Drug Policy:
Azedra™ (iobenguane I-131)

I. PURPOSE
To define and describe the accepted indications for Azedra (iobenguane I-131) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

New Century Health (NCH) is responsible for processing all medication requests from network ordering providers. Medications not authorized by NCH may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

II. INDICATIONS FOR USE/INCLUSION CRITERIA

A. PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:

1. When health plan Medicaid coverage provisions—including any applicable PDLs (Preferred Drug Lists)—conflict with the coverage provisions in this drug policy, health plan Medicaid coverage provisions take precedence per the Preferred Drug Guidelines OR

2. When health plan Exchange coverage provisions—including any applicable PDLs (Preferred Drug Lists)—conflict with the coverage provisions in this drug policy, health plan Exchange coverage provisions take precedence per the Preferred Drug Guidelines OR
3. For Health Plans that utilize NCH UM Oncology Clinical Policies as the initial clinical criteria, the Preferred Drug Guidelines shall follow NCH L1 Pathways when applicable, otherwise shall follow NCH drug policies AND
4. Continuation requests of previously approved, non-preferred medication are not subject to this provision AND
5. When applicable, generic alternatives are preferred over brand-name drugs.

B. Pheochromocytoma/Paraganglioma
1. The member is 12 years of age and older who has unresectable, locally advanced, or metastatic pheochromocytoma or paraganglioma AND
2. Azedra (iobenguane I-131) is being used as a primary treatment for member with a positive MIBG (meta-iodobenzylguanidine) scan AND
3. The member is not a candidate for chemotherapy or surgery.

III. EXCLUSION CRITERIA
A. Azedra (iobenguane I-131) is being used after disease progression while receiving Azedra.
B. Not to be used if platelet count is less than 80,000/mcL or absolute neutrophil count is less than 1,200/mcL.
C. Single dose limit of Azedra (iobenguane I-131) is based on weight:
   1. Weight greater than 62.5 kg: 18,500 Megabecquerel (MBq) (500 Millicuries (mCi)).
   2. Weight 62.5 kg or less: 296 MBq/kg (8 mCi/kg).
D. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

IV. MEDICATION MANAGEMENT
A. Please refer to the FDA label/package insert for details regarding these topics.

V. APPROVAL AUTHORITY
A. Review – Utilization Management Department
B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS
A. None

VII. REFERENCES