     - ii. The member is seeking further cancer treatment (e.g., therapeutic chemotherapy), **or**
   - B. The member meets one of the following:
     - i. The member has a diagnosis of uterine neoplasm, **and**
       - a) The member is undergoing initial evaluation, **or**
     - ii. The member has a gastrointestinal stromal tumor, **and**
       - a) The tumor is negative for KIT and PDGFRA mutations.
2. Repeat testing via a tumor-type agnostic solid tumor molecular profiling panel is considered **medically necessary** when:
   - A. The member has progression of:
     - i. Advanced or metastatic non-small cell lung cancer (NSCLC), **or**
     - ii. Advanced or metastatic gastric adenocarcinoma, **or**
     - iii. Metastatic prostate cancer.
3. Tumor-type agnostic solid tumor molecular profiling panels are considered i**nvestigational** for all other indications.

Note: Additional codes representing additional IHC and/or cytogenetics analyses may be billed alongside the PLA or GSP codes.

Back to top

Targeted RNA Fusion Panels

1. RNA specific fusion panels with 5-50 genes performed on peripheral blood, bone marrow or solid tumors are considered **medically necessary** when:
   - A. The member has a diagnosis of or is undergoing workup for:
     - i. Adult or pediatric acute lymphoblastic leukemia (ALL), **or**
     - ii. Glioma, **or**
     - iii. Histiocytosis, **or**
     - iv. Sarcoma, **or**
   - B. The member has a gastrointestinal stromal tumor, **and**
     - i. The tumor is negative for KIT and PDGFRA somatic mutations, **or**
   - C. The member has non-small cell lung cancer, **and**
     - i. DNA based NGS tumor profiling was negative for actionable mutations, **or**
   - D. The member has a metastatic or advanced solid tumor, **and**
     - i. There is a fusion-targeted therapy with regulatory approval for that cancer type, **or**
     - ii. DNA-based panel testing was negative for oncogenic driver mutations.
2. RNA specific fusion panels are considered **investigational** for all other indications.

Back to top

Broad RNA Fusion Panels

1. RNA fusion panels with 51 or more genes utilizing RNA analysis alone are considered **medically necessary** when:

A. The member has a diagnosis of adult or pediatric acute lymphoblastic leukemia (ALL).

2. RNA fusion panel tests with 51 or more genes utilizing RNA analysis alone are considered **investigational** for all other indications.

Back to top

Broad Molecular Profiling Panels For Hematologic Malignancies and Myeloid Malignancy Panels

1. Broad molecular profiling panels for hematologic malignancies and myeloid malignancy panels in bone marrow or peripheral blood are considered **medically necessary** when:
   - A. The member is undergoing evaluation for acute myeloid leukemia (AML), **or**
   - B. The member has newly diagnosed acute lymphoblastic leukemia (ALL), **or**
   - C. The member has newly diagnosed myelodysplastic syndrome (MDS), **or**
   - D. The member has suspected myelodysplastic syndrome (MDS), **and**
     - i. Other causes of cytopenia(s) have been ruled out, **or**
   - E. The member is suspected to have a myeloproliferative neoplasm (MPN), **and**
     - i. This is the member's initial genetic evaluation for suspected MPN, **or**
     - ii. Previous results of JAK2, *CALR*, and *MPL* analysis were negative, **or**
   - F. The member has a diagnosis of chronic myelogenous leukemia (CML), **and**
     - i. There has been progression to accelerated or blast phase, **or**
     - ii. Results of *BCR-ABL1* kinase domain mutation analysis were negative.
2. Repeat broad molecular profiling panels for hematologic malignancies and myeloid malignancy panels in bone marrow or peripheral blood are considered **medically necessary** when:
   - A. The member has myelodysplastic syndrome (MDS), **and**
     - i. The member has relapsed after allo-HCT (hematopoietic cell transplant), **or**
   - B. The member has acute lymphoblastic leukemia (ALL), **and**
     - i. The member is showing evidence of symptomatic relapse after maintenance therapy, **or**
   - C. The member has acute myeloid leukemia (AML), **and**
     - i. The member has relapsed or refractory disease or progression on treatment.
3. Broad molecular profiling panels for hematologic malignancies and myeloid malignancy panels in bone marrow or peripheral blood are considered **investigational** for all other indications.

Note: If a multigene panel is performed, appropriate panel codes should be used. These clinical criteria are not intended to address liquid biopsies.

