## IMPORTANT SAFETY INFORMATION

#### **INDICATION**

 ELZONRIS is a CD123-directed cytotoxin indicated 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.

#### WARNINGS AND PRECAUTIONS

#### **Capillary Leak Syndrome**

- Capillary leak syndrome (CLS), including life-threatening and fatal cases, has been reported among patients treated with ELZONRIS. In patients receiving ELZONRIS in clinical trials, the overall incidence of CLS was 53% (65/122), including Grade 1 or 2 in 43% (52/122) of patients, Grade 3 in 7% (8/122) of patients, Grade 4 in 1% (1/122) of patients, and four fatalities (3%). The median time to onset was 4 days (range - 1 to 46 days), and all but 5 patients experienced an event in Cycle 1.
- Before initiating therapy with ELZONRIS, ensure that the patient has adequate cardiac function and serum albumin is greater than or equal to 3.2 g/dL. During treatment with ELZONRIS, monitor serum albumin levels prior to the initiation of each dose of ELZONRIS and as indicated clinically thereafter, and assess patients for other signs or symptoms of CLS, including weight gain, new onset or worsening edema, including pulmonary edema, hypotension or hemodynamic instability.

#### **Hypersensitivity Reactions**

 ELZONRIS can cause severe hypersensitivity reactions. In patients receiving ELZONRIS in clinical trials, hypersensitivity reactions were reported in 43% (53/122) of patients treated with ELZONRIS and were Grade ≥ 3 in 7% (9/122). Manifestations of hypersensitivity reported in  $\geq$  5% of patients include rash, pruritus, and stomatitis. Monitor patients for hypersensitivity reactions during treatment with ELZONRIS. Interrupt ELZONRIS infusion and provide supportive care as needed if a hypersensitivity reaction should occur.

#### Hepatotoxicity

- Treatment with ELZONRIS was associated with elevations in liver enzymes. In patients receiving ELZONRIS in clinical trials. elevations in ALT occurred in 79% (96/122) and elevations in AST occurred in 76% (93/122). Grade 3 ALT elevations were reported in 26% (32/122) of patients. Grade 3 AST elevations were reported in 30% (36/122) and Grade 4 AST elevations were reported in 3% (4/122) of patients. Elevated liver enzymes occurred in the majority of patients in Cycle 1 and were reversible following dose interruption.
- Monitor alanine aminotransferase (ALT) and aspartate aminotransferase (AST) prior to each infusion with ELZONRIS. Withhold ELZONRIS temporarily if the transaminases rise to greater than 5 times the upper limit of normal and resume treatment upon normalization or when resolved.

#### **ADVERSE REACTIONS:**

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

#### Please see Full Prescribing Information, including Boxed WARNING

S temline<sup>®</sup>

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.









# **CODING AND BILLING GUIDE FOR ELZONRIS<sup>®</sup>**

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

## **ELZONRIS INJECTION FOR IV USE Permanent J-Code**<sup>1</sup>: **Revenue Code<sup>3</sup>:**

J9269	0636
Injection,	
tagraxofusp-erzs,	
10 mcg	
To meg	

#### INDICATION

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

## 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.

## Full Prescribing Information, including Boxed WARNING.

S temline<sup>®</sup>

A Menarini Group Company

The information contained in this guide is intended to provide a general understanding of the coding and billing process and is not intended to assist healthcare providers in obtaining reimbursement for any specificc laim. This guide is for informational purposes only and does not represent legal or billing advice. The content here is based on information as of October 1, 2019 and is subject to change.

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Please see Important Safety Information, including Boxed WARNING on the last page and accompanying



This guide is designed to help healthcare providers, hospital staff, and coding and billing managers by providing information on coding and billing for ELZONRIS Injection for IV Use, in the hospital settings for all insurance types, including Medicare, Medicare Advantage, Medicaid, and commercial payers.

