

PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Injectable) – Elzonris Prior Authorization Policy

- Elzonris™ (tagraxofusp-erzs intravenous infusion – Stemline)

REVIEW DATE: 12/21/2022

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 2.2022 – June 14, 2022) recommend Elzonris as a single agent for the treatment of blastic plasmacytoid dendritic cell neoplasm.^{2,3}

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Elzonris. 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 criteria (A and B):
 - A) Patient is ≥ 2 years of age; AND
 - B) Elzonris is prescribed by or consultation with an oncologist.

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; November 2022.

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2. The NCCN Drugs & Biologics Compendium. © 2022 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on December 19, 2022. Search term: tagraxofusp.
3. The NCCN Acute Myeloid Leukemia Clinical Practice Guidelines in Oncology (version 2.2022 – November 14, 2022). © 2022 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on December 19, 2022.