ATRIO HEALTH PLANS

Chemotherapy: Hepzato

Hepzato (melphalan hcl) J9248

Prior Authorization Request
Medicare Part B Form

*Instructions: * Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.*

☐	**Standard Request– (72 Hours)**	☐	**Urgent Request** (standard time frame could place the member's life, health or ability in serious jeopardy)
	Date Requested _____		
	Requestor _____ Clinic name: _____ Phone / Fax		

MEMBER INFORMATION

*Name:_____ *ID#:_____ *DOB:_____

PRESCRIBER INFORMATION

*Name:_____ ☐MD ☐FNP ☐DO ☐NP ☐PA *Phone:_____

*Address:_____ *Fax:_____

DISPENSING PROVIDER / ADMINISTRATION INFORMATION

*Name:_____ Phone:_____

*Address:_____ Fax:_____

PROCEDURE / PRODUCT INFORMATION

HCPC Code	Name of Drug	Dose (Wt: _____ kg Ht:_____)	Frequency	End Date if known

☐ **Self-administered** ☐ **Provider-administered** ☐ **Home Infusion**

☐Chart notes attached. **Other important information:**_____

Diagnosis: ICD10: _____ **Description**: _____

☐ Provider attests the diagnosis provided is an FDA-Approved indication for this drug

CLINICAL INFORMATION

☐ **New Start or Initial Request: (Clinical documentation required for all requests)**

☐ A. Uveal Melanoma (must meet all):
- ☐ Diagnosis of unresectable or metastatic uveal melanoma
- ☐ Prescribed by or in consultation with an oncologist
- ☐ Age ≥ 18 years
- ☐ Weight ≥ 35 kg
- ☐ Histologically or cytologically-proven ocular melanoma metastases affecting 50% or less of the parenchyma of the liver
- ☐ Member has one of the following (a or b):
  - ☐ No extrahepatic disease
  - ☐ Extrahepatic disease limited to the bone, lymph nodes, subcutaneous tissues, or lung that is amenable to resection or radiation

☐ Recent (within the last 30 days) hematologic testing demonstrating all the following (a, b, and c):
- ☐ Platelet count ≥ 100,000/μL
- ☐ Hemoglobin ≥ 10 g/dL
- ☐ Neutrophils > 2,000/μL

☐ Patient does not have Child-Pugh Class B or C cirrhosis

☐ Request meets one of the following:
- ☐ Dose does not exceed both of the following:
  - ☐ 3 mg/kg based on ideal body weight every 6 weeks for up to 6 total infusions
  - ☐ 220 mg per infusion
- ☐ Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence)

Prescribed regimen must be FDA-approved or recommended by NCCN

☐ **Provider has reviewed the attached "Criteria for Approval" and attests the member meets ALL required PA criteria.**
If not, please provide **clinical rationale** for formulary exception: _____
_____

☐ Continuation Requests: (Clinical documentation required for all requests)

☐ Uveal Melanoma (must meet all):
- ☐ Currently receiving medication via Louisiana Healthcare Connections benefit, or documentation supports that member is currently receiving Hepzato for a covered indication and has received this medication for at least 30 days;
- ☐ Member has not received ≥ 6 total Hepzato infusions;
- ☐ If request is for a dose increase, request meets one of the following (a or b):*
  - ☐ New dose does not exceed both of the following (i and ii):
    - ☐ 3 mg/kg based on ideal body weight every 6 weeks for up to 6 total infusions;
    - ☐ 220 mg per infusion
  - ☐ New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

☐ **Provider has reviewed the attached "Criteria for Continuation" and attests the member meets ALL required PA Continuation criteria.**

☐ Patient had an adequate response or significant improvement while on this medication.
If not, please provide clinical rationale for continuing this medication: _____
_____

ACKNOWLEDGEMENT

Request By (Signature Required): _____Date:_____/____/____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties. **THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT.** PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.

Prior Authorization Group – Oncology: Hepzato PA

Drug Name(s):

HEPZATO **MELPHALAN HCL**

Criteria for approval of Prior Authorization Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. Prescribed by, or in consultation with an oncologist or other cancer specialist related to the diagnosis.
3. Drug is being used appropriately per CMS recognized compendia, authoritative medical literature, evidence-based guidelines and/or accepted standards of medical practice.
4. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.

- If the member meets all these criteria, they may be approved by the Plan for the requested drug.
- Quantity limits and Tiering will be determined by the Plan.

Exclusion Criteria:

Cannot be prescribed for experimental or investigational use.

Prescriber Restrictions:

Oncologist or other cancer specialist

Coverage Duration:

New Start: Approval will be for 6 months
Continuation: Can be for up to 12 months

FDA Indications:

Hepzato

- Multiple myeloma, As a high-dose conditioning treatment, prior to hematopoietic progenitor (stem) cell transplantation
- Multiple myeloma, Palliative treatment
- Uveal melanoma, With unresectable hepatic metastases affecting less than 50% of the liver and no extrahepatic disease, or extrahepatic disease limited to the bone, lymph nodes, subcutaneous tissues, or lung that is amenable to resection or radiation

Off-Label Uses:

Hepzato

- Bone marrow transplant
- Hodgkin's disease
- Retinoblastoma

Age Restrictions:

Safety and effectiveness have not been established in pediatric patients

Other Clinical Considerations:

Cancer diagnoses: Criteria as per NCCN or other FDA-approved cancer related guidelines.

Resources:

https://www.micromedexsolutions.com/micromedex2/librarian/CS/825819/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYNC/229B1F/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/evidencexpert.GoToDashboard?docId=927876&contentSetId=100&title=Melphalan+Hydrochloride&servicesTitle=Melphalan+Hydrochloride&brandName=Hepzato&UserMdxSearchTerm=hepzato#