

CODING AND BILLING GUIDE FOR



Permanent J-Code 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 | Revenue Code³: 0636 | CPT Codes⁴: 96413 or 96409 |

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 |

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

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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. x 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/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.



Please see accompanying full Prescribing Information, including Boxed WARNING.

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. | | |
| 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. | |

| | | | | | | | | | |
|--|--|--|--|---|--|--|--|--|--|
| 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 | | 39 PAT. CNTL. # b. MED. REC. # 5 FED. TAX NO. | | alpha-numeric code assigned by provider number assigned by provider | | 4 TYPE OF BILL 0234 Leave blank | |
| 8 PATIENT NAME a Last, first, MI, identifier | | 9 PATIENT ADDRESS a Mailing address | | 10 BIRTHDATE 11 SEX 12 DATE MM/DD/CCYY | | 13 HR 14 TYPE 15 SPC 16 DHR 17 STAT 18 19 20 21 CONDITION CODES 22 23 24 25 26 27 28 29 ACDT STATE 30 | | 31 OCCURRENCE DATE 32 CODE MM/DD/YY | |
| 31 OCCURRENCE DATE 32 CODE MM/DD/YY | | 33 OCCURRENCE DATE 34 CODE MM/DD/YY | | 35 OCCURRENCE DATE 36 CODE MM/DD/YY | | 37 OCCURRENCE SPAN FROM THROUGH MM/DD/YY MM/DD/YY | | 38 | |
| 39 CODE a | | 40 CODE b | | 41 CODE c | | 42 | | 43 | |
| 42 REV. CD. | | 43 DESCRIPTION | | 44 HCPCS / RATE / HIPPS CODE | | 45 SERV. DATE | | 46 SERV. UNITS | |
| 0636 | | Elzonris Injection for IV Use | | J9269 | | MM/DD/YY | | x | |
| 0335 | | Elzonris Injection for IV Use | | 96413 | | MM/DD/YY | | 1 | |
| 0335 | | Elzonris Injection for IV Use | | 96409 | | MM/DD/YY | | 1 | |
| PAGE | | OF | | CREATION DATE | | TOTALS | | | |
| 50 PAYER NAME Payer identification - Primary (1 st) | | 51 HEALTH PLAN ID | | 52 REL. INFO. | | 53 ASG. BEN. | | 54 PRIOR PAYMENTS 1 st | |
| Payer identification - Secondary (2 nd) | | | | | | | | 55 EST. AMOUNT DUE 1 st | |
| Payer identification - Tertiary (3 rd) | | | | | | | | 56 NPI 2 nd 3 rd | |
| 58 INSURED'S NAME | | 59 P. REL. | | 60 INSURED'S UNIQUE ID | | 61 GROUP NAME | | 62 INSURANCE GROUP NO. | |
| 63 TREATMENT AUTHORIZATION CODES | | 64 DOCUMENT CONTROL NUMBER | | 65 EMPLOYER NAME (of the insured) Primary (of the insured) Secondary (of the insured) Tertiary | | | | | |
| 66 | | 67 | | 68 | | 69 | | 70 | |
| 69 ADMIT DX C86.4 | | 70 PATIENT REASON DX Reason for visit code | | 71 FPS CODE | | 72 ECI | | 73 | |
| 74 PRINCIPAL PROCEDURE DATE MM/DD/YY | | 75 OTHER PROCEDURE DATE MM/DD/YY | | 76 ATTENDING NPI MD Provider number LAST FIRST | | 77 OPERATING NPI Operating MD number LAST FIRST | | 78 OTHER NPI LAST FIRST | |
| 79 OTHER NPI LAST FIRST | | | | | | | | | |
| 80 REMARKS | | 81 CC a b c d | | | | | | | |

Please see accompanying full Prescribing Information, including Boxed WARNING.



STEMLINE ARC® PROVIDES ACCESS, REIMBURSEMENT SUPPORT, AND CONNECTION TO RESOURCES 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

Connection
ARC Patient Advocates provide an overview of support services, confirm ELZONRIS coverage and financial assistance, and share helpful 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 [ELZONRIS.com/hcp/stemline-arc-summary](https://www.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.

†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.

‡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.

