# NEW TECHNOLOGY ADD-ON PAYMENT

## For Medicare Inpatient Use of AZEDRA® (iobenguane I 131)

AZEDRA® iobenguane I 131 injection for intravenous use

**EFFECTIVE OCTOBER 1, 2019, AZEDRA HAS BEEN APPROVED FOR THE NTAP[1]**

### What is the New Technology Add-on Payment (NTAP) program?[2]

The NTAP program was created by Congress in 2001 to help facilitate access to new, innovative technologies through add-on payments to qualifying Medicare hospital inpatient cases.

### Why is this important?

NTAP increases access to breakthrough, innovative, and life-saving therapies.

### Effective dates:

- Fiscal year 2020[1]
- NTAP approval for AZEDRA will be annually assessed for a period of 2 to 3 years
- Facilities may be able to obtain additional payment on admissions that occurred before 10/1/19 through outlier payments

## BILLING AND REIMBURSEMENT

### How is the NTAP amount calculated?

The amount of the NTAP is limited to the lesser of either (a) 65% of the average cost of the technology or (b) 65% of the costs in excess of the Medicare Severity Diagnosis-Related Group (DRG)-based payment for the case.

Effective October 1, 2019, the maximum NTAP amount for a Medicare inpatient patient treated with AZEDRA will be $98,150 for FY 2020.[1]

### How do I bill for the NTAP?

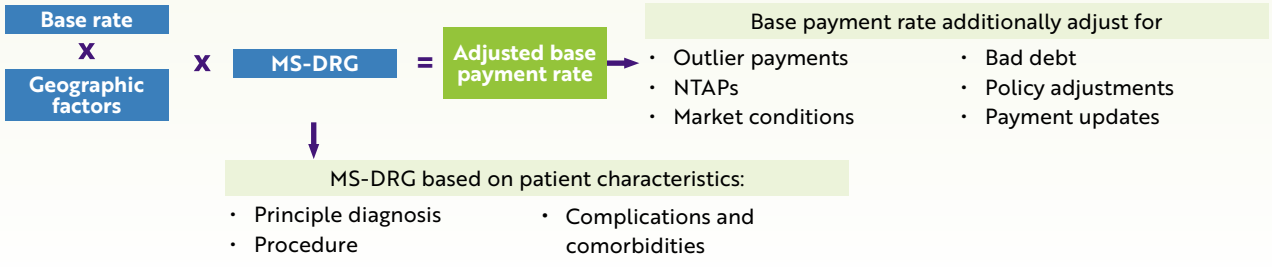
Two new International Classification of Diseases, 10th Revision, Procedure Coding System (ICD-10-PCS) codes have been assigned for the use of AZEDRA to submit for the NTAP on hospital inpatient Medicare claim forms[1]:

**XW033S5** (Introduction of iobenguane I-131 antineoplastic into peripheral vein, percutaneous approach, new technology Group 5)

**XW043S5** (Introduction of iobenguane I-131 antineoplastic into central vein, percutaneous approach, new technology group 5)

Medicare uses these ICD-10-PCS codes to assign each discharge an MS-DRG payment. Hospitals receiving NTAPs are still eligible to receive outlier payments. DRG and outlier payments vary by hospital and are case-dependent. Subsequently, the NTAP amount and total amount of final reimbursement will vary.

### Medicare Inpatient Payment Calculation[3]



# SAMPLE CLAIM FORM

## Sample UB-04 (CMS-1450) Form for Therapeutic Use

**REVENUE CODES (Field 42) AND DESCRIPTIONS (Field 43):**
Use the most appropriate revenue code corresponding to the cost center; eg,
- **0344** for pharmacy (AZEDRA) **and**
- **0342** for the IV infusion service

