CODING AND BILLING GUIDE FOR

ELZONRIS®
(tagraxofusp-erzs) Injection

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

ELZONRIS INJECTION FOR IV USE			
Permanent J-Code[1]: **J9269** Injection, tagraxofusp-erzs, 10 mcg	**ICD-10-PCS[2]:** **XW033Q5** or **XW043Q5*** 	**Revenue Code[3]:** **0636**	**CPT Codes[4]:** **96413** or **96409**

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

*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.

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 specific claim. 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.

Please see accompanying full Prescribing Information, including Boxed WARNING.

Stemline®

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™
- 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[4]	96413 or 96409
DESCRIPTION[5]	Single-dose, sterile glass vial containing 1 mL of solution

NTAP DESIGNATION: ICD-10-PCS CODES LISTED BELOW FOR MEDICAL NECESSITY OF ELZONRIS INJECTION FOR IV USE

- C86.4, the principal diagnosis code for blastic plasmacytoid dendritic cell neoplasm (BPDCN)
- Procedure: Required ICD-10-PCS
- Procedure code: XW033Q5 or XW043Q5

For Medicare patients, non-exempt hospitals that report the correct ICD-10-PCS procedure and diagnosis codes may qualify for additional reimbursement 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.

ELZONRIS Injection for IV Use NTAP and 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)

✓ Use 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)

✓ Ensure 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)[6]
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[7]
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[8,9]
Most health plans cover IV therapies under their medical benefit. CPT codes are used to identify services and procedures provided by a physician.

NDCs[6]

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
2.25 in. × 2 in.	10-digit: 72187-0401-1	CMS-1500; CMS-1450/UB-04
	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.

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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[10]

ICD-10-CM	DESCRIPTION	FORMS	
		CMS-1500	CMS-1450 (UB-04)
C86.4	Blastic NK-cell lymphoma Blastic plasmacytoid dendritic cell neoplasm (BPDCN)	Item 21	Form Locator 67

HCPCS codes[8,9]
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[5,6]		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	Item 24D	Form Locator 44
	96409	Chemotherapy administration; intravenous, push technique, single or initial substance/drug		
Revenue Code	0636	Drugs requiring detailed coding	N/A	Form Locators 42 and 43
PERMANENT J-CODE[1]				
J9269		ELZONRIS Injection, tagraxofusp-erzs, 10 mcg	N/A	Form Locator 44 or electronic comment field

PAYER SPECIFICS

Medicare
Medicare Part B[11]
ELZONRIS Injection for IV Use is covered by Medicare Part B in the outpatient setting.

Medicare Administrative Contractors (MACs)[12]
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[11]
As an infused drug, ELZONRIS Injection for IV Use is not covered under Medicare Part D benefit.

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

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[7]
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 September 5, 2019. **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 August 26, 2019. **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 October 15, 2018. **4.** Optum360. 2018 Coding Companion for Oncology/Hematology. Eden Prairie, MN: Optum360; 2017. **5.** ELZONRIS [prescribing information]. New York, NY, US: Stemline Therapeutics, Inc.; December 2018. **6.** National Drug Code database background information. US Food & Drug Administration website. https://www.fda.gov/drugs/developmentapprovalprocess/ucm070829.htm. Updated March 20, 2017. Accessed October 8, 2018. **7.** ICD-10-CM, ICD-10-PCS, CPT, and HCPCS code sets. Centers for Medicare & Medicaid Services website. https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/ICD9-10CM-ICD10PCS-CPT-HCPCS-Code-Sets-Educational-Tool-ICN900943.pdf Published May 2018. Accessed October 8, 2018. **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 October 9, 2018. **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 October 8, 2018. **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 October 8, 2018. **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 October 9, 2018.

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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-1500 physician office billing: ELZONRIS INJECTION FOR IV USE

LINE	TITLE	INFO	CODES
19		**Note:** The reporting field for electronic claims (SV202-2) is limited to 80 characters. However, some payers may allow utilization of Loop 2300 NTE 01 and 02 if additional space is needed. Check with the payer for additional guidance.	
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		
24D	PROCEDURES, SERVICES, OR SUPPLIES	**Commercial, Medicare, Medicare Advantage, Medicaid fee-for-service HCPCS codes**	• **J9269** Injection, tagraxofusp-erzs, 10 mcg
		CPT - Chemotherapy and complex drug/biologic infusions	• **96413** Chemotherapy administration, IV infusion technique, up to 1 hour, single or initial substance or drug • **96409** Chemotherapy administration, IV push, single or initial substance or drug
24E	DIAGNOSIS POINTER	Specify diagnosis from Item 21, A-L, relating to each CPT/HCPCS code listed in Item 24D.	
24G	NDC SERVICE UNITS	Plan requires the number of NDC units J9269 injection, tagraxofusp-erzs, **10 mcg**, used in Item 24G. Specify the appropriate number of service units as designated by individual payers. There may be variation.	

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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
42	**REVENUE CODE:** Corresponding to HCPCS or CPT© in FL44	DRUG	**Medicare:** Revenue code **0636** or **0335** chemotherapy administration IV
		PROCEDURE	Medicare and most payers require a revenue code for each procedure
	Payers vary on revenue code requirements. Please contact the patient's health plan to confirm required coding in individual situations.		
43	**DESCRIPTION:** ELZONRIS INJECTION FOR IV USE	PRODUCT	**J9269** Injection, tagraxofusp-erzs, 10 mcg
		PROCEDURE	Revenue code: 0636
44	**PRODUCT AND PROCEDURE:** ELZONRIS INJECTION FOR IV USE	PRODUCT	**J9269** Injection, tagraxofusp-erzs, 10 mcg **Revenue code: 0636**
		PROCEDURE CPT	**CHEMOTHERAPY AND COMPLEX DRUG/BIOLOGIC INFUSIONS** • **96413** Chemotherapy administration, IV infusion technique, up to 1 hour, single or initial substance/drug • **96409** Chemotherapy administration, IV push, single or initial substance/drug **Revenue code: 0335**
46	**NDC Service Units:** Plan requires the number of NDC units J9269 injection, tagraxofusp-erzs,**10 mcg**, used in Item 46. Specify the appropriate number of service units as designated by individual payers. There may be variation.		
66	**DIAGNOSIS CODE**		**0**
67	**ICD-10-CM**		**C86.4** is the principal diagnosis code for BPDCN
69	**ADMIT DX**		**C86.4**
	Note: Enter code reflecting histology of patient's disease diagnosis.		
74	**ICD-10-PCS**		**XW033Q5 or XW043Q5**
80	Plans are different and some may require additional information. Please check with the patient's plan to ensure all required information is provided for timely reimbursement.		

Sample CMS-1450/UB-04 annotated form

STEMLINE ARC™ PROVIDES ACCESS, REIMBURSEMENT SUPPORT, AND CARE FOR ELIGIBLE PATIENTS THROUGHOUT TREATMENT WITH ELZONRIS INJECTION FOR IV USE

stemline arc™
access | reimbursement support | care

access	**reimbursement support**	**care**
Support for benefits investigation and verification, information on alternate support, and co-pay support for eligible patients*	Information regarding prior authorization, template letter of medical necessity, appeals of denied claims, and coding & billing support	Dedicated Nurse Advocates provide personalized education and information about product and disease state information, including helpful tools and resources†

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

$0

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‡
- 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§
- 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 StemlineARC.com. 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.

†Dedicated Nurse Advocates are available to provide education and answer questions about treatment with ELZONRIS Injection for IV Use. Nurse Advocate support is not intended to replace discussions between patients and their healthcare providers.

‡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.

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stemline arc™
access | reimbursement support | care