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

DATE REVIEWED: 12/11/2019

OVERVIEW

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.

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

Guidelines

The National Comprehensive Cancer Network clinical practice guidelines for Acute Myeloid Leukemia (Version 2.2020 – September 3, 2019) 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(s). 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 one of the following criteria:

FDA-Approved Indications

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

   Dosing. Approve the following dosing regimen (A and B):
   - **A)** Each individual dose must not exceed 12 mcg/kg administered intravenous; AND
   - **B)** Elzonris should be given on Days 1 through 5 of each 21-day cycle.[1]

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Elzonris has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions.

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

REFERENCES

1. Elzonris™ [prescribing information]. New York, NY: Stemline Therapeutics; December 2018.
2. The NCCN Drugs & Biologics Compendium. © 2019 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on December 3, 2019. Search term: tagraxofusp.
3. The NCCN Acute Myeloid Leukemia Clinical Practice Guidelines in Oncology (Version 2.2020 – September 3, 2019). © 2019 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on December 3, 2019.

HISTORY

Type of Revision	Summary of Changes	Date Reviewed
New policy	--	01/03/2019
Annual revision	No change to the criteria	12/11/2019