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Targeted Therapy Large Molecules

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Outlines

- Introduction
- Rituximab
- Brentuximab Vedotin

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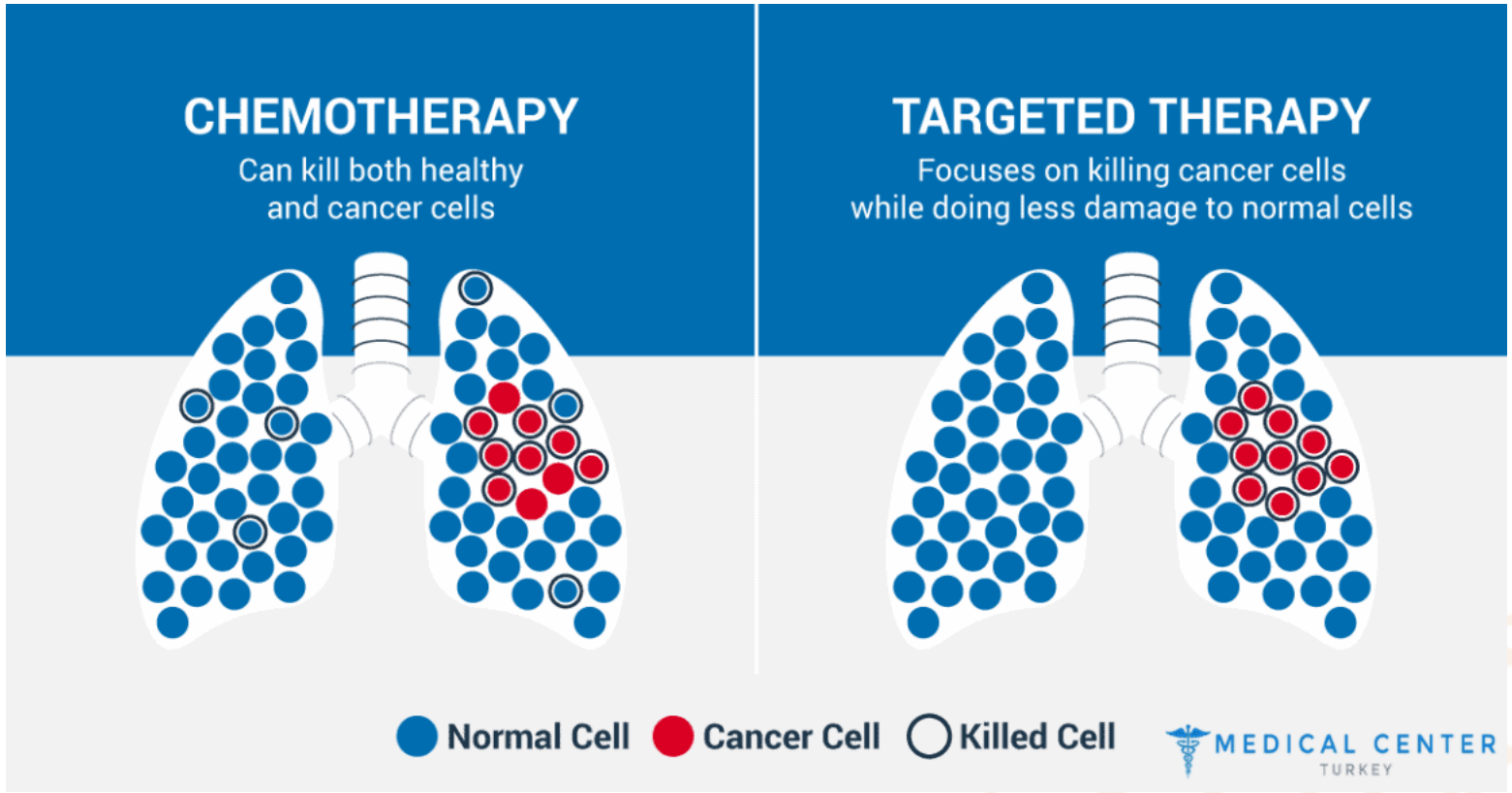
Introduction



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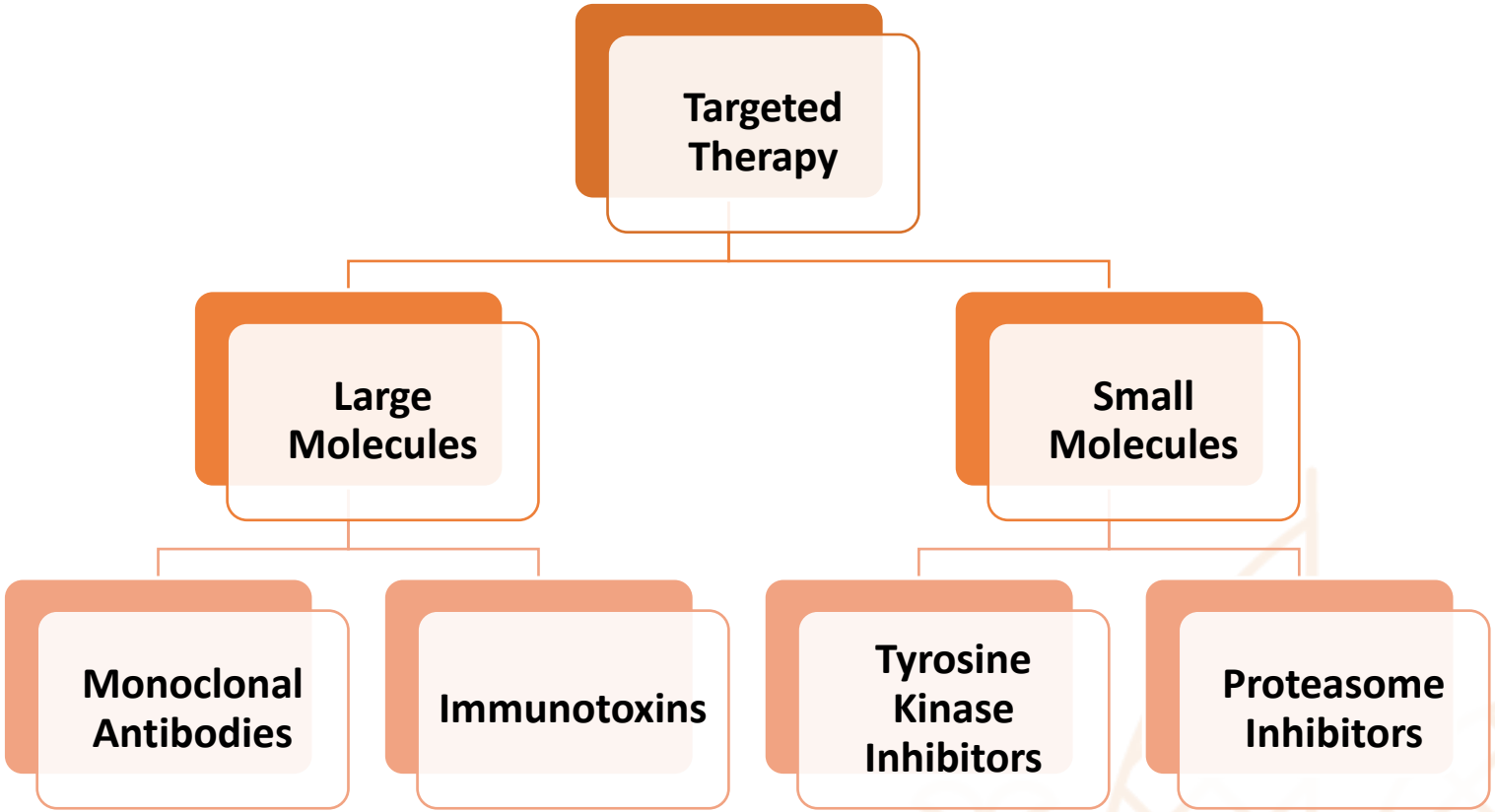
Introduction



