Iobenguane I-131 (Azedra®)

<u>Place of Service</u> Office Administration Outpatient Facility Infusion Administration Infusion Center Administration

HCPCS: A9590 per 1 millicurie

Condition listed in policy (see criteria for details)

Pheochromocytoma or paraganglioma - advanced

AHFS therapeutic class: Antineoplastic agent

Mechanism of action: Radioactive therapeutic agent

#### (1) Special Instructions and pertinent Information

**Covered under the medical benefit**, please submit clinical information for prior authorization review via fax.

### (2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for iobenguane I-131 (Azedra<sup>®</sup>) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

#### Pheochromocytoma or paraganglioma - advanced

1. Unresectable, locally advanced or metastatic disease

#### **Covered Dose**

Dosimetric dose

- Patients greater than 50 kg: 185 to 222 MBq (5 to 6 mCi)
- Patients 50 kg or less: 3.7 MBq/kg (0.1 mCi/kg)

Therapeutic dose for each of the 2 doses

- Patients greater than 62.5 kg: up to 18,500 MBq (500 mCi)
- Patients 62.5 kg or less: up to 296 MBq/kg (8 mCi/kg)
  Therapeutic doses should be administered IV a minimum of 90 days apart

#### Coverage Period

One dosimetric dose and two therapeutic doses

ICD-10:

C74.10-C74.12, C74.90-C74.92, C75.5, C7B.8

(3) The following condition(s) <u>DO NOT</u> require Prior Authorization/Preservice All requests for iobenguane I-131 (Azedra<sup>®</sup>) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

#### (4) This Medication is NOT medically necessary for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

PHP Medi-Cal

iobenguane I-131 (Azedra®)

Effective: 06/28/2023

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:

- 30 mCi/2 mL single-dose vial (dosimetric dose)
- 337.5 mCi/22.5mL single-dose vial (therapeutic dose)

## (6) References

- AHFS<sup>®</sup>. Available by subscription at <u>http://www.lexi.com</u>
- Azedra® (iobenguane I 131) [Prescribing information]. New York, NY: Progenics Pharmaceuticals, Inc.; 3/2021.
- DrugDex<sup>®</sup>. Available by subscription at <u>http://www.micromedexsolutions.com/home/dispatch</u>
- National Comprehensive Cancer Network. Neuroendocrine and Adrenal Tumors (Version 1.2022). Available at: <a href="http://www.nccn.org">www.nccn.org</a>.

# (7) Policy Update

Date of initial review: 3Q2023 Date of next review: 3Q2024 Changes from previous policy version:

• No clinical change to policy following routine annual review.

BSC Drug Coverage Criteria to Determine Medical Necessity Reviewed by P&T Committee