Utilization Review Policy 197

POLICY: Oncology (Injectable) – Azedra Utilization Management Medical Policy

- Azedra® (iobenguane I 131 intravenous infusion – Progenics)

EFFECTIVE DATE: 1/1/2020
LAST REVISION DATE: 09/16/2024

COVERAGE CRITERIA FOR: All UCare Plans

OVERVIEW

Azedra, a radioactive therapeutic agent, is indicated for the treatment of **iobenguane scan positive, unresectable, locally advanced or metastatic pheochromocytoma or paraganglioma** in patients ≥ 12 years of age who require systemic anticancer therapy.[1]

Dosing Information

The recommended Azedra regimen consists of one dosimetric dose and two therapeutic doses; the doses are administered via intravenous infusion.[1] Three scans are recommended after the dosimetric dose. The recommended therapeutic dose is based on body weight and if necessary, reduced based on dosimetry data or adverse events (e.g., myelosuppression, pneumonitis). In one study, patients received the first therapeutic dose 7 to 28 days after the dosimetric dose.[2] The two therapeutic doses should be separated by a minimum of 90 days.[1]

Guidelines

The National Comprehensive Cancer Network (NCCN) guidelines for Neuroendocrine and Adrenal Tumors (version 1.2023 – August 2, 2023) note surgical resection as the mainstay of treatment for benign and malignant pheochromocytomas and paragangliomas.[2] For locally unresectable tumors, observation is recommended if the patient is asymptomatic or has slow-growing, low-volume disease. For patients with locally unresectable or distant metastatic pheochromocytoma or paraganglioma, primary treatment for secreting tumors that are positive on metaiodobenzylguanidine (MIBG) scan include Azedra or other I-131 MIBG therapy (category 2A).

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Azedra. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indications. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with Azedra as well as the monitoring required for adverse events and long-term efficacy, approval requires Azedra to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA
Coverage of Azedra is recommended in those who meet one of the following criteria:

FDA-Approved Indications

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1. **Pheochromocytoma.** Approve for 6 months if the patient meets ALL of the following (A, B, C, D, and E):
   A) Patient is ≥ 12 years of age; AND
   B) Patient has iobenguane scan positive pheochromocytoma; AND
   C) The tumor is unresectable; AND
   D) The tumor is locally advanced or metastatic; AND
   E) The medication is prescribed by or in consultation with an oncologist or radiologist.

   Dosing. Approve the following dosing regimens (A and B):
   A) Approve ONE of the following weight-based dosimetric dose (i or ii):
      i. Patient weighs ≤ 50 kg: Approve up to 3.7 MBq/kg (0.1 mCi/kg) for one dose; OR
      ii. Patient weighs > 50 kg: Approve up to 222 MBq (6 mCi) for one dose; AND
   B) Approve ONE of the following weight-based therapeutic dose (i or ii):
      i. Patient weighs ≤ 62.5 kg: Approve up to 296 MBq/kg (8 mCi/kg) per dose for up to two doses; OR
      ii. Patient weighs > 62.5 kg: Approve up to 18,500 MBq (500 mCi) per dose for up to two doses.

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2. **Paraganglioma.** Approve for 6 months if the patient meets ALL of the following (A, B, C, D, and E):
   A) Patient is ≥ 12 years of age; AND
   B) Patient has iobenguane scan positive paraganglioma; AND
   C) The tumor is unresectable; AND
   D) The tumor is locally advanced or metastatic; AND
   E) The medication is prescribed by or in consultation with an oncologist or radiologist.

   Dosing. Approve the following dosing regimens (A and B):
   A) Approve ONE of the following weight-based dosimetric dose (i or ii):
      i. Patient weighs ≤ 50 kg: Approve up to 3.7 MBq/kg (0.1 mCi/kg) for one dose; OR
      ii. Patient weighs > 50 kg: Approve up to 222 MBq (6 mCi) for one dose; AND
   B) Approve ONE of the following weight-based therapeutic dose (i or ii):
      i. Patient weighs ≤ 62.5 kg: Approve up to 296 MBq/kg (8 mCi/kg) per dose for up to two doses; OR
      ii. Patient weighs > 62.5 kg: Approve up to 18,500 MBq (500 mCi) per dose for up to two doses.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Azedra is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Azedra® I 131 intravenous infusion [prescribing information]. New York, NY: Progenics Pharmaceuticals; March 2021.
2. Noto RB, Pryma DA, Jensen J, et al. Phase 1 study of high-specific-activity I-131 MIBG for metastatic and/or recurrent pheochromocytoma or paraganglioma. *J Clin Endocrinol Metab*. 2018;103:213-220.
3. The NCCN Neuroendocrine and Adrenal Tumors Clinical Practice Guidelines in Oncology (version 1.2023 – August 2, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on June 20, 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	10/11/2023
Annual Revision	No criteria changes.	06/26/2024
UCare P&T Review	Policy reviewed and approved by UCare P&T committee. Annual review process	09/16/2024