

BILLING AND CODING GUIDE

Indication¹

AZEDRA® (iobenguane I 131) is indicated for the treatment of adult and pediatric patients 12 years and older with iobenguane scan positive, unresectable, locally advanced or metastatic pheochromocytoma or paraganglioma who require systemic anticancer therapy.

Important Safety Information

Warning and Precautions:

- **Risk from radiation exposure:** AZEDRA contributes to a patient's overall long-term radiation exposure. Long-term cumulative radiation exposure is associated with an increased risk for cancer. These risks of radiation associated with the use of AZEDRA are greater in pediatric patients than in adults. Minimize radiation exposure to patients, medical personnel, and household contacts during and after treatment with AZEDRA consistent with institutional good radiation safety practices and patient management procedures.
- Myelosuppression: Severe and prolonged myelosuppression occurred during treatment with AZEDRA. Among the 88 patients who received a therapeutic dose of AZEDRA, 33% experienced Grade 4 thrombocytopenia, 16% experienced Grade 4 neutropenia, and 7% experienced Grade 4 anemia. Five percent of patients experienced febrile neutropenia. Monitor blood cell counts weekly for up to 12 weeks or until levels return to baseline or the normal range. Withhold and dose reduce AZEDRA as recommended in the prescribing information based on severity of the cytopenia.
- Secondary myelodysplastic syndrome, leukemia, and other malignancies: Myelodysplastic syndrome (MDS) and acute leukemias were reported in 6.8% of the 88 patients who received a therapeutic dose of AZEDRA. The time to development of MDS or acute leukemia ranged from 12 months to 7 years. Two of the 88 patients developed a non-hematological malignancy.
- **Hypothyroidism:** Hypothyroidism was reported in 3.4% of the 88 patients who received a therapeutic dose of AZEDRA. Initiate thyroid-blocking medications starting at least 1 day before and continuing for 10 days after each AZEDRA dose to reduce the risk of hypothyroidism or thyroid neoplasia. Evaluate for clinical evidence of hypothyroidism and measure thyroid-stimulating hormone (TSH) levels prior to initiating AZEDRA and annually thereafter.
- Elevations in blood pressure: Eleven percent of the 88 patients who received a therapeutic dose of AZEDRA experienced a worsening of pre-existing hypertension defined as an increase in systolic blood pressure to ≥160 mmHg with an increase of 20 mmHg or an increase in diastolic blood pressure to ≥100 mmHg with an increase of 10 mmHg. All changes in blood pressure occurred within the first 24 hours post infusion. Monitor blood pressure frequently during the first 24 hours after each therapeutic dose of AZEDRA.
- Renal toxicity: Of the 88 patients who received a therapeutic dose of AZEDRA, 7% developed renal failure or acute kidney injury and 22% demonstrated a clinically significant decrease in glomerular filtration rate (GFR) measured at 6 or 12 months. Monitor renal function during and after treatment with AZEDRA. Patients with baseline renal impairment may be at greater risk of toxicity; perform more frequent assessments of renal function in patients with mild or moderate impairment. AZEDRA has not been studied in patients with severe renal impairment.
- **Pneumonitis:** Fatal pneumonitis occurred 9 weeks after a single dose in one patient in the expanded access program. Monitor patients for signs and symptoms of pneumonitis and treat appropriately.
- Embryo-fetal toxicity: Based on its mechanism of action, AZEDRA can cause fetal harm. Verify pregnancy status in females of reproductive potential prior to initiating AZEDRA. Advise females and males of reproductive potential of the potential risk to a fetus and to use effective contraception during treatment with AZEDRA and for 7 months after the final dose. Advise males with female partners of reproductive potential to use effective contraception during treatment and for 4 months after the final dose.
- **Risk of infertility:** Radiation exposure associated with AZEDRA may cause infertility in males and females. Radiation absorbed by testes and ovaries from the recommended cumulative dose of AZEDRA is within the range where temporary or permanent infertility can be expected following external beam radiotherapy.

