CODING AND BILLING GUIDE FOR



ELZONRIS™ (tagraxofusp-erzs) INJECTION FOR INTRAVENOUS (IV) USE

HCPCS Level II codes¹⁻⁴: C9049, J3490, J3590,

Revenue code5:

CPT codes6: 96413 or 96409

or J9999

0636

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 July 2019 and is subject to change.

Effective July 1, 2019,

ELZONRIS™ (tagraxofusp-erzs) Injection of Intravenous (IV) Use now has an assigned C-Code:

C9049, ELZONRIS Injection for IV Use, 10 mcg

Please see enclosed full Prescribing Information, including Boxed WARNING.



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 outpatient 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 IN THE HOSPITAL OUTPATIENT SETTING

DISPENSING PACK QUANTITY	1 vial/box
NDC	72187-0401-1 or 72187-0401-01
HCPCS LEVEL II CODES ¹⁻⁴	C9049, J3490, J3590, or J9999
CPT CODES ⁶	96413 or 96409
DESCRIPTION ⁷	Single-dose, sterile glass vial containing 1 mL of solution

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)
- 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)8

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 code9

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^{10,11}

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

NDCs8

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. x 2 in.	10-digit: 72187-0401-1	CMS-1500; CMS-1450/UB-04			
	11-digit: 72187-0401-01	CMS-1500; UB-04			

When filling out the CMS-1500 form, it's important to include the drug name, NDC, and dose given in Item 19. It is also important to confirm with each patient's health plan, as the information required may vary.



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 Use¹²

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

Based on the site of care (ie, provider infusion center vs outpatient infusion center), different forms and codes will be used.

The following ICD-10-CM diagnosis codes are excluded^{12,13}:

- · C84.7 Anaplastic large cell lymphoma, ALK-negative
- C84.6 Anaplastic large cell lymphoma, ALK-positive
- · C84.9 Mature T/NK-cell lymphomas
- · C85.8 Other specified types of non-Hodgkin lymphoma

HCPCS codes^{10,11}

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			
HCPCS LEVEL 1C	ODES**	IV	CMS 1500	CMS 1450/UB-04		
CPT Code*	96413	Chemotherapy administration, IV infusion technique, up to 1 hour, single or initial substance or drug	Item 24D	Form Locator 44		
CF1 Code	96409	Chemotherapy administration; intravenous, push technique, single or initial substance/drug	item 240	FOITI LOCATOI 44		
Revenue Code	0636	Drugs requiring detailed coding	N/A	Form Locators 42 and 43		
HCPCS LEVEL II C	CODES ¹⁻⁴					
C904	9	ELZONRIS Injection, tagraxofusp-erzs, 10 mcg	N/A			
J3490 ⁺ J3590		J3490 [†] Unclassified drugs		Form Locator 44 or electronic		
		J3590 Unclassified biologics		comment field		
J999 ⁽	9	Not otherwise classified, antineoplastic drugs	Item 24D			

^{*}Medicare claims billed in the hospital outpatient setting with date of service after 7/1/2019 may be filled using C9049 with the appropriate billing units.

[†]In the hospital outpatient setting until a permanent HCPCS is assigned by CMS. The earliest date expected is 1/1/2020. When using HCPCS code J3490, report one unit of ELZONRIS Injection for IV Use.

CODING AND BILLING OVERVIEW (cont'd)

PAYER SPECIFICS

Medicare

Medicare Part B14

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

Medicare Administrative Contractors (MACs)¹⁵

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 DME MAC jurisdiction, visit the CMS website.

Medicare Part D14

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 Plans⁹

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. HCPCS code J3490. HCPCS.codes website. https://hcpcs.codes/j-codes/J3490. Accessed October 15, 2018. 2. HCPCS code J3590. HCPCS.codes website. https:// hcpcs.codes/j-codes/J3590. Accessed October 15, 2018. 3. HCPCS code J9999. HCPCS.codes website. https://hcpcs.codes/j-codes/J9999. Accessed October 15, 2018. 4. July 2009 update of the Hospital Outpatient Prospective Payment System. Centers for Medicare & Medicaid Services website. https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM6492.pdf. Accessed October 15, 2018. 5. 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. 6. Optum360. 2018 Coding Companion for Oncology/Hematology. Eden Prairie, MN: Optum360; 2017. 7. ELZONRIS [prescribing information]. New York, NY, US: Stemline Therapeutics, Inc.; December 2018. 8. 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. 9. 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-COde-Sets-Educational-Tool-ICN900943.pdf Published May 2018. Accessed October 8, 2018. 10. 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. 11. 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. 12. 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. 13. Arber DA, Orazi A, Hasserjian R, et al. The 2016 revision to the World Health Organization classification of myeloid neoplasms and acute leukemia. Blood. 2016;127(20):2391-2405. 14. 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. 15. 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.