## **FIND IN THIS GUIDE**

- Coding and billing overview, processing a claim, overview of codes (NDC, ICD-10-CM, CPT, and HCPCS)
- Payer specifics: Medicare, Medicare Advantage, Medicaid, commercial payers
- Stemline ARC<sup>®</sup>
- Appendix:
- Sample annotated physician office billing CMS-1500
- Sample annotated hospital outpatient billing CMS-1450/UB-04
- Summary of billing codes

## SUMMARY OF CODING AND BILLING FOR ELZONRIS INJECTION FOR IV USE

DISPENSING PACK QUANTITY	1 vial/box
NDC	72187-0401-1 or 72187-0401-01
PERMANENT J-CODE	J9269 Injection, tagraxofusp-erzs, 10 mcg
CPT CODES <sup>4</sup>	96413 or 96409
DESCRIPTION <sup>5</sup>	Single-dose, sterile glass vial containing 1 mL of solution

**ELZONRIS Injection for IV Use J-Code effective October 1, 2019.** 

## CODING AND BILLING FOR ELZONRIS INJECTION FOR IV USE

#### Processing a claim

#### To process a claim, it is important to:

- Complete the correct form (CMS-1500, CMS-1450/UB-04)
- ✓ Include correct codes: NDC, ICD-10-CM, CPT, and HCPCS
- 🔮 Ensure all patient information (name, address, insurance ID number) is accurate
- Verify the name of the healthcare provider and National Provider Identifier (NPI)
- Vise the most appropriate ICD-10-CM diagnosis and CPT procedure codes associated with each patient's diagnosis and care
- Specify the setting or place of service (POS) where the infusion was provided (eg, hospital setting) and dose given (10-mcg increments)
- Sensure patient medical records contain documentation that supports the diagnosis and procedure codes submitted on the claim
- 🕑 Complete all claim form fields accurately and provide information upon request

#### **Overview of codes**

Once you have administered ELZONRIS Injection for IV Use to your patient, you may submit a claim to the patient's health plan. Correct coding is essential for timely claims processing and reimbursement. Important codes include the following:

#### National Drug Codes (NDCs)<sup>6</sup>

NDCs help healthcare providers and health plans identify specific product package sizes. Some health plans require healthcare providers to use an 11-digit NDC when reporting a drug on a claim form. Converting the 10-digit NDC for ELZONRIS Injection for IV Use to an 11-digit NDC requires the use of a leading zero in the product code.

International Classification of Disease, 10th Revision, Clinical Modification (ICD-10-CM) diagnosis code<sup>7</sup> Use the current ICD-10-CM codes to report a patient's diagnosis on claim submissions. Be sure to use the correct coding when submitting a claim for the item or service.

Healthcare Common Procedure Coding System (HCPCS) codes<sup>8,9</sup> Most health plans cover IV therapies under their medical benefit. CPT codes are used to identify services and procedures provided by a physician.

#### NDCs<sup>6</sup>

ELZONRIS Injection for IV Use NDC numbers are listed below. Please note that converting the 10-digit NDC to an 11-digit NDC requires the use of a leading zero in the product code.

ELZONRIS INJECTION FOR IV USE PACKAGE SIZE	NDC	FORMS
	10-digit: 72187-0401-1	CMS-1500; CMS-1450/UB-04
2.25 in. × 2 in.	11-digit: 72187-0401-01	CMS-1500; UB-04

Always confirm coding requirements with each patient's individual health plan, as the information required may vary.



## CODING AND BILLING OVERVIEW (cont'd)

#### ICD-10-CM diagnosis codes

It's important to check with the health plan to verify coding and special billing requirements. The ICD-10-CM diagnosis code for ELZONRIS Injection for IV use is shown below.

The ICD-10-CM diagnosis code for ELZONRIS Injection for IV use<sup>10</sup>

		FO	RMS
ICD-10-C		CMS-1500	CMS-1450 (UB-04)
C86.4	Blastic NK-cell lymphoma Blastic plasmacytoid dendritic cell neoplasm (BPDCN)	ltem 21	Form Locator 67

#### HCPCS codes<sup>8,9</sup>

Most health plans cover IV therapies under their medical benefit. CPT codes are used to identify services and procedures provided by a physician.

