Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 184.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Azedra (iobenguane I 131)

I. Policy:
Azedra (iobenguane I 131)

II. Purpose/Objective:
To provide a policy of coverage regarding Azedra (iobenguane I 131)

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment
Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION:
Azedra (iobenguane I 131) is an I 131 labeled iobenguane. Iobenguane is similar in structure to the neurotransmitter norepinephrine (NE) and is subject to the same uptake and accumulation pathways as NE. Iobenguane is taken up by the NE transporter in adrenergic nerve terminals and accumulates in adrenergically innervated tissues, such as the heart, lungs, adrenal medulla, salivary glands, liver, and spleen as well as tumors of neural crest origin. Azedra is taken up and accumulates within pheochromocytoma and paraganglioma cells, and radiation resulting from radioactive decay of I 131 causes cell death and tumor necrosis.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Azedra (iobenguane I 131) will be considered medically necessary for all lines of business when ALL of the following criteria are met:

Pheochromocytoma/Paraganglioma
- Prescription is written by a hematologist/oncologist **AND**
- Medical record documentation that patient is 12 years of age or older **AND**
- Medical record documentation of a diagnosis of unresectable, locally advanced or metastatic pheochromocytoma or paraganglioma **AND**
- Medical record documentation of a positive iobenguane scan (ex. MIBG (metaiodobenzylguanidine) scan, iobenguane I 131)

AUTHORIZATION DURATION: Azedra will be approved for a one time authorization of three (3) total doses (one dosimetric dose and two therapeutic doses).

Note: After the member receives the initial dosimetric dose, a dosimetry and biodistribution assessment should occur to determine if a dose adjustment is needed prior to giving the therapeutic doses as follows:
- 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).
- Acquire additional images on Day 1 or 2 following patient voiding (Scan 2).
- Acquire additional images between Days 2-5 following patient voiding (Scan 3).

For each individual patient, calculate the radiation dose estimates to normal organs and tissues per unit activity [D (organ)] of administered dose using data extracted from these 3 images. Calculate in accordance with the Medical Internal Radiation Dose (MIRD) schema or related methodology. Whenever possible, use patient-specific organ masses (e.g., estimated from imaging).

Based on dosimetry assessment determine if a dose adjustment is needed for therapeutic dose. Administer a total of 2 therapeutic doses intravenously a minimum of 90 days apart.

Note: For Medicaid (GHP Family), any requests for services that do not meet criteria set in the PARP will be evaluated on a case-by-case basis.

LINE OF BUSINESS:

Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

This policy will be revised as necessary and reviewed no less than annually**.**

Devised: 11/20/18

Revised: 8/23/22 (Medicaid PARP statement), 8/22/23 (LOB carve out, Medicaid business segment)

Reviewed: 9/30/19, 8/26/20, 8/23/21