ELZONRIS®
(tagraxofusp-erzs) Injection

Permanent J-Code and NTAP designation for ELZONRIS® (tagraxofusp-erzs) Injection for Intravenous (IV) Use, effective October 1, 2019

(Product not to scale)

J-Code: J9269

NTAP designation: XW033Q5 or XW043Q5*

Centers for Medicare & Medicaid Services (CMS) granted ELZONRIS Injection for IV Use a New Technology Add-On Payment (NTAP) designation for inpatient utilization.†

Coding and billing for ELZONRIS Injection for IV Use in the hospital inpatient setting

Permanent J-Code, effective October 1, 2019	**J9269**
ICD-10-PCS, effective October 1, 2019	**XW033Q5** or **XW043Q5***
Dispensing pack quantity	1 vial/box
NDC	72187-0401-1 or 72187-0401-01
Revenue Code	0636
CPT Codes	96413 or 96409
ICD-10 Diagnostic Code	C86.4
Description	Single-dose, sterile glass vial containing 1 mL of solution

*Procedure code required to initiate NTAP payment.

†Medicare beneficiaries at qualified facilities that report an appropriate diagnosis code and ICD-10-PCS for the inpatient administration of ELZONRIS Injection for IV Use may be eligible for additional payment. NTAP as defined by CMS is issued to new technology meeting specific criteria and thresholds. The technology must be: 1) New: 2 or 3 years following FDA approval; 2) Existing MS-DRG must be inadequate; and 3) Technology must have substantial clinical improvement over existing services. The amount of payment is the lesser of 65% of the cost of ELZONRIS Injection for IV Use **OR** 65% of the amount by which the cost of the case exceeds the MS-DRG payment.

INDICATION

- ELZONRIS is a CD123-directed cytotoxin for the treatment of blastic plasmacytoid dendritic cell neoplasm (BPDCN) in adults and in pediatric patients 2 years and older

IMPORTANT SAFETY INFORMATION

Boxed WARNING: CAPILLARY LEAK SYNDROME

- **Capillary Leak Syndrome (CLS), which may be life-threatening or fatal, can occur in patients receiving ELZONRIS. Monitor for signs and symptoms of CLS and take actions as recommended**

Please see additional Important Safety Information on the following page and full Prescribing Information, including Boxed WARNING.

Stemline®

Medication and Coding Information

ELZONRIS Injection for IV Use is a preservative-free, sterile, clear, colorless, 1,000 mcg in 1 mL solution supplied in a single-dose glass vial. Each carton contains one vial.

For clinical questions about ELZONRIS Injection for IV Use, please email StemlineUS@druginfo.com.

Stemline Therapeutics, Inc. does not influence or advocate for the use of any one distributor and makes no representation or guarantee of services or coverage of a product.

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IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS

Capillary Leak Syndrome

- ELZONRIS can cause capillary leak syndrome (CLS), which may be life-threatening or fatal if not properly managed. The overall incidence of CLS in clinical trials was 55% in patients receiving ELZONRIS, including 46% in Grades 1 or 2, 6% in Grade 3, 1% in Grade 4, and 2 fatal events. Common signs and symptoms (incidence ≥ 20%) associated with CLS that were reported during treatment with ELZONRIS include hypoalbuminemia, edema, weight gain, and hypotension
- Before initiating therapy with ELZONRIS, ensure that the patient has adequate cardiac function and serum albumin is ≥ 3.2 g/dL
- During treatment with ELZONRIS, ensure that serum albumin levels are ≥ 3.5 g/dL and have not been reduced by ≥ 0.5 g/dL from the albumin value measured prior to dosing initiation of the current cycle. Monitor serum albumin levels prior to the initiation of each dose or more often as indicated clinically thereafter. Additionally, assess patients for other signs or symptoms of CLS, including weight gain, new onset or worsening edema including pulmonary edema, hypotension, or hemodynamic instability
- Counsel patients to seek immediate medical attention should signs or symptoms of CLS occur at any time

Hypersensitivity Reactions

- ELZONRIS can cause severe hypersensitivity reactions. Grade 3 or higher events were reported in 10% of patients in clinical trials. Monitor patients for hypersensitivity reactions during treatment with ELZONRIS. Interrupt ELZONRIS infusion and provide supportive care as needed if a hypersensitivity reaction should occur. If the reaction is severe, discontinue ELZONRIS permanently

Hepatotoxicity

- Elevations in liver enzymes can occur with ELZONRIS. Grade 3 or higher elevations in liver enzymes occurred in approximately 40% of patients in clinical trials
- Monitor alanine aminotransferase (ALT) and aspartate aminotransferase (AST) prior to each infusion with ELZONRIS. Temporarily withhold ELZONRIS if the transaminases rise to greater than 5 times the upper limit of normal (ULN) and resume treatment upon normalization or when resolved

ADVERSE REACTIONS:

The most common adverse reactions in the clinical trials (incidence ≥ 30%) are capillary leak syndrome, nausea, fatigue, peripheral edema, pyrexia, and weight increase. The most common laboratory abnormalities (incidence ≥ 50%) are decreases in albumin, platelets, hemoglobin, calcium, sodium, and increases in glucose, ALT, and AST.

Please see full Prescribing Information, including Boxed WARNING.

To report SUSPECTED ADVERSE REACTIONS, contact Stemline Therapeutics, Inc. at 1-877-332-7961 or contact the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

VISIT ELZONRIS.COM/HCP FOR MORE INFORMATION.

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