BlueCross BlueShield Federal Employee Program

EGRIFTA SV (tesamorelin)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Egrifta SV is approved by the FDA for HIV-associated lipodystrophy which is defined as a condition in which excess fat develops in different areas of the body, especially around the liver, stomach and other abdominal organs commonly observed in HIV-infected patients. Egrifta SV is a growth hormone releasing factor (GRF) analog that acts on pituitary cells in the brain to stimulate the production and release of endogenous growth hormone (1).

Egrifta SV stimulates growth hormone production and increases serum IGF-1. Given that IGF-1 is a growth factor and the effect of prolonged elevations in IGF-1 levels on the development or progression of malignancies is unknown, any pre-existing malignancy should be inactive and treatment should be completed prior to initiating therapy with Egrifta SV. IGF-1 levels should be monitored closely during Egrifta SV therapy. Careful consideration should be given to discontinuing Egrifta SV in patients with persistent elevations of IGF-1 levels, particularly if the efficacy response is not robust (1).

Regulatory Status

FDA-approved indication:
Egrifta SV is a growth hormone releasing factor (GRF) analog indicated for the reduction of excess abdominal fat in HIV-infected patients with lipodystrophy (1).

Limitations of Use: (1)

- Long-term cardiovascular benefit and safety of Egrifta SV have not been established
- Not indicated for weight loss management (weight neutral effect)
- There are no data to support improved compliance with anti-retroviral therapies in HIV-positive patients taking Egrifta SV

Egrifta SV is contraindicated in women who are pregnant, in patients with disruption of the hypothalamic-pituitary axis due to hypophysectomy, hypopituitarism, pituitary tumor or surgery, head irradiation or head trauma, in patients with known hypersensitivity to Egrifta SV and or mannitol, and in patients with active malignancies. Egrifta SV therapy should be discontinued if pregnancy occurs; therefore, a positive pregnancy test prohibits therapy (1).

Preexisting malignancy should be inactive and its treatment complete prior to starting Egrifta SV therapy (1).

Egrifta SV treatment may result in glucose intolerance. An increased risk of developing diabetes with Egrifta SV relative to placebo was observed. Therefore, glucose status should be carefully evaluated prior to initiating Egrifta SV treatment. Patients must have their glucose status checked routinely (1).

Summary

Egrifta SV is approved for HIV-associated lipodystrophy in patients 18 years of age and older. It is contraindicated in women who are pregnant and preexisting malignancies. Treatment may result in glucose intolerance (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Egrifta SV while maintaining optimal therapeutic outcomes.

References

1. Egrifta SV [package insert]. Montreal, Canada: Theratechnologies Inc.; February 2022.