Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 172.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Trisenox (arsenic trioxide)

I. Policy:
Trisenox (arsenic trioxide)

II. Purpose/Objective:
To provide a policy of coverage regarding Trisenox (arsenic trioxide)

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:
Trisenox (arsenic trioxide) is an arsenical which induces apoptosis in APL cells via morphological changes and DNA fragmentation. It also damages or degrades the fusion protein promyelocytic leukemia (PML)-retinoic acid receptor (RAR) alpha.

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

Trisenox (arsenic trioxide) 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 hematologist or oncologist **AND**
- Medical record documentation of newly-diagnosed low-risk acute promyelocytic leukemia (APL) characterized by the presence of the t(15,17) translocation or PML/RAR-alpha gene expression AND that Trisenox is being used in combination with tretinoin **OR**
- Medical record documention the Trisenox is being used for induction of remission and consolidation in patients with acute promyelocytic leukemia (APL) who are refractory to, or have relapsed from, retinoid and anthracycline chemotherapy, and whose APL is characterized by the presence of the t(15,17) translocation or PML/RAR-alpha gene expression

AND

- 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: Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate. Trisenox 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.

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

- Prescription written by a hematologist or oncologist **AND**
- Medical record documentation of newly-diagnosed low-risk acute promyelocytic leukemia (APL) characterized by the presence of the t(15,17) translocation or PML/RAR-alpha gene expression AND that Trisenox is being used in combination with tretinoin **OR**
- Medical record documention the Trisenox is being used for induction of remission and consolidation in patients with acute promyelocytic leukemia (APL) who are refractory to, or have relapsed from, retinoid and anthracycline chemotherapy, and whose APL is characterized by the presence of the t(15,17) translocation or PML/RAR-alpha gene expression

AUTHORIZATION DURATION: Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate. Trisenox will no longer be covered if patient experiences toxicity or worsening of disease.

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. Trisenox [prescribing information] North Wales, PA: Teva Pharmaceuticals; August 2022.

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

Devised: 3/20/18

Revised: 9/16/22 (Medicaid PARP statement), 9/12/23 (LOB carve out, Medicaid business segment, added generic drug language), 12/30/23 (references added)

Reviewed: 1/30/19, 11/1/19, 9/30/20, 9/16/21

MA UM Committee approval: 12/31/23