Somatuline Depot (lanreotide)

**Line(s) of Business:**
- HMO; PPO; QUEST Integration
- Medicare Advantage

**Original Effective Date:** 10/01/2015
**Current Effective Date:** 12/01/2017

**POLICY**

**A. 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 Indications:**
- Somatuline Depot is indicated for the long-term treatment of acromegalic patients who have had an inadequate response to surgery and/or radiotherapy, or for whom surgery and/or radiotherapy is not an option.
- Somatuline Depot is indicated for the treatment of patients with unresectable, well- or moderately-differentiated, locally advanced or metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NETs) to improve progression-free survival

**Compendial Uses:**
- Gastrointestinal (GI), lung and thymus NETs
- Pancreatic neuroendocrine tumors
- Adrenal gland tumors

**B. REQUIRED DOCUMENTATION**
The following information is necessary to initiate the prior authorization review:
- Initial therapy, acromegaly: pretreatment IGF-1 level
- Continuation of therapy, acromegaly: current IGF-1 level

**C. CRITERIA FOR APPROVAL**

1. **Acromegaly**
   Authorization of 12 months may be granted to members who are prescribed Somatuline Depot for the initial treatment of acromegaly when ALL of the following criteria are met:
   a. Member has clinical evidence of acromegaly (See Appendix A)
   b. Member has a high pretreatment IGF-1 level for age and/or gender (See Appendix B)
   c. 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 (See Appendix C)
2. **Gastrointestinal tract, lung and thymus NETs**
   Authorization of 12 months may be granted to members who are prescribed Somatuline Depot for the treatment of gastrointestinal tract, lung or thymus NETs.

3. **Pancreatic NETs**
   Authorization of 12 months may be granted to members who are prescribed Somatuline Depot for the treatment of pancreatic NETs.

4. **Adrenal gland tumors**
   Authorization of 12 months may be granted to members who are prescribed Somatuline Depot for the treatment of adrenal gland tumors.

D. **CONTINUATION OF THERAPY**
   1. No previous authorization/precertification:
      All members (including new members and members currently receiving treatment without prior authorization) must meet criteria for initial approval in section C.
   2. Reauthorization:
      a. **Acromegaly**
         Authorization of 12 months may be granted to members who are prescribed Somatuline Depot for the continuing treatment of acromegaly when the member’s IGF-1 level has decreased or normalized since initiation of therapy and the medication was previously authorized by HMSA/CVS.
      b. **All other indications**
         Authorization of 12 months may be granted to members requesting authorization for continuation of therapy when the criteria for approval in section C are met.

E. **DOSAGE AND ADMINISTRATION**
   Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

F. **APPENDICES**
   **Appendix A: Clinical Evidence of Acromegaly** (not all-inclusive)
   - Frontal bossing
   - Coarse facial features
   - Thick lips
   - Protruding jaw with widely spaced teeth
   - Large hands and feet

   **Appendix B: Normal IGF-1 Levels for Age and Sex**
   The normal range varies based on the laboratory performing the analysis. One must obtain lab-specific values to make this determination.

   **Appendix C: Clinical Reasons for Not Having Surgery**
   - The member has medically unstable conditions (poor surgical candidate)
   - The member is at high risk for complications of anesthesia because of airway difficulties
• The member has major systemic manifestations of acromegaly including cardiomyopathy, severe hypertension and uncontrolled diabetes
• The member refuses surgery or prefers the medical option over surgery
• There is a lack of an available skilled surgeon
• Tumor cannot be localized

G. ADMINISTRATIVE GUIDELINES
Precertification is required. Please refer to the HMSA medical policy web site for the fax form.

H. IMPORTANT REMINDER
The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii’s Patients’ Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), generally accepted standards of medical practice and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA’s determination as to medical necessity in a given case, the physician may request that CVS/caremark reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.

I. REFERENCES

Document History

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