



RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Signifor LAR (pasireotide pamoate) is a once a month long-acting release intramuscular injection for the treatment of acromegaly in patients who are not surgical candidates or have had an inadequate response to surgery, and for patients with Cushing's disease for whom pituitary surgery is not an option or has not been curative. Acromegaly is a rare and debilitating endocrine disorder caused by excess production of growth hormone (GH) and insulin-like growth factor-1 (IGF-1) levels. Cushing's disease is characterized by excess cortisol production. Signifor LAR exerts its pharmacological activity via binding to somatostatin receptors (SSTR). Pasireotide binds to SSTR2 and SSTR5 subtype receptors which may be relevant for inhibition of GH and corticotropin secretion (1).

Regulatory Status

FDA-approved indications: Signifor LAR is a somatostatin analog indicated for the treatment of: (1)

1. Patients with acromegaly who have had an inadequate response to surgery and/or for whom surgery is not an option
2. Patients with Cushing's disease for whom pituitary surgery is not an option or has not been curative

Elevations in blood glucose levels have been seen in healthy volunteers and patients treated with Signifor LAR. The glycemic status [fasting plasma glucose (FPG) or hemoglobin A1c (HbA1c)] should be assessed prior to starting treatment with Signifor LAR (1).

The safety and efficacy of Signifor LAR in pediatric patients have not been studied (1).

Summary

Signifor LAR is a somatostatin analog indicated for the treatment of adult patients with acromegaly who have had an inadequate response to surgery and/or for whom surgery is not an option, and for patients with Cushing's disease for whom pituitary surgery is not an option or has not been curative. Elevations in blood glucose levels have been seen in healthy volunteers and patients treated with Signifor LAR. The safety and efficacy of Signifor LAR in pediatric patients have not been studied (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of



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SIGNIFOR LAR
(pasireotide pamoate)

Signifor LAR while maintaining optimal therapeutic outcomes.

References

1. Signifor LAR [package insert]. Lebanon, NJ: Recordati Rare Diseases Inc.; July 2024.