

**EFFECTIVE DATE:** 09|01|2019

**POLICY LAST UPDATED:** 05|07|2019

## OVERVIEW

Elzonris™ (tagraxofusp-erzs) is for the treatment of blastic plasmacytoid dendritic cell neoplasm (BPDCN) in adults and pediatric patients 2 years and older.

This policy is applicable to BlueCHiP for Medicare products only. For Commercial Products, see related policy section.

## MEDICAL CRITERIA

Elzonris™ (tagraxofusp-erzs) will be approved when ALL of the following are met:

1. ONE of the following:

A. There is documentation the patient is currently being treated with the requested agent

**OR**

B. The prescriber states the patient is currently being treated with the requested agent AND is at risk if therapy is changed

**OR**

C. The patient has an FDA labeled indication for the requested agent AND ALL of the following:

i. ONE of the following:

1. The requested indication does NOT require genetic/specific diagnostic testing (e.g., ALK, EGFR, HER2, KRAS) in FDA labeling

**OR**

2. The requested indication requires genetic/specific diagnostic testing in the FDA labeling AND ONE of the following:

a. BOTH of the following

i. Genetic/diagnostic testing has been performed

**AND**

ii. The results of the genetic/diagnostic testing indicate therapy with the requested agent is appropriate

**OR**

b. The requested indication does not require genetic/specific diagnostic testing in NCCN with level of evidence 1 or 2a

**AND**

ii. ONE of the following:

1. The requested agent is FDA labeled as a first-line agent for the requested indication

**OR**

2. The patient has used the appropriate number and type(s) of prerequisite agent(s) listed in the FDA labeling for the requested indication

**OR**

3. The patient has used the appropriate number and type(s) of prerequisite agent(s) supported by NCCN 1 or 2A recommended use for the requested indication

**OR**

4. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to ALL of the required prerequisite agent(s) listed in the FDA labeling for the requested indication

**AND**

iii. ONE of the following:

1. The requested agent is approved for use as monotherapy in the FDA labeling for the requested indication

**OR**

2. The requested agent will be used with all agent(s) and/or treatments (e.g., radiation) listed for concomitant use in the FDA labeling for the requested indication

**OR**

3. The requested agent will be used with all agent(s) and/or treatments supported in NCCN 1 or 2a recommended use for the requested indication

**AND**

iv. ONE of the following:

1. The FDA label does NOT include a performance status requirement

**OR**

2. The patient meets the performance status requirement in the FDA labeling

**OR**

D. The patient has an NCCN 1 or 2A recommended indication [i.e., this indication must be supported by ALL requirements in the NCCN “Recommended Use” box (e.g., performance status, disease severity, previous failures, monotherapy vs combination therapy, etc.)]

**AND**

2. The patient does NOT have any FDA labeled contraindications to the requested agent

**AND**

3. The requested dose and duration is within FDA labeling or NCCN 1 or 2A compendia supported dosing for the requested indication

**Length of Approval:** 12 months or for duration of treatment as supported in FDA labeling or in NCCN 1 or 2a recommendations for the requested indication, whichever is shorter.

### **PRIOR AUTHORIZATION**

Prior authorization is required for BlueCHiP for Medicare.

### **POLICY STATEMENT**

#### **BlueCHiP for Medicare**

Elzonris™ (tagraxofusp-erzs) is medically necessary when the criteria above have been met.

### **COVERAGE**

Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable physician administered drug medically necessary benefits/coverage.

### **BACKGROUND**

Elzonris (tagraxofusp-erzs), a CD123-directed cytotoxin, is a fusion protein comprised of a recombinant human interleukin-3 (IL-3) and truncated diphtheria toxin (DT) that inhibits protein synthesis and causes cell death in CD1230expressing cells.

### **CODING**

#### **BlueCHiP for Medicare**

The following HCPCS code is covered when the medical criteria have been met:

**C9049** Injection, tagraxofusp-erzs, 10 mcg

## RELATED POLICIES

Prior Authorization of Drugs

## PUBLISHED

Provider Update, July 2019

## REFERENCES

1. Elzonris Prescribing Information. Stemline Therapeutics Inc. December 2018.

DRAFT

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