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: Somatuline Drug information
Revision History:

Date Reviewed/No Updates: 1/13/15 by C. Sanders, MD  
Date Approved by P&T Committee: 1/27/15  
Date Reviewed/Updated: 07/28/15 by C. Sanders, MD  
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Date Reviewed/No Updates: 1/26/16 by C. Sanders, MD; R. Sterling, MD  
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Date Reviewed/No Updates: 1/24/17 by C. Sanders, MD; R. Sterling, MD  
Date Approved by P&T Committee: 1/24/17  
Date Reviewed/No Updates: 1/23/18 by C. Sanders, MD; R. Sterling, MD  
Date Approved by P&T Committee: 1/23/18

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