 важное сообщение

Политика лекарств была разработана с учитом необходимости, общепринятых стандартов медицинской практики, а также с оценкой медицинской литературы и статуса одобрения правительством.

Решения о предоставлении помощи должны быть основаны на действующих контрактных положениях в каждом конкретном случае. В случае противоречий между этими руководствами и контрактными положениями, последние будут иметь преимущество.

Цель Политики лекарств – предоставить руководство по покрытию. Политика лекарств не подразумевает назначение медицинских услуг.

Описание

Тесаморелин (Егрифта) – это синтетический гормон, используемый для снижения абдоминальных жиров у пациентов с липодистрофией. Он вводится в мышцу живота подкожно. Тесаморелин не доказан способностью улучшить липидный профиль, не имеет долгосрочного кардиоваскулярного эффекта и не улучшает сопоставимость с режимом HIV-терапии.

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Policy/Criteria

I. Most contracts require prior authorization approval of tesamorelin prior to coverage. Tesamorelin may be considered medically necessary when criteria A, B, and C below are met.

A. The patient is infected with human immunodeficiency virus (HIV).

AND

B. There is excess accumulation of abdominal fat due to HIV-associated lipodystrophy with the following gender-specific measures:
   1. For males:
      a. Waist circumference greater than 37.4 inches (95 cm).
      AND
      b. Waist-to-hip ratio greater than 0.94.
   OR
   2. For females:
      a. Waist circumference greater than 37 inches (94 cm).
      AND
      b. Waist-to-hip ratio greater than 0.88.

AND

C. Documentation in chart notes that the excess accumulation of abdominal fat has impaired function, such as significantly limiting instrumental activities of daily living (for example, meal preparation, household chores). Intermittent occupational tasks that are not required as a daily part of job functioning are not considered instrumental activities of daily living.

II. Administration and Authorization Period

A. OmedaRx considers tesamorelin to be a self-administered medication.

B. When prior authorization is approved, tesamorelin may be authorized as follows:
   1. Up to 60, 1-mg vials per month.
   2. Up to 30, 2-mg vials per month.
   3. Quantities exceeding 60, 1-mg vials or 30, 2-mg vials per month are considered not medically necessary.

C. Authorization shall be reviewed as follows to confirm that medical necessity criteria are met and that the medication is effective.
   1. Initial authorization shall be reviewed at 6 months.
   2. Continued authorization or re-authorization (after the initial 6-month period) shall be reviewed at least annually. Clinical documentation indicating a decrease in waist circumference and that the functional impairment resolved or improved must be provided.
III. Tesamorelin is considered not medically necessary when used for all other conditions, including but not limited to:
   A. Improving long-term cardiovascular outcomes in patients with HIV infection.
   B. For weight loss management in patients with HIV infection.
   C. For improving adherence with antiretroviral (ARV) medication regimens.
   D. Metabolic abnormalities (metabolic syndrome)

IV. Tesamorelin is considered investigational when used for all other conditions.

Position Statement
- Tesamorelin (Egrifta) is a synthetic analog of human growth hormone-releasing hormone (GHRH) used to reduce excess abdominal fat in HIV-infected patients with lipodystrophy.
- HIV lipodystrophy is characterized by loss of peripheral subcutaneous adipose tissue (especially in the face, limbs and buttocks) and an increase in visceral fat accumulation (characterized by increased abdominal girth) and lipomas, particularly on the back of the neck (buffalo hump).
- Tesamorelin has been reported to reduce abdominal fat in HIV lipodystrophy. However, this change in visceral adipose tissue (VAT) was not accompanied by robust or consistent changes in self-perception of body image or lipid abnormalities.
- Additionally, tesamorelin has not been shown to improve long-term cardiovascular outcomes, assist in weight loss, or improve adherence to antiretroviral regimens.
- Tesamorelin is self-administered as a 2-mg subcutaneous injection once daily.
- Tesamorelin has not been evaluated in patients who are not infected with HIV.
- Tesamorelin is not for use and has not been evaluated for the purpose of cosmetic procedures.

Summary
Clinical Efficacy
- The safety and effectiveness of tesamorelin have been evaluated in two, randomized controlled trials in 816 HIV-infected patients with excess abdominal fat due to lipodystrophy.\(^{[1,2]}\) There is uncertain confidence in the evidence from these trials.
  * The studies compared tesamorelin with placebo.
  * The primary endpoint was percent change from baseline to week 26 in visceral adipose tissue (VAT). [VAT change was defined as cross-sectional area in cm\(^2\) measured by CT scan at the L4-L5 level].
  * Decrease in visceral adipose tissue (VAT) has not been correlated with clinical outcomes such as improvement in long-term cardiovascular risk.\(^{[3]}\)
  * Other study flaws included a high proportion of study dropouts (20%) and missing post-dose VAT measurements (10%).
Excess abdominal fat was defined in the clinical studies based on the following criteria: \cite{1,2}

* Males: Waist circumference > 37.4 inches (95 cm) and a waist-to-hip ratio > 0.94.
* Females: Waist circumference > 37 inches (94 cm) and a waist-to-hip ratio > 0.88.

The study reported a 14% to 18% decrease in VAT from baseline with tesamorelin at 26 weeks. There was no change in VAT in those patients who were randomized to placebo. \cite{1,2}

Despite the significant loss in VAT, there were no robust or consistent changes in secondary supportive efficacy measures such as improved self-perception of body image or lipid abnormalities. \cite{1-3}

Any observed decreases in VAT were reversed (patients returned to baseline) within 6 months of discontinuing tesamorelin therapy based on two unreliable extension studies. \cite{2,4}

The FDA has not endorsed reduction in VAT as a validated surrogate marker for any clinical outcome, including long-term cardiovascular benefit. \cite{3}

Tesamorelin has not been studied in other patient populations, including HIV negative patients with “metabolic syndrome”.

**Safety**

- The most commonly reported adverse reactions with tesamorelin include rash, injection site reactions (e.g. pain, itching, swelling), joint pain, pain in the extremities, fluid retention, high blood sugar, and carpal tunnel syndrome. \cite{5}

- There is an increased risk of developing diabetes when using tesamorelin. \cite{5}

- Patients with active malignancies (cancers) should not be treated with tesamorelin. \cite{5}

**Dosing considerations**

- Tesamorelin is self-administered via subcutaneous injection into the abdomen. The dose is 2 mg once per day. \cite{5}

- It is supplied in 2-mg vials which must be reconstituted prior to injection. \cite{5}

- The safety and efficacy of higher doses have not been established.

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Revision History

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