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Section:	Prescription Drugs	**Effective Date:**	April 1, 2021
Subsection:	Antineoplastic Agents	**Original Policy Date:**	January 11, 2019
Subject:	Elzonris	**Page:**	1 of 4

Last Review Date: March 12, 2021

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** in patients 2 years of age or older with blastic plasmacytoid dendritic cell neoplasm (BPDCN) and if the conditions indicated below are met.

Elzonris is considered **investigational** in patients under 2 years of age and 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 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.; December 2018.

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

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 12, 2021 and is effective on April 1, 2021.