Effective Date: 06/1/2020
Reviewed: 3/2020, 7/2021, 5/2022, 5/2023, 5/2024, 7/2025, 2/2026 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. Prescribed by or in consultation with an endocrinologist
2. Documentation that the diagnosis of acromegaly has been confirmed by one of the following:
    a. Serum GH level > 1ng/ml after 2-hour OGTT at time of diagnosis; OR
    b. Elevated serum insulin-like growth factor-1 (IGF-1) [above the age and gender adjusted normal range per physician's lab] at diagnosis
3. Documentation that the member has a recent high pretreatment insulin-like growth factor-1 (IGF-1) level for age and/or gender based on the laboratory reference range.
4. 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.

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.