Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 158.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Tepadina (thiotepa)

I. Policy:
Tepadina (thiotepa)

II. Purpose/Objective:
To provide a policy of coverage regarding Tepadina (thiotepa)

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:
Tepadina (thiotepa) is an alkylating agent that produces cross-linking of DNA strands leading to inhibition of DNA, RNA, and protein synthesis; thiotepa is cell-cycle independent.

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

Tepadina (thiotepa) will be considered medically necessary for the commercial, exchange, CHIP, and Medicaid lines of business when ALL of the following criteria are met:

- Prescription written by a pediatric hematologist/oncologist or pediatric transplant specialist **AND**
- Medical record documentation that the patient has a diagnosis of beta-thalassemia major **AND**
- Medical record documentation that the patient's disease is class 3 in severity as evidenced by the presence of ALL of the following:
    - Liver size > 2 cm
    - Presence of liver fibrosis; and
    - Inadequate iron chelation **AND**
- Medical record documentation that the patient is undergoing allogeneic hematopoietic progenitor stem cell transplant (HSCT) **AND**
- Medical record documentation that Tepadina is being used as part of a preparative regimen consisting of high-dose busulfan and cyclophosphamide **AND**
- Medical record documentation that the patient is under 18 years of age

OR

Requests for any of the following indications will be reviewed based on medical necessity:

- For treatment of adenocarcinoma of the breast or ovary
- For controlling intracavitary effusions secondary to diffuse or localized neoplastic diseases of various serosal cavities.
- For treatment of superficial papillary carcinoma of the urinary bladder.

AND

For all indications:

- If a brand drug is being requested when a therapeutically equivalent generic drug exists):
    - Medical record documentation of a therapeutic failure on, or intolerance to the generic formulary agent(s) **OR**
    - Medical record documentation of a therapeutic failure on, intolerance to, or contraindication to the inactive ingredients of the generic formulary agent(s)

AUTHORIZATION DURATION for Beta-thalassemia Major: Approved requests should be authorized one time for a total of **two doses**, with a quantity limit for an appropriate number of vials* of each strength based on the patient's weight (dose is 5mg/kg).

*Supplied as 15mg single-dose vial or 100mg single-dose vial

For ALL other indications: Initial approval will be for **6 months** or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional **6 months** or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

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.

Tepadina (thiotepa) will be considered medically necessary for the Medicare line of business when ALL of the following criteria are met:

- Prescription written by a pediatric hematologist/oncologist or pediatric transplant specialist **AND**
- Medical record documentation that the patient has a diagnosis of beta-thalassemia major **AND**
- Medical record documentation that the patient's disease is class 3 in severity as evidenced by the presence of ALL of the following:
    - Liver size > 2 cm
    - Presence of liver fibrosis; and
    - Inadequate iron chelation **AND**
- Medical record documentation that the patient is undergoing allogeneic hematopoietic progenitor stem cell transplant (HSCT) **AND**
- Medical record documentation that Tepadina is being used as part of a preparative regimen consisting of high-dose busulfan and cyclophosphamide **AND**
- Medical record documentation that the patient is under 18 years of age

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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.

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

Devised: 9/19/17

Revised: 11/8/17 (per DHS), 3/20/18 (criteria dx), 3/19/19 (auth duration), 12/19/22 (LOB carve out, Medicaid PARP statement), 12/6/23 (Medicaid business segment, added generic drug language)

Reviewed: 1/1/20, 1/1/21, 12/21/21