Polatuzumab Vedotin, riTUXimab, cycloPHOSphamide, DOXOrubicin and prednisoLONE Therapy

INDICATIONS FOR USE:

INDICATION	ICD10	Regimen Code	HSE approved reimbursement status*
Polatuzumab Vedotin in combination with riTUXimab, cycloPHOSphamide, DOXOrubicin and prednisoLONE for the treatment of adult patients with previously untreated diffuse large B-cell lymphoma (DLBCL).	C83, C85	00833a	ODMS 01/08/2024

*this applies to post 2012 indications

TREATMENT:

The starting dose of the drugs detailed below may be adjusted downward by the prescribing clinician, using their independent medical judgement, to consider each patients individual clinical circumstances.

Polatuzumab vedotin, riTUXimab, cycloPHOSphamide, DOXOrubicin and prednisoLONE are administered on day 1 of a 21 day cycle for 6 cycles. Two further cycles of riTUXimab may be administered at the discretion of the prescribing Consultant.

Facilities to treat anaphylaxis MUST be present when systemic anti-cancer therapy (SACT) is administered.

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Day	Drug	Dose	Route	Diluent & Rate	Cycle
1-5	prednisoLONE	100mg(**)	PO		1-6
1	riTUXimab	375mg/m^2	IV infusion[1] Observe post infusion[1]	500mL 0.9% NaCl at a maximum rate of 400mg/hour[1]	1-6[2]
1	Polatuzumab vedotin	1.8mg/kg	IV infusion	100mL 0.9% NaCl over 90 minutes[3,4,5]	1-6
1	DOXOrubicin[6]	50mg/m^2	IV Bolus	Into the side arm of a fast running 0.9% NaCl infusion	1-6
1	cycloPHOSphamide	750mg/m^2	IV infusion[7]	250 mL 0.9% NaCl over 30 minutes	1-6
6 onwards (For 5-7 days)	G-CSF[8]	5mcg/kg	SC (Round to nearest whole syringe)	Daily injection until ANC >1x10^9/L for 2 consecutive days	1-6

[1] See Table 1: Guidance for administration of riTUXimab.

[2] An additional 2 cycles may be administered at the discretion of the prescribing consultant.

[3] Polatuzumab vedotin should be diluted to a concentration of 0.72-2.7mg/mL.

[4] Polatuzumab vedotin must be administered using a sterile, non-pyrogenic, low protein binding 0.2 micron or 0.22 micron filter.

[5] The initial dose of polatuzumab vedotin should be administered over 90 minutes. Patients should be monitored during the infusion and for at least 90 minutes following completion of the initial dose. If well tolerated subsequent infusions may be given over 30 minutes and the patients monitored for a further 30 minutes after the end of the infusion.

[6] Lifetime cumulative dose of DOXOrubicin is 450mg/m^2.
In establishing the maximal cumulative dose of an anthracycline, consideration should be given to the risk factors outlined below[i] and to the age of the patient.

[7] cycloPHOSphamide may also be administered as an IV bolus over 5-10mins.

[8] G-CSF support is required with this regimen **(Refer to local policy or see Suggested support above)**

**Alternative steroid regimens may be used at consultant discretion.

Note: Administration volumes and fluids have been standardised to facilitate electronic prescribing system builds.

Table 1: Guidance for administration of riTUXimab

The recommended initial rate for infusion is 50 mg/hr; after the first 30 minutes, it can be escalated in 50 mg/hr increments every 30 minutes, to a maximum of 400 mg/hr. Subsequent infusions can be infused at an initial rate of 100 mg/hr, and increased by 100 mg/hr increments at 30 minute intervals, to a maximum of 400 mg/hr. Development of an allergic reaction may require a slower infusion rate. See Hypersensitivity/Infusion reactions under Adverse Effects/Regimen Specific Complications below. Any deviation from the advised infusion rate should be noted in local policies.
Recommended Observation period: Patients should be observed for at least six hours after the start of the first infusion and for two hours after the start of the subsequent infusions for symptoms like fever and chills or other infusion-related symptoms. Any deviation should be noted in local policies.
riTUXimab should be diluted to a final concentration of 1-4mg/ml.