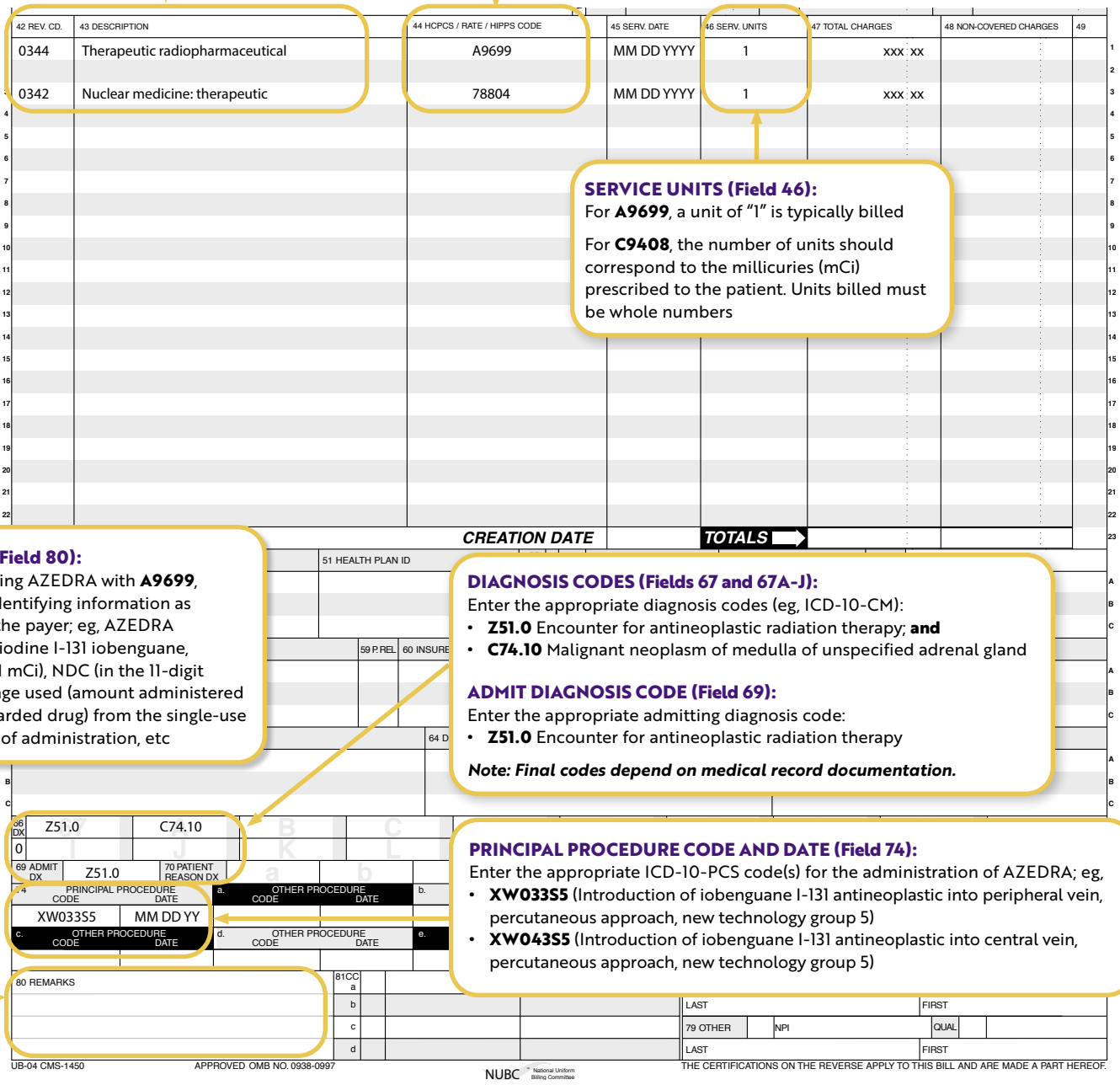
***Note: Other revenue codes may apply***

**PRODUCT AND PROCEDURE CODES (Field 44):**
Administration procedure: Indicate the appropriate HCPCS code and CPT code to represent AZEDRA and administration

Appropriate coding for AZEDRA may include:
- **A9699** Radiopharmaceutical, therapeutic, not otherwise classified
- **C9408** Iodine I-131 iobenguane, therapeutic, 1 mCi

CPT code(s) should be reported to identify administration services such as the following example:
- **78804** Radiopharmaceutical localization of tumor or distribution of radiopharmaceutical agent(s); whole body, requiring 2 or more days imaging

***Note: Other procedure codes may apply***




**SERVICE UNITS (Field 46):**
For **A9699**, a unit of "1" is typically billed

For **C9408**, the number of units should correspond to the millicuries (mCi) prescribed to the patient. Units billed must be whole numbers

**REMARKS (Field 80):**
When reporting AZEDRA with **A9699**, enter drug-identifying information as required by the payer; eg, AZEDRA therapeutic (iodine I-131 iobenguane, therapeutic, 1 mCi), NDC (in the 11-digit format), dosage used (amount administered and any discarded drug) from the single-use vial, method of administration, etc

**DIAGNOSIS CODES (Fields 67 and 67A-J):**
Enter the appropriate diagnosis codes (eg, ICD-10-CM):
- **Z51.0** Encounter for antineoplastic radiation therapy; **and**
- **C74.10** Malignant neoplasm of medulla of unspecified adrenal gland

**ADMIT DIAGNOSIS CODE (Field 69):**
Enter the appropriate admitting diagnosis code:
- **Z51.0** Encounter for antineoplastic radiation therapy

***Note: Final codes depend on medical record documentation.***

**PRINCIPAL PROCEDURE CODE AND DATE (Field 74):**
Enter the appropriate ICD-10-PCS code(s) for the administration of AZEDRA; eg,
- **XW033S5** (Introduction of iobenguane I-131 antineoplastic into peripheral vein, percutaneous approach, new technology group 5)
- **XW043S5** (Introduction of iobenguane I-131 antineoplastic into central vein, percutaneous approach, new technology group 5)

**Please see Important Safety Information on pages 3 and 4. For important risk and use information about AZEDRA, please click here for full Prescribing Information.**

AZEDRA®
iobenguane I 131 injection for intravenous use

## FOR REIMBURSEMENT SUPPORT AND QUESTIONS REGARDING NTAP, CALL AZEDRA SERVICE CONNECTION® AT

1-844-AZEDRA1
(1-844-293-3721)

Monday through Friday
9:00 AM to 5:00 PM EST

## Indication

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.

**Please see additional Important Safety Information on next page. For important risk and use information about AZEDRA, please click here for full Prescribing Information.**

## Important Safety Information (continued)

**Warning and Precautions (continued):**

- **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.

## References:

1. 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-systems-for-acute-care-hospitals-and-the. Accessed August 13, 2019.
2. Centers for Medicare & Medicaid Services. New medical services and new technologies. http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech.html. Accessed August 8, 2019.
3. Medicare Payment Advisory Committee. Hospital Acute Inpatient Services Payment System. http://www.medpac.gov/docs/default-source/payment-basics/medpac_payment_basics_17_hospital_final65a311adfa9c665e80adff00009edf9c.pdf?sfvrsn=0. Accessed August 8, 2019.

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