PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Injectable) – Arsenic Trioxide Prior Authorization Policy
- Trisenox® (arsenic trioxide intravenous infusion – Teva, generic)

REVIEW DATE: 10/16/2024

OVERVIEW

Arsenic trioxide is indicated for **acute promyelocytic leukemia (APL)**: [1]

- In combination with tretinoin for the treatment of adults with newly diagnosed low-risk disease whose APL is characterized by the presence of the t(15;17) translocation or PML/RAR-alpha gene expression.
- For induction of remission and consolidation in patients with 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.

Guidelines

Arsenic trioxide is addressed in National Comprehensive Cancer Network (NCCN) Guidelines.

- **Acute Myeloid Leukemia:** Guidelines (version 3.2024 – May 17, 2024) recommend arsenic trioxide for induction and consolidation therapy in low-risk (white blood cell [WBC] count < 10,000/µL) and in high-risk (WBC > 10,000/µL) APL with or without cardiac issues.[2,3] NCCN also recommends arsenic trioxide for the first relapse (either morphologic or molecular) and as single-agent consolidation therapy in patients who are not transplant candidates and are polymerase chain reaction negative following second remission (morphologic).
- **T-Cell Lymphoma:** Guidelines (version 4.2024 – May 28, 2024) recommend arsenic trioxide as a single agent for the second-line or subsequent treatment of non-responders to first-line therapy for adult T-cell leukemia/lymphoma, acute or lymphoma subtypes.[2,4]

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of arsenic trioxide. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with arsenic trioxide as well as the monitoring required for adverse events and long-term efficacy, approval requires arsenic trioxide to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of arsenic trioxide is recommended in those who meet one of the following criteria:

FDA-Approved Indication

1. **Acute Promyelocytic Leukemia**. Approve for 1 year if the medication is prescribed by or in consultation with an oncologist.

Other Uses with Supportive Evidence

2. **Adult T-Cell Leukemia/Lymphoma**. Approve for 1 year if the patient meets ALL of the following (A, B, C, D, and E):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has acute or lymphoma subtype; AND
   C) Patient has tried chemotherapy; AND
   Note: Examples include CHOP (cyclophosphamide, doxorubicin, vincristine, and prednisone), CHOEP (cyclophosphamide, doxorubicin, vincristine, etoposide, and prednisone).
   D) Arsenic trioxide will be used as a single agent; AND
   E) The medication is prescribed by or in consultation with an oncologist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of arsenic trioxide is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Trisenox® intravenous infusion [prescribing information]. North Wales, PA: Teva; October 2022.
2. The NCCN Drugs and Biologics Compendium. © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on October 8, 2024. Search term: arsenic trioxide.
3. The NCCN Acute Myeloid Leukemia Clinical Practice Guidelines in Oncology (version 3.2024 – May 17, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on October 8, 2024.
4. The NCCN T-Cell Lymphomas Clinical Practice Guidelines in Oncology (version 4.2024 – May 28, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on October 8, 2024.