Medical Policy:

Elzonris® (tagraxofusp-erzs) Intravenous

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.186	March 18, 2024	April 1, 2019

Definitions

Elzonris is a CD123-directed cytotoxin consisting of recombinant human interleukin-3 (IL-3) fused with truncated diphtheria toxin and is produced by recombinant DNA technology in Escherichia coli cells, for blastic plasmacytoid dendritic cell neoplasm (BPDCN) in adults and pediatric patients 2 years and older. Elzonris inhibits protein synthesis and causes cell death in cells expressing CD-123. Elzonris can be used in both naïve and previously-treated populations. It is the first treatment approved for BPDCN as well as the first approved CD123-targeted therapy. Elzonris was evaluated by the FDA under Priority Review, and was given Breakthrough Therapy Designation, and Orphan Drug Designation. Elzonris is indicated for the treatment of blastic plasmacytoid dendritic cell neoplasm in adults and pediatric patients > 2 years of age.

Length of Authorization

Coverage will be provided for 6 months and may be renewed.

Dosing Limits [Medical Benefit]

Max Units (per dose and over time):

1. 2000 mcg on days 1-5 of every 21 day cycle (200 billable units on days 1-5 of every 21-day cycle)

Guideline

I. Initial Approval Criteria

Elzonris *may be considered medically necessary if the below condition is met* ***AND*** *use is consistent with the medical necessity criteria that follows:*

1. **Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN).**
    A. The patient is ≥ 2 years of age; **AND**
    B. The patient has been clinically diagnosed with BPDCN in the peripheral blood, bone marrow, spleen, lymph nodes, skin, and/or other sites; **AND**
    C. The patient has adequate cardiac function and serum albumin ≥ 3.2g/dL prior to every course of therapy; **AND**
    D. Patient does not have active or suspected CNS leukemia; **AND**
    E. Must be used as a single agent; **AND**
        i. Used as induction therapy in patients who are candidates for intensive remission therapy; **OR**
        ii. Used as treatment until progression if a complete response (CR) was achieved after induction; **OR**
        iii. Used as treatment for relapsed/refractory disease if not already used; **AND**
    F. Elzonris is prescribed by or consultation with an oncologist.

II. Renewal Criteria

1. Patient continues to meet INITIAL APPROVAL CRITERIA with lack of adverse reactions or toxicities to medication (i.e. Capillary leak syndrome).

Limitations/Exclusions

Coverage is not recommended for circumstances not listed in the Initial Approval Criteria.

Dosage/Administration

Indication	Dose
Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN)	Administer at 12 mcg/kg intravenously over 15 minutes once daily on Days 1 through 5 of each 21-day cycle.

Applicable Procedure Codes

Code	Description
J9269	Injection, tagraxofusp-erzs, 10 mcg

Applicable NDCs

Code	Description

72187-0401-01	Elzonris 1000 mcg/mL single dose vial.

ICD-10 Diagnoses

Code	Description
C86.4	Blastic NK-cell lymphoma

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	3/18/2024	Annual Review: Updated dosing limits. Initial Criteria: Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN). Updated the following statement to read: "The patient has been clinically diagnosed with BPDCN in the peripheral blood, bone marrow, spleen, lymph nodes, skin, and/or other sites;" Modified the following from: The patient does not have a diagnosis of acute promyelocytic leukemia (APL, FAB M3);" to " Patient does not have active or suspected CNS leukemia" Removed "treatment naïve" from the following statement: "Used as induction therapy in treatment-naïve patients who are candidates for intensive remission therapy; "
EmblemHealth & ConnectiCare	07/06/2023	Annual Review: Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN). Initial Criteria: Removed "The patient has an ECOG score of 0-2; AND" Added "Must be used as a single agent; AND 1. Used as induction therapy in treatment-naïve patients who are candidates for intensive remission therapy; OR 2. Used as treatment until progression if a complete response (CR) was achieved after induction; OR 3. Used as treatment for relapsed/refractory disease if not already used; AND"
EmblemHealth & ConnectiCare	04/21/2022	Transferred policy to new template
EmblemHealth & ConnectiCare	07/01/2021	Removed C9049, code deleted
EmblemHealth & ConnectiCare	12/30/2020	Annual review: no policy changes
EmblemHealth & ConnectiCare	09/23/2019	Removed code J9999. Added code J9269, effect 10/01/2019.
EmblemHealth & ConnectiCare	06/01/2019	Removed unclassified code C9399. Added new Code C9049
EmblemHealth & ConnectiCare	04/01/2019	New Policy

References

1. Elzonris™ [prescribing information]. New York, NY: Stemline Therapeutics; December 2018. Clinical

Pharmacology Elsevier Gold Standard. Revised December, 2018.
2. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2018.
3. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2020.
4. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD. 201