tesamorelin (Egrifta®)

Policy # 00454
Original Effective Date: 06/17/2015
Current Effective Date: 07/10/2023

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of tesamorelin (Egrifta®)‡ for the reduction of excess abdominal fat in HIV (human immunodeficiency virus)-infected patients with lipodystrophy to be **not medically necessary.****

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of tesamorelin (Egrifta) for indications other than the reduction of excess abdominal fat in HIV infected patients with lipodystrophy to be **investigational.***

Background/Overview

Egrifta is a growth hormone releasing factor (GRF) analog indicated for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy. Growth hormone releasing factor, also known as growth hormone-releasing hormone (GHRH), is a hypothalamic peptide that acts on the pituitary somatotroph cells to stimulate the synthesis and pulsatile release of endogenous growth hormone (GH), which is both anabolic and lipolytic. Growth hormone exerts its effects by interacting with specific receptors on a variety of target cells, including chondrocytes, osteoblasts, myocytes, hepatocytes, and adipocytes, resulting in a host of pharmacodynamic effects. Some, but not all these effects, are primarily mediated by insulin like growth factor-1 (IGF-1) produced in the liver and in peripheral tissues. The recommended dose of Egrifta is 2mg injected subcutaneously once daily. Long-term cardiovascular benefit and safety of Egrifta have not been studied. Egrifta is not indicated for weight loss management. There are no data to support improved compliance with anti-retroviral therapies in HIV-positive patients taking Egrifta.

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HIV associated lipodystrophy typically refers to changes in fat distribution that are often associated with metabolic abnormalities. Patients can either experience lipoatrophy (loss of subcutaneous fat, most noticeably in the limbs, face, and/or buttocks area) or fat accumulation (gain of visceral fat in the abdomen and may experience a buffalo hump or breast enlargement).

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Egrifta is a growth hormone releasing factor analog indicated for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy. Egrifta was initially approved by the FDA in November of 2010.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. FDA approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

Egrifta was studied in two phase III, randomized, placebo-controlled trials in HIV infected patients with excess abdominal fat. Both trials had 26 week randomized main phases, and then patients were re-randomized in extension phases until week 52. The primary endpoint of the studies was the percent change from baseline to week 26 in visceral adipose tissue (VAT), assessed via computed tomography (CT) scan at the L4-L5 vertebral level. The mean change in VAT was -18% in the Egrifta group and +2% in the placebo group in study 1 and -14% in the Egrifta group and -2% in the placebo group in study 2. The mean treatment differences were statistically significant in both study 1 (-20%) and study 2 (-12%). Eligible patients were then moved to an extension phase. Patients that received Egrifta in the main phase were re-randomized in study 1 and study 2 to either Egrifa or placebo. Those that received placebo during the main phase received Egrifta during the extension phase. The purpose of the extension phase was to assess maintenance of VAT reduction and to gather long-term safety data. The mean change in VAT from week 26 to week 52 in those patients continuing on Egrifta was 0% and +22% for those that switched from placebo to Egrifta in study 1. The mean change in VAT from week 26 to week 52 in those patients continuing on Egrifta was -5%

and +16% for those that switched from placebo to Egrifta in study 2. The mean treatment differences were statistically significant in study 1 (-17%) and study 2 (-18%).

Although Egrifta is FDA approved for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy, an improvement in net health outcomes has not been demonstrated. The long-term cardiovascular benefit of Egrifta has not been studied. Secondary endpoints such as lipid abnormalities and improved patient-reported body image were considered correlates of VAT reduction, however changes in these measures were not robust or consistent. Therefore, Egrifta is considered not medically necessary for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy as there is insufficient peer reviewed literature to support improvement in health outcomes.

References

1. Egrifta [package insert]. Theratechnologies, Inc. Montreal, Quebec. Updated 9/2014.
2. Egrifta AMCP Dossier. Updated November 2014.

Policy History

Original Effective Date: 06/17/2015
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06/04/2015	Medical Policy Committee review
06/17/2015	Medical Policy Implementation Committee approval. New policy.
06/02/2016	Medical Policy Committee review
06/20/2016	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/01/2017	Medical Policy Committee review
06/21/2017	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/07/2018	Medical Policy Committee review
06/20/2018	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/06/2019	Medical Policy Committee review
06/19/2019	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

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06/04/2020	Medical Policy Committee review
06/10/2020	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/03/2021	Medical Policy Committee review
06/09/2021	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/02/2022	Medical Policy Committee review
06/08/2022	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/01/2023	Medical Policy Committee review
06/14/2023	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 06/2024

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment,

would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.