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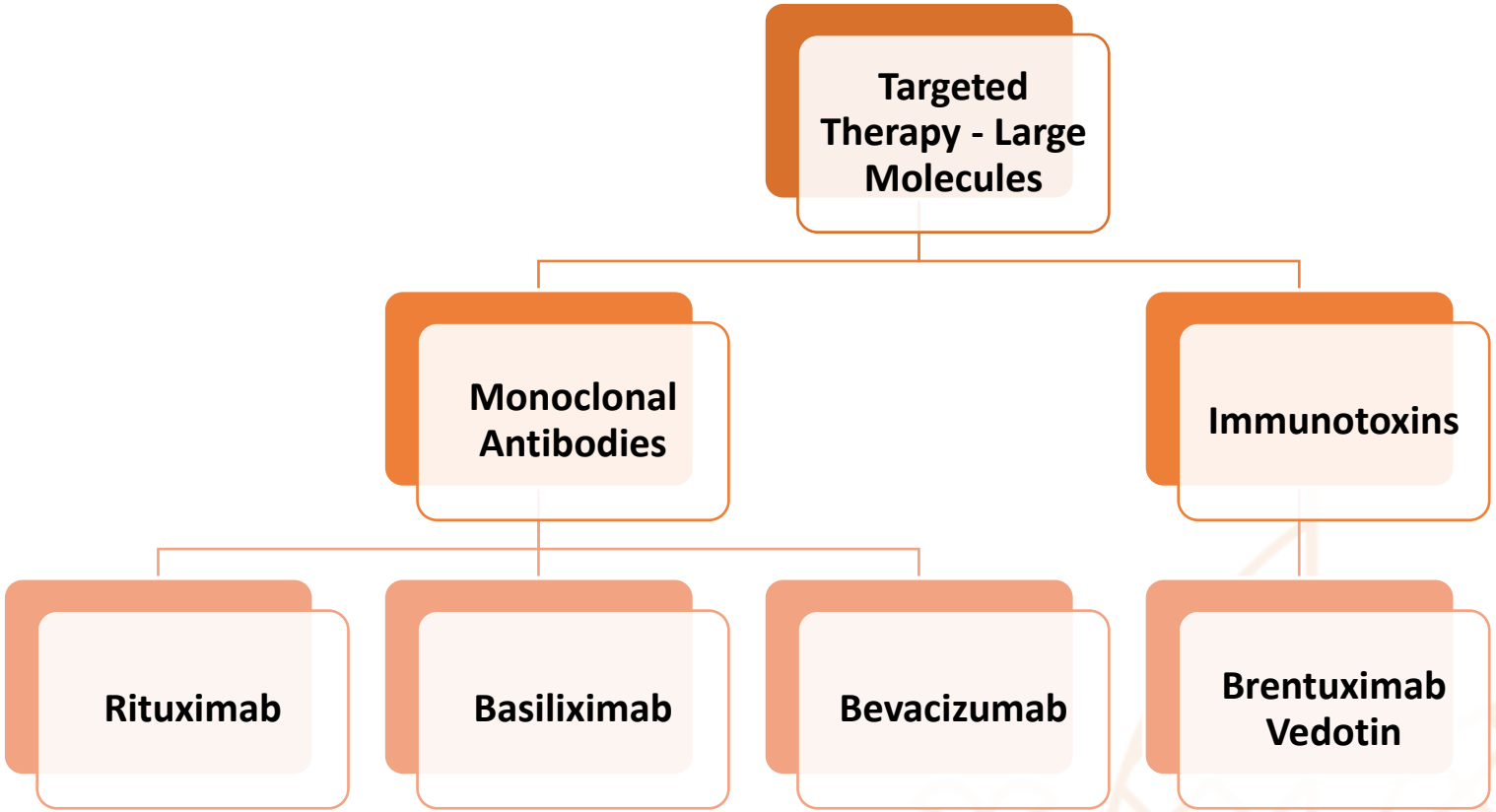
Introduction