HCPCS LEVEL I CODES <sup>5,6</sup>		DESCRIPTION	FORMS			
		IV	CMS-1500	CMS-1450/UB-04		
CPT Code	96413	Chemotherapy administration, IV infusion technique, up to 1 hour, single or initial substance/drug	ltem 24D	Form Locator 44		
CFTCOde	96409	Chemotherapy administration; intravenous, push technique, single or initial substance/drug	item 24D	FOITH LOCALOF 44		
Revenue Code	0636	Drugs requiring detailed coding	N/A	Form Locators 42 and 43		
PERMANENT J-C	ODE <sup>1</sup>					
J926	9	ELZONRIS Injection, tagraxofusp-erzs, 10 mcg	N/A	Form Locator 44 or electronic comment field		

## **PAYER SPECIFICS**

#### Medicare

Medicare Part B<sup>11</sup>

ELZONRIS Injection for IV Use is covered by Medicare Part B in the outpatient setting.

#### Medicare Administrative Contractors (MACs)<sup>12</sup>

MACs are multistate regional contractors responsible for administering both Medicare Part A and Medicare Part B claims. MACs are the central point of contact for providers of healthcare services. MACs are the primary operational contact between the Medicare fee-for-service (FFS) program and the healthcare providers enrolled in the program.

To find your Medicare Part B or durable medical equipment (DME) MAC jurisdiction, visit the CMS website.

#### Medicare Part D<sup>11</sup>

As an infused drug, ELZONRIS Injection for IV Use is not covered under Medicare Part D benefit.

#### Medicaid

ELZONRIS Injection for IV Use may be available under state Medicaid programs. Each state Medicaid program has its own eligibility standards, so coverage will vary from state to state. It's important to understand how your patient's Medicaid coverage works by contacting the Medicaid program or accessing the specific coverage information. Some Medicaid plans require prior authorization.

#### Commercial Health Plans<sup>7</sup>

Commercial health plans may provide coverage for ELZONRIS Injection for IV Use under the pharmacy or medical benefit. While commercial health plans may provide coverage under either of these benefits, the medical benefit will be utilized for the majority of plans. Please contact your patient's health plan for further guidance. Specific coverage requirements and restrictions depend on a given patient's benefits and may vary by plan type and site of service.

References: 1. Centers for Medicare & Medicaid Services. C-Codes Effective October 1, 2019. Available at https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/ HCPCS-Quarterly-Update.html. Accessed January 16, 2025. 2. Centers for Medicare & Medicaid Services. Fiscal year 2020 final rule. Available at https://www.cms.gov/ Medicare/Medicare-Fee-for-Service Payment/AcuteInpatientPPS/FY2020-IPPS-Final-Rule-Home-Page-Items/FY2020-IPPS-Final-Rule-Data-Files.html. Accessed January 16, 2025. 3. MLN Matters article index 2017 through August 2018. Centers for Medicare & Medicaid Services website. https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/2017-2018MLNMattersArticlesIndex.pdf. Accessed January 16, 2025. 4. Optum360. 2018 Coding Companion for Oncology/Hematology. Eden Prairie, MN: Optum360; 2017. 5. ELZONRIS [prescribing information]. New York, NY: Stemline Therapeutics, Inc.; July 2023. 6. National Drug Code database background information. US Food & Drug Administration website. https://www.fda.gov/drugs/developmentapprovalprocess/ucm070829.html. Updated March 20, 2017. Accessed January 16, 2025. 7. ICD-10-CM, ICD-10-PCS, CPT, and HCPCS code sets. Centers for Medicare & Medicaid Services website. https://www.cms.gov/Outreachand-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/ICD9-10CM-ICD10PCS-CPT-HCPCS-Code-Sets-Educational-Tool-ICN900943.pdf Published May 2018. Accessed January 16, 2025. 8. Einodshofer MT, Duren LN. Cost management through care management, part 2: the importance of managing specialty drug utilization in the medical benefit. Am Health Drug Benefits. 2012;5(6):359-364. 9. HCPCS coding questions. Centers for Medicare & Medicaid Services website. https://www.cms.gov/ Medicare/Coding/MedHCPCSGenInfo/HCPCS\_Coding\_Questions.html. Updated July 22, 2013. Accessed January 16, 2025. 10. 2018 ICD-10 CM and GEMs. Centers for Medicare & Medicaid Services website. https://www.cms.gov/Medicare/Coding/ICD10/2018-ICD-10-CM-and-GEMs.html. Updated August 11, 2018. Accessed January 16, 2025. 11. Medicare drug coverage under Medicare Part A, Part B, Part C, & Part D. Centers for Medicare & Medicaid Services website. https://www.cms.gov/outreach-and-education/ outreach/partnerships/downloads/11315-p.pdf. Updated August 2017. Accessed January 16, 2025. 12. What is a MAC. Centers for Medicare & Medicaid Services website. https://www.cms.gov/Medicare/Medicare-Contracting/Medicare-Administrative-Contractors/What-is-a-MAC.html. Updated October 26, 2017. Accessed January 16, 2025.

