

Elzonris™ (tagraxofusp-erzs) (Intravenous)

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Dates Reviewed: 02/2019, 02/2020, 04/2021, 04/2022, 04/2023

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	<p>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.</p> <ul style="list-style-type: none"> • 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

Nondiscrimination & Language Access Policy

Aspirus Health Plan, Inc. complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, sex, sexual orientation, or gender identity. We do not exclude people or treat them differently because of race, color, national origin, age, disability, sex, sexual orientation, or gender identity.

We will:

Provide free aids and services to people with disabilities to communicate effectively with us, such as:

- Qualified sign language interpreters
- Written information in other formats (large print, audio, accessible electronic formats, other formats)

Provide free language services to people whose primary language is not English, such as:

- Qualified interpreters
- Information written in other languages

If you need these services, contact us at the phone number shown on the inside cover of this contract, your id card, or aspirushealthplan.com.

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

Nondiscrimination Grievance Coordinator
Aspirus Health Plan, Inc.
PO Box 1062
Minneapolis, MN 55440
Phone: 1.866.631.5404 (TTY: 711)
Fax: 763.847.4010
Email: customerservice@aspirushealthplan.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Nondiscrimination Grievance Coordinator 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>.

Language Assistance Services

Albanian: KUJDES: Nëse flitni shqip, për ju ka në dispozicion shërbime të asistencës gjuhësore, pa pagesë. Telefononi në 1.866.631.5404 (TTY: 711).

Arabic: تنبيه: إذا كنت تتحدث اللغة العربية، فإن خدمات المساعدة اللغوية متاحة لك مجاناً. اتصل بن اعلى رقم الهاتف 1.866.631.5404 (رقم هاتف الصم والبك : 711)

French: ATTENTION : Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelezle 1.866.631.5404 (ATS : 711).

German: ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 1.866.631.5404 (TTY: 711).

Hindi: _यान द_ : य_द आप िहंदी बोलते ह_ तो आपके िलए मु_त म_ भाषा सहायता सेवाएं उपल_ध ह_। 1.866.631.5404 (TTY: 711) पर कॉल कर_।

Hmong: LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1.866.631.5404 (TTY: 711).

Korean: 주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 1.866.631.5404 (TTY: 711)번으로 전화해 주십시오.

Polish: UWAGA: Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer 1.866.631.5404 (TTY: 711).

Russian: ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 1.866.631.5404 (телетайп: 711).

Spanish: ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1.866.631.5404 (TTY: 711).

Tagalog: PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nangwalang bayad. Tumawag sa 1.866.631.5404 (TTY: 711)

Traditional Chinese: 注意: 如果您使用繁體中文, 您可以免費獲得語言援助服務。請致電 1.866.631.5404 (TTY:711)。

Vietnamese: CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1.866.631.5404 (TTY: 711).

Pennsylvania Dutch: Wann du Deitsch (Pennsylvania German / Dutch) schwetzsch, kannscht du mitaus Koschte ebbergricke, ass dihr helft mit die englisch Schprooch. Ruf selli Nummer uff: Call 1.866.631.5404 (TTY: 711).

Lao: ໄປ່ດຊາຍ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ, ໂດຍບໍ່ເສັຽຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທ 1.866.631.5404 (TTY:711).