Elzonris (tagraxofusp-erzs)

**Background**
Elzonris (tagraxofusp-erzs) is a CD123-directed cytotoxin composed of recombinant human interleukin-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).
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**

### Policy History

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<tr>
<td>January 2019</td>
<td>Addition to PA</td>
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**Section:** Prescription Drugs  
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**Subsection:** Antineoplastic Agents  
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**Subject:** Elzonris  
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| March 2019 | Annual review |
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**Keywords**

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 20, 2019 and is effective on July 1, 2019.