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| Effective Date: 06/1/2020                                   |
| Reviewed: 3/2020, 7/2021, 5/2022,<br>5/2023, 5/2024, 7/2025 |
| Scope: Medicaid                                             |

# NON-ONCOLOGY POLICY

## OCTREOTIDE INJECTION

**For oncology indications, please refer to NHPRI Somatostatin Analog Policy**

### I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

#### FDA-Approved Indication:

##### Acromegaly

Sandostatin is indicated to reduce blood levels of growth hormone and IGF-1 (somatomedin C) in acromegaly patients who have had inadequate response to or cannot be treated with surgical resection, pituitary irradiation, and bromocriptine at maximally tolerated doses.

#### Compendial Uses:

Congenital hyperinsulinism (CHI)/persistent hyperinsulinemic hypoglycemia of infancy (PHHI)

### II. CRITERIA FOR APPROVAL

#### **A. Acromegaly**

Authorization of 12 months may be granted for the treatment of acromegaly when all of the following criteria are met:

1. Documentation that the member has a high pretreatment insulin-like growth factor-1 (IGF-1) level for age and/or gender based on the laboratory reference range.
2. Documentation that the member had an inadequate or partial response to surgery or radiotherapy OR there is a clinical reason why the member has not had surgery or radiotherapy

#### **B. Congenital hyperinsulinism (CHI)/persistent hyperinsulinemic hypoglycemia of infancy**

Authorization of 6 months may be granted with documentation of CHI and persistent hyperinsulinemic hypoglycemia in an infant.

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### III. CONTINUATION OF THERAPY

#### A. Acromegaly

Authorization of 12 months may be granted for continuation of therapy with documentation for acromegaly when the member's IGF-1 level has decreased or normalized since initiation of therapy.

#### B. All other indications

Members (including new members) requesting authorization with documentation for continuation of therapy must meet all initial authorization criteria.

### IV. REFERENCES

1. Octreotide acetate [package insert]. Rockford, IL: Mylan Institutional LLC; July 2024.
2. Sandostatin [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; November 2023.
3. Sandostatin LAR Depot [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; July 2023.
4. Katznelson L, Laws ER, Melmed S, et al. Acromegaly: an endocrine society clinical practice guideline. *J Clin Endocrinol Metab*. 2014;99:3933-3951.
5. American Association of Clinical Endocrinologists Acromegaly Guidelines Task Force. Medical guidelines for clinical practice for the diagnosis and treatment of acromegaly – 2011 update. *Endocr Pract*. 2011;17(suppl 4):1-44.