Adverse Reactions:

The most common severe (Grade 3–4) adverse reactions observed in AZEDRA clinical trials (≥10%) were lymphopenia (78%), neutropenia (59%), thrombocytopenia (50%), fatigue (26%), anemia (24%), increased international normalized ratio (18%), nausea (16%), dizziness (13%), hypertension (11%), and vomiting (10%). Twelve percent of patients discontinued treatment due to adverse reactions (thrombocytopenia, anemia, lymphopenia, nausea and vomiting, multiple hematologic adverse reactions).

Drug Interactions:

Based on the mechanism of action of iobenguane, drugs that reduce catecholamine uptake or that deplete catecholamine stores may interfere with iobenguane uptake into cells and therefore interfere with dosimetry calculations or the efficacy of AZEDRA. These drugs were not permitted in clinical trials that assessed the safety and efficacy of AZEDRA. Discontinue the drugs listed in the prescribing information for at least 5 half-lives before administration of either the dosimetry dose or a therapeutic dose of AZEDRA. Do not administer these drugs until at least 7 days after each AZEDRA dose.

For important risk and use information about AZEDRA, please click here for full Prescribing Information.

To report suspected adverse reactions, contact Progenics Pharmaceuticals, Inc. at 844-668-3950 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Reference: AZEDRA® prescribing information. New York, NY: Progenics Pharmaceuticals, Inc.; 08 2018.

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Guide Overview

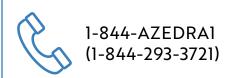
Progenics Pharmaceuticals, Inc. has developed this billing and coding guide to assist healthcare providers (HCPs) with reimbursement questions related to AZEDRA® (iobenguane I 131) injection for intravenous (IV) use and its administration. Please note that the current information is subject to change as new coding and coverage information becomes available.

The following billing and coding guide is intended to provide information to HCPs, does not seek to maximize payment, and should not be mistaken for official payer guidance. Progenics does not warrant, promise, guarantee, or make any statement that the diagnosis codes supplied in this guide are appropriate, that the use of this information will result in coverage or payment for AZEDRA, or that any payment received will cover HCPs' costs.

It is the responsibility of HCPs to remain in compliance with healthcare payer guidelines and policies. Therefore, HCPs should review individual payer requirements and guidance prior to the submission of a claim.



For assistance with reimbursement-related questions for AZEDRA, please contact AZEDRA Service Connection® at:





Our reimbursement counselors are available to assist you Monday through Friday, 9:00 AM to 5:00 PM EST

Disease and Product Overview

AZEDRA is indicated for the treatment of adult and pediatric patients 12 years and older with iobenguane scan positive, unresectable, locally advanced or metastatic pheochromocytoma or paraganglioma who require systemic therapy. AZEDRA consists of a small molecule that specifically targets neuroendocrine tumors (pheochromocytoma and paraganglioma) and a radioisotope that is designed for use as an imaging agent and for therapy.

AZEDRA dosimetric dose is administered via IV injection followed by 2 therapeutic doses approximately 90 days apart that are administered via IV infusion.

Dosimetric Doses

Patients weighing >50 kg: 5 to 6 mCi (185 to 222 MBq)

Patients weighing ≤50 kg: **0.1 mCi/kg (3.7 MBq/kg)**

Therapeutic Doses

Patients weighing >62.5 kg: **500 mCi (18.5 GBq)**

Patients weighing ≤62.5 kg: 8 mCi/kg (296 MBq/kg)

Coding

This guide offers a detailed overview of the coding related to AZEDRA. Coding is a uniform language that describes medical, surgical, and diagnostic services to healthcare payers based on information documented in the patient's medical record and communicated by the HCP. HCPs use different types of codes across different sites of service.

Below is a table of the commonly used code sets for AZEDRA.