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Rapid rate infusion schedule [ii]**See NCCP guidance here**
If patients did **not** experience a serious infusion related reaction with their first or subsequent infusions of a dose of riTUXimab administered over the standard infusion schedule, a more rapid infusion can be administered for second and subsequent infusions using the same concentration as in previous infusions. Initiate at a rate of 20% of the total dose for the first 30 minutes and then 80% of the dose for the next 60 minutes (total infusion time of 90 minutes). If the more rapid infusion is tolerated, this infusion schedule can be used when administering subsequent infusions.
Patients who have clinically significant cardiovascular disease, including arrhythmias, or previous serious infusion reactions to any prior biologic therapy or to riTUXimab, should not be administered the more rapid infusion.

ELIGIBILITY:

- Indications as above
- IPI score of 2 to 5
- ECOG 0-2
- Adequate haematological, renal and liver status

Table 2: International Prognostic Index (IPI) Score

Pre-treatment Characteristic	Value	Score
Age	>60	1 point each
Tumour Stage	III/IV	
Extranodal sites	>1	
Performance status	≥2	
Serum LDH	>1 x ULN	
Risk Group		
IPI Score 0-1	Low risk	
IPI Score 2	Low intermediate risk	
IPI Score 3	High intermediate risk	
IPI Score 4-5	High risk	

EXCLUSIONS:

- Hypersensitivity to polatuzumab vedotin, riTUXimab, cycloPHOSphamide, DOXOrubicin, prednisoLONE or any of the excipients
- A cumulative life-long dose of 450mg/m^2 of DOXOrubicin should only be exceeded with extreme caution as there is a risk of irreversible congestive heart failure
- Active, severe infections (e.g. tuberculosis, sepsis and opportunistic infections)
- Patients in a severely immunocompromised state
- Pregnancy or Lactation
- Primary or secondary CNS lymphoma
- Current Grade >1 peripheral neuropathy
- AST or ALT > 2.5 x upper limit of normal and total bilirubin > 1.5 x upper limit of normal

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PRESCRIPTIVE AUTHORITY:

The treatment plan must be initiated by a Consultant Haematologist working in the area of haematological malignancies

TESTS:

Baseline tests:

- FBC, renal and liver profile
- LDH, uric acid, SPEP
- ECG
- MUGA or ECHO should be considered prior to the administration of DOXOrubicin
- Blood glucose
- Assessment of neuropathy status
- Virology screen - Hepatitis B (HBsAg, HBcoreAb) & C, HIV*
  *See Regimen Specific Complications

Regular tests:

- FBC, renal and liver profile and LDH prior to each cycle
- Evaluate for peripheral neuropathy prior to each cycle
- MUGA or ECHO as clinically indicated
- Assessment of neuropathy status

Disease monitoring:

Disease monitoring should be in line with the patient's treatment plan and any other test/s as directed by the supervising Consultant.

DOSE MODIFICATIONS:

- Any dose modification should be discussed with a Consultant
- No dose reductions of riTUXimab are recommended

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Haematological:

Table 3: Dose modification in haematological toxicity

ANC ($x10^9$/L)	Dose	Platelets ($x10^9$/L)	Dose
≥1	100%	≥75	100%
<1	Hold all treatment until ANC recovers to >1. • If ANC recovers to ≥1 on or before day 7, resume all treatment without any additional dose reductions • If ANC recovers to >1 after day 7: ○ resume all treatment, consider a dose reduction of cycloPHOSphamide and/or DOXOrubicin by 25-50% ○ If cycloPHOSphamide and/or DOXOrubicin are already reduced by 25%, consider reducing one or both agents to 50%	<75	Hold all treatment until platelets recover to >75. • If platelets recover to >75 on or before day 7, resume all treatment without any additional dose reductions • If platelets recover to >75 after day 7: ○ restart all treatment, consider a dose reduction of cycloPHOSphamide and/or DOXOrubicin by 25-50% ○ If cycloPHOSphamide and/or DOXOrubicin are already reduced by 25%, consider reducing one or both agents to 50%

