Azedra® (iobenguane I-131)
(Intravenous)

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I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for 6 months for 3 doses only (one imaging dosimetric dose followed by two therapeutic doses at least 90 days apart).
- Renewal: Prior authorization validity may NOT be renewed.

II. Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:

- Imaging dosimetric dose: 30 billable units
- Therapeutic dose: 675 billable units x 2 doses, at least 90 days apart

III. Initial Approval Criteria [1]

Prior authorization validity is provided in the following conditions:

- Patient is at least 12 years of age; **AND**
- Patient has a negative pregnancy test (in females of reproductive potential) prior to initiating treatment; **AND**
- Patient's disease is iobenguane scan-positive (e.g., on CT-scan or MRI, etc.) in at least one tumor site; **AND**
- Patient is receiving appropriate thyroid blockade (i.e., inorganic iodine) starting at least 24 hours before and continuing for 10 days after each Azedra dose; **AND**
- Patient has not received any form of radiation therapy, including systemic radiotherapy, whole-body radiation or external beam radiotherapy to > 25% of bone marrow; **AND**

Pheochromocytoma/Paraganglioma † ‡ Φ [1-4]

- Patient has locally advanced, unresectable, or metastatic disease; **AND**
- Patient's disease requires systemic chemotherapy

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria [1]

Duration of authorization has not been exceeded *(refer to Section I)*

V. Dosage/Administration [1]

Indication	Dose
All Indications	• Azedra is administered as an initial imaging dosimetric dose followed by two therapeutic doses that are administered at least 90 days apart. **Initial Imaging Dosimetric Dose** – Patients weighing greater than 50 kg: 185 to 222 MBq (5 or 6 mCi) intravenously – Patients weighing 50 kg or less: 3.7 MBq/kg (0.1 mCi/kg) intravenously • Therapeutic doses are calculated based on a series of 3 scans after the imaging dosimetric dose – Acquire anterior/posterior whole body gamma camera images within 1 hour of the Azedra dosimetric dose and prior to patient voiding (Day 0; Scan 1) – Acquire additional images on Day 1 or 2 following patient voiding (Scan 2) – Acquire additional images between Days 2-5 following patient voiding (Scan 3) **Therapeutic Dose** – Patients weighing greater than 62.5 kg: 18,500 MBq (500 mCi) intravenously for 2 doses at least 90 days apart – Patients weighing 62.5 kg or less: 296 MBq/kg (8 mCi/kg) intravenously for 2 doses at least 90 days apart • Therapeutic dose reductions may be required based on the calculated estimated critical organ absorption limits
***NOTE:** Azedra is a radiopharmaceutical. Handle with appropriate safety measures to minimize radiation exposure. Use waterproof gloves and effective radiation shielding when handling. Azedra should be used by or under the control of physicians who are qualified by specific training and experience in the safe use and handling of radiopharmaceuticals, and whose experience and training have been approved by the appropriate governmental agency authorized to license the use of radiopharmaceuticals.*	

VI. Billing Code/Availability Information

HCPCS Code:

- A9590 – Iodine i-131 iobenguane, 1 millicurie; 1 billable unit = 1 millicurie

NDC(s):

- Azedra 555 MBq/mL (15 mCi/mL) at TOC as a clear solution in a single-dose vial.
  - Dosimetric: 1,110 MBq (30 mCi) of iobenguane I-131 at calibration time (NDC 71258-0015-xx)

- Therapeutic: 12,488 MBq (337.5 mCi) of iobenguane I-131 at calibration time (NDC 71258-0015-xx)

VII. References

1. Azedra [package insert]. N. Billerica, MA; Progenics Pharmaceuticals, Inc., a Lantheus company; February 2023. Accessed September 2025.
2. Pryma D, Chin B, Noto R, et al. Azedra (iobenguane I 131) in patients with malignant, recurrent and/or unresectable pheochromocytoma or paraganglioma (PPGL): Updated efficacy and safety results from a multi-center, open-label, pivotal phase 2 study. J Clin Oncol 36, 2018 (suppl; abstr 4005).
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) iobenguane I-131. National Comprehensive Cancer Network, 2025. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed September 2025.
4. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for Neuroendocrine and Adrenal Tumors. Version 2.2025. National Comprehensive Cancer Network, 2025. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed September 2025.

Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	No: PA not a priority
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
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
C74.90	Malignant neoplasm of unspecified part of unspecified adrenal gland
C74.91	Malignant neoplasm of unspecified part of right adrenal gland
C74.92	Malignant neoplasm of unspecified part of left adrenal gland
C75.5	Malignant neoplasm of aortic body and other paraganglia
C7B.8	Other secondary neuroendocrine tumors
Z85.858	Personal history of malignant neoplasm of other endocrine glands

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCA/LCD): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC