

Hepzato (melphalan hepatic delivery system)
Effective 08/11/2025

Plan	<input checked="" type="checkbox"/> MassHealth <input type="checkbox"/> Commercial/Exchange		Program Type	<input checked="" type="checkbox"/> Prior Authorization
Benefit	<input type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit			<input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Specialty Limitations	N/A			
Contact Information	Medical Benefit Pharmacy Benefit		Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
Exceptions	N/A			

Overview

Hepzato for injection, as a component of the Hepzato Kit, is indicated as a liver-directed treatment for adult patients with 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.

Coverage Guidelines

Authorization may be reviewed on a case by case basis for members who are new to the plan currently receiving treatment with requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

Authorization may be granted for members when all the following criteria are met:

1. Diagnosis of uveal melanoma with unresectable hepatic metastases
2. Member is ≥ 18 years of age
3. Prescriber is an oncologist or consult notes from an oncologist are provided
4. Member has liver metastases that affect $< 50\%$ of the liver
5. ONE of the following:
 - a. Member does not have any extra hepatic disease
 - b. Extra hepatic disease is limited to the bone, lymph nodes, subcutaneous tissue, or lung and is amenable to resection or radiation
6. Member's ideal body weight
7. Appropriate dosing
8. Requested duration is \leq six doses

Continuation of Therapy

Provider provides documentation of positive response to therapy.

Limitations

1. Initial approvals may be granted for 6 months.
2. Reauthorizations may be granted for a total of 6 doses.

References

1. Hepzato® kit [package insert]. Queensbury (NY): Delcath Systems, Inc.; 2023 Dec.
2. FDA approves melphalan hepatic delivery system for adult patients with unresectable hepatic-dominant metastatic uveal melanoma [press release on the internet]. The ASCO Post. 2023 Sep 25 [cited 2024 Apr 25]. Available from: <https://ascopost.com/issues/september-25-2023/fda-approves-melphalan-hepatic-delivery-system-for-adult-patients-with-unresectable-hepatic-dominant-metastatic-uveal-melanoma/#:~:text=On%20August%2014%2C%20the%20U.S.,no%20extrahepatic%20disease%2C%20or%20e.>

Review History

09/11/24 – Created for P&T. Adopted MH criteria. Hepzato will be available through MB with a PA. Effective 10/1/24

7/9/25 – Reviewed and updated for P&T. Added criterion requiring the member's ideal body weight. Effective 8/11/25