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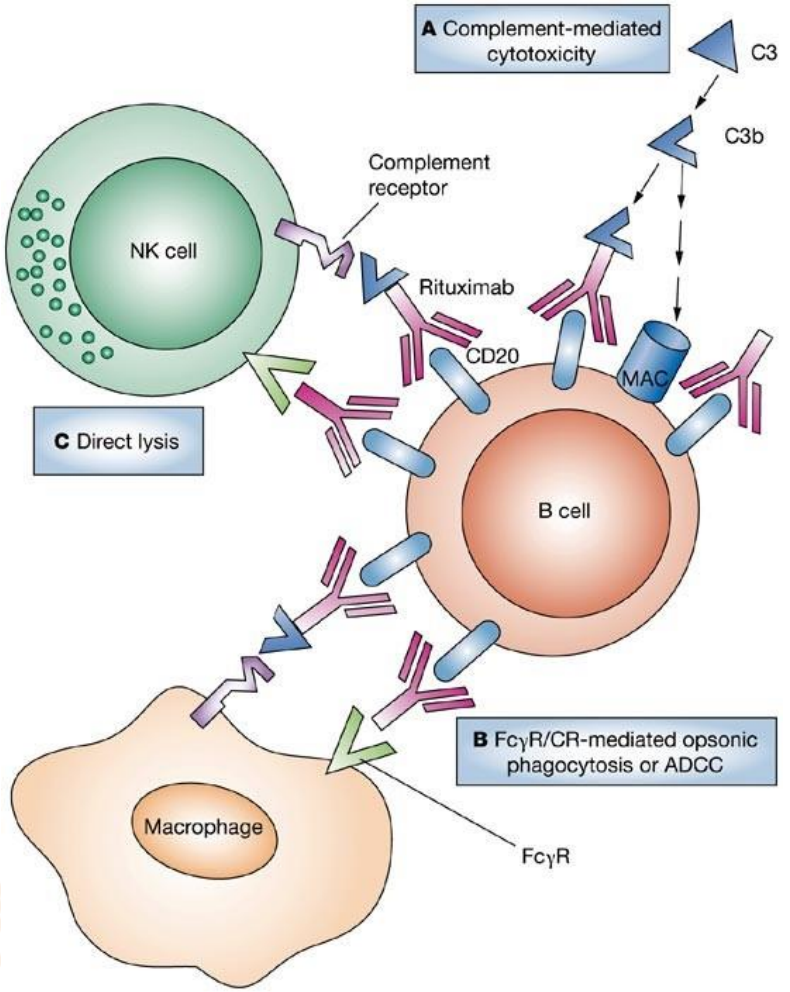
Rituximab

Mechanism of Action

Rituximab is a monoclonal antibody directed against the CD20 antigen on the surface of B-lymphocytes. CD20 regulates cell cycle initiation; and, possibly, functions as a calcium channel. Rituximab binds to the antigen on the cell surface, activating complement-dependent B-cell cytotoxicity; and to human Fc receptors, mediating cell killing through an antibody-dependent cellular toxicity.



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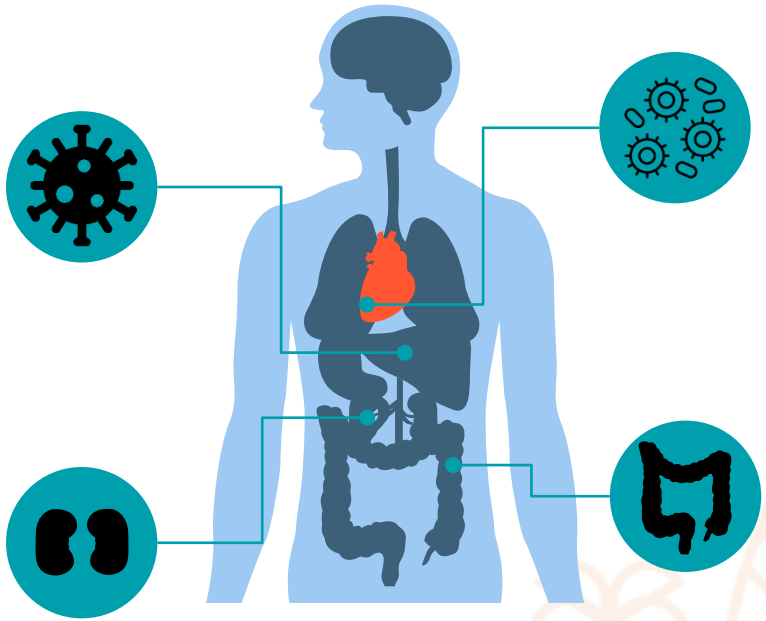
Rituximab

Toxicities & Management

Hepatitis B Virus Reactivation

Screen all patients for HBV infection before treatment initiation, and monitor patients during and after treatment with rituximab. Discontinue rituximab and concomitant medications in the event of HBV reactivation.

Renal Toxicity



Hypogammaglobulinemia and Infection

IgG replacement, which may be given IV or SC.

Bowel Obstruction/ Perforation

Evaluate abdominal pain or repeated vomiting

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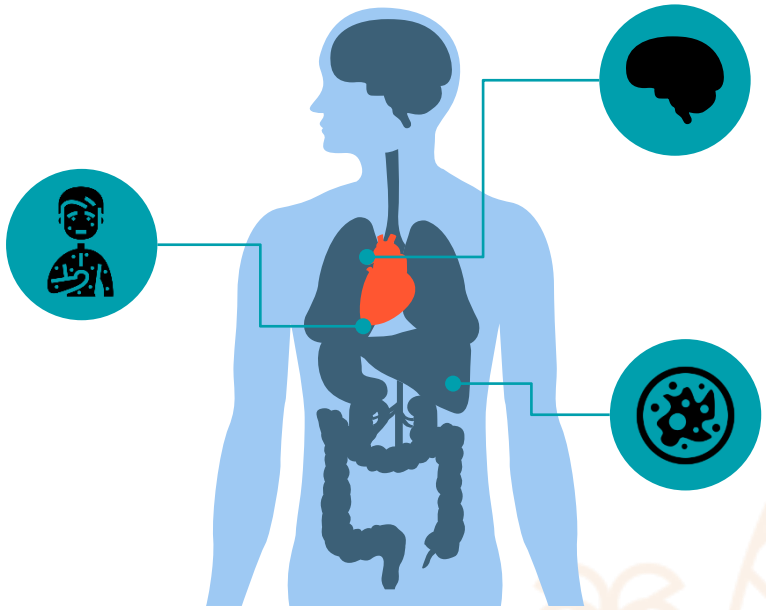
Rituximab

Toxicities & Management

Infusion-Related Reactions

Priming IV lines with the drug. Standardized premedication, including acetaminophen, diphenhydramine and dexamethasone should be considered for all patients receiving first-dose rituximab infusions to reduce hypersensitivity.



PML

If PML is confirmed the drug must be permanently discontinued.

Tumor Lysis Syndrome

Administer prophylaxis (anti-hyperuricemic therapy, aggressive hydration) in patients at high risk (high numbers of circulating malignant cells ≥25,000/mm3 or high tumor burden). Correct electrolyte abnormalities and administer supportive care as indicated.

Rituximab

Drug Interactions

Influenza Virus Vaccines (Risk D: Consider Therapy Modification) - Anti-CD20 B-Cell Depleting Therapies may diminish the therapeutic effect of Influenza Virus Vaccines.

Administer influenza vaccines 2 weeks prior to starting anti-CD20 B-cell depleting therapies. Vaccination of patients treated with these agents in the past 6 months is not recommended.

Rituximab

Drug Interactions

Cisplatin (Risk C: Monitor Therapy) - Both increase nephrotoxicity and/or ototoxicity. Potential for renal toxicity when used in combination with cisplatin.

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Rituximab

Monitoring Parameters

Signs/symptoms of hypersensitivity reactions (during and for 15 minutes after administration).

