

Acromegaly, Carcinoid, Cushing Syndrome Agents
Somavert (pegvisomant)
Signifor LAR (pasireotide injectable suspension)
Effective 06/01/2025

Plan	<input checked="" type="checkbox"/> MassHealth UPPL <input type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization
Benefit	<input type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit		<input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Specialty Limitations	N/A		
Contact Information	Medical and Specialty Medications		
	All Plans	Phone: 877-519-1908	Fax: 855-540-3693
Contact Information	Non-Specialty Medications		
	All Plans	Phone: 800-711-4555	Fax: 844-403-1029
Notes	Somavert (pegvisomant) is also available on the pharmacy benefit. Please see the MassHealth Drug List for coverage and criteria. Additional agents from this class are available through the pharmacy benefit. Please see the MassHealth Drug List for coverage and criteria.		

Overview

Somavert is 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.

Signifor LAR is indicated for:

- the treatment of patients with acromegaly who have had an inadequate response to surgery and/or for whom surgery is not an option.
- the treatment of patients with Cushing's disease for whom pituitary surgery is not an option or has not been curative.

Coverage Guidelines

Authorization may be reviewed on a case by case basis for members who are new to the plan currently receiving treatment with requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

Authorization may be granted for members when all the following criteria are met:

Signifor LAR (pasireotide injectable suspension)

Cushing's disease

- Diagnosis of Cushing's disease
- ONE** of the following:
 - Member has failed surgical intervention (reoccurrence after surgery or failed tumor removal)

- b. Surgical interventions are not an option at this time
- 3. Inadequate response, adverse reaction to ONE, or contraindication to ALL of the following (Metopirone [metyrapone] is an acceptable trial):
 - a. cabergoline
 - b. ketoconazole tablet
 - c. Lysodren® (mitotane)
- 4. Quantity requested is ≤ 1 kit or vial/30 days

Acromegaly

- 1. Diagnosis of acromegaly
- 2. Member is under the care of an endocrinologist
- 3. **ONE** of the following:
 - a. Member has persistent or recurring disease following surgery and/or radiation
 - b. Member is not a candidate for surgery
- 4. **ONE** of the following:
 - a. Inadequate response or adverse reaction to one somatostatin analog that does not require PA
 - b. Contraindication to the use of somatostatin analogs
- 5. **ONE** of the following:
 - a. Member has moderate-to-severe disease symptoms
 - b. Member has mild disease and **ONE** of the following:
 - i. Inadequate response or adverse reaction to one dopamine analog (e.g., cabergoline, bromocriptine) in combination with a somatostatin analog for overlap of 3 months within a 6 month period
 - ii. Adverse reaction to one somatostatin analog that does not require PA
 - iii. Contraindication to the use of dopamine analogs
- 6. Quantity requested is ≤ 1 kit or vial/30 days

Somavert (pegvisomant)

- 1. Diagnosis of acromegaly
- 2. Member is under the care of an endocrinologist
- 3. **ONE** of the following:
 - a. Member has persistent or recurring disease following surgery and/or radiation
 - b. Member is not a candidate for surgery
- 4. **ONE** of the following:
 - a. Inadequate response or adverse reaction to one somatostatin analog that does not require PA
 - b. Contraindication to the use of somatostatin analogs
- 5. **ONE** of the following:
 - a. Member has moderate-to-severe disease symptoms
 - b. Member has mild disease and **ONE** of the following:
 - i. Inadequate response or adverse reaction to one dopamine analog (e.g., cabergoline, bromocriptine) in combination with a somatostatin analog for overlap of 3 months within a 6 month period
 - ii. Adverse reaction to one somatostatin analog that does not require PA
 - iii. Contraindication to the use of dopamine analogs



6. Quantity requested is ≤ 1 vial/day

Continuation of Therapy

Reauthorization by physician will infer a positive response to therapy.

Limitations

1. Initial approvals and reauthorizations will be granted for 12 months.

References

1. Melmed S, Katznelson L. Causes and clinical manifestations of acromegaly. In: Basow DS (Ed). UpToDate [database on the internet]. Waltham (MA): UpToDate; 2021 Dec [cited 2022 Jan 19]. Available from: <http://www.utdol.com/utd/index.do>.
2. Melmed S, Katznelson L. Treatment of acromegaly. In: Basow DS (Ed). UpToDate [database on the internet]. Waltham (MA): UpToDate; 2021 Dec [cited 2022 Jan 19]. Available from: <http://www.utdol.com/utd/index.do>.
3. Katznelson L, Atkinson JL, Cook DM, Ezzat SZ, Hamrahian AH, Miller KK et al. American Association of Clinical Endocrinologists medical guidelines for clinical practice for the diagnosis and treatment of acromegaly--2011 update. Endocr Pract. 2011 Jul-Aug;17 Suppl 4:1-44.
4. Katznelson L, Laws ER Jr, Melmed S, Molitch ME, Murad MH, Utz A et al. Acromegaly: an endocrine society clinical practice guideline. J Clin Endocrinol Metab. 2014 Nov;99(11):3933-51.
5. Somavert® [package insert on the Internet]. New York (NY): Pharmacia and Upjohn; 2021 Aug.
6. Signifor® LAR [package insert on the internet]. East Hanover (NJ): Novartis Pharmaceuticals Corporation; 2020 Jun.
7. Thanabalasingham G, Grossman AB. Acromegaly: Beyond surgery. Indian J Endocrinol Metab. 2013 Jul;17(4):563-7.
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11. Nieman LK. Overview of Treatment of Cushing's Syndrome. In: Basow DS (Ed). UpToDate [database on the internet]. Waltham (MA): UpToDate; 2021 Dec [cited 2022 Jan 19]. Available from: <http://www.utdol.com/utd/index.do>.
12. Nieman LK. Medical Therapy of hypercortisolism (Cushing's Syndrome). In: Basow DS (Ed). UpToDate [database on the internet]. Waltham (MA): UpToDate; 2021 Dec [cited 2022 Jan 19]. Available from: <http://www.utdol.com/utd/index.do>.
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14. Montana State University. The HPA Axis: Alcohol-Induced Pseudo-Cushing's Syndrome [homepage on the Internet]. Bozeman (MT): 2013 [cited 2016 Dec 29]. Available from: <http://www.montana.edu/wwwai/imsd/alcohol/Vanessa/vwhpa.htm>.
15. FDA Approves New Treatment for Adults with Cushing's Disease [press release on the internet]. Silver Spring (MD): Food and Drug Administration; 2020 Mar 6 [cited 2020 May 4] Available from: <https://www.fda.gov/news-events/press-announcements/fda-approves-new-treatment-adults-cushings-disease>.
16. Fleseriu M, Biller BMK, Freda PU, Gadhelha MR, Giustina A, Katznelson L, et al. A Pituitary Society update to acromegaly management guidelines. *Pituitary*. 2021 Feb;24(1):1-13. doi: 10.1007/s11102-020-01091-7. Epub 2020 Oct 20.

Review History

11/16/2022 – Created for Nov P&T. Matched MH UPPL. The following medications will require a prior authorization on the pharmacy benefit: Somavert, Signifor, Signifor LAR. Combined Mycapssa, Xermelo, Isturisa, Korlym, and Signifor LAR agents and matched MH UPPL criteria. Effective 2/1/23

5/15/25 – Reviewed and updated for P&T. Updated header to differentiate MB drugs vs Rx drugs in this class. Medical criteria remains. Pharmacy criteria was removed and can be accessed via MHD. Effective 6/1/25

