Azedra® (Iobenguane I-131) (Intravenous)

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Definition

Azedra is a radioactive therapeutic agent that releases radiation resulting from radioactive decay of I-131 causing cell death and tumor necrosis. Iobenguane has a similar structure to the neurotransmitter norepinephrine. It is taken up by the norepinephrine transporter in adrenergic nerve terminals and accumulates in adrenergically innervated tissues (i.e., heart, lungs, adrenal medulla, salivary glands, liver, and spleen) as well as tumors of neural crest origin, such as pheochromocytomas and paragangliomas. These neuroendocrine tumors express high levels of the norepinephrine transporter on their cell surfaces.

Azedra (iobenguane I-131) is FDA approved 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.

Length of Authorization

Coverage will be provided for 6 months and may be renewed.

Guideline

I. Initial Approval Criteria

Azedra *may be considered medically necessary if one of the below conditions are met* ***AND*** *use is consistent with the medical necessity criteria that follows:*

Pheochromocytoma/Paraganglioma†

- The member has unresectable, locally advanced, or metastatic pheochromocytoma or paraganglioma; **AND**
- Azedra (iobenguane I-131) is being used as a primary treatment if prior positive MIBG scan; **AND**
- The member is not a candidate for chemotherapy or surgery.

† FDA-labeled indication(s);

Limitations/Exclusions

Azedra is not considered medically necessary when any of the following selection criteria are met:

- Azedra (iobenguane I-131) is being used after disease progression with the same regimen or had previous systemic radiotherapy treatments.
- Not to be used if platelet count is less than 80,000/mcL or absolute neutrophil count is less than 1,200/mcL.
- Single dose limit of Azedra (iobenguane I-131) is based on weight:
    - Weight greater than 62.5 kg: 18,500 Megabecquerel (MBq) (500 Millicuries (mCi)).
    - Weight 62.5 kg or less: 296 MBq/kg (8 mCi/kg).
- Indications not supported by CMS recognized compendia or acceptable peer reviewed literature may be deemed as not approvable and therefore not reimbursable.

II. RENEWAL CRITERIA

Same as initial prior authorization policy criteria.

Dosage/Administration

Indication	Dose
Therapy consists of a dosimetric dose followed by 2 therapeutic doses given at least 90 days apart.	
Pheochromocytoma/Paraganglioma (Dosimetric Dose)	– Weight > 50 kg ○ 185 to 222MBq (5 to 6mCi) – Weight ≤ 50 kg ○ 3.7 MBq/kg (0.1 mCi/kg)
(Therapeutic Dose)	– Weight > 62.5 kg ○ 18,500 MBq (500mCi) – Weight ≤ 62.5 kg ○ 296 MBq/kg (8 mCi/kg)

Applicable Procedure Codes

C9407	Iodine I-131 iobenguane, diagnostic, 1 millicurie
C9408	Iodine I-131 iobenguane, therapeutic, 1 millicurie

Applicable NDCs

71258-0015-02	Azedra (Iobenguane I-131) 15 mci/1ml injection solution, 2 ml vial
71258-0015-22	Azedra (Iobenguane I-131) 15 mci/1ml injection solution, 22.5 ml vial

Applicable 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
C75.5	Malignant neoplasm of aortic body and other paraganglia
C7A.1	Malignant poorly differentiated neuroendocrine tumors
C7A.8	Other malignant neuroendocrine tumors
D35.00	Benign neoplasm of unspecified adrenal gland
D35.01	Benign neoplasm of right adrenal gland
D35.02	Benign neoplasm of left adrenal gland
D35.6	Benign neoplasm of aortic body and other paraganglia
D44.7	Neoplasm of uncertain behavior of aortic body and other paraganglia
Z51.0	Encounter for antineoplastic radiation therapy

References

1. Azedra PI prescribing information. Progenics Pharmaceuticals, Inc 2018.
2. Clinical Pharmacology Elsevier Gold Standard. 2018.
3. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2018.
4. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2018.
5. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD. 2018.