Back to top

Colorectal Cancer Focused Molecular Profiling Panels

1. Colorectal cancer focused molecular profiling panels in solid tumors are considered **medically necessary** when:
   - A. The member has suspected or proven metastatic colorectal cancer, **and**
   - B. The panel contains at a minimum the following genes: *KRAS*, *NRAS*, *BRAF.*
2. Colorectal cancer-focused molecular profiling panels are considered **investigational** for all other indications.

Note: If a panel is performed, appropriate panel codes should be used.

Back to top

Lung Cancer Focused Molecular Profiling Panels

1. Lung cancer focused molecular profiling panels are considered **medically necessary** when:
   - A. The member has a diagnosis of any of the following:
     - i. Advanced (stage IIIb or higher) or metastatic lung adenocarcinoma, **or**
     - ii. Advanced (stage IIIb or higher) or metastatic large cell lung carcinoma, **or**
     - iii. Advanced (stage IIIb or higher) or metastatic squamous cell lung carcinoma, **or**
     - iv. Advanced (stage IIIb or higher) or metastatic non-small cell lung cancer (NSCLC) not otherwise specified (NOS), **and**
   - B. The member is seeking further cancer treatment (e.g., therapeutic chemotherapy)**.**
2. Repeat lung cancer-focused molecular profiling panels are considered **medically necessary** when the member has progression on targeted therapy for non-small cell lung cancer.
3. Lung cancer-focused molecular profiling panels are considered **investigational** for all other indications.

Note: If a panel is performed, appropriate panel codes should be used.

Back to top

Cutaneous Melanoma Focused Molecular Profiling Panels

1. Cutaneous melanoma focused molecular profiling panels are considered **medically necessary** when:
   - A. The member has a diagnosis of one of the following:
     - i. Stage III melanoma or higher, **or**
     - ii. Recurrent melanoma, **and**
   - B. The member is seeking further cancer treatment (e.g., therapeutic chemotherapy), **and**

C. One of the following:
i. The member has not had previous somatic testing via a multigene cancer panel for the same primary melanoma diagnosis, **or**
ii. The member **has** had previous somatic testing via a multigene cancer panel for a primary melanoma diagnosis and has a **new** primary melanoma diagnosis for which this testing is being ordered.

2. Cutaneous melanoma focused molecular profiling panels are considered **investigational** for all other indications.

Note: If a panel is performed, appropriate panel codes should be used.

Back to top

Acute Myeloid Leukemia (AML) Focused Molecular Profiling Panels

1. Acute myeloid leukemia focused molecular profiling panels for the diagnosis or evaluation of acute myeloid leukemia (AML) are considered **medically** necessary when:
A. The member has a suspected or confirmed diagnosis of acute myeloid leukemia (AML).
2. Acute myeloid leukemia focused molecular profiling panels for the diagnosis or evaluation of acute myeloid leukemia (AML) are considered **investigational** for all other indications.

Note: If a multigene panel is performed, appropriate panel codes should be used.

Back to top

Myeloproliferative Neoplasms (MPNs) Panels

1. Myeloproliferative neoplasm (MPN) molecular profiling panels are considered **medically necessary** when:
A. The member is suspected to have a myeloproliferative neoplasm (i.e., polycythemia vera, essential thrombocythemia, primary myelofibrosis, and chronic myeloid leukemia), **and**
B. The panel includes, at a minimum, testing of the following genes: JAK2, CALR, and MPL.
2. Myeloproliferative neoplasm (MPN) molecular profiling panels are considered **investigational** for all other indications.

Back to top

Single-Gene Testing of Solid Tumors and Hematologic Malignancies

Tumor Specific *BCR/ABL1* Kinase Domain Analysis

1. Tumor specific *BCR/ABL1* kinase domain analysis in hematologic malignancies is considered **medically necessary** when:
A. The member has a diagnosis of any of the following:
i. Chronic myeloid leukemia (CML), **or**
ii. Ph-positive acute lymphocytic leukemia (ALL), **and**
B. The member has any of the following:
i. Inadequate initial response to TKI therapy, **or**
ii. Loss of response to TKI therapy, **or**
iii. Disease progression to the accelerated or blast phase, **or**
iv. Relapsed/refractory disease.

