Lomustine 130mg/m^2 Therapy

INDICATIONS FOR USE:

INDICATION	ICD10	Regimen Code	HSE Approved Reimbursement Status*
Recurrent malignant glioma	C71	00805a	N/A

*This is for post 2012 indications only

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.

Lomustine is administered every 6 weeks until disease progression or unacceptable toxicity occurs.

Day	Drug	Dose	Route	Cycle
1	Lomustine[a, b]	[c] 130mg/m^2 (Max dose 280mg)	PO	Every 6 weeks
[a]Lomustine is commonly available as 40mg capsules.				
[b]Lomustine is an unlicensed drug. If the drug is not to be dispensed by the hospital, then the hospital should ensure communication with the patient's community pharmacy to ensure there is no interruption in treatment.				
[C]The dose may be reduced for patients with prior treatment with alkylating agents at the discretion of the prescribing Consultant.				

ELIGIBILITY:

- Indication as above
- ECOG 0-2
- Adequate haematologic, renal and hepatic function

EXCLUSIONS:

- Hypersensitivity to lomustine or any of the excipients
- Pregnancy
- Breastfeeding

PRESCRIPTIVE AUTHORITY:

The treatment plan must be initiated by a Consultant Medical Oncologist

TESTS:

Baseline tests:

- FBC, renal and liver profile
- Pulmonary function tests as clinically indicated for patients considered high risk of pulmonary toxicity

Regular tests:

- FBC, renal and liver profile
- Pulmonary function tests as clinically indicated for patients considered high risk of pulmonary toxicity

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.

Haematological:

Table 1: Dose modifications in haematological toxicity

ANC (x 10^9/L)		Platelets (x 10^9/L)	Dose
≥1.0	and	≥100	100%
<1.0	And/or	< 80	Delay lomustine treatment until ANC ≥1.0 and platelets ≥100. Consider dose reduction

Renal and Hepatic Impairment:

Table 2: Dose modification in renal and hepatic impairment

Renal Impairment		**Hepatic Impairment**
CrCl (mL/min)	**Dose**	Mild and moderate: no need for dose adjustment is expected. Severe: not recommended.
>50	No dose adjustment is needed	
30-50	75% of the original dose	
<30	Not recommended	
Haemodialysis	Not recommended	
Renal and hepatic dose modifications- Giraud et al 2023		

Management of adverse events:

Table 3: Dose Modifications for Adverse Events

Adverse reactions	Recommended dose modification
Grade ≥3 non-haematological toxicity	Delay until resolution to baseline Reduce dose by 50% for clinically relevant toxicities. Resume full dose if event does not recur for 42 days after restarting therapy.

SUPPORTIVE CARE:

EMETOGENIC POTENTIAL:

- As outlined in NCCP Classification Document for Systemic Anti Cancer Therapy (SACT) Induced Nausea and Vomiting linked here

Lomustine: Moderate to High **(Refer to local policy)**

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

- NCCP Supportive Care Antiemetic Medicines for **Inclusion in NCIS** (Medical Oncology) - link here
- NCCP Supportive Care Antiemetic Medicines for **Inclusion in NCIS** (Haemato-oncology) - link here

PREMEDICATIONS: None usually required unless the patient has had a previous hypersensitivity

OTHER SUPPORTIVE CARE:

- Lomustine can cause birth defects. Men and women are recommended to take contraceptive precautions during therapy with lomustine and for 6 months after treatment.

ADVERSE EFFECTS:

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

REGIMEN SPECIFIC COMPLICATIONS:

- Consider rare risk of pulmonary fibrosis

DRUG INTERACTIONS:

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

REFERENCES:

1. Wick W, et al. Phase III Study of Enzastaurin Compared with Lomustine in the Treatment of Recurrent Intracranial Glioblastoma. J Clin Oncol 2010; 28(7):1168-1174
2. Giraud E L, Lijster B D, et al. Dose recommendations for anticancer drugs in patients with renal or hepatic impairment: an update. Available at: https://pubmed.ncbi.nlm.nih.gov/37269847/
3. 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
4. Lomustine Summary of Product Characteristics. Accessed March 2024. Last updated January 2024. Available at: https://www.medac.eu/fileadmin/user_upload/medac-eu/SPCs/common_SPCs/Lomustine_medac-spc-common.pdf

Version	Date	Amendment	Approved By
1	15/05/2023		Prof Patrick Morris
2	18/07/2024	Reviewed. Updated footer on treatment table. Dose modifications for renal and hepatic impairment updated in line with Giraud et al, 2023. Updated in line with NCCP standardisation. Added Regimen Specific Complications section.	Prof Patrick Morris

Comments and feedback welcome at oncologydrugs@cancercontrol.ie.