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Rituximab

Pharmacogenomics

Clinical Annotation for rs2229109 (ABCB1); Bleomycin, Cyclophosphamide, Doxorubicin, Prednisone, Rituximab, Vincristine and Vindesine; Lymphoma, Non-Hodgkin (Level 3 Toxicity)

ALLELE	PHENOTYPE
CC	Patients with the CC genotype and non-Hodgkin lymphoma may have a lower risk of diarrhea and vomiting when treated with R-CHOP type regimens, as compared to patients with the CT genotype. Other genetic and clinical factors may also influence risk of diarrhea and vomiting when treated with R-CHOP type regimens.
CT	Patients with the CT genotype and non-Hodgkin lymphoma may have a greater risk of diarrhea and vomiting when treated with R-CHOP type regimens, as compared to patients with the CC genotype. Other genetic and clinical factors may also influence risk of diarrhea and vomiting when treated with R-CHOP type regimens.
TT	No patients with the TT genotype were studied, but patients with the CT genotype and non-Hodgkin lymphoma may have a greater risk of diarrhea and vomiting when treated with R-CHOP type regimens, as compared to patients with the CC genotype. Other genetic and clinical factors may also influence risk of diarrhea and vomiting when treated with R-CHOP type regimens.

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Rituximab

Pharmacogenomics

Clinical Annotation for rs396991 (FCGR3A); Rituximab (Level 3 Efficacy)

ALLELE	PHENOTYPE
AA	Lymphoma patients with the AA genotype who are treated with rituximab may be less likely to have tumor shrinkage as compared to patients with the AC or CC genotype. Other genetic and clinical factors may also influence a patient's response to rituximab.
AC	Lymphoma patients with the AC genotype who are treated with rituximab may be more likely to have tumor shrinkage as compared to patients with the AA genotype. Other genetic and clinical factors may also influence a patient's response to rituximab.
CC	Lymphoma patients with the CC genotype who are treated with rituximab may be more likely to have tumor shrinkage as compared to patients with the AA genotype. Other genetic and clinical factors may also influence a patient's response to rituximab.

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Rituximab

Pharmacogenomics

Clinical Annotation for rs3957357 (GSTA1); Cyclophosphamide, Doxorubicin, Prednisone, Rituximab and Vincristine; Lymphoma, Large B-Cell, Diffuse (level 3 Efficacy)

ALLELE	PHENOTYPE
AA	Patients with the AA genotype and diffuse large B-cell lymphoma may have a longer event-free survival time when treated with the R-CHOP chemotherapy regimen as compared to patients with the GG genotype. Other genetic and clinical factors may also influence event-free survival time.
AG	Patients with the AG genotype and diffuse large B-cell lymphoma may have a longer event-free survival time when treated with the R-CHOP chemotherapy regimen as compared to patients with the GG genotype. Other genetic and clinical factors may also influence event-free survival time.
GG	Patients with the GG genotype and diffuse large B-cell lymphoma may have a shorter event-free survival time when treated with the R-CHOP chemotherapy regimen as compared to patients with the AA or AG genotype. Other genetic and clinical factors may also influence event-free survival time.

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Rituximab

Indications

1. Mature B-Cell Lymphoma
2. Non-Hodgkin Lymphoma B-cell, CD 20+; relapsed and refractory

Rituximab

Mature B-Cell Lymphoma/Leukemia
CCHE-NHL Updated May 2021

Ataxia patients LMB protocol modifications

Group A

Completely resected stage I, & completely resected abdominal stage II
2 courses R-COPAD

D0	D1	D2	D3	D4	D5	D6
Rituximab	Pred CTX VCR Adria	Pred CTX	Pred CTX	Pred	Pred	VCR

Rituximab: 375mg/m^2
Prednisone (Pred): 60 mg/m^2/day (divided into bid doses) orally (or IV) on days 1-5 inclusive then reduced to zero over 3days.
Cyclophosphamide(CTX): 125 mg/m^2 12 hourly as 15-minute infusion on D1-3 inclusive (250 mg/ m^2 /day) The first dose should be given on day 1 prior to the start of the doxorubicin infusion. Hydration should be maintained at a rate of 3000 mls/m^2/day (125 mls/m^2/hr). Continue hydration until 12 hours after the last dose of cyclophosphamide.
Adriamycin(Adria): 30mg/m^2 as 6-hour infusion, after the first dose of Cyclophosphamide.
Vincristine (VCR): 1mg/m^2 IV bolus D1 and D6. (Maximum single dose 2.0 mg).

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Rituximab

Induction
R-COPADM3-I > R-COPADM3–II

D0	D1	D2	D3	D4	D5	D6
Rituximab	Pred HDMTX VCR	Pred CTX Adria IT	Pred CTX	Pred CTX IT*	Pred	IT

Rituximab: 375mg/m^2
Prednisone (Pred): 60 mg/m2/day (divided into BID doses) orally on days 1 -5 inclusive then reduced to zero over 3 days.
Cyclophosphamide(CTX): 125 mg/m^2 12 hourly as 15-minute infusion on D2-4 inclusive (250 mg/ m^2 /day) The first dose should be given on day 1 prior to the start of the doxorubicin infusion. Hydration should be maintained at a rate of 3000 mls/m^2/day (125 mls/m^2/hr). Continue hydration until 12 hours after the last dose of cyclophosphamide.
Adriamycin (Adria): 30mg/m^2 as 6-hour infusion, after the first dose of Cyclophosphamide.
Vincristine (VCR): 1mg/m^2 IV bolus D1 (Maximum single dose 2.0 mg).
High Dose Methotrexate (HDMTX): 1g/m^2 iv infusion over 4 hours with rescue Ca leucovorin according to protocol.
IT (HC + MTX) *: Additional Intrathecal on D4 for patients with **CNS disease (Group C).**
Calcium Leucovorin: 15 mg/m^2 orally every 6 hours for a total of 12 doses (or as required depending on methotrexate levels).

Rituximab

Mature B-Cell Lymphoma/Leukemia
CCHE-NHL Updated May 2021

Consolidation

CYMI **CYMII**

D0	D1	D2	D3	D4	D5	D6	D7
Rituximab	HDMTX	Ara-C IT_1	Ara-C	Ara-C IT*	Ara-C	Ara-C	IT_2

Rituximab: 375mg/m^2

High Dose Methotrexate (HDMTX): 1g/m^2 1g/m^2 iv infusion over 4 hours with rescue Ca leucovorin according to protocol .

Calcium Leucovorin: 15 mg/m_2 orally every 6 hours for a total of 12 doses (or as required depending on methotrexate levels).