Back to top

Tumor Specific *BCR/ABL1* FISH, Qualitative, or Quantitative Tests

1. Tumor specific *BCR/ABL1* FISH, qualitative, or quantitative tests in hematologic malignancies is considered **medically necessary** when:
A. The member is suspected to have a myeloproliferative neoplasm (i.e., polycythemia vera, essential thrombocythemia, primary myelofibrosis, and chronic myeloid leukemia), **or**
B. The member is undergoing diagnostic workup for:
i. Acute lymphoblastic leukemia (ALL), **or**
ii. Acute myeloid leukemia (AML), **or**
iii. Chronic myelogenous leukemia (CML), **or**
iv. B-cell lymphoma, **or**
C. The member is undergoing monitoring of disease progression (i.e., for minimal residual disease (MRD) monitoring using a quantitative test only) for:
i. Acute lymphoblastic leukemia (ALL), **or**
ii. Acute myeloid leukemia (AML), **or**
iii. Chronic myelogenous leukemia (CML), **or**
iv. B-cell lymphoma.

Back to top

Tumor Specific *BRAF* Variant Analysis

1. Tumor specific *BRAF* variant analysis in solid tumors and hematologic malignancies is considered **medically necessary** when:
A. The member has a diagnosis of:
i. Suspected or proven metastatic colorectal cancer, **or**
ii. Advanced or metastatic non-small-cell lung cancer (NSCLC), **or**

iii. Stage III or stage IV cutaneous melanoma, **or**
iv. Indeterminate thyroid nodules requiring biopsy, **or**
v. Anaplastic thyroid carcinoma, **or**
vi. Locally recurrent, advanced and/or metastatic papillary thyroid cancer, **or**
vii. Locally recurrent, advanced and/or metastatic follicular thyroid cancer, **or**
viii. Locally recurrent, advanced and/or metastatic Hurthle cell thyroid carcinoma, **or**
ix. Low-grade glioma or pilocytic astrocytoma, **or**
x. Resectable or borderline resectable, or locally advanced/metastatic pancreatic adenocarcinoma, **or**
xi. Metastatic small bowel adenocarcinoma, **or**
xii. Locally advanced, recurrent or metastatic esophageal or esophagogastric junction cancer, **or**
xiii. Locally advanced, recurrent or metastatic gastric cancer, **or**

B. The member is being evaluated for:
i. Hairy cell leukemia (for individuals without cHCL [classical hairy cell leukemia] immunophenotype), **or**
ii. Histiocytosis (Langerhans cell histiocytosis or Erdheim-Chester disease).

Back to top

Tumor Specific *BRCA1/2* Variant Analysis

1. Tumor specific *BRCA1/2* variant analysis in solid tumors is considered **medically necessary** when:
A. The member has a diagnosis of:
i. Ovarian, fallopian tube and/or primary peritoneal cancer, **or**
ii. Metastatic prostate cancer, **or**
iii. Resectable, borderline resectable, or locally advanced / metastatic pancreatic cancer.

Back to top

Tumor Specific *CALR* Variant Analysis

1. Tumor specific *CALR* variant analysis is considered **medically necessary** when:
A. The member is suspected to have a myeloproliferative neoplasm (i.e., polycythemia vera, essential thrombocythemia, primary myelofibrosis, and chronic myeloid leukemia), **or**
B. The member is suspected to have a myelodysplastic syndrome (MDS).

Back to top

Tumor Specific *CEBPA* Variant Analysis

1. Tumor specific *CEBPA* variant analysis in hematologic malignancies is considered **medically necessary** when:
A. The member is undergoing evaluation for acute myeloid leukemia (AML).

Back to top

Tumor Specific *EGFR* Variant Analysis

1. Tumor specific *EGFR* variant analysis in solid tumors is considered **medically necessary** when:
A. The member has a diagnosis of:
i. Stage IB or higher lung adenocarcinoma, **or**
ii. Stage IB or higher large cell lung carcinoma, **or**
iii. Stage IB or higher squamous cell lung carcinoma, **or**
iv. Stage IB or higher non-small cell lung cancer (NSCLC) not otherwise specified (NOS).

Back to top

Tumor Specific ESR1 Variant Analysis

1. Tumor specific ESR1 variant analysis in solid tumors is considered **medically necessary** when:
A. The member is one of the following:
i. Pre-menopausal female receiving ovarian ablation or suppression, **or**
ii. Postmenopausal female, **or**
iii. Adult male, **and**
B. The member has a diagnosis of ER-positive and HER2-negative breast cancer, **and**
C. The member has disease progression after one or two prior lines of endocrine therapy, including one line containing a CDK4/6 inhibitor.

Back to top

Tumor Specific *FLT3* Variant Analysis

1. Tumor specific *FLT3* variant analysis in hematologic malignancies is considered **medically necessary** when:
A. The member has suspected or confirmed acute myeloid leukemia (AML), **or**
B. The member has a diagnosis of:
i. Acute lymphocytic leukemia (ALL), **or**
ii. Myelodysplastic syndrome (MDS), **or**

iii. Myeloproliferative neoplasm.

