

PHARMACY POLICY STATEMENT

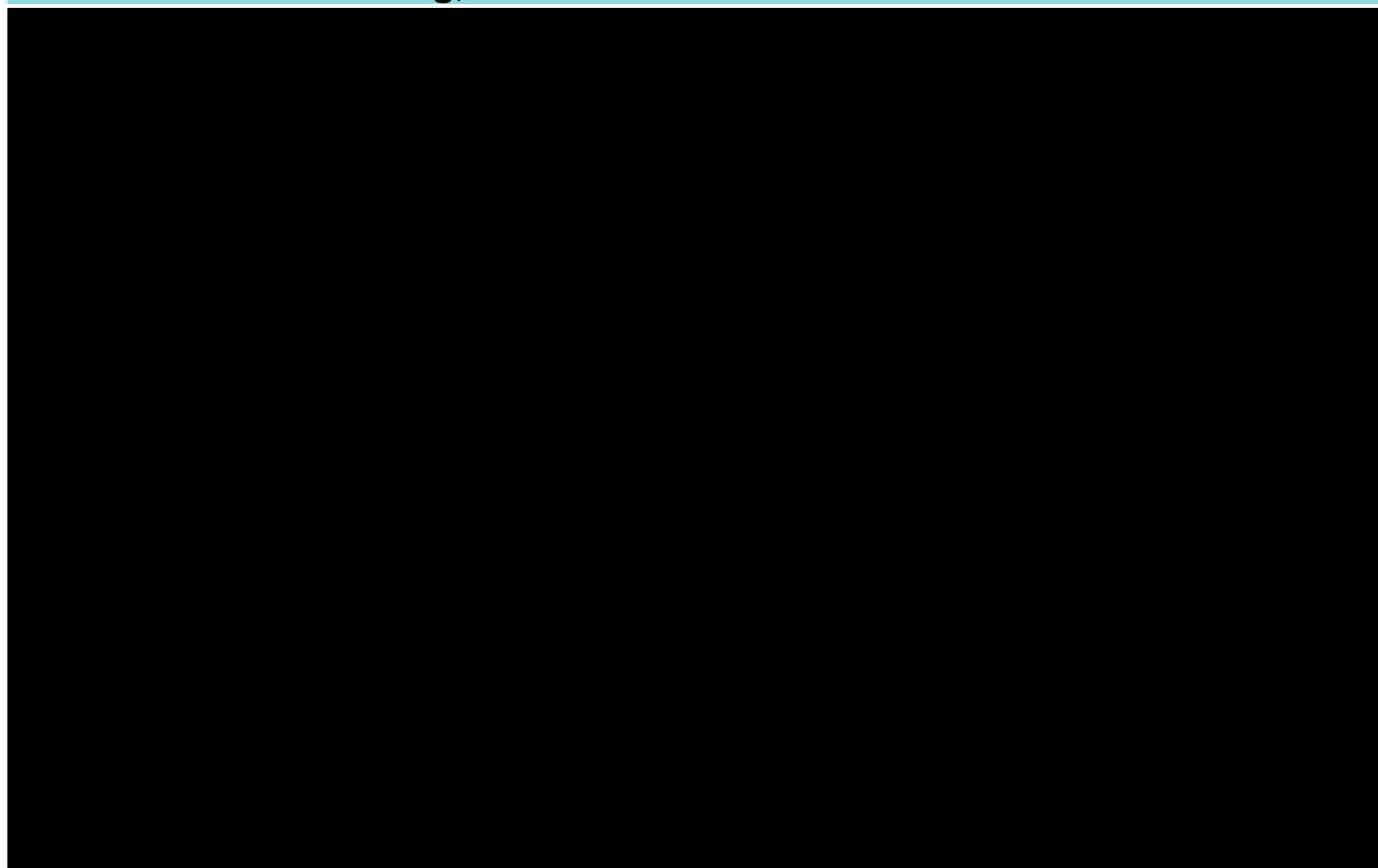
North Carolina Marketplace

DRUG NAME	Serostim (somatropin)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Serostim is an anabolic and anticatabolic agent initially approved by the FDA in 1996. It is indicated for the treatment of HIV patients with wasting or cachexia to increase lean body mass and body weight, and improve physical endurance. Concomitant antiretroviral therapy is necessary. HIV associated wasting is a serious condition that may be a concern for patients living with HIV, including those with undetectable viral loads and normal CD4 counts who are well controlled on antiretroviral therapy (ART). The 3 key symptoms of HIV associated wasting are loss of lean body mass (LBM) and body weight, and decreased physical endurance. Serostim significantly increased LBM and body weight, and improved physical endurance in clinical trials.

Serostim (somatropin) will be considered for coverage when the following criteria are met:

HIV-Associated Wasting, Cachexia



2. Documentation HIV wasting is still present (i.e, demonstrated by BMI < 27 kg/m²); AND
3. Duration of treatment has not exceeded 48 weeks.

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

CareSource considers Serostim (somatropin) 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 policy.

DATE	ACTION/DESCRIPTION
10/25/2018	New policy for Serostim created.
11/10/2022	Annual review. Transferred to new format. Updated references. Modified the diagnostic of HIV-associated weight loss. Added quantity limits and weight-based maximum daily dosing guidance. Added note stating Serostim has not been studied longer than 48 weeks.
09/18/2023	Added in consultation with prescribing specialty; added history malignancy exclusion; added documentation of weight; updated references; added reauthorization criteria that duration cannot exceed 48 weeks; removed note that Serostim has not been studied longer than 48 weeks.