Cytrabine (Ara-C): 100 mg/m_2 in 1000 mls/m_2 dextrose saline as infusion over 24 hours. Repeat daily from Day 2-6 inclusive.

IT_1 (HC + MTX): Each dose adjusted.

IT_2 (HC + Ara-C): Each dose adjusted.

IT (HC + MTX) *: Additional Intrathecal on D4 for patients with **CNS disease (Group C)**.

Further reduction of cytotoxic chemotherapy should be suggested guided by the patient general

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Rituximab

Mature B-Cell Lymphoma/Leukemia
CCHE-NHL #4-3-2016
Roadmap updated 2021

Group B

GROUP B (Non-resected stage I & II, stage III & st IV (CNS– ve, BM < 25%)

Induction

COPADM3 (I) ⟶ **COPADM3 (II)**

Start Date (/ /) Start Date (/ /)

D -2	Day 0	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6
Rituximab	Rituximab	Pred. HDMTX VCR	Pred. CTX Adria IT	Pred. CTX	Pred. CTX	Pred.	IT

COPADM3(I) &(II):

VCR (Vincristine): 2.0 mg/m^2 (max dose 2 mg) as IV bolus on Day 1
-IT (HC+ MTX): Age adjusted on D2, 6
-Adria: 60 mg/m^2 as 6 hour infusion, after first dose of cyclophosphamide.
-Ca Leucovorin: 15 mg/m^2 orally every 6 hours for a total of 12 doses (or as required depending on methotrexate levels,
-Pred. (Prednisone): 60 mg/m^2/day (divided into bid doses) orally on Days 1 - 5 inclusive then reduced to zero over 3 days
-HDMTX (High dose Methotrexate): 3000 mg/m^2 in 500 mls/m^2 dextrose 5% as IV infusion over 3 hours on Day 1.

-CTX (Cyclophosphamide) :250 mg/m^2/dose every 12 hours (500 mg/m^2/day) as an infusion over 15 mins on days 2-4 (6 doses). The first dose is given before start of the doxorubicin infusion which is interrupted to give subsequent doses. Continue hydration at a rate of 3000 mls/m^2/day until 12 hours after the last dose of cyclophosphamide.
-Rituximab*: 375mg/m^2, Day -2,0, IV.

Notes:
**The interval between 1st and 2nd induction phase should be reduced to minimum. Each course should be given upon hematological recovery (ANC=1000, Pt=100,000).*
**CBC, Lytes, BUN, creatinine, bilirubin, SGOT/SGPT, uric and phosphorus should be done twice weekly during chemotherapy.*
**Rituximab addition criteria: Stage 3 with High LDH (above twice normal) & stage 4 CNS –ve with bone marrow involvement <25%.*

Rituximab

Mature B-Cell Lymphoma/Leukemia
CCHE-NHL #4-3-2016
Roadmap updated 2021

Group B

GROUP B (Non resected stage I & II, stage III & st IV (CNS– ve, BM < 25%)

Consolidation

CYM (I) → **CR evaluation** → **CYM (II)**

Start Date (/ /) Start Date (/ /)

Day 0	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Rituximab	HDMTX	Ara-C IT_1	Ara-C	Ara-C	Ara-C	Ara-C	IT_2

CYM(I) &(II):

HDMTX (High dose Methotrexate): 3000 mg/m2 in 500 mls/m^2 dextrose 5% as IV infusion over 3 hours on Day 1.
Ca Leucovorin: 15 mg/m2 orally every 6 hours for a total of 12 doses (or as required depending on methotrexate levels
Ara-C: 100 mg/m^2 in 1000 mls/m^2 dextrose saline as infusion over 24 hours. Repeat daily from Day 2-6 inclusive.
IT_2 (HC+ Ara-C): Age adjusted on D7
IT_3 (HC+ MTX): Age adjusted on D2

Ca Leucovorin: 15 mg/m^2 orally every 6 hours for a total of 12 doses (or as required depending on methotrexate levels.

-**Rituximab***: 375mg/m^2, Day 0, IV.

Notes:

**The interval between 1st and 2nd consolidation phase should be reduced to minimum. Each course should be given upon hematological recovery (ANC=1000, Pt=100,000).*
**CBC, Lytes, BUN, creatinine, bilirubin, SGOT/SGPT, uric and phosphorus should be done twice weekly during chemotherapy*
**CR evaluation after CYM (I) including CSF exam if initially positive, BM exam, PET CT and imaging studies of 1ry tumor site should be done after count recovery*
-if not CR upgrade to group C

****Rituximab addition criteria: Stage 3 with High LDH (above twice normal) & stage 4 CNS –ve with bone marrow involvement <25%.***

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Rituximab

Mature B-Cell Lymphoma/Leukemia
CCHE-NHL #4-3-2016
Roadmap updated 18-8-2022

Group C (B-ALL/L3 with >25% BM blasts/CNS involvement/Group B COP failures i.e., <20%reduction)

Induction

COPADM8 (I)
Start Date (/ /)

D -2	D 0	D1	D2	D3	D4	D5	D6	D7
Rituximab	Rituximab	Pred. HDMTX VCR	Pred. **CTX1** Adria CaLeu IT	Pred. **CTX1**	Pred. **CTX1** IT	Pred.	Pred. IT	Pred.

COPADM8 (II)
Start Date (/ /)

D -2	D 0	D1	D2	D3	D4	D5	D6	D7
Rituximab	Rituximab	Pred. HDMTX VCR	Pred. **CTX 2** Adria CaLeu IT	Pred. **CTX 2**	Pred. **CTX 2** IT	Pred.	Pred. IT	Pred.

-VCR (Vincristine): 2.0 mg/m² (max dose 2 mg) as IV bolus on Day 1
-IT (HC+ MTX+ Ara-C): Age adjusted on Days 2, 4, 6. Administer Day 2 IT 12-24 hours after HDMTX starts and before leucovorin rescue begins.
- Adria (Doxorubicin): 60 mg/m² as 6 hour infusion, after first dose of cyclophosphamide on Day 2.
-Ca Leucovorin: 15 mg/m2 orally or IV every 6 hours for a total of 12 doses (or as required depending on methotrexate levels. Begin at 24 hours from the start of MTX infusion.
-Prednisone: 60 mg/m²/day (divided into bid doses) orally on Days 1 - 7.
-*HDMTX (High dose Methotrexate): 8000 mg/m² in 500 mls/m² dextrose 5% as IV infusion over 4 hours on Day 1. **Over 24h starting from 2nd COPADM for CSF +ve patients only.**
Trimethoprim (150 mg/m²/day) plus sulfamethoxazole (750 mg/m²/day) (TMP-SMZ) *in two divided doses on 3 consecutive days weekly to be started 48 hours after elimination of HDMTX.*

- Rituximab: 375 mg/m2, day -2 and day 0 , I.V infusion

CTX 1(Cyclophosphamide) :250 mg/m²/dose every 12 hours (500 mg/m²/day) as an infusion over 15 minutes on Days 2-4 (6 doses). The first dose is given before start of the doxorubicin infusion. Continue hydration at a rate of 3000 mls/m²/day until 12 hours after the last dose of cyclophosphamide.

