

CODING AND BILLING GUIDE FOR



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-Code¹: J9269 Injection, tagraxofusp- erzs, 10 mcg	ICD-10-PCS²: XW033Q5 or XW043Q5*	Revenue Code³: 0636	CPT Codes⁴: 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.



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 code⁷
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.

NDCs⁶
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.



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 Use¹⁰

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 B¹¹

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 D¹¹

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 Plans⁷

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/HCPSCReleaseCodeSets/HCPSC-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 HCPSC 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. HCPSC coding questions. Centers for Medicare & Medicaid Services website. https://www.cms.gov/Medicare/Coding/MedHCPSCGenInfo/HCPSC_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.



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	<ul style="list-style-type: none"> • J9269 Injection, tagraxofusp-erzs, 10 mcg
		CPT - Chemotherapy and complex drug/biologic infusions	<ul style="list-style-type: none"> • 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.	

HEALTH INSURANCE CLAIM FORM

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

PICA										PICA									
1. MEDICARE MEDICAID TRICARE CHAMPVA GROUP HEALTH PLAN FECA BLK LUNG OTHER (Medicare#) (Medicaid#) (ID#/DoD#) (Member ID#) (ID#) (ID#) (ID#)										1a. INSURED'S I.D. NUMBER (For Program in Item 1) Enter Medicare HICN									
2. PATIENT'S NAME (Last Name, First Name, Middle Initial)										3. PATIENT'S BIRTH DATE SEX MM DD CCYY M F									
4. INSURED'S NAME (Last Name, First Name, Middle Initial) When insured and patient are the same: SAME										5. PATIENT'S ADDRESS (No., Street) Self Spouse Child Other									
6. INSURED'S ADDRESS (No., Street) When insured and patient are the same: SAME										7. INSURED'S ADDRESS (No., Street) When insured and patient are the same: SAME									
CITY STATE										CITY STATE									
ZIP CODE TELEPHONE (include Area Code)										ZIP CODE TELEPHONE (include Area Code)									
9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)										10. IS PATIENT'S CONDITION RELATED TO: a. EMPLOYMENT? (Current or Previous) b. AUTO ACCIDENT? PLACE (State) c. OTHER ACCIDENT?									
a. OTHER INSURED'S POLICY OR GROUP NUMBER i.e., Medigap Policy number b. RESERVED FOR NUCC USE Leave blank c. RESERVED FOR NUCC USE Leave blank										11. INSURED'S POLICY GROUP OR FECA NUMBER Must be complete a. INSURED'S DATE OF BIRTH SEX MM DD CCYY M F b. OTHER CLAIM ID (Designated by NUCC) c. INSURANCE PLAN NAME OR PROGRAM NAME 9-digit PAYER ID# of primary insurer d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES NO If yes, complete items 9, 10, and 11.									
d. INSURANCE PLAN NAME OR PROGRAM NAME COBA Medigap-based identifier										12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE (I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below.) SIGNED Can be "SIGNATURE ON FILE" DATE MM DD CCYY									
14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (M/P) MM DD YY QUAL.										15. OTHER DATE QUAL. MM DD YY									
17. NAME OF REFERRING PROVIDER OR OTHER SOURCE DN Name										16. DATED PATIENT UNABLE TO WORK IN CURRENT OCCUPATION FROM MM DD YY TO MM DD YY									
18. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)										19. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES FROM MM DD YY TO MM DD YY									
21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY (Include A-L to service line below (24E)) A. C86.4 B. C. D. E. F. G. H. I. J. K. L.										20. OUTSIDE LAB? \$ CHARGES YES NO									
24. A. DATE(S) OF SERVICE To B. PLACE OF SERVICE C. D. PROCEDURES, SERVICES, OR SUPPLIES (Specify Unusual Circumstances) E. DIAGNOSIS POINTER F. \$ CHARGES G. DAYS OUT H. EPSDT Family Plan I. ID. QUAL. J. RENDERING PROVIDER ID. # 1 MM DD YY MM DD YY 19, 20, or 21 J9269 A x NPI 2 96413 A 1 NPI 3 96409 A 1 NPI 4 NPI 5 NPI 6 NPI										22. RESUBMISSION CODE ORIGINAL REF. NO. Leave blank 23. PRIOR AUTHORIZATION NUMBER									
25. FEDERAL TAX I.D. NUMBER SSN EIN Required field										26. PATIENT'S ACCOUNT NO. Number assigned by Provider									
27. ACCEPT ASSIGNMENT? YES NO										28. TOTAL CHARGE \$									
29. AMOUNT PAID \$										30. Rsvd for NUCC Use									
31. SIGNATURE OF PHYSICIAN OR SUPPLIER (Including degrees or credentials. (I certify that the statements on the reverse apply to this bill and are made a part thereof.)										32. SERVICE FACILITY LOCATION INFORMATION									
33. BILLING PROVIDER INFO & PH #										a. NPI of service facility b. NPI Billing Provider									

NUCC Instruction Manual available at: www.nucc.org

PLEASE PRINT OR TYPE

APPROVED OMB-0938-1197 FORM 1500 (02-12)

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.		

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1 Billing provider name Address; city, state, zip code + extension Area code, phone, fax, country code		2 Billing provider designated pay-to Name, address, city, state, ID		3a PAT. CNTL. # b. MED. REC. #	alpha-numeric code assigned by provider number assigned by provider		4 TYPE OF BILL 0234
5 FED. TAX NO. 12-3456789		6 STATEMENT COVERS PERIOD FROM MM/DD/YY		7 THROUGH MM/DD/YY		Leave blank	
8 PATIENT NAME a Last, first, MI, identifier		9 PATIENT ADDRESS b		c Mailing address d			
10 BIRTHDATE MM/DD/CCYY		11 SEX MM/DD/YY		12 DATE MM/DD/YY		13 HR 14 TYPE 15 SRC 16 DHR 17 STAT	
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798		799		800		801	
802		803		804		805	
806		807		808		809	
810		811		812		813	
814		815		816		817	
818		819		820		821	
822		823		824		825	
826		827		828		829	
830		831		832		833	
834		835		836		837	
838		839		840		841	
842		843		844		845	
846		847		848		849	
850		851		852		853	
854		855		856		857	
858		859		860		861	
862		863		864		865	
866		867		868		869	
870		871		872		873	
874		875		876		877	
878		879		880		881	
882		883		884		885	
886		887		888		889	
890		891		892		893	
894		895		896		897	
898		899		900		901	
902		903		904		905	
906		907		908		909	
910		911		912		913	
914		915					

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



access

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

Care

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



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.

