I. Medication Description

Elzonris (tagraxofusp-erzs) is a CD123-directed cytotoxin. Tagraxofusp consists of a cytotoxic agent, truncated diphtheria toxin (DT), attached to a recombinant fusion protein, IL3. The IL3 domain binds to its natural receptor, DT is released into the cytosol and causes protein synthesis inhibition and cell death in CD123-expressing cells. Blastic plasmacytoid dendritic cell neoplasm blast cells have high CD123 or interleukin-3 receptor (IL3)-alpha surface expression.

II. Position Statement

Coverage is determined through a prior authorization process with supporting clinical documentation for every request.

III. Policy

Coverage of Elzonris is available when the following criteria have been met:

- Member is at least 2 years of age AND
- The medication is prescribed by a hematologist/oncologist AND
- Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN) diagnosis has been established with histological and/or cytological evidence in the peripheral blood, bone marrow, spleen, lymph nodes, skin, and/or other sites (supporting documentation must be provided) AND
- Provider confirms that the following conditions have been ruled out:
  - Acute promyelocytic leukemia (APL, FAB M3) AND
  - CNS leukemia AND
- Member has adequate baseline organ functions:
  - Member does not have a clinically significant cardiovascular disease (e.g., uncontrolled or any NYHA Class 3 or 4 congestive heart failure, uncontrolled angina, history of myocardial infarction or stroke within 6 months of therapy initiation, uncontrolled hypertension or clinically significant arrhythmias not controlled by medication, baseline left ventricular ejection fraction less than 40%, etc) AND
  - Member does not have a clinically significant renal or hepatic disease AND
- Provider confirms that:
  - Elzonris therapy will be initiated when serum albumin is ≥ 3.2g/dL prior to the first dose of the first cycle AND
  - The first cycle of Elzonris will be administered in the inpatient setting with patient observation through at least 24 hours after the last infusion AND
o Subsequent cycles of Elzonris will be administered in the inpatient setting or in a suitable outpatient ambulatory care setting that is equipped with appropriate monitoring **AND**

- The requested use is supported by the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines (NCCN Guidelines®) and/or NCCN Drugs & Biologics Compendium (NCCN Compendium®) with a recommendation of category level 1 or 2A, if BPDCN clinical practice guideline is available.

IV. **Quantity Limitations**

Coverage is available to allow sufficient quantities in accordance with FDA-approved prescribing information.

V. **Coverage Duration**

Initial coverage is provided for five 21-day cycles and may be renewed.

VI. **Coverage Renewal Criteria**

Coverage can be renewed in five 21-day cycle increments based upon the following criteria (supporting documentation required):

- Evident clinical response, stabilization of disease/absence of disease progression **AND**
- Absence of unacceptable toxicity from the drug.

VII. **Billing/Coding Information**

- Available as injection: 1,000 mcg in 1 mL in a single-dose vial.
- C9049: 1 billable unit= 10mcg

VIII. **Summary of Policy Changes**

- 5/15/19: new policy
- 7/1/19: updated billing/coding information
- 11/15/19: no policy changes

IX. **References**


*These guidelines are not applicable to benefits covered under Medicare Advantage. Medicare Advantage benefit coverage requests are reviewed in accordance with the guidance set forth in Chapter 15 Section 50 of the Centers for Medicare & Medicaid Services Medicare Benefit Policy Manual.*
The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.

The preceding policy applies only to members for whom the above named pharmacy benefit medications are included on their covered formulary. Members with closed formulary benefits are subject to trying all appropriate formulary alternatives before a coverage exception for a non-formulary medication will be considered.

The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.