

**HARVARD PILGRIM HEALTH CARE  
RECOMMENDED MEDICATION REQUEST GUIDELINES**

**LIPODYSTROPHY AGENTS**

Generic	Brand	HICL	GCN	Exception/Other
TESAMORELIN ACETATE	EGRIFTA	37268		
SOMATROPIN	SEROSTIM		63405 25955 25960	BRAND = SEROSTIM

PLEASE USE DRUG SPECIFIC CRITERIA

**GUIDELINES FOR USE**

**SEROSTIM**

1. Is the patient currently being treated with antiretroviral medications?

If yes, continue to #2.

If no, do not approve. Please use status code #238 and the denial text provided.

**DENIAL TEXT:** Per your health plan's Lipodystrophy Agents guideline, Serostim is only covered when prescribed in combination with antiretroviral medications. Your physician did not indicate that you are being treated with antiretroviral medications and therefore your request was not approved.

2. Does the patient have HIV-associated wasting or cachexia?

If yes, continue to #4.

If no, continue to #3.

3. Does the patient have excess abdominal fat secondary to HIV-associated lipodystrophy?

If yes, continue to #4.

If no, do not approve. Please use status code #238 and the denial text provided.

**DENIAL TEXT:** Per your health plan's Lipodystrophy Agents guideline, Serostim is only covered when prescribed for the reduction of excess abdominal fat secondary to HIV-associated lipodystrophy and for the treatment of HIV patients with wasting or cachexia to increase lean body mass and weight and improve physical endurance. Your provider did not indicate that you are being treated for any of these conditions and therefore your request was not approved.

4. **Approve for 24 months by GPID.** Please use status code #057 and the approval text provided.

**APPROVAL TEXT:** Serostim has been approved for your condition for a 24-month period.

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**GUIDELINES FOR USE (CONTINUED)**

**EGRIFTA**

1. Is Egrifta not on the member's formulary?

If yes, continue to #2.

If no, continue to #3.

2. Has the patient tried and failed Serostim, or did the provider indicate there is clinical rationale for not using Serostim?

If yes, continue to #3.

If no, do not approve. Please use status code #238 and the denial text provided.

**DENIAL TEXT:** Per your health plan's non-formulary Lipodystrophy Agents guideline, Egrifta is only covered for patients who have tried and failed or cannot use Serostim. Your provider did not indicate that you have tried Serostim and therefore your request was not approved.

3. Does the patient have excess abdominal fat secondary to HIV-associated lipodystrophy?

If yes, continue to #4.

If no, do not approve. Please use status code #238 and the denial text provided.

**DENIAL TEXT:** Per your health plan's Lipodystrophy Agents guideline, Egrifta is only covered when prescribed for the reduction of excess abdominal fat secondary to HIV-associated lipodystrophy. Your provider did not indicate that you are being treated for this condition and therefore your request was not approved.

4. **Approve for 24 months by HICL.** Please use status code #057 and the approval text provided.

**Requests for products on formulary with a restriction,**

**APPROVAL TEXT:** Your request for Egrifta (tesamorelin acetate) has been approved for your condition for a 24 month period.

**Requests for products not on formulary,**

**APPROVAL TEXT:** Your request for Egrifta (tesamorelin acetate) has been approved for your condition for a 24 month period and at the highest cost-share tier. Refer to your Harvard Pilgrim ID card for the amount you pay for drugs on that tier.

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**RATIONALE**

To ensure Egrifta and Serostim are being used to treat lipodystrophy associated with HIV disease and for the treatment of wasting and cachexia to increase lean body mass and weight.

**FDA APPROVED INDICATIONS**

Egrifta is indicated for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy.

Serostim is indicated for the treatment of HIV patients with wasting or cachexia to increase lean body mass and weight, and improve physical endurance. Concomitant antiretroviral therapy is also necessary.

**REFERENCES**

- Egrifta Prescribing Information. Theratechnologies, Inc. Available at [www.egrifta.com/hcp/Default.aspx](http://www.egrifta.com/hcp/Default.aspx). Accessed October 11, 2012.
- Serostim Prescribing Information. Serono. August 2007.

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