Azedra® (iobenguane I-131)
(Intravenous)

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I. Length of Authorization

Coverage will be provided for 6 months for 3 doses only (one imaging dosimetric dose followed by two therapeutic doses at least 90 days apart) and may NOT be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- N/A

B. 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]

Coverage 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]

Coverage cannot be renewed.

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 millicurie = 1 billable unit

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 August 2024.
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, 2024. 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 August 2024.
4. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for Neuroendocrine and Adrenal Tumors. Version 2.2024. National Comprehensive Cancer Network, 2024. 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 August 2024.

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
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