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Section:	Prescription Drugs	**Effective Date:**	April 1, 2024
Subsection:	Antineoplastic Agents	**Original Policy Date:**	January 11, 2019
Subject:	Elzonris	**Page:**	1 of 4

Last Review Date: March 8, 2024

Elzonris

Description

Elzonris (tagraxofusp-erzs)

Background

Elzonris (tagraxofusp-erzs) is a CD123-directed cytotoxin composed of recombinant human interkeukin-3 (IL-3) and truncated diphtheria toxin (DT) fusion protein that inhibits protein synthesis and causes cell death in CD123-expressing cells (1).

Regulatory Status

FDA-approved indication: Elzonris is a CD123-directed cytotoxin for the treatment of blastic plasmacytoid dendritic cell neoplasm (BPDCN) in adults and pediatric patients 2 years and older (1).

Elzonris has a boxed warning for capillary leak syndrome (CLS). Before initiating therapy with Elzonris, patients should be ensured to have adequate cardiac function and serum albumin is greater than or equal to 3.2 g/dL. During treatment when Elzonris, serum albumin levels should be monitored prior to the initiation of each dose and as indicated clinically thereafter (1).

Patients should be premedicated with an H1-histamine antagonist, H2-histamine antagonist, corticosteroid, and acetaminophen approximately 60 minutes prior to each Elzonris infusion. Vital signs, albumin, transaminases, and creatinine should be monitored prior to preparing each dose of Elzonris (1).

The safety and effectiveness of Elzonris in pediatric patients less than 2 years of age have not been established (1).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Elzonris may be considered **medically necessary** if the conditions indicated below are met.

Elzonris may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 2 years of age or older

Diagnosis

Patient must have the following:

Blastic plasmacytoid dendritic cell neoplasm (BPDCN)

AND ALL of the following:

1. Serum albumin 3.2 ≥ g/dL
2. Prescriber agrees to monitor for capillary leak syndrome (CLS)
3. Prescriber agrees to monitor serum albumin, liver function tests (LFTs), and serum creatinine (SCr)

Prior – Approval *Renewal* Requirements

Age 2 years of age or older

Diagnosis

Patient must have the following:

Blastic plasmacytoid dendritic cell neoplasm (BPDCN)

AND ALL of the following:

1. **NO** disease progression or unacceptable toxicity
2. Prescriber agrees to monitor for capillary leak syndrome (CLS)
3. Prescriber agrees to monitor serum albumin, liver function tests (LFTs), and serum creatinine (SCr)

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Elzonris (tagraxofusp-erzs) is a CD123-directed cytotoxin composed of recombinant human interkeukin-3 (IL-3) and truncated diphtheria toxin (DT) fusion protein that inhibits protein synthesis and causes cell death in CD123-expressing cells. The safety and effectiveness of Elzonris in pediatric patients less than 2 years of age have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Elzonris while maintaining optimal therapeutic outcomes.

References

1. Elzonris [package insert]. New York, NY: Stemline Therapeutics, Inc.; July 2023.
2. NCCN Drugs & Biologics Compendium® Tagraxofusp-erzs 2024. National Comprehensive Cancer Network, Inc. Accessed on January 30, 2024.

Policy History

Date	Action
January 2019	Addition to PA
March 2019	Annual review

June 2019	Annual review
June 2020	Annual review
March 2021	Annual review
March 2022	Annual review and reference update
March 2023	Annual review and reference update
December 2023	Annual review and reference update
March 2024	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.