AvMed

MEDICAL PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-877-535-1391**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

For Medicare Members: 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 Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

Drug Requested: Azedra® (iobenguane I-131) **IV (A9590)**

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member AvMed #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight (if applicable): _____ **Date weight obtained:** _____

❑ Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

(Continued on next page)

Quantity Limits:

A. 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

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

- Iodine I-131 iobenguane, 1 millicurie; 1 millicurie = 1 billable unit
- Dosimetric dose: 185 to 222 MBq (up to 6 billable units each)
- Therapeutic doses (2 doses at least 90 days apart): 18,500 MBq (500 billable units each)

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Approval Criteria – Coverage cannot be renewed

- ❑ Member is at least 12 years of age
- ❑ Requesting provider is an oncologist
- ❑ **For female members of reproductive potential**, a negative pregnancy test has been confirmed
- ❑ Member has locally advanced, unresectable or metastatic pheochromocytoma or paraganglioma
- ❑ Member's disease is iobenguane scan-positive (e.g., on CT-scan or MRI) in at least one tumor site
- ❑ Member has **NOT** received any form of radiation therapy, including systemic radiotherapy, whole-body radiation or external beam radiotherapy to > 25% of bone marrow
- ❑ Member's condition requires systemic chemotherapy
- ❑ Member's condition of pheochromocytoma/paraganglioma has progressed from previous therapy, or member is not a candidate for chemotherapy (i.e., sunitinib) or other curative therapies
- ❑ Member has a life expectancy of at least 6 months
- ❑ Member has a Karnofsky Performance Status score ≥ 60
- ❑ Member will be receiving appropriate thyroid blockade (i.e., inorganic iodine) starting at least 24 hours before and continuing for 10 days after each Azedra dose
- ❑ Member does **NOT** have uncontrolled/unstable hypertension

(Continued on next page)

- ❑ Provider will follow the recommended dosage per weight and timeline indication detailed in the table below:

Indication	Dose
Pheochromocytoma or paraganglioma	• Azedra is administered as an initial imaging dosimetric dose followed by therapeutic doses that are at least 90 days apart. **Initial Imaging Dosimetric Dose** o Patients weighing greater than 50 kg: 185 to 222 MBq (5 or 6 mCi) intravenously o 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 o 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) o Acquire additional images on Day 1 or 2 following patient voiding (Scan 2) o Acquire additional images between Days 2-5 following patient voiding (Scan 3) Therapeutic Dose o Patients weighing greater than 62.5 kg: 18,500 MBq (500 mCi) intravenously for 2 doses at least 90 days apart o 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

Reauthorization Criteria – Coverage cannot be renewed

Medication being provided by: Please check applicable box below.

- ❑ **Location/site of drug administration:** _____Av_____

  NPI or DEA # of administering location: _____

OR

- ❑ **Specialty Pharmacy – PropriumRx**

For urgent reviews: Practitioner should call AvMed Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. AvMed's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

*****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.*****

****Previous therapies will be verified through pharmacy paid claims or submitted chart notes.****