CTX 2(Cyclophosphamide) :500 mg/m²/dose every 12 hours (1000 mg/m²/day) as an infusion over 15 minutes on Days 2-4 (6 doses). The first dose is given before start of the doxorubicin infusion. Continue hydration until 12 hours after the last dose of cyclophosphamide.

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Rituximab

Mature B-Cell Lymphoma/Leukemia
CCHE-NHL #4-3-2016
Roadmap updated 18-8-2022

Group C (B-ALL/L3 with >25% BM blasts/CNS involvement/Group B COP failures i.e., <20%reduction)

Consolidation

CYVE(I) Start Date (/ /) —*HDMTX→ **CYVE(II)** Start Date (/ /) → **Evaluation** → **CR** → **Continue on protocol**

Day 0	Day 1	Day 2	Day 3	Day 4	Day 5
Rituximab	Ara-C	Ara-C HDAra VP-16	Ara-C HDAra VP-16	Ara-C HDAra VP-16	Ara-C HDAra VP-16

Evaluation → **Residual mass** → **Biopsy** → **-VE** → **Continue on protocol**
Biopsy → **+VE** → **Off the protocol: for Combined Clinic**

CYVE(I) &(II):
Ara-C: 50 mg/m^2 by continuous infusion over 12 hours in dextrose saline. Repeat daily x 5(Days 1 to 5 inclusive)
Vp-16: 200 mg/m^2 in 500 mls/m^2 dextrose saline as IV infusion over 2 hours daily x 4 doses (Days 2- 5 inclusive). Etoposide starts 3 hours after the end of high dose cytarabine (HDAra).
***HDMTX:** between CYVE I and II over 4-hour infusion, **for CNS+ve patients only.**
HDAra(High dose Ara-C): 3000 mg/m^2 as IV infusion over 3 hours, to start at the end of the 12 hour infusion of cytarabine at the end of the first dose Ara-C.

Rituximab: 375mg/m2, day 0, I.V infusion

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Brentuximab Vedotin

Mechanism of Action

Brentuximab Vedotin is an antibody drug conjugate (ADC) directed at CD30 consisting of 3 components:

1) a CD30-specific chimeric IgG1 antibody cAC10;
2) a microtubule-disrupting agent, monomethylauristatin E (MMAE); and
3) a protease cleavable dipeptide linker (which covalently conjugates MMAE to cAC10).

The conjugate binds to cells which express CD30, and forms a complex which is internalized within the cell and releases MMAE. MMAE binds to the tubules and disrupts the cellular microtubule network, inducing cell cycle arrest (G2/M phase) and apoptosis.

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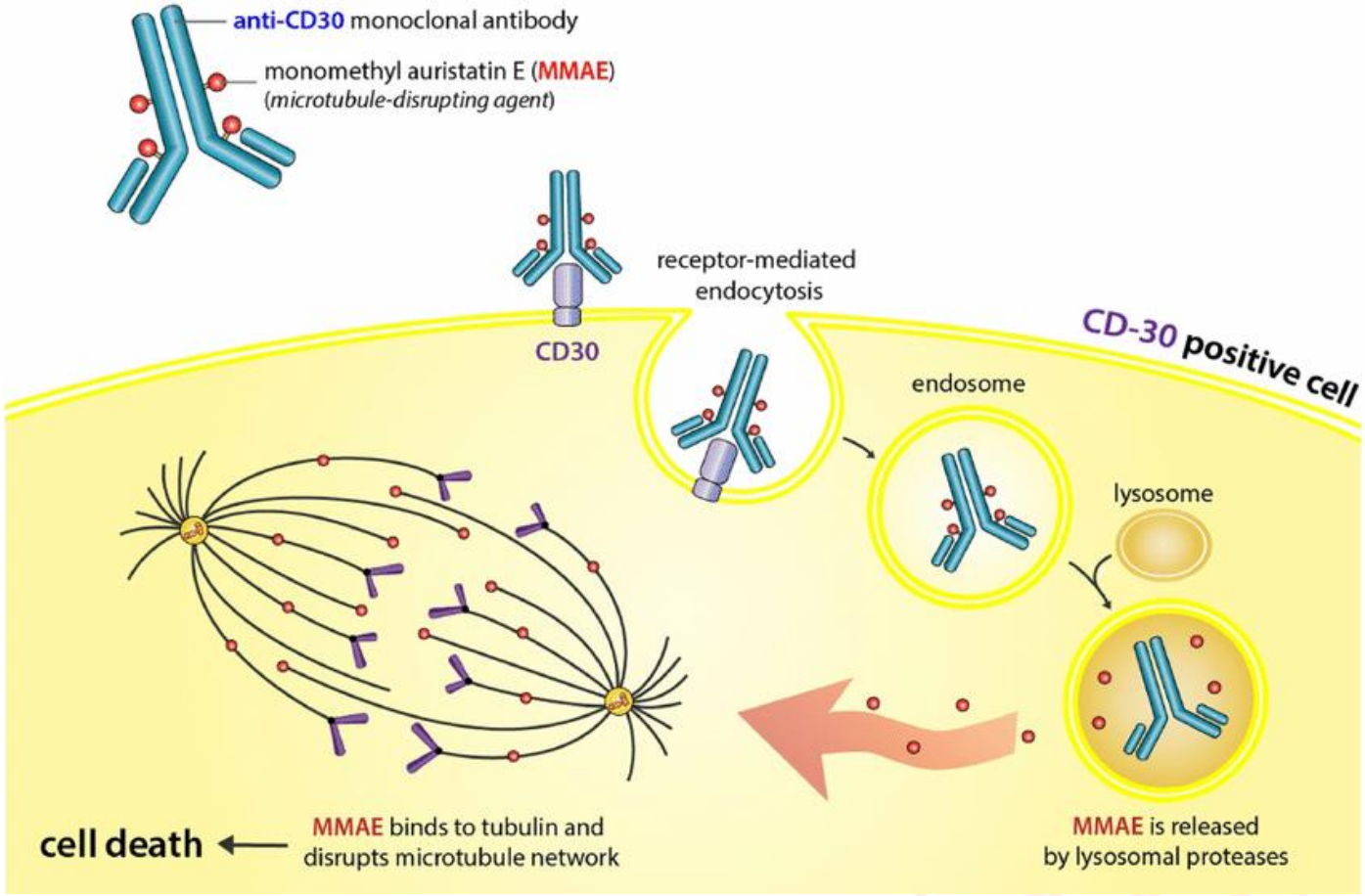
Brentuximab Vedotin



