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

      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 diptheria 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:
J9269 Injection, tagraxofusp-erzs, 10 mcg (Effective 10/1/19)
C9049 Injection, tagraxofusp-erzs, 10 mcg (Deleted 10/1/19)

**RELATED POLICIES**
Prior Authorization of Drugs

**PUBLISHED**
Provider Update, July 2019

**REFERENCES**