Back to top

Tumor Specific *IDH1* and *IDH2* Variant Analysis

1. Tumor specific *IDH1* and *IDH2* variant analysis in solid tumors or hematologic malignancies is considered **medically necessary** when:
   - A. The member has a diagnosis of:
     - i. Glioma, **or**
     - ii. Acute myeloid leukemia (AML).

Back to top

Tumor Specific *IGHV* Variant Somatic Hypermutation Analysis

1. Tumor specific *IGHV* somatic hypermutation analysis in hematologic malignancies is considered **medically necessary** when:
   - A. The member is undergoing work up for or has a diagnosis of:
     - i. Chronic lymphocytic leukemia (CLL), **or**
     - ii. Small lymphocytic leukemia (SLL), **or**
     - iii. Primary cutaneous B-cell lymphoma, **or**
     - iv. B-cell lymphoma.

Back to top

Tumor Specific *JAK2* Variant Analysis

1. Tumor specific *JAK2* variant analysis in solid tumors or hematologic malignancies is considered **medically necessary** when:
   - A. The member is suspected to have a myeloproliferative neoplasm (MPN) (i.e., polycythemia vera, essential thrombocythemia, primary myelofibrosis, and chronic myeloid leukemia), **or**
   - B. The member has acute lymphoblastic leukemia (ALL), **or**
   - C. The member is suspected to have a myelodysplastic syndrome (MDS).

Back to top

Tumor Specific *KIT* Variant Analysis

1. Tumor specific *KIT* variant analysis in solid tumors or hematologic malignancies is considered **medically necessary** when:
   - A. The member is being evaluated for systemic mastocytosis, **or**
   - B. The member has a diagnosis of acute myeloid leukemia (AML), **or**
   - C. The member has stage IV cutaneous melanoma, **or**
   - D. The member has a suspected or confirmed gastrointestinal stromal tumor (GIST).

Back to top

Tumor Specific *KRAS* Variant Analysis

1. Tumor specific *KRAS* variant analysis in solid tumors is considered **medically necessary** when:
   - A. The member has suspected or proven metastatic colorectal cancer, **or**
   - B. The member is undergoing workup for metastasis of non-small cell lung cancer, **or**
   - C. The member has resectable, borderline resectable or locally advanced/metastatic pancreatic adenocarcinoma, **or**
   - D. The member has unresectable or metastatic gallbladder cancer, **or**
   - E. The member has unresectable or metastatic intrahepatic or extrahepatic cholangiocarcinoma.

Back to top

Tumor Specific *MGMT* Methylation Analysis

1. Tumor specific *MGMT* promoter methylation analysis in solid tumors is considered **medically necessary** when:
   - A. The member has a diagnosis of:
     - i. High grade (stage III or IV) anaplastic oligodendroglioma, **or**
     - ii. High grade (stage III or IV) anaplastic astrocytoma, **or**
     - iii. High grade (stage III or IV) anaplastic glioma, **or**
     - iv. High grade (stage III or IV) glioblastoma.

Back to top

Tumor Specific *MLH1* Methylation Analysis

1. Tumor specific *MLH1* promoter methylation analysis in solid tumors is considered **medically necessary** when:
   - A. The member has a diagnosis of any of the following:
     - i. Colorectal cancer, **or**
     - ii. Endometrial (uterine) cancer, **and**
   - B. Previous tumor testing showed loss of *MLH1* on immunohistochemistry analysis.

Back to top

Tumor Specific *MPL* Variant Analysis

1. Tumor specific *MPL* variant analysis in hematologic malignancies is considered **medically necessary** when:
   - A. The member is suspected to have a myeloproliferative neoplasm (MPN) (i.e., polycythemia vera, essential thrombocythemia, primary myelofibrosis, and chronic myeloid leukemia), **or**
   - B. The member is suspected to have a myelodysplastic syndrome (MDS).