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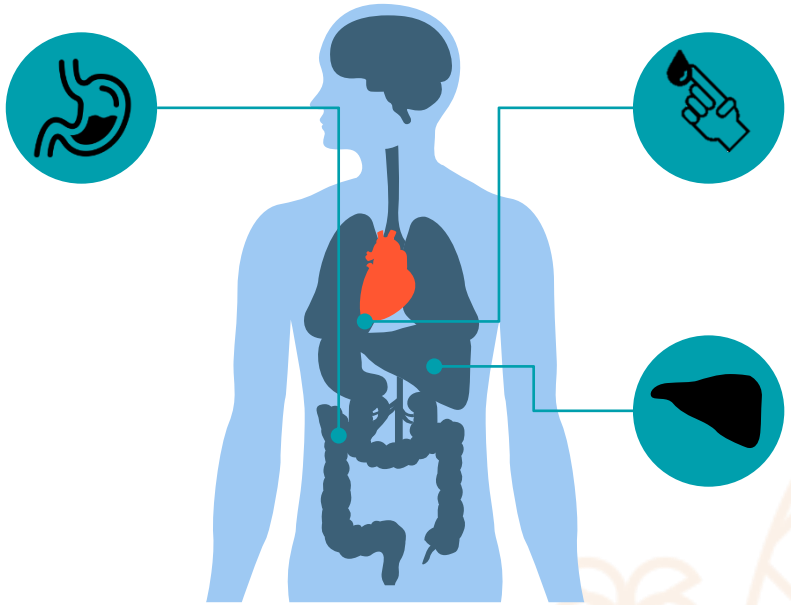
Brentuximab Vedotin

Toxicities & Management

GI Toxicity

Prompt diagnostic evaluation and management should be performed if new or worsening GI symptoms (including severe abdominal pain) occur.



Hyperglycemia

As normal hyperglycemia management but monitoring is enough.

Hepatotoxicity

Delay, dose adjustments or discontinuation of the drug.

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Brentuximab Vedotin

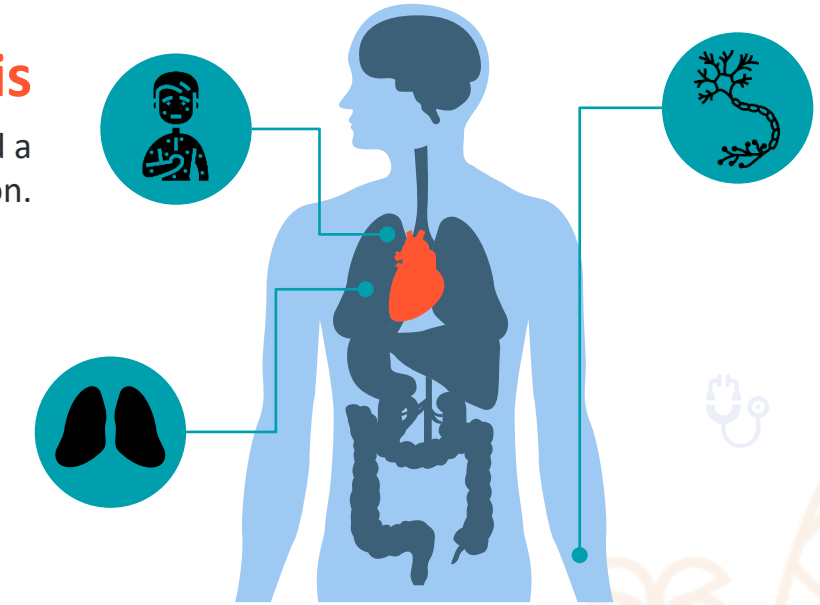
Toxicities & Management

Infusion Reactions/ Anaphylaxis

Paracetamol, an Antihistamine and a Corticosteroid as pre-medication.

Pulmonary Toxicity

Discontinuing the offending drug and administering Corticosteroid therapy either orally or intravenously according to severity.



Peripheral Neuropathy

Delay, dose adjustments or discontinuation of the drug.

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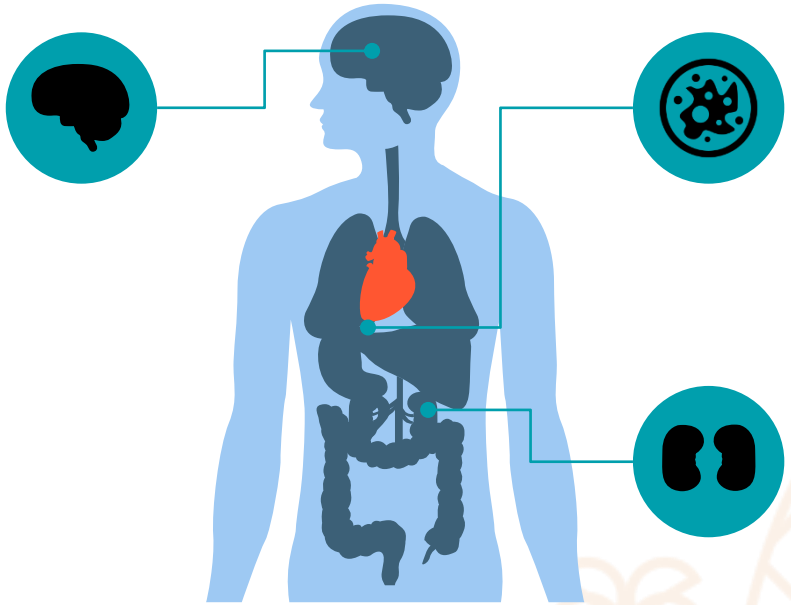
Brentuximab Vedotin

Toxicities & Management

PML

If PML is confirmed the drug must be permanently discontinued.



Tumor Lysis Syndrome

Administer prophylaxis (anti-hyperuricemic therapy, aggressive hydration) in patients at high risk. Correct electrolyte abnormalities and administer supportive care as indicated.

Renal Impairment

Dosage Adjustment to 1.2 mg/kg administered as an intravenous infusion over 30 minutes every 3 weeks with close monitoring.

