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| POLICY NUMBER UM_Onc_1069 | SUBJECT Trisenox™ (arsenic trioxide) | | DEPT/PROGRAM UM Dept | PAGE 1 OF 2 |
| DATES COMMITTEE REVIEWED 02/20/11, 12/07/11, 09/13/13, 10/06/14, 12/18/15, 08/25/16, 06/09/17, 08/08/18, 07/10/19, 12/11/19, 07/08/20 | APPROVAL DATE July 8, 2020 | EFFECTIVE DATE July 31, 2020 | COMMITTEE APPROVAL DATES (latest version listed last) 02/20/11, 12/07/11, 09/13/13, 10/06/14, 12/18/15, 08/25/16, 06/09/17, 08/08/18, 07/10/19, 12/11/19, 07/08/20 | |
| PRIMARY BUSINESS OWNER: UM APPROVED BY: Dr. Andrew Hertler | | COMMITTEE/BOARD APPROVAL Utilization Management Committee | | |
| URAC STANDARDS | | NCQA STANDARDS UM 2 | ADDITIONAL AREAS OF IMPACT | |
| CMS REQUIREMENTS | STATE/FEDERAL REQUIREMENTS | | APPLICABLE LINES OF BUSINESS Commercial, Exchange, Medicaid | |

I. PURPOSE

To define and describe the accepted indications for Trisenox (arsenic trioxide) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

New Century is responsible for processing all medication requests from network ordering providers. Medications not authorized by New Century may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

II. INDICATIONS FOR USE/INCLUSION CRITERIA

1. PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:

- a. When health plan Medicaid coverage provisions- including any applicable PDLs (Preferred Drug Lists)- conflict with the coverage provisions in this drug policy, health plan Medicaid coverage provisions take precedence per the **Preferred Drug Guidelines OR**
- b. When health plan Exchange coverage provisions- including any applicable PDLs (Preferred Drug Lists)- conflict with the coverage provisions in this drug policy, health plan Exchange coverage provisions take precedence per the **Preferred Drug Guidelines OR**
- c. For Health Plans that utilize NCH UM Oncology Clinical Policies as the initial clinical criteria, the **Preferred Drug Guidelines shall follow NCH L1 Pathways** when applicable, otherwise shall follow NCH drug policies **AND**
- d. Continuation requests of previously approved non-preferred medication are not subject to this provision **AND**
- e. When available, generic alternatives are preferred over brand-name drugs.

2. Acute Promyelocytic Leukemia (APL)

- a. Trisenox (arsenic trioxide) may be used for the treatment of Acute Promyelocytic Leukemia (APL) -regardless of the APL Risk Category- as induction and/or consolidation therapy, either as a single agent OR in combination with one or more of the following agents: ATRA (all-trans-retinoic-acid), Gemtuzumab Ozogamicin, and an anthracycline (daunorubicin or idarubicin).



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III. EXCLUSION CRITERIA

1. Dosing exceeds single dose limit of Trisenox (arsenic trioxide) 0.15 mg/kg.
2. Total induction doses of Trisenox (arsenic trioxide) exceed 60 doses.
3. Total maintenance/consolidation doses of Trisenox (arsenic trioxide) exceed 25 doses up to 5 weeks.
4. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature

IV. MEDICATION MANAGEMENT

Please refer to the FDA label/package insert for details regarding these topics.

V. APPROVAL AUTHORITY

1. Review – Utilization Management Department
2. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

None

VII. REFERENCES

1. Trisenox prescribing information. Cephalon, Inc. Frazer, PA. 2019.
2. Clinical Pharmacology Elsevier Gold Standard. 2020.
3. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2020
4. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2020.
5. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD. 2020.