Somatuline is a 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.

Pre-Authorization Criteria: long term treatment of acromegaly in patients who are not candidates for or are unresponsive to surgery and/or radiotherapy; treatment of unresectable, well- or moderately-differentiated, locally advanced or metastatic gastroenteropancreatic tumors (GEP-NET tumors; 120 mg strength only, see below)

Dosing: Adult:
Acromegaly: Adults (per U.S. labeling) or Children ≥16 years and Adults (per Canadian labeling): SubQ: 90 mg once every 4 weeks for 3 months; after initial 90 days of therapy, adjust dose based on clinical response of patient, growth hormone (GH) levels, and/or insulin-like growth factor 1 (IGF-1) levels as follows:
GH ≤1 ng/mL, IGF-1 normal, symptoms stable: 60 mg once every 4 weeks; once stabilized on 60 mg every 4 weeks, may consider regimen of 120 mg every 6-8 weeks (extended-interval dosing)
GH >1-2.5 ng/mL, IGF-1 normal, symptoms stable: 90 mg once every 4 weeks; once stabilized on 90 mg every 4 weeks, may consider regimen of 120 mg every 6-8 weeks (extended-interval dosing)
GH >2.5 ng/mL, IGF-1 elevated and/or uncontrolled symptoms: 120 mg once every 4 weeks

GEP-NET tumors: dosing restricted to 120 mg once every 4 weeks, deep subcutaneous injection

Dosing: Pediatric:
Acromegaly: Children ≥16 years (Canadian labeling): Refer to adult dosing.

Dosing: Geriatric:
Refer to adult dosing.

**Dosing: Renal Impairment:**
*U.S. labeling:* Moderate-to-severe impairment: Recommended starting dose: 60 mg; use of an extended-interval dose of 120 mg every 6-8 weeks should be done with caution.

**Dosing: Hepatic Impairment:**
*U.S. labeling:* Moderate-to-severe impairment: Recommended starting dose: 60 mg; use of an extended-interval dose of 120 mg every 6-8 weeks should be done with caution.

**Dosage Forms: U.S.:**
Excipient information presented when available (limited, particularly for generics); consult specific product labeling.
- Solution, Subcutaneous:
  - Somatuline Depot: 120 mg/0.5 mL (0.5 mL); 60 mg/0.2 mL (0.2 mL); 90 mg/0.3 mL (0.3 mL)

Generic Equivalent Available: U.S.-No

**Administration:**
Administer by deep subcutaneous injection into superior outer quadrant of buttocks. Do not fold skin. Alternate injection sites.

**Adverse Reactions:**
10%: bradycardia, diarrhea, abdominal pain, flatulence, nausea, weight loss
Other Serious Less Common Reactions: cholelithiasis, gallbladder sludge, hyperglycemia, hypoglycemia, hypothyroidism, bradycardia, hypertension, anemia.

**References:**
7. [www.epocrates.com](http://www.epocrates.com): Somatuline Drug information
**Revision History:**
Date Reviewed/No Updates: 01.13.15 by C. Sanders, MD
Date Approved by P&T Committee: 01.27.15
Date Reviewed/Updated: 07.28.15 by C. Sanders, MD
Date Approved by P&T Committee: 07.28.15
Date Reviewed/No Updates: 01.26.16 by C. Sanders, MD; R. Sterling, MD
Date Approved by P&T Committee: 01.26.16
Date Reviewed/No Updates: 01.24.17 by C. Sanders, MD; R. Sterling, MD
Date Approved by P&T Committee: 01.24.17

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<td>Catherine Sanders, MD; Robert Sterling, MD</td>
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