Utilization Review Policy 155

POLICY: Oncology – Elzonris™ (tagraxofusp-erzs injection for intravenous use – Stemline Therapeutics)

EFFECTIVE DATE: 1/1/2020
LAST REVISION DATE: 09/16/2024

COVERAGE CRITERIA FOR: All UCare Plans

OVERVIEW

Elzonris is indicated for the treatment of blastic plasmacytoid dendritic cell neoplasm in patients ≥ 2 years of age.[1]

Elzonris is a CD-123 directed cytotoxin, consisting of recombinant human interleukin-3 (IL-3) fused with truncated diphtheria toxin and is produced by recombinant DNA technology in *Escherichia coli* cells.[1] Elzonris inhibits protein synthesis and causes cell death in cells expressing CD-123.

Guidelines

The National Comprehensive Cancer Network clinical practice guidelines for **Acute Myeloid Leukemia** (version 6.2023 – October 24, 2023) recommend Elzonris as a single agent for the treatment of blastic plasmacytoid dendritic cell neoplasm.[2,3]

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Elzonris. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Elzonris as well as the monitoring required for adverse events and long-term efficacy, approval requires Elzonris to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Elzonris is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Blastic Plasmacytoid Dendritic Cell Neoplasm.** Approve for 1 year if the patient meets BOTH of the following (A and B):
   A) Patient is ≥ 2 years of age; AND
   B) Elzonris is prescribed by or consultation with an oncologist.

   Dosing. Approve up to 12 mcg/kg administered intravenously on Days 1 through 5 of each 21-day cycle.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Elzonris 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. Elzonris™ [prescribing information]. New York, NY: Stemline Therapeutics; July 2023.
2. The NCCN Drugs & Biologics Compendium. © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 3, 2024. Search term: tagraxofusp.
3. The NCCN Acute Myeloid Leukemia Clinical Practice Guidelines in Oncology (version 6.2023 – October 24, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 3, 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	12/21/2022
Annual Revision	No criteria changes.	01/10/2024
UCare P&T Review	Policy reviewed and approved by UCare P&T committee. Annual review process	09/16/2024