Back to top

Tumor Specific Microsatellite Instability (MSI) Analysis

1. Tumor specific microsatellite instability (MSI) analysis in solid tumors is considered **medically necessary** when:
   - A. The member has a diagnosis of:
     - i. Colorectal cancer, **or**
     - ii. Endometrial cancer, **or**
     - iii. Gastric cancer, **or**
     - iv. Esophageal and esophagogastric junction cancer, **or**
     - v. Recurrent, progressive or metastatic cervical carcinoma, **or**
     - vi. Testicular cancer with progression after high dose chemotherapy or third-line therapy, **or**
     - vii. Unresectable or metastatic gallbladder cancer, **or**
     - viii. Unresectable or metastatic intrahepatic or extrahepatic cholangiocarcinoma, **or**
     - ix. Unresectable or metastatic breast cancer, **or**
     - x. Small bowel adenocarcinoma, **or**
     - xi. Resectable, borderline resectable, or metastatic pancreatic cancer, **or**
     - xii. Metastatic occult primary, **or**
     - xiii. Recurrent, progressive or metastatic squamous cell carcinoma of the vulva, **or**
     - xiv. Metastatic chondrosarcoma, **or**
     - xv. Metastatic chordoma, **or**
     - xvi. Widely metastatic Ewing sarcoma, **or**
     - xvii. Metastatic osteosarcoma, **or**
     - xviii. Recurrent or metastatic vaginal cancer, or
     - xix. Recurrent ovarian cancer.

Back to top

Tumor Specific *NPM1* Variant Analysis

1. Tumor specific *NPM1* variant analysis in hematological malignancies is considered **medically necessary** when:
   - A. The member has cytogenetically normal acute myeloid leukemia (AML).

Tumor Specific *NRAS* Variant Analysis

1. Tumor specific *NRAS* variant analysis in solid tumors is considered **medically necessary** when:
   - A. The member has suspected or proven metastatic colorectal cancer.

Tumor Specific *PIK3CA* Variant Analysis

1. Tumor specific *PIK3CA* variant analysis in solid tumors is considered **medically necessary** when:
   - A. The member has a diagnosis of recurrent or stage IV, HR positive, HER2 negative invasive breast cancer**.**

Back to top

Tumor Specific *TP53* Variant Analysis

1. Tumor specific *TP53* variant analysis in bone marrow or peripheral blood is considered **medically necessary** when:
   - A. The member has a diagnosis of:
     - i. Acute myeloid leukemia (AML), **or**
     - ii. Chronic lymphocytic leukemia (CLL), **or**
     - iii. Small lymphocytic leukemia (SLL), **or**
   - B. The member is undergoing diagnostic workup for mantle cell lymphoma (MCL).

Back to top

HLA Typing For Transplantation

1. HLA typing for transplantation is considered **medically necessary** when the member meets the following:
   - A. The member is being considered for any of the following:
     - i. Recipient of bone marrow transplantation, **or**
     - ii. Donor for bone marrow transplantation, **or**
     - iii. Recipient of solid organ transplantation, **or**
     - iv. Donor for solid organ transplantation.
2. HLA typing for transplantation is considered **investigational** for all other indications.

Back to top

HealthPartners

Measurable (Minimal) Residual Disease (MRD) Analysis

Hematologic Minimal Residual Disease (MRD) Testing

1. Measurable (minimal) residual disease analysis in bone marrow or peripheral blood is considered **medically necessary** when:
    - A. The member has a diagnosis of:
        - i. Acute Lymphocytic Leukemia (ALL), **or**
        - ii. Multiple Myeloma, **or**
        - iii. Chronic Lymphocytic Leukemia (CLL).

Back to top

Evidence-Based Solid Tumor Minimal Residual Disease (MRD) Testing

1. Minimal residual disease (MRD) analysis for solid tumors using cell free DNA with sufficient evidence of clinical utility and validity is considered **medically necessary** when:
    - A. The identification of recurrent, refractory, or progressive disease will require a change in management, **and**
    - B. The member is not undergoing concurrent molecular laboratory testing for surveillance or monitoring for recurrent, refractory, or progressive disease, **and**
    - C. The member meets one of the following:
        - i. The member is currently being treated for cancer, **and**
            - a) The test has not previously been done for this cancer diagnosis, **or**
            - b) There is a clinical suspicion that the molecular profile of the member's tumor has changed, **or**
        - ii. The member is not currently being treated for their cancer, **and**
            - a) The test has not been done in the past 12 months, **or**
            - b) There is a clinical suspicion for tumor recurrence, **and**
    - D. The member meets one of the following:
        - i. The member is being tested via Guardant360 Response or Guardant Reveal **and** has one of the following:
            - a) Metastatic colon cancer, **or**
            - b) Colon cancer at any stage, **and**
                - (i) The member is being monitored for response to immune checkpoint inhibitor therapy, **or**
        - ii. The member is being tested via Signatera and has one of the following:
            - a) Metastatic colon cancer, **or**
            - b) Muscle invasive bladder cancer, **or**
            - c) Metastatic breast cancer, **or**
            - d) Any solid tumor, **and**
                - (i) The member is being monitored for response to immune checkpoint inhibitor therapy.
2. Minimal residual disease (MRD) analysis with sufficient evidence of clinical utility and validity using solid tumor tissue is considered **investigational** for all other indications where clinical utility and validity have not been demonstrated.