		S	Site of Service			
Coding System	Description	Hospital Inpatient	Hospital Outpatient (HOPD)	Free- Standing		
National Drug Code (NDC)	Numeric, universal, and unique 3-segment product identifier used to report human drugs	\bigcirc	\bigcirc	\bigcirc		
Healthcare Common Procedure Coding System (HCPCS) Level II	Alpha-numeric coding system used to report specific drugs, supplies, and other healthcare equipment (eg, J-codes, C-codes, Q-codes)	\bigcirc	\bigcirc	\bigcirc		
Current Procedural Terminology® (CPT) (HCPCS Level I)	Numeric coding system used to report medical services and procedures provided by HCPs	\bigcirc	\bigcirc	\bigcirc		
International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM)	Alpha-numeric coding system used to report patient conditions, illnesses, or symptoms that document medical necessity for specific healthcare services in all settings of care		\bigcirc	\bigcirc		
International Classification of Diseases, 10th Revision, Procedure Coding System (ICD-10-PCS)*	Alpha-numeric coding system used to report procedures and other services performed in healthcare facilities	\bigcirc	\bigcirc			
Revenue Codes	3-digit numeric codes that indicate the cost center for an individual service on a facility claim; some payers require specific combinations of revenue codes and HCPCS codes for claims to be processed					

^{*} ICD-10-PCS codes are required in the hospital inpatient site of service but may be used in the HOPD site of service for itemization purposes.

ICD-10-CM Diagnosis Codes Across All Sites of Service

ICD-10-CM diagnosis codes indicate a patient's medical condition and the reason a procedure was performed. Coding conventions typically dictate that a patient's diagnosis (and treatment) be coded to the highest level of specificity possible.

The following diagnosis codes are applicable to describe patients with iobenguane scan positive, unresectable, locally advanced or metastatic pheochromocytoma or paraganglioma who require systemic anticancer therapy:

ICD-10-CM Code and De	ICD-10-CM Code and Description ²			
C74.10	Malignant neoplasm of medulla of unspecified adrenal gland			
C74.11	Malignant neoplasm of medulla of right adrenal gland			
C74.12	Malignant neoplasm of medulla of left adrenal gland			
C75.5	Malignant neoplasm of aortic body and other paraganglia			
C7A.1	Malignant poorly differentiated neuroendocrine tumors			
C7A.8	Other malignant neuroendocrine tumors			
D35.00	Benign neoplasm of unspecified adrenal gland			
D35.01	Benign neoplasm of right adrenal gland			
D35.02	Benign neoplasm of left adrenal gland			
D35.6	Benign neoplasm of aortic body and other paraganglia			
D44.7	Neoplasm of uncertain behavior of aortic body and other paraganglia			
Z51.0	Encounter for antineoplastic radiation therapy			

Dosimetric Use in the Hospital Outpatient Department (HOPD) and Freestanding Sites of Service

The table below shows the suggested coding for the dosimetric use in both the HOPD and freestanding (eg, physician office) sites of service.

Product Information Coding

Effective for dates of service on or after January 1, 2020, Centers for Medicare & Medicaid Services (CMS) has assigned a permanent Healthcare Common Procedure Coding System (HCPCS) for AZEDRA; A9590 Iodine I-131, iobenguane, 1 millicurie.^{3,*}

Code	Drug/Convice	Code and Description	Site	of Service
Code	Drug/ Service	Orug/Service Code and Description		Freestanding
NDC	AZEDRA (to be used when required by the payer)	71258- 0015-02 : Single-dose 30 mL vial of AZEDRA containing a total volume of 22.5 (±2.5) mL of solution with a total radioactivity of 240–413 mCi/vial (8,880–15,281 MBq/vial) at calibration time ¹	\bigcirc	
HCPCS	AZEDRA	A9590 Iodine I-131, iobenguane, 1 millicurie ³	\bigcirc	\bigcirc
Revenue Code	AZEDRA	 0250 Pharmacy, general classification⁴ 0258 Pharmacy, IV solutions⁴ 0343 Diagnostic radiopharmaceutical⁴ 0636 Drugs requiring detailed coding⁴ 	\bigcirc	