Brentuximab Vedotin

Drug Interactions

Bleomycin (Risk X: Avoid Combination) - Brentuximab Vedotin may enhance the adverse/toxic effect of Bleomycin. Specifically, the risk for pulmonary toxicity may be increased.

Due to the risk for pulmonary injury, concurrent use with bleomycin is contraindicated. Pulmonary symptoms/toxicities reported with brentuximab in combination with ABVD consisted of cough, dyspnea, and interstitial infiltration/inflammation.

Most patients responded to corticosteroids.

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Brentuximab Vedotin

Drug Interactions

Strong CYP3A4 Inducers and Inhibitors (Risk C: Monitor Therapy) – May decrease/increase the serum concentration of Brentuximab Vedotin. Specifically, concentrations of the active MMAE component may be decreased/increased.

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Brentuximab Vedotin

Monitoring Parameters

- CBC with differential prior to each dose (more frequently if clinically indicated).
- Monitor for infusion reaction, TLS, signs of infection, and for signs of neuropathy (hypoesthesia, hyperesthesia, paresthesia, discomfort, burning sensation, or neuropathic pain or weakness).

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Brentuximab Vedotin

Indications

Hodgkin Lymphoma, Classic; High-Risk:

IV: 1.8 mg/kg/dose for Children ≥2 years and Adolescents; Maximum Dose: 180 mg/dose

Administer every 3 weeks with each cycle of chemotherapy up to 5 doses total. For patients weighing >100 kg, calculate dose based on a weight of 100 kg. For use in previously untreated patients and administered in combination with chemotherapy along with Filgrastim.

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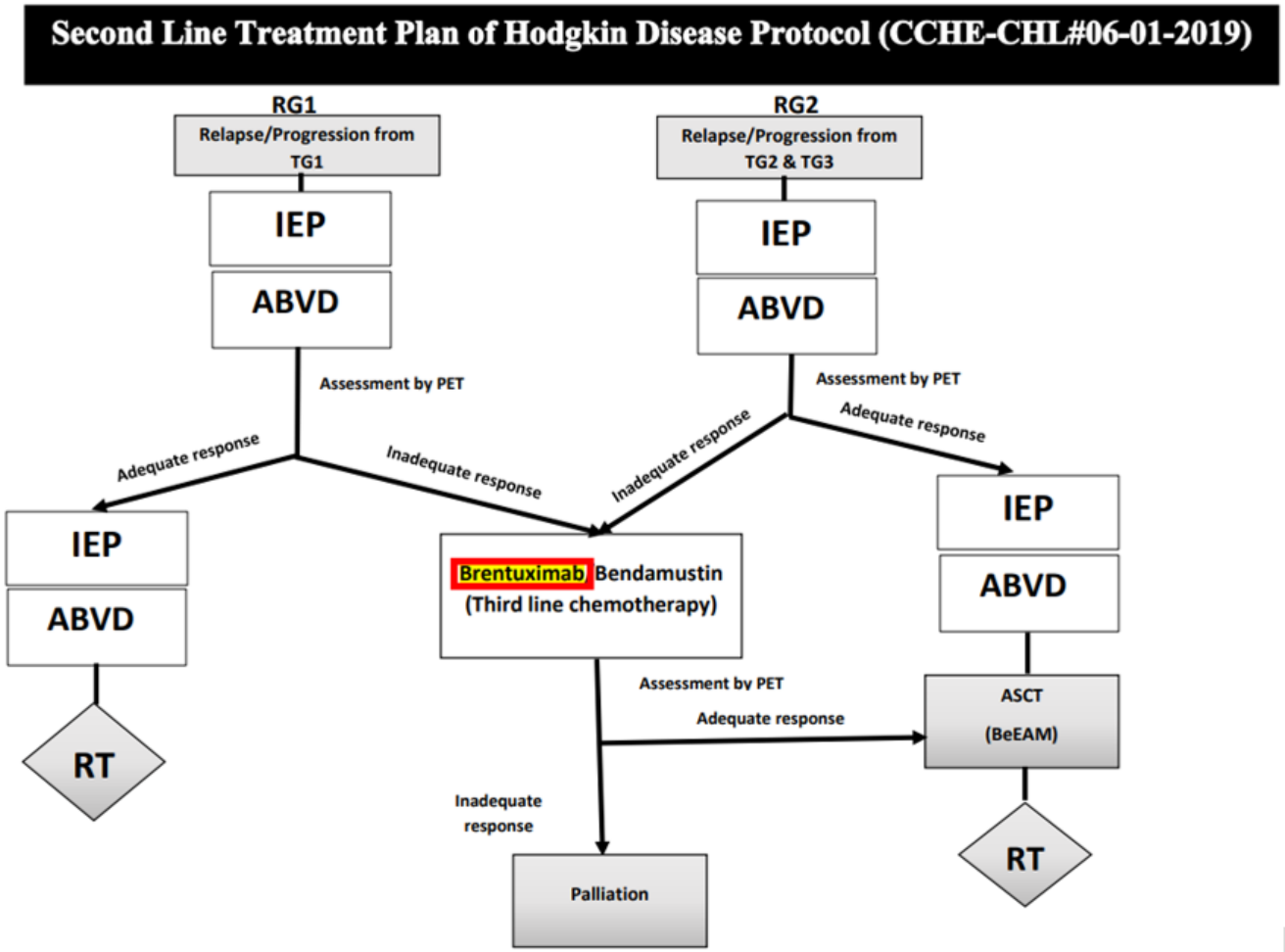
Brentuximab Vedotin



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Egypt Cancer Network Canada
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Children's Cancer Hospital Foundation - Egypt
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Brentuximab Vedotin

ABVD
Adriamycin (Doxorubicin): 25mg/m^2 iv bolus (D_1, D_{15})
Bleomycin: 10,000iu/m^2 200mls N.Saline/30mins (D_1, D_{15})
Vinblastine: 6mg/m^2 iv bolus (D_1, D_{15})
Dacarbazine: 375mg/m^2 250mls N. Saline/1hr (D_1, D_{15})

IEP
• **Ifosfamide:** 2000 mg/m^2 i.v., 22-hour infusion (D_1-D_5)
• **Etoposide/Etopophos:** 125 mg/ m^2 i.v., 1-2 hour infusion (D_1-D_5)
• **Prednisone/ Prednisolone:** 100 mg/ m^2 p.o. in 3 doses (D_1-D_5)

Brentuximab/Bendamustin
Brentuximab Vedotin: 1.8mg/kg iv bolus (D_1)
Bendamustine: 90 mg/m^2 IV day (D_2, D_3)

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Thank You

Your Feedback will be much Appreciated!

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