# Elzonris™ (tagraxofusp-erzs)
## (Intravenous)

Document Number: IC-0426

**Last Review Date: 04/06/2021**
**Date of Origin:** 02/04/2019
**Dates Reviewed: 02/2019, 02/2020, 04/2021**

## I. Length of Authorization

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

## II. Dosing Limits

**A. Quantity Limit (max daily dose) [NDC unit]:**

- Elzonris 1000 mcg/1 mL single dose vial: 10 vials per 21 day cycle

**B. Max Units (per dose and over time) [HCPCS Unit]:**

- 200 billable units on days 1-5 of every 21 day cycle

## III. Initial Approval Criteria [1]

Coverage is provided in the following conditions:

- Patient is at least 2 years of age; **AND**
- Patient has a baseline serum albumin level of at least 3.2 g/dL; **AND**

**Universal Criteria** [1-6]

- Patient has CD-123 positive/expressing disease; **AND**
- Patient does not have 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 initiating therapy, uncontrolled hypertension or clinically significant arrhythmias not controlled by medication, baseline left ventricular ejection fraction < 40%); **AND**
- Patient does not have active or suspected CNS leukemia; **AND**

**Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN) † Φ** [1-6]

- Must be used as a single agent; **AND**
- Patient must have a definitive diagnosis of BPDCN in the peripheral blood, bone marrow, spleen, lymph nodes, skin, and/or other sites; **AND**
    - Used as induction therapy in treatment-naïve patients who are candidates for intensive remission therapy; **OR**

- Used as treatment until progression if a complete response (CR) was achieved after induction; **OR**
- Used as treatment for relapsed/refractory disease if not already used

† FDA-labeled indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

## IV. Renewal Criteria [1-6]

- Patient continues to meet universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: capillary leak syndrome, severe hypersensitivity reactions, severe hepatotoxicity, etc.; **AND**
- Disease stabilization or improvement as evidenced by a complete response [CR] *(i.e., morphologic, cytogenetic or molecular complete response)* or clinical complete response [CRc] (*i.e., complete response with residual skin abnormality not indicative of active disease*)

## V. Dosage/Administration [1,2,6]

| Indication | Dose* |
|---|---|
| BPDCN | Administer at 12 mcg/kg intravenously over 15 minutes once daily on days 1 to 5 of a 21-day cycle. The dosing period may be extended for dose delays up to day 10 of the cycle. Continue treatment until disease progression or unacceptable toxicity.<br>• Administer Cycle 1 in the inpatient setting with patient observation through at least 24 hours after the last infusion. Subsequent cycles are suitable for administration in the outpatient ambulatory care setting with appropriate monitoring. |

**Store in a freezer between-25°C and -15°C (-13°F and 5°F).*

## VI. Billing Code/Availability Information

HCPCS code:

- J9269 – Injection, tagraxofusp-erzs, 10 micrograms; 1 billable unit = 10 mcg

NDC:

- Elzonris 1000 mcg/1 mL single-dose vials: 72187-0401-xx

## VII. References


1. Elzonris [package insert]. New York, NY; Stemline Therapeutics; December 2018. Accessed March 2021.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) tagraxofusp-erzs. National Comprehensive Cancer Network, 2021. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc." To view the most

recent and complete version of the Compendium, go online to NCCN.org. Accessed March 2021.

3. Pemmaraju N, Sweet KL, Lane AA, et al. Results of Pivotal Phase 2 Trial of SL-401 in Patients with Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN). Blood 2017 130:1298
4. Sweet KL, Pemmaraju N, Lane AA, et al. Lead-in Stage Results of a Pivotal Trial of SL-401, an Interleukin-3 Receptor (IL-3R) Targeting Biologic, in Patients with Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN) or Acute Myeloid Leukemia (AML). Blood 2015 126:3795
5. Pemmaraju N, Lane AA, Sweet KL, et al. Results from Phase 2 Trial Ongoing Expansion Stage of SL-401 in Patients with Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN). Blood 2016 128:342
6. Pemmaraju N, Lane AA, Sweet KL, et al. Tagraxofusp in Blastic Plasmacytoid Dendritic-Cell Neoplasm. N Engl J Med. 2019 Apr 25;380(17):1628-1637. doi: 10.1056/NEJMoa1815105.

## Appendix 1 – Covered Diagnosis Codes

| ICD-10 | ICD-10 Description |
|---|---|
| C86.4 | Blastic NK-cell lymphoma |

## Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

| Medicare Part B Administrative Contractor (MAC) Jurisdictions | | |
|---|---|---|
| **Jurisdiction** | **Applicable State/US Territory** | **Contractor** |
| E (1) | CA, HI, NV, AS, GU, CNMI | Noridian Healthcare Solutions, LLC |
| F (2 & 3) | AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ | Noridian Healthcare Solutions, LLC |
| 5 | KS, NE, IA, MO | Wisconsin Physicians Service Insurance Corp (WPS) |
| 6 | MN, WI, IL | National Government Services, Inc. (NGS) |
| H (4 & 7) | LA, AR, MS, TX, OK, CO, NM | Novitas Solutions, Inc. |
| 8 | MI, IN | Wisconsin Physicians Service Insurance Corp (WPS) |
| N (9) | FL, PR, VI | First Coast Service Options, Inc. |
| J (10) | TN, GA, AL | Palmetto GBA, LLC |

| Medicare Part B Administrative Contractor (MAC) Jurisdictions | | |
|---|---|---|
| **Jurisdiction** | **Applicable State/US Territory** | **Contractor** |
| M (11) | NC, SC, WV, VA (excluding below) | Palmetto GBA, LLC |
| L (12) | DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA) | Novitas Solutions, Inc. |
| K (13 & 14) | NY, CT, MA, RI, VT, ME, NH | National Government Services, Inc. (NGS) |