Back to top

Emerging Evidence Solid Tumor Minimal Residual Disease (MRD) Testing

1. Minimal residual disease (MRD) analysis with insufficient evidence of clinical validity using solid tumor tissue is considered **investigational**.

Back to top

HPV-Related Solid Tumor Minimal Residual Disease (MRD) Testing

1. Minimal residual disease analysis for HPV-related head and neck cancers using cell-free DNA is **medically necessary** when:
    - A. The member has a personal history of HPV-driven oropharyngeal cancer, **and**
    - B. The identification of recurrence or progression of disease will require a change in management, **and**
    - C. The member is not undergoing concurrent surveillance or monitoring for recurrence or progression by any other method, **and**
    - D. The member meets one of the following:
        - i. The member is currently being treated for HPV-driven oropharyngeal cancer, **and**
            - a) The test has not previously been done for this episode of cancer, **or**
        - ii. The member is not currently being treated for HPV-driven oropharyngeal cancer, **and**
            - a) The test has not been done in the past 12 months.

2. Minimal residual disease analysis using tumor tissue from HPV-related head and neck cancers is considered **investigational** for all other indications.

Back to top

Tumor Mutational Burden (TMB)

1. Tumor mutational burden (TMB) testing is considered **medically necessary** when:
   - A. The member has a diagnosis of:
     - i. Recurrent, relapsed, refractory, metastatic, or advanced stages III or IV cancer, **and**
     - ii. The member has had progression of the cancer following prior treatment, **and**
     - iii. The member has no remaining satisfactory treatment options, **and**
   - B. The member does not have central nervous system cancer.

Back to top

Red Blood Cell Genotyping in Multiple Myeloma

1. Red blood cell genotyping in individuals with multiple myeloma is considered **medically necessary** when:
   - A. The member has a diagnosis of multiple myeloma, **and**
   - B. The member is currently being treated or will be treated with either of the following:
     - i. Daratumumab (Darazalex), **or**
     - ii. Isatuximab (Sarclisa).

Back to top

Cancer Exome and Genome Sequencing

1. Cancer exome and genome sequencing in solid tumors and hematologic malignancies is considered **investigational**.

Back to top

Genetic Testing to Confirm the Identity of Laboratory Specimens

1. Genetic testing to confirm the identity of laboratory specimens (e.g., know error), when billed separately, is considered **investigational** because it is generally considered to be an existing component of the genetic testing process for quality assurance.

Definitions

1. **Tumor mutation burden:** A measurement of **mutations** carried by **tumor** cells and is a predictive biomarker that is being studied to evaluate its association with response to immunotherapy.
2. **Advanced cancer**: Cancer that is unlikely to be cured or controlled with treatment. The cancer may have spread from where it first started to nearby tissue, lymph nodes, or distant parts of the body. Treatment may be given to help shrink the tumor, slow the growth of cancer cells, or relieve symptoms.
3. **Myeloproliferative Neoplasms:** Rare overlapping blood diseases in which the bone marrow makes too many red blood cells, white blood cells, or platelets.

There are seven subcategories of myeloproliferative neoplasms:

- Chronic myeloid leukemia (CML)
- Polycythemia vera (PV)
- Primary myelofibrosis (PMF)
- Essential thrombocytopenia (ET)
- Chronic neutrophilic leukemia
- Chronic eosinophilic leukemia
- Chronic eosinophilic leukemia-not otherwise specified
- MPN, unclassifiable (MPN-U)

4. **Myelodysplastic Syndromes (MDS):** A group of disorders characterized by abnormalities of the bone marrow, leading to low numbers of one or more types of blood cells. The WHO system recognizes 6 main types of MDS:

- MDS with multilineage dysplasia (MDS-MLD)
- MDS with single lineage dysplasia (MDS-SLD)
- MDS with ring sideroblasts (MDS-RS)
- MDS with excess blasts (MDS-EB)
- MDS with isolated del(5q)
- MDS, unclassifiable (MDS-U)

5. **Widely metastatic cancer**: Cancer for which local control cannot be delivered to all areas of disease (per National Comprehensive Cancer Care Network (NCCN))

Products

This information is for most, but not all, HealthPartners plans. Please read your plan documents to see if your plan has limits or will not cover some items. If there is a difference between this general information and your plan documents, your plan documents will be used to determine your coverage. These coverage criteria do not apply to Medicare Products. For more information regarding Medicare coverage criteria or for a copy of a Medicare coverage policy, contact Member Services at 952-883-7272 or 1-877-778-8384.