Renal and Hepatic Impairment:

Table 4: Dose modification in renal and hepatic impairment

Renal Impairment		Hepatic Impairment	
riTUXimab	Renal impairment: no need for dose adjustment is expected Haemodialysis: no dose adjustment is needed	No need for dose adjustment is expected	
Polatuzumab vedotin	No dose adjustment is required in patients with CrCl ≥ 30 mL/min. Due to limited data a recommended dose has not been determined for patients with CrCl <30mL/min.	**Mild** (bilirubin greater than upper limit of normal [ULN) to less than or equal to 1.5 × ULN or aspartate transaminase (AST) greater than ULN).	No adjustment in the starting dose is required
		Moderate or severe (bilirubin greater than 1.5 × ULN)	Polatuzumab vedotin should be avoided. There is limited data for use in moderate to severe impairment

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cycloPHOSphamide	**CrCl (ml/min)**	**Dose**	Mild and moderate: no need for dose adjustment is expected. Severe: not recommended, due to risk of reduced efficacy	
	≥30	no dose adjustment is needed		
	10-29	consider 75% of the original dose		
	<10	not recommended, if unavoidable consider 50% of the original dose		
	Haemodialysis	not recommended, if unavoidable consider 50% of the original dose		
DOXOrubicin	**CrCl (ml/min)**	**Dose**	**Bilirubin (micromol/L)**	**Dose**
	>10	no dose adjustment is needed	20-50	50% of the original dose
	<10	No need for dose adjustment is expected	51-86	25% of the original dose
	Haemodialysis	75% of original dose may be considered	>86 or Child-Pugh C	Not recommended
riTUXimab, cycloPHOSphamide, DOXOrubicin: Renal and hepatic – Giraud et al 2023 Polatuzumab Vedotin: Renal and hepatic – As per SmPC				

Management of adverse events:

Table 5: Dose modifications of polatuzumab vedotin for peripheral neuropathy (PN)

Severity of PN on Day 1 of any cycle	Recommended dose modification
Grade 2[a]	**Sensory neuropathy:** • Reduce polatuzumab vedotin to 1.4 mg/kg • If Grade 2 persists or recurs at Day 1 of a future cycle, reduce polatuzumab vedotin to 1.0 mg/kg • If already at 1.0 mg/kg and Grade 2 occurs at Day 1 of a future cycle, discontinue polatuzumab vedotin **Motor neuropathy:** • Withhold polatuzumab vedotin dosing until improvement to Grade ≤1 • Restart polatuzumab vedotin at the next cycle at 1.4 mg/kg • If already at 1.4 mg/kg and Grade 2 occurs at Day 1 of a future cycle, withhold polatuzumab vedotin dosing until improvement to Grade ≤ 1. Restart polatuzumab vedotin at 1.0 mg/kg • If already at 1.0 mg/kg and Grade 2 occurs at Day 1 of a future cycle, discontinue polatuzumab vedotin If concurrent sensory and motor neuropathy, follow the most severe restriction recommendation above

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Grade 3[a]	**Sensory neuropathy:** • Withhold polatuzumab vedotin dosing until improvement to Grade ≤ 2. • Reduce polatuzumab vedotin to 1.4 mg/kg • If already at 1.4 mg/kg, reduce polatuzumab vedotin to 1.0 mg/kg. If already at 1.0 mg/kg, discontinue polatuzumab vedotin **Motor neuropathy:** • Withhold polatuzumab vedotin dosing until improvement to Grade ≤ 1 • Restart polatuzumab vedotin at the next cycle at 1.4 mg/kg • If already at 1.4 mg/kg and Grade 2–3 occurs, withhold polatuzumab vedotin dosing until improvement to Grade ≤ 1. Restart polatuzumab vedotin at 1.0 mg/kg • If already at 1.0 mg/kg and Grade 2–3 occurs, discontinue polatuzumab vedotin If concurrent sensory and motor neuropathy, follow the most severe restriction recommendation above
Grade 4	Discontinue polatuzumab vedotin