#### To find your Medicare Part B or DME MAC jurisdiction, visit the CMS website.



## **APPENDIX SAMPLE ANNOTATED FORMS**

**Note:** Sample form and annotations are for example only. Providers must contact their patient's health plan representative to confirm required coding and documentation for individual situations.

• Incomplete or invalid information will render form invalid and unable to be processed, causing payment delays

#### Sample CMS-1500 physician office billing: ELZONRIS INJECTION FOR IV USE

LINE	TITLE	INFO	CODES
19		d for electronic claims (SV202-2) is limited to 80 character of additional space is needed. Check with the payer	
21	DIAGNOSIS CODE	Enter appropriate ICD-10-CM diagnosis code(s) corresponding to patient's diagnosis.	BPDCN ICD-10-CM: C86.4
24	DATES, PROCEDURES	, POINTER, AND MODIFIER	
		Commercial, Medicare, Medicare Advantage, Medicaid fee-for-service HCPCS codes	• J9269 Injection, tagraxofusp-erzs, 10 mcg
24D	PROCEDURES, Services, or Supplies	CPT - Chemotherapy and complex drug/biologic infusions	<ul> <li>96413 Chemotherapy administration, IV infusion technique, up to 1 hour, single or initial substance or drug</li> <li>96409 Chemotherapy administration, IV push, single or initial substance or drug</li> </ul>
24E	DIAGNOSIS POINTER	Specify diagnosis from Item 21, A-L, relating to each C	PT/HCPCS code listed in Item 24D.
24G	NDC SERVICE UNITS	Plan requires the number of NDC units J9269 injectior Specify the appropriate number of service units as des	

#### HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

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## **APPENDIX SAMPLE ANNOTATED FORMS**

**Note:** Sample form and annotations are for example only. Providers must contact their patient's health plan representative to confirm required coding and documentation for individual situations.

• Incomplete or invalid information will render form invalid and unable to be processed, causing payment delays

### Sample CMS-1450/UB-04 hospital outpatient billing: ELZONRIS INJECTION FOR IV USE

LINE	DESCRIPTION		CODES
	REVENUE CODE:	DRUG	Medicare: Revenue code 0636 or 0335 chemotherapy administration IV
42	Corresponding to HCPCS or CPT <sup>©</sup> in FL44	PROCEDURE	Medicare and most payers require a revenue code for each procedure
	Payers vary on revenue code requirements. individual situations.	Please contact the	e patient's health plan to confirm required coding in
40	DESCRIPTION: ELZONRIS INJECTION	PRODUCT	J9269 Injection, tagraxofusp-erzs, 10 mcg
43	FOR IV USE PROCEDURE Revenue code: 0636	Revenue code: 0636	
		PRODUCT	J9269 Injection, tagraxofusp-erzs, 10 mcg Revenue code: 0636
44	PRODUCT AND PROCEDURE: ELZONRIS INJECTION FOR IV USE	PROCEDURE CPT	<ul> <li>CHEMOTHERAPY AND COMPLEX DRUG/BIOLOGIC INFUSIONS</li> <li>96413 Chemotherapy administration, IV infusion technique, up to 1 hour, single or initial substance/drug</li> <li>96409 Chemotherapy administration, IV push, single or initial substance/drug</li> <li>Revenue code: 0335</li> </ul>
46	NDC Service Units: Plan requires the number the appropriate number of service units as de		59 injection, tagraxofusp-erzs, <b>10 mcg</b> , used in Item 46. Specify dual payers. There may be variation.
66	DIAGNOSIS CODE		0
67	ICD-10-CM		<b>C86.4</b> is the principal diagnosis code for BPDCN
69	ADMIT DX		C86.4
Note: Er	nter code reflecting histology of patient's dise	ase diagnosis.	
80	Plans are different and some may require an information is provided for timely reimburse		on. Please check with the patient's plan to ensure all required



