PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Injectable) – Azedra Prior Authorization Policy
- Azedra® (iobenguane I 131 intravenous infusion – Progenics)

REVIEW DATE: 09/14/2022

OVERVIEW

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

Guidelines

The National Comprehensive Cancer Network (NCCN) guidelines for Neuroendocrine and Adrenal Tumors (version 1.2022 – May 23, 2022) 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 when possible, radiation therapy is recommended with cytoreductive resection. Alternatively, if the tumors are positive on metaiodobenzylguanidine (MIBG) scan, treatment with Azedra or other I-131 MIBG therapy is recommended. If the tumors are somatostatin receptor-positive, peptide receptor radionuclide therapy with Lutathera® (lutetium Lu 177 dotatate injection) or treatment with octreotide or lanreotide (if symptomatic) may be considered.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Azedra. 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

1. **Pheochromocytoma.** Approve Azedra for 6 months if the patient meets the following criteria (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.

2. **Paraganglioma.** Approve Azedra for 6 months if the patient meets the following criteria (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.

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. The NCCN Neuroendocrine and Adrenal Tumors Clinical Practice Guidelines in Oncology (version 1.2022 – May 23, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on September 7, 2022.