Administration, Supplies, and Services Coding

			Site of Service		
Code	Drug/Service	Code and Description	HOPD	Freestanding	
HCPCS	Same-day physician visit	G0463 HOPD clinic visit for assessment and management of a patient (Medicare only) ³	\bigcirc		
	IV infusion	78804 Radiopharmaceutical localization of tumor or distribution of radiopharmaceutical agent(s); whole body, requiring 2 or more days imaging ⁵ 79101 Radiopharmaceutical therapy, by intravenous administration ⁵	\bigcirc		
СРТ	Dosimetry calculations and handling of AZEDRA	77300 Basic radiation dosimetry calculation, central axis depth dose calculation, TDF, NSD, gap calculation, off-axis factor, tissue inhomogeneity factors, calculation of nonionizing radiation surface and depth dose, as required during course of treatment, only when prescribed by the treating physician ⁵ 77790 Supervision, handling, and loading of radiation source ⁵	\bigcirc		
	Same-day physician visit (reported by physician)	99212–99215 Established evaluation and management (outpatient) Levels 2–5 ⁵		\bigcirc	
ICD-10- PCS	IV infusion*	XW033S5 Introduction of iobenguane I-131 antineoplastic into peripheral vein, percutaneous approach, new technology group 56 XW043S5 Introduction of iobenguane I-131 antineoplastic into central vein, percutaneous approach, new technology group 56	\bigcirc		
Revenue Code	IV infusion	0260 IV therapy ⁴ 0341 Nuclear medicine – diagnostic ⁴	\bigcirc		

^{*} Additional nuclear medicine imaging codes may also be appropriate when administering AZEDRA.

Imaging Coding

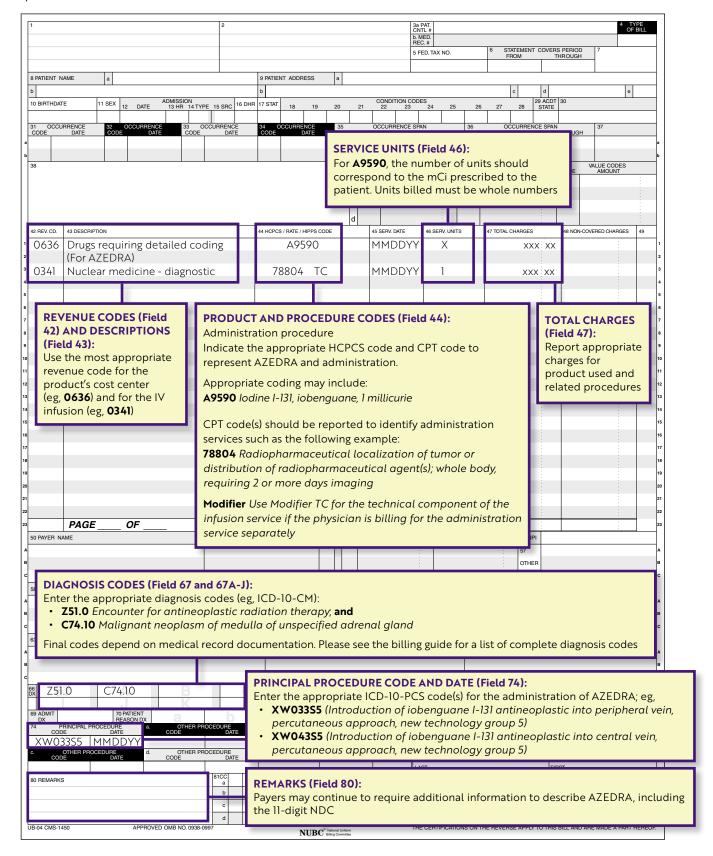
			Site of Service		
Code	Drug/Service Code and Description		HOPD	Freestanding	
	Other imaging: computed tomography (CT) scan of kidney, lung, and liver; with contrast	 71250 Computed tomography, thorax; without contrast material(s)⁵ 72192 Computed tomographic angiography, pelvis, without contrast material(s)⁵ 74150 Computed tomography, abdomen; without contrast material⁵ 74176 Computed tomography, abdomen and pelvis, without contrast material⁵ 		\bigcirc	
СРТ	Other imaging: magnetic resonance imaging (MRI) of kidney, lung, and liver; with contrast	71550 Magnetic resonance (eg, proton) imaging, chest (eg, for evaluation of hilar and mediastinal lymphadenopathy); without contrast material(s) ⁵ 72195 Magnetic resonance (eg, proton) imaging, pelvis; without contrast material(s) ⁵ 74181 Magnetic resonance (eg, proton) imaging, abdomen; without contrast material(s) ⁵ 74185 Magnetic resonance angiography, abdomen, with or without contrast material(s) ⁵			
Revenue	Other imaging: CT scan of kidney, lung, and liver; with contrast	0359 CT scan-other CT scans ⁴	\bigcirc		
Code	Other imaging: MRI of kidney, lung, and liver; with contrast	0614 MRT/MRI-other ⁴	\bigcirc		

