

Medical Policy:

Elzonris® (tagraxofusp-erzs) Intravenous

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

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as “EmblemHealth”), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

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 ≥ 3.2 g/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: <u>Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN)</u> . 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