**Somatuline Depot (lanreotide)**

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

**Effective Date:**  
10/01/2015

**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 Indication:**

- 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.

**Compendial Uses:**

- Poorly differentiated (high-grade) neuroendocrine tumors (NETs)/Large or small cell tumors
- Carcinoid tumors
- Pancreatic endocrine tumors (islet cell 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 24 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. **NET/Large or small cell tumors**

   Authorization of 24 months may be granted to members who are prescribed Somatuline Depot for the treatment of poorly differentiated (high-grade) NETs or large or small cell tumors.
3. **Carcinoid tumors**  
Authorization of 24 months may be granted to members who are prescribed Somatuline Depot for the treatment of carcinoid tumors.

4. **Pancreatic endocrine tumors (islet cell tumors)**  
Authorization of 24 months may be granted to members who are prescribed Somatuline Depot for the treatment of pancreatic endocrine tumors (islet cell tumors).

D. **CONTINUATION OF THERAPY**  
1. **Acromegaly**  
Authorization of 24 months may be granted to members who are prescribed Somatuline Depot for the continuing treatment of acromegaly when ALL of the following criteria are met:  
   a. Member has clinical evidence of acromegaly (See Appendix A)  
   b. Member’s IGF-1 level has decreased or normalized since initiation of therapy

2. **All other approvable indications**  
All members (including new members) requesting authorization for continuation of therapy must meet ALL initial authorization criteria.

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
REFERENCES