Sample UB-04 Claim Form to Medicare for Dosimetric Use

Use the UB-04 claim form when submitting a claim for dosimetric use in the HOPD site of service.

Completing the CMS-1450 for HOPD

Sample UB-04 (CMS 1450) Form to A/B Medicare Administrative Contractor (MAC) | HOPD Administration for Dosimetric Use

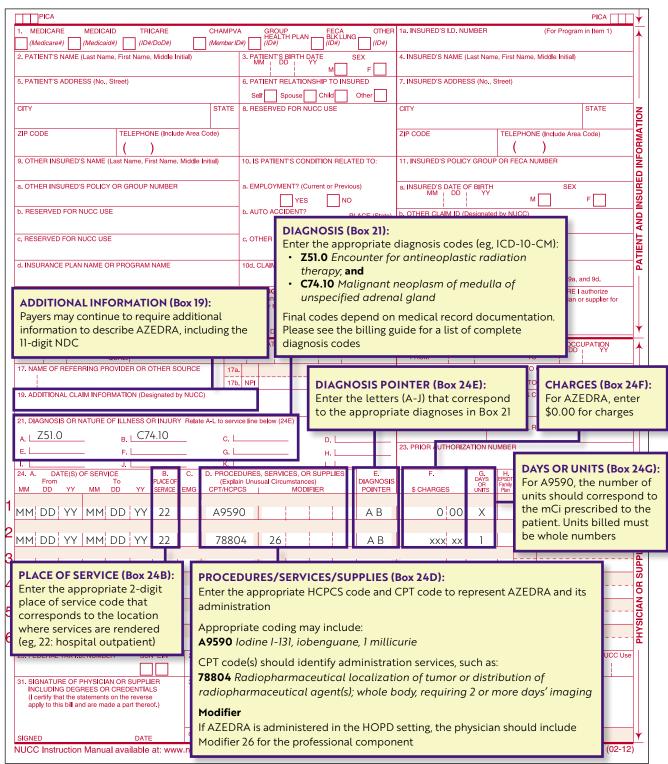


Sample CMS-1500 Claim Form for Dosimetric Use

A physician may bill separately for the administration of the IV infusion using a CMS-1500 form, where appropriate. For example, under Medicare Part B policy, a physician may submit a CMS-1500 claim form for AZEDRA's administration (separately from the UB-04 form submitted by the HOPD) if they are not employed by the hospital that purchased AZEDRA and where the administration took place. Below is a sample claim for submission of the CMS-1500 claim form.

Completing the CMS-1500 for Split Billing

Sample CMS-1500 Form | Billing for Physician Services



Therapeutic Use in the Inpatient Hospital Site of Service

Below is the suggested coding for therapeutic use in the hospital inpatient site of service.

