PHARMACY POLICY STATEMENT
North Carolina Marketplace

DRUG NAME	Somatostatin analogs (Injectable; First generation): Sandostatin (octreotide), Sandostatin LAR (octreotide), Somatuline Depot (lanreotide), Bynfezia Pen (octreotide)
BILLING CODE	J2354/ J2353/ J1930/ NDC

Octreotide: Initial 50mcg subQ/IV 3 times daily, titrate as indicated, usual maintenance dose 100mcg 3 times daily, max 500mcg 3 times daily. NOTE: Doses in excess of 300mcg per day seldom confer additional benefit.
Sandostatin LAR: Start at 20mg IM every 4 weeks for 3 months, then adjust according to GH and IGF-1 per package insert, no more than 40mg every 4 weeks. (1 kit per 28 days, or 2 per 28 for the 20mg)
Somatuline depot: Start at 90mg subQ every 4 weeks for 3 months, then adjust according to GH and IGF-1 per package insert, no more than 120mg every 4 weeks. (1 syringe per 28 days)
Bynfezia Pen: Initial 50mcg subQ 3 times daily, titrate as indicated, usual maintenance dose 100mcg 3 times daily, max 500mcg 3 times daily. NOTE: Doses in excess of 300mcg per day seldom confer additional benefit.

If all the above requirements are met, the medication will be approved for 6 months.

For reauthorization :
1. Chart notes/lab report must show normalized or improved (decreased) IGF-1

If all the above requirements are met, the medication will be approved for an additional 12 months.

Carcinoid Syndrome

For initial authorization:
1. Member is 18 years of age or older; AND
2. Medication must be prescribed by or in consultation with an oncologist or gastroenterologist; AND
3. Member has a neuroendocrine tumor, including carcinoid tumor or vasoactive intestinal peptide tumor (VIPoma); AND
4. Member is experiencing flushing and/or diarrhea symptoms associated with carcinoid syndrome (or VIPoma syndrome), not attributed to another cause.
5. For Somatuline Depot only: Must have a trial and failure of Sandostatin LAR.
6. For Bynfezia only:
   a) Baseline thyroid function testing is required; AND
   b) Trial and failure of short acting octreotide (generic Sandostatin).
7. Dosage allowed/Quantity limit:
   Octreotide: 100mcg-750mcg per day subQ/IV in divided doses.
   Sandostatin LAR: 10mg to 30mg IM every 4 weeks. (1 kit per 28 days)
   Somatuline depot: 120mg subQ every 4 weeks. (1 syringe per 28 days)
   Bynfezia: 100-750mcg per day subQ in divided doses.

If all the above requirements are met, the medication will be approved for 6 months.

For reauthorization :
1. For short-acting products (octreotide, Bynfezia): Chart notes must document symptomatic improvement of flushing and/or diarrhea episodes.
2. For long-acting products (Sandostatin LAR, Somatuline Depot): Chart notes must document reduced frequency of short-acting somatostatin analog rescue therapy for symptom control.

If all the above requirements are met, the medication will be approved for an additional 12 months.

NOTE to Reviewer: A short-acting product may be used concurrently with a long-acting product.

Gastroenteropancreatic Neuroendocrine Tumors (GEP -NETs)

CareSource considers Somatostatin analogs (Injectable; First generation) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off- Label poli cy.

DATE	