SPECIALTY GUIDELINE MANAGEMENT

EGRIFTA (tesamorelin)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications
Egrift is indicated for the reduction of excess abdominal fat in human immunodeficiency virus (HIV)-infected patients with lipodystrophy

Limitations of Use:
1. Long-term cardiovascular benefit and safety of Egrifta have not been studied.
2. Egrifta is not indicated for weight loss management (weight neutral effect).
3. There are no data to support improved compliance with anti-retroviral therapies in HIV-positive patients taking Egrifta.

All other indications are considered experimental/investigational and are not a covered benefit.

II. EXCLUSIONS

Coverage will not be provided for weight loss.

III. PRESCRIBER SPECIALTIES

This medication must be prescribed by or in consultation with an infectious disease specialist.

IV. CRITERIA FOR INITIAL APPROVAL

Authorization of 6 months may be granted for treatment of lipodystrophy when all of the following criteria are met:
A. The member has HIV infection
B. Egrifta is used to reduce excess abdominal fat
C. The member is currently receiving anti-retroviral therapy

V. CONTINUATION OF THERAPY

Authorization of 6 months may be granted for continuation of therapy to reduce excess abdominal fat when all of the following criteria are met:

A. The member has HIV infection and lipodystrophy
B. The member is currently receiving anti-retroviral therapy

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C. The member has demonstrated a clear clinical improvement from baseline that is supported by a waist circumference or CT scan

VI. REFERENCES

1. Egrifta [package insert]. Montreal, Québec: Theratechnologies, Inc.; June 2015.
2. Brown TT. Approach to the human immunodeficiency virus-infected patient with lipodystrophy. *J Clin Endocrinol Metab*. 2008;93(8):2937-2945.