Medical Policy:

Tepadina (thiotepa)

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.171	January 2, 2024	July 15, 2019

Definitions

Tepadina 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.

Length of Authorization

Coverage will be provided for 6 months and may be renewed

Guideline

I. Initial Approval Criteria

Tepadina *may be considered medically necessary if one of the below conditions are met* ***AND*** *use is consistent with the medical necessity criteria that follows:*

- Order is written by a hematologist/oncologist; **AND**
- Medical record documentation for one of the following indications:

1. **Class 3 Beta-Thalassemia**
    A. Patient's disease is Class 3 in severity evidenced by the presence of ALL of the following; **AND**
        i. Liver size > 2 cm
        ii. Presence of liver fibrosis
        iii. Inadequate iron chelation; **AND**
    B. Medical record documentation the patient is undergoing allogeneic hematopoietic progenitor stem cell transplant (HSCT); **AND**
    C. Medical record documentation that Tepadina is being used as part of a preparative regimen consisting of high-dose busulfan and cyclophosphamide; **AND**
    D. Medical record documentation that the patient is under 18 years of age.
2. **Adenocarcinoma of the Breast or Ovary**
3. **Malignant Effusions**
4. **Superficial Papillary Carcinoma of the Urinary Bladder**

Limitations/Exclusions

Tepadina is not considered medically necessary for when any of the following selection criteria is met:

1. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature may be deemed as not approvable and therefore not reimbursable.

II. **Renewal Criteria**

1. Patient continues to meet INITIAL APPROVAL CRITERIA.
2. Tumor response with disease stabilization or reduction of tumor size and spread.

Dosage/Administration

Please see package insert for dosing information

Applicable Procedure Codes

Code	Description
J9340	Injection, Thiotepa, 15 mg, 1 billable unit = 15 mg

Applicable NDCs

Code	Description
70121-1631-01	Tepadina single use vial; 15 mg powder for injection
70121-1630-01	Tepadina 15mg Solution Reconstituted

ICD-10 Diagnoses

Code	Description
C50.919	Malignant neoplasm of unspecified site of unspecified female breast
C56.9	Malignant neoplasm of unspecified ovary
C67.0	Malignant neoplasm of trigone of bladder
C67.1	Malignant neoplasm of dome of bladder

C67.2	Malignant neoplasm of lateral wall of bladder
C67.3	Malignant neoplasm of anterior wall of bladder
C67.4	Malignant neoplasm of posterior wall of bladder
C67.5	Malignant neoplasm of bladder neck
C67.6	Malignant neoplasm of ureteric orifice
C67.7	Malignant neoplasm of urachus
C67.8	Malignant neoplasm of overlapping sites of bladder
C67.9	Malignant neoplasm of bladder, unspecified
D09.0	Carcinoma in situ of bladder
D56.1	Beta thalassemia
J91.0	Malignant Pleural effusion

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	1/2/2024	Annual Review: updated NDCs, no criteria changes
EmblemHealth & ConnectiCare	4/18/2023	Annual Review: no changes
EmblemHealth & ConnectiCare	1/13/2023	Transfer to New Template
EmblemHealth & ConnectiCare	7/15/2019	New Policy

References

1. Product Information: TEPADINA® intravenous, intracavitary, intravesical injection, thiotepa intravenous, intracavitary, intravesical injection . ADIENNE SA (per FDA), Cedar Park, TX, 2017