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	
	PRODUCT	Commercial, Medicare, Medicare Advantage, Medicaid fee-for-service HCPCS codes	J3490, J3590, or J9999	
	INFORMATION Plan may accept	National Drug Code (NDC) number	10-digit: 72187-0401-1 11-digit: 72187-0401-01	
19	Not-Otherwise- Classified (NOC)	To report ELZONRIS INJECTION FOR IV USE, use of NO • Name of drug (brand/generic): ELZONRIS INJECTION • Dose, strength, unit of measure (ie, mg, ml, or unit), a	N FOR IV USE/tagraxofusp	
		nts necessitate that the field also contain information or ber, drug name, unit of measure (ie, mg, ml, or unit), and		
		d for electronic claims (SV202-2) is limited to 80 charact 02 if additional space is needed. Check with the payer 1		
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	 C9049 Injection for IV infusion, tagraxofusp-erzs, 10 mcg J3490 Unclassified drug J3590 Unclassified biologics J9999 NOC, antineoplastic drugs 	
240		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 C	PT/HCPCS code listed in Item 24D.	
24G	NDC SERVICE UNITS	Plan requires the number of NDC units C9049 injection Specify the appropriate number of service units as des		

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	5. PATIENT'S ADDRESS (No., Street)	6. PATIENT RELATIONSHIP TO INSUREC: Self Spouse Child Other	7. INSURED'S ADDRESS (No., Street) When insured and patient are the same: SAME	
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	b. RESERVED FOR NUCC USE	b. AUTO ACCIDENT? PLACE (State)	b. OTHER CLAIM ID (Designated by NUCC)	N O
	Leave blank	YES NO NO		AN
	c. RESERVED FOR NUCC USE Leave blank	c. OTHER ACCIDENT?	o. INSURANCE PLAN NAME OF PROGRAM NAME 9-digit PAYER ID# of primary insurer	PATIENT AND INSURED INFORMATION
	d. INSURANCE PLAN NAME OR PROGRAM NAME	10d, CLAIM CODES (Designated by NUCC)	d. IS THERE ANOTHER HEALTH BENEFIT PLAN?	PAT
	COBA Medigap-based identifier	Medicaid info. (MDC##)	YES NO If yes, complete items 9, 9a, and 9d.	1
	READ BACK OF FORM BEFORE COMPLETING 12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE. I authorize the r	elease of any medical or other information necessary	 INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for 	
	to process this claim. I also request payment of government benefits either to below.		services described below.	
	_{SIGNED} Can be "SIGNATURE ON FILE"	MM DD CCYY	SIGNED	*
	MM DD YY	OTHER DATE L. DD YY MM DD YY	16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION FROM MM DD YY TO MM DD YY	1
	17. NAME OF REFERRING PROVIDER OR OTHER SOURCE 17a.	PIPE DD 77	18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES	1
		NPI	FROM MM DD YY TO MM DD YY	
	19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC) Elzonris (tagraxofusp) injection for IV Use; NDC:72187-0401-1; D	ose: 12 mca/ka: cost	20. OUTSIDE LAB? \$ CHARGES	
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	31. SIGNATURE OF PHYSICIAN OR SUPPLIER 32. SERVICE FAC			
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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/UB04 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® 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	patient's health plan to confirm required coding in				
43	DESCRIPTION: ELZONRIS INJECTION	PRODUCT	C9049, J3490, J3590, or J9999				
43	FOR IV USE	PROCEDURE	Revenue code: 0636				
		PRODUCT	C9049, J3490, J3590, or J9999 Revenue code: 0636				
44	PRODUCT AND PROCEDURE: ELZONRIS INJECTION FOR IV USE	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				
	SERVICE UNITS: Injection, tagraxofusp-erzs, 10 mcg	HCPCS	• C9049, J3490, J3590, or J9999				
46	Medicaid and other payers may have different requirements. Please confirm with the payer.						
	Effective January 1, 2017, Medicare requires when applicable.	s the use of the JW	/ modifier on all claims that include wasted product				
66	DIAGNOSIS CODE		0				
67	ICD-10-CM		C86.4 is the principal diagnosis code for BPDCN				
69	ADMIT DX		C86.4				
Note: Er	nter code reflecting histology of patient's dise	ase diagnosis.					
	REMARKS: ELZONRIS INJECTION FOR IV USE	HCPCS	• C9049 • J3490, J3590, or J9999				
	NDC	10-digit: 11-digit:	72187-0401-1 72187-0401-01				
80	Plans may accept NOC. However, this requires additional information: Name of drug (brand/generic): ELZONRIS INJECTION FOR IV USE/tagraxofusp-erzs NDC number: 10-digit: 72187-0401-1 or 11-digit: 72187-0401-01 Dose, strength, unit of measure (ie, mg, ml, or unit), and route of administration: infusion Cost						
	HIPAA 5010 requirements necessitate that the including the NDC number, drug name, unit of		n information on any other injectable drug being used by the patient, mL, or unit), and cost.				

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STEMLINE ARC PROVIDES ACCESS, REIMBURSEMENT SUPPORT, AND CARE TO ELIGIBLE PATIENTS TAKING ELZONRIS INJECTION FOR IV USE



(a) ccess

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

reimbursement support

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 hospitals, offices, and patients 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 HCPCS, NDCs, and ICD-10 codes



Stemline Commercial Co-Pay Program[‡]

Eligible patients may pay as little as \$0 for 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^{II}

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 8:00 AM to 8:00 PM ET, 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.

[‡]Patients must meet eligibility criteria. 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.

§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.

"Sternline 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 Sternline ARC. The information is provided as a resource to patients. The foundations that we discuss with patients are not exhaustive or indicative of Sternline Therapeutics, Inc.'s endorsement or financial support. There may be other foundations to support the patient's disease state.





