



Intrathecal Methotrexate for haematological malignancies

INDICATIONS FOR USE:

INDICATION	ICD10	Regimen Code	HSE approved Reimbursement Status*
Central Nervous System (CNS) prophylaxis and treatment in patients with Acute Myeloid Leukaemia (AML)	C92	00869a	N/A
CNS treatment in patients with Acute Lymphoblastic Leukaemia (ALL)	C91	00869b	N/A
Prophylaxis and treatment of CNS disease in Non-Hodgkin Lymphomas	C83, C85	00869c	N/A

^{*} 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 patient's individual clinical circumstances.

CSF should be sampled prior to intrathecal (IT) administration.

The day of administration will depend on the indication and concurrent systemic anti-cancer therapy (SACT) regimen.

Facilities to treat anaphylaxis MUST be present when the SACT is administered

Refer to NCCP Guidance on the Safe Use of Intrathecal Chemotherapy in the Treatment of Cancer https://www.hse.ie/eng/services/list/5/cancer/profinfo/medonc/safetyreview/itcguidance.pdf There should be a register for the Hospital of named personnel who are trained and certified competent to participate in intrathecal chemotherapy tasks.

Day	Drug	Dose	Route	Diluent & Rate	Cycle
1 ^a	Methotrexate	12.5mg	Intrathecal	N/A	As per concurrent SACT regimen
^a Day of administration may vary depending on concurrent SACT regimen or at the discretion of the treating physician.					

ELIGIBILITY:

• Indications as above

EXCLUSIONS:

- Hypersensitivity to methotrexate or any of the excipients
- Raised intracranial pressure (ICP) or impending herniation
- Local Infection at the puncture site

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Tumour Group: Lymphoma and Other Lymphoproliferative Disorders, Leukaemia and Myeloid Neoplasms NCCP Regimen Code: 00869	IHS Contributor: Amjad Hayat	Page 1 of 4

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Severe thrombocytopenia and coagulopathy that is not correctable

PRESCRIPTIVE AUTHORITY:

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

TESTS:

Baseline tests:

- FBC, renal and liver profile
- Coagulation screen as per local policy.

Regular tests:

• Coagulation screen as per local policy prior to each dose.

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:

Dose modifications are not usually recommended.

SUPPORTIVE CARE:

EMETOGENIC POTENTIAL:

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

Antiemetics are not routinely required with this regimen (Refer to local policy)

For information:

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

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

PREMEDICATIONS: Not usually required.

OTHER SUPPORTIVE CARE:

 Anticoagulants and antiplatelets can increase the risk of bleeding when intrathecal therapy is given during lumbar puncture. Consider the risk of bleeding versus the risk of thrombosis and hold

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anticoagulants and antiplatelets prior to intrathecal treatment as per local guidelines.

- Refer to local guidelines for management of patients post lumbar puncture.
- Headaches may occur post lumbar puncture. Analgesic cover should be considered.

ADVERSE EFFECTS:

Please refer to the relevant Summary of Product Characteristics (SmPC) for full details.

REGIMEN SPECIFIC COMPLICATIONS:

- Post procedure: headache, dizziness, bruising, swelling and discomfort at injection site; less common – arachnoiditis, fever, infection and rarely leucoencephalopathy
- Intrathecal methotrexate can reach the blood stream and can have systemic effects.
- Prolonged cytopenias are known to occur in rare cases following intrathecal administration which may affect stem cell harvesting.

DRUG INTERACTIONS:

• Current drug interaction databases should be consulted for more information.

REFERENCES:

- 1. Kuitunen H, et al. Impact of central nervous system (CNS) prophylaxis on the incidence of CNS relapse in patients with high-risk diffuse large B cell/follicular grade 3B lymphoma. Annals of Hematology, 2020. 99: 1823–1831.
- 2. McKay P, et al. The prevention of central nervous system relapse in diffuse large B-cell lymphoma: a British Society for Haematology good practice paper. British Journal of Haematology, 2020. 190: 708–714
- 3. McMillan A, et al. Guideline on the prevention of secondary central nervous system lymphoma:
 British Committee for Standards in Haematology. British Journal of Haematology, 2013. 163: 168–
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- 4. Dodd KC, Emsley HCA, Desborough MJR, et al. Periprocedural antithrombotic management for lumbar puncture: Association of British Neurologists clinical guideline. Pract Neurol 2018; 18:436–446.
- NCCP Classification Document for Systemic Anti-Cancer Therapy (SACT) Induced Nausea and Vomiting. V6 2025. 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
- Methotrexate 50mg/2mL Summary of Product Characteristics. Last Updated 30/05/2024. Accessed
 August 2024. Available at: https://www.hpra.ie/img/uploaded/swedocuments/Licence_PA0822-206-002_30052024165736.pdf

Version	Date	Amendment	Approved By
1	22/07/2025		Dr Amjad Hayat

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Comments and feedback welcome at oncologydrugs@cancercontrol.ie.

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