[a] R-CHP may continue to be administered

Table 6: Dose modifications of polatuzumab vedotin for infusion-related reactions (IRRs)

Severity of IRR on Day 1 of any cycle	Recommended dose modification
Grade 1–3 IRR	• Interrupt polatuzumab vedotin infusion and give supportive treatment • For the first instance of Grade 3 wheezing, bronchospasm, or generalised urticaria, permanently discontinue polatuzumab vedotin • For recurrent Grade 2 wheezing or urticaria, or for recurrence of any Grade 3 symptoms, permanently discontinue polatuzumab vedotin • Otherwise, upon complete resolution of symptoms, infusion may be resumed at 50% of the rate achieved prior to interruption. In the absence of infusion-related symptoms, the rate of infusion may be escalated in increments of 50 mg/hour every 30 minutes • For the next cycle, infuse polatuzumab vedotin over 90 minutes. If no infusion related reaction occurs, subsequent infusions may be administered over 30 minutes. Administer premedication for all cycles
Grade 4 IRR	• Stop polatuzumab vedotin infusion immediately • Give supportive treatment • Permanently discontinue polatuzumab vedotin

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SUPPORTIVE CARE:

EMETOGENIC POTENTIAL:

- As outlined in NCCP Classification Document for Systemic AntiCancer Therapy (SACT) Induced Nausea and Vomiting- Available on the NCCP website

Polatuzumab vedotin: Low **(Refer to local policy)**
riTUXimab: Minimal **(Refer to local policy)**
DOXOrubicin/cycloPHOSphamide: High **(Refer to local policy)**

For information:
Within NCIS regimens, anti-emetics have been standardised by the Medical Oncologists and Haemato-oncologists and information is available in the following document:

- NCCP Supportive Care Antiemetic Medicines for **Inclusion in NCIS** (Medical Oncology) - Available on the NCCP website
- NCCP Supportive Care Antiemetic Medicines for **Inclusion in NCIS** (Haemato-oncology) - Available on the NCCP website

PREMEDICATIONS:

- Premedication consisting of an anti-pyretic and an anti-histamine should always be administered before each infusion of riTUXimab and polatuzumab vedotin. Please see Tables 7 and 8 for suggested pre-medications.

Table 7: Suggested pre-medications prior to infusion of riTUXimab and polatuzumab vedotin (cycles 1-6) :

Drugs	Dose	Route
Paracetamol	1g	PO 60 minutes prior to riTUXimab infusion
Chlorphenamine	10mg	IV bolus 60 minutes prior to riTUXimab infusion
Ensure glucocorticoid component of the treatment regimen (prednisoLONE 100mg) is given at least 60 minutes prior to riTUXimab infusion.		

Table 8: Suggested pre-medications prior to infusion of riTUXimab (cycles 7 and 8 – if required) :

Drugs	Dose	Route
Paracetamol	1g	PO 60minutes prior to riTUXimab infusion
Chlorphenamine	10mg	IV bolus 60minutes prior to riTUXimab infusion
Hydrocortisone	100mg	IV bolus 60 minutes prior to riTUXimab infusion

OTHER SUPPORTIVE CARE:

- Tumour lysis syndrome prophylaxis **(Refer to local policy)**
- Anti-viral prophylaxis **(Refer to local policy)**
- Anti-fungal prophylaxis (Avoid the concurrent use of azoles and vincristine) **(Refer to local policy)**
- Proton-Pump inhibitor during steroid treatment **(Refer to local policy)**
- PJP prophylaxis **(Refer to local policy)**
- Patients should have an increased fluid intake of 2-3 litres on day 1 and 2 to prevent haemorrhagic cystitis associated with cycloPHOSphamide

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- Bone prophylaxis should be considered **(Refer to local policy)**
- Women of childbearing potential should be advised to use effective contraception during treatment with polatuzumab vedotin and for at least 9 months after the last dose. Male patients with female partners of childbearing potential should be advised to use effective contraception during treatment with polatuzumab vedotin and for at least 6 months after the last dose.

