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 diptheria toxin (DT) that inhibits protein synthesis and causes cell death in CD1230expressing cells.

CODING

BlueCHiP for Medicare

There is no specific HCPCS code; claims must be filed with an unlisted code such as J9999 and the NDC number

RELATED POLICIES
Prior Authorization of Drugs

PUBLISHED
Provider Update, July 2019

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