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## STEMLINE ARC® PROVIDES ACCESS, REIMBURSEMENT SUPPORT, AND CONNECTION TO RESOURCES FOR ELIGIBLE PATIENTS THROUGHOUT TREATMENT WITH ELZONRIS INJECTION FOR IV USE



#### CCESS

Support for benefits investigation and verification, information on alternate support, and co-pay support for eligible patients\*

#### eimbursement support Information regarding prior authorization, template letter of medical necessity, appeals of denied claims, and coding & billing support

#### Connection **ARC Patient Advocates** provide an overview of support services, confirm **ELZONRIS** coverage and financial assistance, and share helpful resources<sup>+</sup>

#### Stemline ARC is here to help patients, hospitals, and offices alike. We provide:

- · Hospital and office access/procurement support
- · Support for prior authorization, medical exceptions, and appeals of denied claims
- Billing and coding guidance, including J-code, NDC, ICD-10, and MS-DRG



#### Stemline Commercial Co-Pay Program

• Eligible patients may pay as little as \$0 per month supply of ELZONRIS Injection for IV Use



#### Stemline Patient Assistance Program<sup>‡</sup>

 The Stemline Patient Assistance Program provides ELZONRIS Injection for IV Use to eligible patients who are under- or uninsured. Patients must meet certain criteria to qualify. Call 1-833-4-STEMLINE (1-833-478-3654) for more information



#### Independent Third-Party Foundations<sup>§</sup>

Stemline ARC can provide information about independent third-party foundations for eligible patients

For more information about Stemline ARC, call 1-833-4-STEMLINE (1-833-478-3654) from 9:00 AM to 6:00 PM EST, Monday through Friday, or visit ELZONRIS.com/hcp/stemline-arc-summary. Fax completed enrollment form to 1-833-329-7836.

\*In order to be eligible for the Stemline Commercial Co-Pay Program, the patient must not have government-funded health insurance (eg, Medicare, Medicaid, or any other federal or state program), must be taking ELZONRIS Injection for IV Use for an FDA-approved indication, and must confirm that they meet all of the eligibility criteria and agree to the rules set forth in the terms and conditions for the program. Patients and healthcare providers are responsible for completing and submitting enrollment forms and coverage or reimbursement documentation. Stemline Therapeutics, Inc. makes no representation or guarantee concerning coverage or reimbursement of any service or item.

<sup>†</sup>ARC Patient Advocates are available to provide resource information and answer questions about financial assistance, insurance benefits, and coverage for ELZONRIS. This supplemental support is not intended to replace discussions between patients and their healthcare providers.

<sup>+</sup>To be eligible for this program, insured patients must have exhausted all other forms of patient assistance and meet financial criteria. Insured and uninsured patients must also meet certain eligibility criteria.

Stemline Therapeutics, Inc. does not influence or control the operations or eligibility criteria of any independent charitable assistance foundation and cannot guarantee assistance after information has been provided by Stemline ARC. The information is provided as a resource to patients. The foundations that we discuss with patients are not exhaustive or indicative of Stemline Therapeutics, Inc.'s endorsement or financial support. There may be other foundations to support the patient's disease state.





Scan the OR code and visit Stemline ARC website to know more about access and support