ADVERSE EFFECTS

- Please refer to the relevant Summary of Product Characteristics (SmPC) for details.
- Polatuzumab vedotin is subject to additional monitoring. Healthcare professionals are asked to report any suspected adverse reactions.

REGIMEN SPECIFIC COMPLICATIONS:

- **Hepatitis B Reactivation**: Patients should be tested for both HBsAg and HBcoreAb as per local policy. If either test is positive, such patients should be treated with anti-viral therapy **(Refer to local infectious disease policy).** These patients should be considered for assessment by hepatology.

DRUG INTERACTIONS:

- Current SmPC and drug interaction databases should be consulted for information.

COMPANY SUPPORT RESOURCES/Useful Links:

Please note that this is for information only and does not constitute endorsement by the NCCP

riTUXimab

- Please refer to the HPRA website (www.hpra.ie) for the individual product for list of relevant support resources.

REFERENCES:

1. Tilly H, et al. Polatuzumab Vedotin in Previously Untreated Diffuse Large B-Cell Lymphoma. N Engl J Med 2022; 386:351-363
2. The International Non-Hodgkin's Lymphoma Prognostic Factors Project. A Predictive Model for Aggressive Non-Hodgkin's Lymphoma. N Engl J Med 1993;329:987-994
3. Giraud EL, de Lijster B, Krens SD, Desar IME, Boerrigter E, van Erp NP. Dose recommendations for anticancer drugs in patients with renal or hepatic impairment: an update. Lancet Oncol 2023; 24: e229.
4. NCCP Classification Document for Systemic Anti-Cancer Therapy (SACT) Induced Nausea and Vomiting. V5 2023. Available at: https://www.hse.ie/eng/services/list/5/cancer/profinfo/chemoprotocols/nccp-classification-document-for-systemic-anti-cancer-therapy-sact-induced-nausea-and-vomiting.pdf

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5. Polatuzumab vedotin (Polivy®) Summary of Product Characteristics. Accessed June 2024. Available at: https://www.ema.europa.eu/en/documents/product-information/polivy-epar-product-information_en.pdf
6. riTUXimab Summary of Product Characteristics. Accessed June 2024. Available at: https://www.ema.europa.eu/en/documents/product-information/mabthera-epar-product-information_en.pdf
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Version	Date	Amendment	Approved By
1	18/07/2024		NCCP Lymphoid SACT CAG
1a	01/08/2024	Reimbursement status updated	NCCP
2	22/08/2024	Addition of table to clarify riTUXimab pre-meds in cycles 7 and 8.	NCCP Lymphoid SACT CAG
3	06/11/2024	Amended order of drug administration (DOXOrubicin moved up above cycloPHOSphamide)	NCCP Lymphoid SACT CAG
3a	08/05/2025	Update to ICD-10 code.	NCCP

Comments and feedback welcome at oncologydrugs@cancercontrol.ie.

[i] Cardiotoxicity is a risk associated with anthracycline therapy that may be manifested by early (acute) or late (delayed) effects.
Risk factors for developing anthracycline-induced cardiotoxicity include:
• high cumulative dose, previous therapy with other anthracyclines or anthracenediones
• prior or concomitant radiotherapy to the mediastinal/pericardial area
• pre-existing heart disease
• concomitant use of other potentially cardiotoxic drugs
In establishing the maximal cumulative dose of an anthracycline, consideration should be given to the risk factors above and to the age of the patient

[ii] The rapid infusion is an unlicensed means of administration of riTUXimab for the indication described above, in Ireland. Patient's should be informed of this and consented to treatment in line with the hospital's policy on the use of unlicensed medication and unlicensed or "off label" indications. Prescribers should be fully aware of their responsibility in communicating any relevant information to the patient and also ensuring that the unlicensed or "off label" means of administration has been acknowledged by the hospital's Drugs and Therapeutics Committee, or equivalent, in line with hospital policy.

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