Protocol for Egrifta (tesamorelin)
Approved April 2024

Egrifta is a growth hormone-releasing factor (GHRF) analog indicated for the reduction of excess abdominal fat in HIV-infected adult patients with lipodystrophy.

Criteria for approval:

1. Patient has a diagnosis of HIV-associated lipodystrophy
2. Patient is currently receiving anti-retroviral therapy
3. Medication is prescribed by, or consultation with an infectious disease specialist, an HIV practitioner, or an endocrinologist
4. Documentation that the following baseline information has been obtained within the last 30-day period and is available:
    a. Hemoglobin A1C
    b. Insulin-like Growth Factor-1 (IGF-1)
5. Patient has no contraindication to treatment such as:
    a. Active malignancy
    b. Disruption of the hypothalamic-pituitary axis due to hypophysectomy, hypopituitarism, pituitary tumor/surgery, head irradiation or head trauma
    c. Pregnancy (consider risk)
6. Medication is prescribed in accordance with Food and Drug Administration (FDA) established indication and dosing regimens or in accordance with medically appropriate off-label indication and dosing according to American Hospital Formulary Service, Micromedex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs (Lexicomp), national guidelines, or other peer-reviewed evidence

Continuation of therapy:

1. Patient is responding positively to therapy as evidenced by documentation of decrease in visceral adipose tissue.
2. There is no evidence of exacerbation of glucose intolerance and increased IGF-1 levels
3. Medication will be discontinued in 6 months if there is no treatment response
4. Medication is prescribed in accordance with Food and Drug Administration (FDA) established indication and dosing regimens or in accordance with medically appropriate off-label indication and dosing according to American Hospital Formulary Service, Micromedex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs (Lexicomp), national guidelines, or other peer-reviewed evidence

Limitations of use:

a. Long-term cardiovascular safety of Egrifta has not been established
b. Not indicated for weight loss management
c. There is no data to support improved compliance with anti-retroviral therapies in HIV-positive patients taking Egrifta

Approval Duration and Quantity Restrictions:
Initial and Renewal Approval: 6 months

Quantity Level Limit: 30 vials per 30 days
Reference Formulary for drug specific quantity level limits

References:

1. Egrifta [prescribing information]. Theratechnologies Inc., Montréal, Québec, Canada H3A 1T8. July 2019
2. Clinical Pharmacology® Gold Standard Series [Internet database]. Tampa FL. Elsevier 2020. Updated periodically
3. Glesby MJ. (2022). Treatment of HIV-associated lipodystrophy. UpToDate. Retrieved February 4, 2023 from https://www.uptodate.com/contents/treatment-of-hiv-associated-lipodystrophy