UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 2101-10
Program	Prior Authorization/Medical Necessity
Medication	Somavert® (pegvisomant)
P&T Approval Date	7/2016, 7/2017, 7/2018, 7/2019, 7/2020, 7/2021, 7/2022, 7/2023, 7/2024
Effective Date	10/1/2024

1. Background:

Somavert (pegvisomant) is a growth hormone receptor antagonist indicated for the treatment of acromegaly in patients who have had an inadequate response to surgery or radiation therapy, or for whom these therapies are not appropriate. The goal of treatment is to normalize serum insulin-like growth factor-I (IGF-I) levels.[1]

The American Association of Clinical Endocrinologists (AACE) recommends pegvisomant in patients for whom surgical treatment and somatostatin analogues (SSAs) have proved ineffective or for those who are intolerant of SSAs.[2] The AACE and the Endocrine Society also recommend that dopamine agonists may be considered as first-line medical therapy, particularly in patients with mild biochemical activity, such as in the setting of modestly elevated serum IGF-I levels in the absence or concomitant presence of SSA therapy.[2,3]

2. Coverage Criteria [a]:

A. Acromegaly

1. **Initial Authorization**

a. **Somavert** will be approved based on **one** of the following criteria:

(1) **All** of the following:

(a) Diagnosis of acromegaly confirmed by **one** of the following:

i. Serum GH level > 1 ng/mL after a 2-hour oral glucose tolerance test (OGTT) at time of diagnosis

-OR-

ii. Elevated serum IGF-1 level (above the age and gender adjusted normal range as provided by the physician's lab) at time of diagnosis

-AND-

(b) **One** of the following:

i. Inadequate response to **one** of the following:
- Surgery
- Radiation therapy

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- Dopamine agonist (e.g., bromocriptine, cabergoline) therapy

-OR-

ii. Not a candidate for **any** of the following:
- Surgery
- Radiation therapy
- Dopamine agonist (e.g., bromocriptine, cabergoline) therapy

-AND-

(c) Inadequate response, intolerance, or contraindication to a long-acting somatostatin analog [e.g., Sandostatin LAR (octreotide), Somatuline Depot (lanreotide)]

-OR-

(2) Patient is currently on Somavert therapy for acromegaly

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Somavert** will be approved based on the following criteria:

(1) Documentation of positive clinical response to Somavert therapy (e.g., age-normalized serum IGF-1 level)

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Somavert [prescribing information]. New York, NY: Pfizer Inc.; July 2023.
2. Katznelson L, Atkinson JL, Cook DM, et al.; American Association of Clinical Endocrinologists. American Association of Clinical Endocrinologists medical guidelines for clinical practice for the diagnosis and treatment of acromegaly–2011 update. Endocr Pract. 2011;17 Suppl 4:1-44.

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3. Katznelson L, Laws ER Jr, Melmed S, et al. Acromegaly: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2014;99(11):3933-3951.
4. Fleseriu, M, Biller, BMK, Freda, PU, et al. A Pituitary Society update to acromegaly management guidelines. Pituitary. 2021;24(1):1–13.

Program	Prior Authorization/Medical Necessity – Somavert® (pegvisomant)
Change Control	
7/2016	New Program
11/2016	Administrative change. Added California coverage information.
7/2017	Annual review. No changes to the program. State mandate reference language updated.
7/2018	Annual review. No changes to the program.
7/2019	Annual review. No changes to the program.
7/2020	Annual review. No changes to coverage criteria.
7/2021	Annual review. No changes to coverage criteria. Updated references.
7/2022	Annual review. Updated background per American Association of Clinical Endocrinologists and Endocrine Society guidelines. Updated brand/generic naming to reflect availability of generic octreotide. Updated references.
7/2023	Annual review. Updated formatting of SSA requirement for initial authorization. Added example of positive clinical response to therapy for reauthorization. Updated formatting of references.
7/2024	Annual review with no changes to coverage criteria. Updated references.

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