Product Information Coding

Code	Drug/Service	Code and Description
NDC	AZEDRA	71258- <u>0015-22</u> : Single-dose 30 mL vial of AZEDRA containing a total volume of 22.5 (±2.5) mL of solution with a total radioactivity of 240–413 mCi/vial (8,880–15,281 MBq/vial) at calibration time ¹
HCPCS	AZEDRA	A9590 Iodine I-131, iobenguane, 1 millicurie
Revenue Code	AZEDRA	 0250 Pharmacy, general classification⁴ 0258 Pharmacy, IV solutions⁴ 0344 Therapeutic radiopharmaceutical⁴

Administration, Supplies, and Services Coding

Code	Drug/Service	Code and Description
	IV infusion	79101 Radiopharmaceutical therapy, by IV administration ⁵
СРТ	Same-day physician visit (reported and billed separately by physician)	99231–99233 Subsequent hospital care, per day, for the evaluation and management of a patient, Levels 1–3 ⁵
ICD-10-PCS	IV infusion*	XW033S5 Introduction of iobenguane I-131 antineoplastic into peripheral vein, percutaneous approach, new technology group 56 XW043S5 Introduction of iobenguane I-131 antineoplastic into central vein, percutaneous approach, new technology group 56
Revenue Code	IV infusion	0260 IV therapy ⁴ 0342 Nuclear medicine, therapeutic ⁴

^{*} Additional nuclear medicine imaging codes may also be appropriate when administering AZEDRA.

Progenics assumes that facilities will refer to the relevant Medicare Severity Diagnosis-Related Group (MS-DRG) for each inpatient admission. Please note that, when appropriate, a physician may bill separately for the administration of the IV infusion using a CMS-1500 form.

Therapeutic Use in the HOPD Site of Service

Below is the suggested coding for therapeutic use in the HOPD site of service. Therapeutic use in the outpatient setting will be strictly for pediatric patients.

Product Information Coding

Code	Drug/Service	Code and Description
NDC	AZEDRA	71258- <u>0015-22</u> : Single-dose 30 mL vial of AZEDRA containing a total volume of 22.5 (±2.5) mL of solution with a total radioactivity of 240–413 mCi/vial (8,880–15,281 MBq/vial) at calibration time ¹
HCPCS	AZEDRA	A9590 Iodine I-131, iobenguane, 1 millicurie ³
Revenue Code	AZEDRA	 0250 Pharmacy, general classification⁴ 0258 Pharmacy, IV solution⁴ 0344 Therapeutic radiopharmaceutical⁴ 0636 Drugs requiring detailed coding⁴

Administration, Supplies, and Services Coding

Code	Drug/Service	Code and Description
	IV infusion	79101 Radiopharmaceutical therapy, by IV administration ⁵
СРТ	Same-day physician visit (reported and billed separately by physician)	99212–99215 Established evaluation / management (outpatient), Levels 2–5 ⁵
HCPCS	Same-day physician visit (reported and billed separately by physician)	G0463 Hospital outpatient clinic visit for assessment and management of a patient (Medicare only) ³
ICD-10- PCS	IV infusion*	XW033S5 Introduction of iobenguane I-131 antineoplastic into peripheral vein, percutaneous approach, new technology group 56 XW043S5 Introduction of iobenguane I-131 antineoplastic into central vein, percutaneous approach, new technology group 56
Revenue Code	IV infusion	0260 IV therapy ⁴ 0342 Nuclear medicine, therapeutic ⁴

^{*} Additional nuclear medicine imaging codes may also be appropriate when administering AZEDRA.

