

# AvMed

## PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST\*

**Directions:** The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request. All other information may be filled in by office staff; **fax to 1-305-671-0200.** No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process can be delayed.**

### Somatostatin Analog Drugs & Somavert<sup>®</sup> (PHARMACY)

**Drug Requested:** (select drug below)

<input type="checkbox"/> Bynfezia <sup>®</sup> (octreotide) SQ Injection	<input type="checkbox"/> Sandostatin <sup>®</sup> LAR Depot (octreotide)
<input type="checkbox"/> lanreotide acetate extended release SQ injection 120 mg/0.5 mL	<input type="checkbox"/> Signifor <sup>®</sup> (pasireotide) SQ Injection
<input type="checkbox"/> Mycapssa <sup>®</sup> (octreotide) Oral Tablet	<input type="checkbox"/> Signifor <sup>®</sup> LAR (pasireotide) SQ Injection
<input type="checkbox"/> octreotide injection (generic Sandostatin <sup>®</sup> )	<input type="checkbox"/> Somatuline <sup>®</sup> Depot (lanreotide) injection
<input type="checkbox"/> Palsonify <sup>™</sup> (paltusotine) Oral Tablet	<input type="checkbox"/> Somavert <sup>®</sup> (pegvisomant) Injection – GH receptor antagonist

**MEMBER & PRESCRIBER INFORMATION:** Authorization may be delayed if incomplete.

Member Name: \_\_\_\_\_

Member Sentara #: \_\_\_\_\_ Date of Birth: \_\_\_\_\_

Prescriber Name: \_\_\_\_\_

Prescriber Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Office Contact Name: \_\_\_\_\_

Phone Number: \_\_\_\_\_ Fax Number: \_\_\_\_\_

NPI #: \_\_\_\_\_

**DRUG INFORMATION:** Authorization may be delayed if incomplete.

Drug Form/Strength: \_\_\_\_\_

Dosing Schedule: \_\_\_\_\_ Length of Therapy: \_\_\_\_\_

Diagnosis: \_\_\_\_\_ ICD Code, if applicable: \_\_\_\_\_

Weight (if applicable): \_\_\_\_\_ Date weight obtained: \_\_\_\_\_

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**CLINICAL CRITERIA:** Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

**Diagnosis: Acromegaly (Bynfezia, lanreotide, octreotide, Sandostatin LAR, Signifor LAR, Somatuline Depot, Somavert)**

**Initial Authorization: 12 months**

- Member is 18 years of age or older

**AND**

- Provider is an endocrinologist or neurosurgeon

**AND**

- Member has undergone pituitary surgery and/or irradiation, or surgery is contraindicated (**chart notes must be submitted to document diagnosis and surgical history or contraindication to surgery**)

**AND**

- Diagnosis confirmed by elevated IGF-1 levels as well as inadequate suppression of growth hormone (GH) levels (**current labs must be submitted for documentation**)

**AND**

- For Sandostatin LAR, Signifor LAR, Somatuline Depot and Somavert:** Medication will not be used in combination with long-acting somatostatin analogs

**AND**

- For Somavert only:** Medication requires trial and failure of a long-acting injectable octreotide product (e.g., Sandostatin LAR, Somatuline Depot)

**Diagnosis: Acromegaly (Bynfezia, lanreotide, octreotide, Sandostatin LAR, Signifor LAR, Somatuline Depot, Somavert)**

**Reauthorization: 12 months**

- No toxicity has been observed while taking the requested medication

**AND**

- Response is demonstrated by **BOTH** of the following (**Chart notes and current lab test results must be submitted for documentation**)

- Reduction of GH levels from pre-treatment baseline
- Normalization of IGF-1 level

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**Diagnosis: Acromegaly (Mycapssa, Palsonify)**

**Initial Authorization: 6 months**

- Member is 18 years of age or older

**AND**

- Provider is an endocrinologist or neurosurgeon

**AND**

- Member has undergone pituitary surgery and/or irradiation, or surgery is contraindicated (**chart notes must be submitted to document diagnosis and surgical history or contraindication to surgery**)

