**BENEFIT DESCRIPTION AND LIMITATIONS OF COVERAGE**

ITEM: Somatuline® Depot (lanreotide injection)

PRODUCT LINES: Commercial HMO/PPO/CDHP

COVERED UNDER:  
- HMO: Rx and Medical (provider setting)  
- PPO/CDHP: Rx

DESCRIPTION: Synthetic octapeptide analogue of somatostatin which is a peptide inhibitor of multiple endocrine, neuroendocrine, and exocrine mechanisms. Displays a greater affinity for somatostatin type 2 (SSTR2) and type 5 (SSTR5) receptors found in pituitary gland, pancreas, and growth hormone (GH) secreting neoplasms of pituitary gland and a lesser affinity for somatostatin receptors 1, 3, and 4. Reduces GH secretion and also reduces the levels of insulin-like growth factor-1.

CPT/HCPCS Code: J1930

Company Supplying: Ipsen Pharma Biotech

Setting: Subcutaneous injection

Coverage Criteria: Up-To-Date Treatment Algorithm as of 10/27/2010

Approval Period: Initial: 3 months; Continuation based on response.

**Recommended Authorization Criteria**

Coverage of Somatuline® Depot (lanreotide injection) is recommended in those who meet the following criteria and appropriate place in treatment algorithm:

**FDA-Approved Indication**

1. **Acromegaly.** 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 a synthetic octapeptide analog of the natural hormone, somatostatin. The primary effect of Somatuline Depot in acromegaly is a reduction of GH and/or IGF-1 levels to normal and with long-term use reduces prolactin levels. Somatuline Depot also is an inhibitor of various endocrine, neuroendocrine, exocrine, and paracrine functions.

   **Dosing:** May be initially approved in normal renal and hepatic patients at 90 mg given at 4-week intervals for 3 months when
   a) The Member must have the definitive diagnosis of acromegaly from an endocrinologist.

   AND
b) The requesting physician has documented that the Member is not a candidate for surgery and/or radiation, or has had an inadequate response to surgery and/or radiation.

After 3 months the dose may be adjusted as follows:
- For GH > 1 to ≤ 2.5 ng/mL, IGF-1 normal and clinical symptoms controlled: maintain dose at 90 mg every 4 weeks;
- For GH > 2.5 ng/mL, IGF-1 elevated and/or clinical symptoms uncontrolled: increase dose to 120 mg every 4 weeks;
- For GH ≤ 1 ng/mL, IGF-1 normal and clinical symptoms controlled: reduce dose to 60 mg every 4 weeks.

The starting dose for in patients with moderate and severe renal or hepatic impairment should be 60 mg at 4-week intervals for 3 months, followed by dose adjustment in increments as outlined above.

**Exclusions**

Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria.

**APPROVAL:**

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