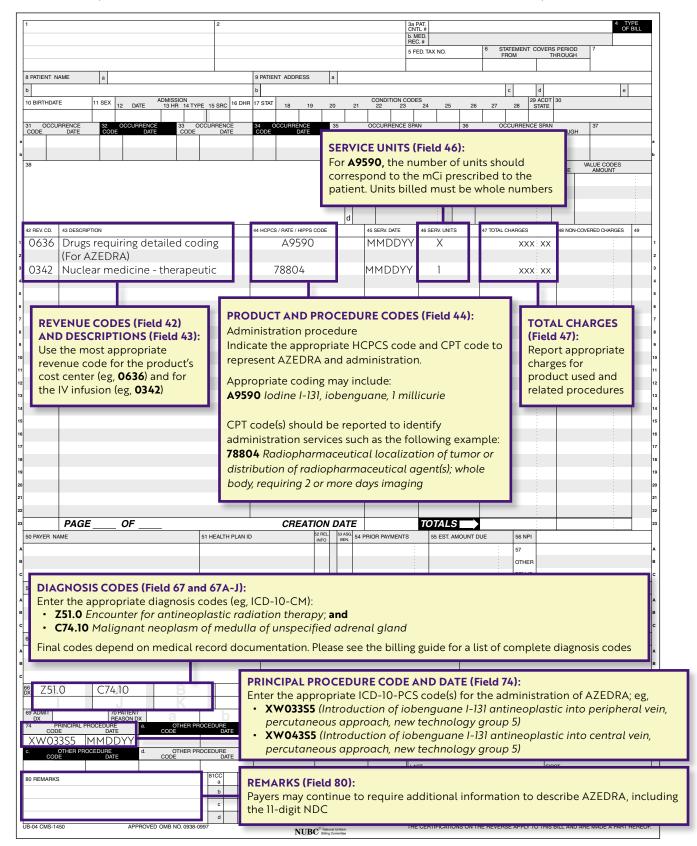
A physician may bill separately for the administration of the IV infusion using a CMS-1500 form, when appropriate.

Sample UB-04 Claim Form for Therapeutic Use

Use the UB-04 claim form when submitting a claim for therapeutic use in the HOPD site of service.

Completing the CMS-1450 for HOPD

Sample UB-04 (CMS 1450) Form to A/B MAC | HOPD Administration for Therapeutic Use



Sample CMS-1500 Claim Form for Therapeutic Use

A physician may bill separately for the administration of the IV infusion using a CMS-1500 form, where appropriate. For example, under Medicare Part B policy, a physician may submit a CMS-1500 claim form for AZEDRA's administration (separately from the UB-04 form submitted by the HOPD) if they are not employed by the hospital that purchased AZEDRA and where the administration took place. Below is a sample claim for submission of the CMS-1500 claim form.

Completing the CMS-1500 for Split Billing

Sample CMS-1500 Form | Billing for Physician Services

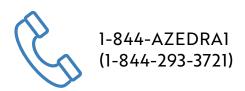
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AZEDRA Service Connection® Offers Support to Address Your Reimbursement Questions

AZEDRA Service Connection® is a patient and provider support program that offers assistance with challenging reimbursement and billing questions. Our reimbursement counselors are readily available to answer questions about AZEDRA. Specifically, we can assist HCPs and their staff with benefit verifications, prior authorization requirements, denied claims questions, health plan appeal processes, and referrals to patient assistance programs.



For assistance with reimbursement-related questions for AZEDRA, please contact AZEDRA Service Connection® at:





Our reimbursement counselors are available to assist you Monday through Friday, 9:00 AM to 5:00 PM EST

References

- 1. AZEDRA [package insert]. New York, NY: Progenics Pharmaceuticals, Inc; August 2018.
- 2. AAPC. 2019 Official ICD-10-CM Expert for Providers and Facilities. AAPC. October 2018.
- 3. Centers for Medicare & Medicaid Services. 2020 alpha-numeric HCPCS file. https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS-Items/2020-Alpha-Numeric-HCPCS-File.
- Noridian Healthcare Solutions. Revenue codes. https://med.noridianmedicare.com/web/jea/topics/claim-submission/revenue-codes. Last Updated September 26, 2018.
- 5. AMA. CPT Copyright 2017 American Medical Association. All rights reserved. CPT® is a registered trademark of the American Medical Association.
- 6. Centers for Medicare & Medicaid Services. CY 2020 IPPS final rule. https://www.federalregister.gov/documents/2019/08/16/2019-16762/medicare-program-hospital-inpatient-prospective-payment-systemsfor-acute-care-hospitals-and-the. Posted on August 16, 2016.



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