

PHARMACY POLICY STATEMENT

Ohio Medicaid

DRUG NAME	Somavert (pegvisomant)
BILLING CODE	Must use valid NDC
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
STATUS	Prior Authorization Required

Somavert 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. Somavert binds to growth hormone (GH) receptors on cell surfaces, where it blocks the binding of endogenous GH, and thus interferes with GH signal transduction. Inhibition of GH action results in decreased serum concentrations of IGF-I, as well as other GH-responsive serum proteins.

Acromegaly is typically the result of a GH-secreting pituitary adenoma, thus surgical resection is the preferred treatment whenever possible as the best chance for a cure. If disease persists after surgery, a first-generation long-acting somatostatin receptor ligand such as octreotide is recommended as first-line therapy. Somavert does not target the tumor.

Somavert (pegvisomant) will be considered for coverage when the following criteria are met:

Acromegaly

For **initial** authorization:

1. Member is 18 years old or older; AND
2. Medication must be prescribed by or in consultation with an endocrinologist; AND
3. Member has diagnosis of uncontrolled acromegaly confirmed by insulin-like growth factor (IGF-1) elevation above normal (lab report required); AND
4. Member had an inadequate response to surgery or radiation, or member is ineligible for these treatments (documentation required); AND
5. Member remains uncontrolled (persistent IGF-1 elevation) after optimized treatment with octreotide or lanreotide for at least 3 months (*NOTE: Somavert may be used in combination with octreotide or lanreotide if member had a partial response (as opposed to no response) after 3 months; cabergoline is another option that may be added instead and does not require prior auth); AND*
6. Member has had baseline liver function testing.
7. **Dosage allowed/Quantity limit:** Loading dose 40mg subQ under provider supervision. Titrate to normalize IGF-1; dosing range 10mg-30mg subQ once daily. (QL 30 vials per 30 days)

If all the above requirements are met, the medication will be approved for 3 months.

For **reauthorization**:

1. Chart notes/lab report must show normalized or improved (decreased) IGF-1.

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Somavert (pegvisomant) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
11/02/2020	New policy for Somavert created.
03/31/2022	Transferred to new template. Updated references.

References:

1. Somavert [package insert]. NY, NY: Pharmacia and Upjohn Company LLC; 8/2021.
2. Katznelson L, Laws ER, Melmed S, et al. Acromegaly: An Endocrine Society Clinical Practice Guideline. *The Journal of Clinical Endocrinology & Metabolism*. 2014;99(11):3933-3951. doi:10.1210/jc.2014-2700
3. Melmed S, Bronstein MD, Chanson P, et al. A Consensus Statement on acromegaly therapeutic outcomes. *Nature Reviews Endocrinology*. 2018;14(9):552-561. doi:10.1038/s41574-018-0058-5
4. Zahr R, Fleseriu M. Updates in Diagnosis and Treatment of Acromegaly. *Eur Endocrinol*. 2018;14(2):57-61. doi:10.17925/EE.2018.14.2.57
5. Fleseriu M, Biller BMK, Freda PU, et al. A Pituitary Society update to acromegaly management guidelines. *Pituitary*. 2021;24(1):1-13. doi:10.1007/s11102-020-01091-7

Effective date: 10/01/2022

Revised date: 03/31/2022