Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 321.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Hepzato Kit (melphalan/hepatic delivery system [HDS])

I. Policy:
Hepzato Kit (melphalan/hepatic delivery system [HDS])

II. Purpose/Objective:
To provide a policy of coverage regarding Hepzato Kit (melphalan/hepatic delivery system [HDS])

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment
Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION:
Hepzato Kit (melphalan/hepatic delivery system [HDS]) is an alkylating drug of the bischloroethylamine type. Its

cytotoxicity is likely related to the extent of it's interstrand cross-linking with DNA, probably by binding at the N7 position of guanine. It is active against both resting and rapidly dividing tumor cells.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

GRANDFATHER PROVISION – Members already established on therapy are eligible for approval as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

Hepzato Kit (melphalan/hepatic delivery system [HDS]) will be considered medically necessary for ALL lines of business when ALL of the following criteria are met:

- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of unresectable metastatic uveal melanoma **AND**
- Medical record documentation of unresectable hepatic metastases affecting less than 50% of the liver **AND**
- One of the following:
    - Medical record documentation of no extrahepatic disease **OR**
    - Medical record documentation of extrahepatic disease limited to bone, lymph nodes, subcutaneous tissues, or lung that is amenable to resection or radiation

AUTHORIZATION DURATION: 24 Months

QUANTITY LIMIT: Six (6) kits per lifetime (Facets RX Count: 1500)

Note: For Medicaid (GHP Family), any requests for services that do not meet criteria set in the PARP will be evaluated on a case-by-case basis.

LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

REFERENCES:

1. Hepzato [Prescribing Information]. Queensbury NY. Delcanth Systems Inc. August 2023.

This policy will be revised as necessary and reviewed no less than annually**.**

Devised: 7/16/24

Revised:

Reviewed:

MA UM Committee approval: 8/30/24