Tagraxofusp-erzs (Elzonris®)

NDC CODE(S) 72187-0401-xx ELZONRIS 1000MCG/ML Solution (STEMLINE THERAPEUTICS)

DESCRIPTION

Tagraxofusp-erzs is a monoclonal antibody that binds the cytokine interleukin-6 (IL-6). This prevents IL-6 from binding to both soluble and membrane-bound IL-6 receptors. IL-6 is involved in diverse physiological processes, including coordination of the immune response to infection. When IL-6 is overproduced by cells within the lymph nodes it contributes to overgrowth of lymphatic cells and other systemic symptoms.

POLICY

- Tagraxofusp-erzs for the treatment of blastic plasmacytoid dendritic cell neoplasm (BPDCN) is considered ***medically necessary*** if the medical appropriateness criteria are met. **(See Medical Appropriateness below.)**

- Tagraxofusp-erzs for the treatment of other conditions/diseases is considered ***investigational.***

MEDICAL APPROPRIATENESS

INITIAL APPROVAL CRITERIA

- 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

- 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)

- 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;
  - 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

RENEWAL CRITERIA

- 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 the Initial Approval Criteria; **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)*

DOSAGE/ADMINISTRATION

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 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).*

LENGTH OF AUTHORIZATION

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

DOSING LIMITS

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

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

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the Medical Policy and a health plan, the express terms of the health plan will govern.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

SOURCES

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.
7. Lexi-Comp Online. (2019, February). AHFS DI. *Tagraxofusp-erzs. .* Retrieved February 10, 2020 from Lexi-Comp Online with AHFS.
8. MICROMEDEX Healthcare Series. Drugdex Drug Evaluations. (2019, January). *Tagraxofusp-erzs.* Retrieved February 10, 2020 from MICROMEDEX Healthcare Series.

EFFECTIVE DATE 8/31/2021

ID_MRx