

Medical Policy:

Tepadina (thiotepa)

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

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as “EmblemHealth”), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

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 |

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|-------|--|
| 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