**AND**

- Diagnosis confirmed by elevated IGF-1 levels as well as inadequate suppression of growth hormone (GH) levels (**current labs must be submitted for documentation**)

**AND**

- Medication will not be used in combination with long-acting somatostatin analogs

**AND**

- For Mycapssa Requests:** Member must meet **BOTH** of the following:

- Member must be established on an injectable somatostatin analogue for  $\geq 6$  months with a stable dose for  $\geq 3$  months and has shown a clinical response
- There must be a documented medical necessity for use of oral capsules over injectable alternatives (**chart notes must be submitted to document contraindication to injectable therapy**)

**AND**

- For Palsonify Requests:** Member must meet **BOTH** of the following:

- Medication requires trial and failure of **TWO** long-acting injectable octreotide or lanreotide products (e.g., Somatuline Depot, Sandostatin LAR) (**chart notes and/or lab results must be submitted to document therapy failures**)
- For doses above 60 mg once daily, documentation of medical necessity for high dose must be submitted (i.e. long-term use of moderate to strong CYP3A4 inducer medication that may not be discontinued, concomitant use of proton pump inhibitors that may not be discontinued; etc.)

**Diagnosis: Acromegaly (Mycapssa, Palsonify)**

**Reauthorization: 12 months**

- No toxicity has been observed while taking requested medication

**AND**

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**AND**

- ❑ Response is demonstrated by **BOTH** of the following (**Chart notes and current lab test results must be submitted for documentation**)
  - ❑ Reduction of GH levels from pre-treatment baseline
  - ❑ Normalization of IGF-1 level

**AND**

- ❑ Medication will not be used in combination with long-acting somatostatin analogs

**AND**

- ❑ **For Palsonify Requests:** For doses above 60 mg once daily, documentation of medical necessity for high dose must be submitted (i.e. long-term use of moderate to strong CYP3A4 inducer medication that may not be discontinued, concomitant use of proton pump inhibitors that may not be discontinued; etc.)

**❑ Diagnosis – Cushing’s Disease (Signifor SQ, Signifor LAR)**

**Initial Authorization: 6 months**

- ❑ Member is 18 years of age or older

**AND**

- ❑ Provider is an endocrinologist or neurosurgeon

**AND**

- ❑ Member has diagnosis of Cushing’s disease and pituitary surgery is not an option or has not been curative (**chart notes must be submitted to document diagnosis and surgical history or contraindication to surgery**)

**AND**

- ❑ Member’s baseline 24-hour urinary free cortisol level is greater than 1.5 times the upper limit of normal (**labs must be submitted for documentation**)

**AND**

- ❑ Current baseline labs are attached documenting **ALL** the following: liver function tests, fasting plasma glucose, hemoglobin A1c, thyroid function, baseline ECG, and gallbladder ultrasound

**❑ Diagnosis – Cushing’s Disease (Signifor SQ, Signifor LAR)**

**Reauthorization: 12 months**

- ❑ Member’s current 24-hour urinary free cortisol level is below the upper limit of normal mean (**labs must be submitted for documentation**)

**AND**

- ❑ Current labs documenting member’s liver function, fasting plasma glucose and hemoglobin A1c are attached

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**AND**

- ❑ Improvements in blood pressure, triglycerides, low-density lipoprotein cholesterol, weight and health related quality of life have been maintained while on Signifor therapy (**Chart notes must be submitted for documentation**)

❑ **Diagnosis: Other**

**Please submit documentation showing medical necessity**

**Medication being provided by Specialty Pharmacy – Proprium Rx**

*Not all drugs may be covered under every Plan*

*If a drug is non-formulary on a Plan, documentation of medical necessity will be required.*

*\*\*Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.\*\**

*\*Previous therapies will be verified through pharmacy paid claims or submitted chart notes.\**