Approved Medical Director Committee 06/17/2021; Revised: 12/17/2021, 04/12/2022, 10/04/2022, 03/13/2023, 09/26/2023, 03/19/2024, 09/12/2024; Reviewed: 12/2021, 07/2022, 01/2023, 07/2023, 01/2024, 07/2024, 01/2025

References

1. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer. Version 7.2024. https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf.
2. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Colon Cancer. Version 4.2024. http://www.nccn.org/professionals/physician_gls/PDF/colon.pdf.
3. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Genetic/Familial High-Risk Assessment: Colorectal. Version 2.2024. https://www.nccn.org/professionals/physician_gls/pdf/genetics_colon.pdf.
4. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Breast Cancer. Version 4.2024. https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf
5. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Ovarian Cancer, Including Fallopian Tube Cancer and Primary Peritoneal Cancer. Version 3.2024. https://www.nccn.org/professionals/physician_gls/pdf/ovarian.pdf.
6. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Myelodysplastic Syndromes. Version 3.2024 https://www.nccn.org/professionals/physician_gls/pdf/mds.pdf
7. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Pancreatic Adenocarcinoma. Version 3.2024. https://www.nccn.org/professionals/physician_gls/pdf/pancreatic.pdf
8. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Gastrointestinal Stromal Tumors (GISTs). Version 2.2024. https://www.nccn.org/professionals/physician_gls/pdf/gist.pdf
9. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Cutaneous Melanoma. Version 2.2024. https://www.nccn.org/professionals/physician_gls/pdf/cutaneous_melanoma.pdf
10. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Acute Myeloid Leukemia. Version 3.2024. https://www.nccn.org/professionals/physician_gls/pdf/aml.pdf
11. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Systemic Mastocytosis. Version 3.2024. https://www.nccn.org/professionals/physician_gls/pdf/mastocytosis.pdf
12. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Myeloproliferative Neoplasms. Version 1.2024. https://www.nccn.org/professionals/physician_gls/pdf/mpn.pdf
13. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Thyroid Carcinoma. Version 2.2024. https://www.nccn.org/professionals/physician_gls/pdf/thyroid.pdf
14. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Uterine Neoplasms. Version 2.2024. https://www.nccn.org/professionals/physician_gls/pdf/uterine.pdf
15. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Chronic Myeloid Leukemia. Version 2.2024. https://www.nccn.org/professionals/physician_gls/pdf/cml.pdf
16. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Pediatric Acute Lymphoblastic Leukemia. Version 6.2024. https://www.nccn.org/professionals/physician_gls/pdf/ped_all.pdf
17. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Acute Lymphoblastic Leukemia. Version 2.2024. https://www.nccn.org/professionals/physician_gls/pdf/all.pdf
18. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in B-Cell Lymphomas. Version 2.2024. https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf
19. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Hairy Cell Leukemia. Version 2.2024. https://www.nccn.org/professionals/physician_gls/pdf/hairy_cell.pdf
20. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Central Nervous System Cancers. Version 2.2024. https://www.nccn.org/professionals/physician_gls/pdf/cns.pdf
21. Konstantinopoulos PA, Norquist B, Lacchetti C, et al. Germline and Somatic Tumor Testing in Epithelial Ovarian Cancer: ASCO Guideline. J Clin Oncol. 2020; 38(11):1222-1245. doi:10.1200/JCO.19.02960
22. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Prostate Cancer. Version 4.2024. https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf
23. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Gastric Cancer. Version 2.2024. https://www.nccn.org/professionals/physician_gls/pdf/gastric.pdf
24. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Esophageal and Esophagogastric Junction Cancer. Version .2024. https://www.nccn.org/professionals/physician_gls/pdf/esophageal.pdf
25. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Chronic Lymphocytic Leukemia/Small Lymphocytic Leukemia. Version 3.2024. https://www.nccn.org/professionals/physician_gls/pdf/cll.pdf
26. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Cervical Cancer. Version 3.2024. https://www.nccn.org/professionals/physician_gls/pdf/cervical.pdf
27. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Biliary Tract Cancers. Version 3.2024. https://www.nccn.org/professionals/physician_gls/pdf/hepatobiliary.pdf
28. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Occult Primary (Cancer of Unknown Primary [CUP]). Version 1.2025. https://www.nccn.org/professionals/physician_gls/pdf/occult.pdf

29. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Testicular Cancer. Version 1.2024. https://www.nccn.org/professionals/physician_gls/pdf/testicular.pdf
30. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Multiple Myeloma. Version 4.2024. https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf
31. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Small Bowel Adenocarcinoma. Version 4.2024. https://www.nccn.org/professionals/physician_gls/pdf/small_bowel.pdf
32. National Comprehensive Cancer Network. Biomarker Compendium. https://www.nccn.org/professionals/biomarkers/content/ Accessed 04/01/2024.
33. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Primary Cutaneous Lymphomas. Version 2.2024. https://www.nccn.org/professionals/physician_gls/pdf/primary_cutaneous.pdf
34. Association for the Advancement of Blood and Biotherapies Association Bulletin #16-02: Mitigating the Anti-CD38 Interference with Serologic Testing. (2016, January 15). https://www.aabb.org/docs/default-source/default-document-library/resources/association-bulletins/ab16-02.pdf
35. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Histiocytic Neoplasms. Version 2.2024. https://www.nccn.org/professionals/physician_gls/pdf/histiocytic_neoplasms.pdf
36. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Soft Tissue Sarcoma. Version 2.2024. https://www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf
37. Chakravarty D, Johnson A, Sklar J, et al. Somatic Genomic Testing in Patients With Metastatic or Advanced Cancer: ASCO Provisional Clinical Opinion [published correction appears in J Clin Oncol. 2022 Jun 20;40(18):2068]. J Clin Oncol. 2022;40(11):1231-1258. doi:10.1200/JCO.21.02767
38. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Vulvar Cancer. Version 4.2024. https://www.nccn.org/professionals/physician_gls/pdf/vulvar.pdf
39. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Ampullary Adenocarcinoma. Version 2.2024. https://www.nccn.org/professionals/physician_gls/pdf/ampullary.pdf
40. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Bone Cancer. Version 2.2024. https://www.nccn.org/professionals/physician_gls/pdf/bone.pdf
41. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Head and Neck Cancers. Version 4.2024. https://www.nccn.org/professionals/physician_gls/pdf/head-and-neck.pdf
42. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Neuroendocrine and Adrenal Tumors. Version 2.2024. https://www.nccn.org/professionals/physician_gls/pdf/neuroendocrine.pdf
43. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Vaginal Cancer. Version 1.2025. https://www.nccn.org/professionals/physician_gls/pdf/vaginal.pdf
44. Merck & CO, Inc. KEYTRUDA (pembrolizumab). U.S. Food and Drug Administration. Website: https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/125514s071s090lbl.pdf. Accessed 4/24/2024.
45. Centers for Medicare & Medicaid Services. Medicare Coverage Database: Local Coverage Determination. MolDX: Minimal Residual Disease Testing for Cancer (L38779). Available at: https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=38779
46. Centers for Medicare & Medicaid Services. Medicare Coverage Database: Billing and Coding: MolDX: Minimal Residual Disease Testing for Solid Tumor Cancers (A58376). Available at: https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=58376
47. Viatte, MD, PhD, et al. Human leukocyte antigens (HLA): A roadmap. In: UpToDate, Connor RF (ed), Wolters Kluwer (Accessed on May 8, 2024). https://www.uptodate.com/contents/human-leukocyte-antigens-hla-a-roadmap
48. Negrin, R.S., MD, et al. Donor selection for hematopoietic cell transplantation. In: UpToDate, Connor, RF (ed), Wolters Kluwer (Accessed May 8, 2024). https://www.uptodate.com/contents/donor-selection-for-hematopoietic-cell-transplantation
49. 2024 CONSULTATION GUIDELINES Recommended Timing for Transplant Consultation. Published jointly by NMDPSM and the American Society for Transplantation and Cellular Therapy (ASTCT). Available at: https://bethematchclinical.org/transplant-indications-and-outcomes/referral-timing-guidelines/
50. Tait BD, Süsal C, Gebel HM, et al. Consensus guidelines on the testing and clinical management issues associated with HLA and non-HLA antibodies in transplantation. Transplantation. 2013;95(1):19-47. doi:10.1097/TP.0b013e31827a19cc
51. “Requirements for Performing and Reporting HLA Typing” OTPN (Effective Date: 4/2/2024). Available at: https://optn.transplant.hrsa.gov/media/eavh5bf3/optn_policies.pdf
52. FoundationOne CDx Technical Information (PMA approval number: P170019). US Food and Drug Administration. Website: https://www.accessdata.fda.gov/cdrh_docs/pdf17/P170019C.pdf. Accessed 08/12/2024.
53. Minnesota statue 62Q.473 Biomarker Testing.
54. Iowa statute 514C.36 Biomarker Testing.