Elzonris™ (tagraxofusp-erzs)
(Intravenous)

Document Number: IC-0426

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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 serum albumin level of at least 3.2 g/dL prior to initiating therapy and will be monitored subsequently throughout therapy; **AND**

Universal Criteria [1-6]

- Patient has CD123-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 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 Approved 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]

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. • Administer Cycle 1 in the inpatient setting with patient observation through at least 24 hours after the last infusion. Subsequent cycles may be administered in a suitable outpatient ambulatory care setting that is equipped with appropriate monitoring.

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; November 2022. Accessed March 2023.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) tagraxofusp-erzs. National Comprehensive Cancer Network, 2023. 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 2023.

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: https://www.cms.gov/medicare-coverage-database/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)

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
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)
15	KY, OH	CGS Administrators, LLC

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If you need these services, contact a Grievance Specialist.

If you believe that PCHP has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:

Grievance Specialist
PreferredOne Community Health Plan
PO Box 59052
Minneapolis, MN 55459-0052
Phone: 1.800.940.5049 (TTY: 763.847.4013)
Fax: 763.847.4010
customerservice@preferredone.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, a Grievance Specialist is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html.

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U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

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