BlueCross BlueShield Federal Employee Program

SIGNIFOR
(pasireotide)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Signifor (pasireotide diaspartate) is an injection for the treatment of Cushing's disease patients who cannot be helped through surgery. Cushing's disease is caused by over-production of cortisol, a hormone made by the adrenal glands. Signifor exerts its pharmacological activity via binding to somatostatin receptors (SSTRs). Pasireotide binds and activates the SSTRs resulting in inhibition of ACTH (adrenocorticotropic hormone) secretion, which leads to decreased cortisol secretion (1).

Regulatory Status

FDA-approved indication: Signifor is a somatostatin analog indicated for the treatment of adult patients with Cushing's disease for whom pituitary surgery is not an option or has not been curative (1).

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

Signifor is associated with QT prolongation and liver test elevations. It is recommended to obtain a baseline electrocardiogram and liver tests and monitor during treatment. Hypokalemia and hypomagnesemia must be corrected prior to Signifor administration and should be monitored periodically during therapy (1).

Bradycardia has been reported with the use of Signifor. Patients with cardiac disease and/or risk factors for bradycardia, such as history of clinically significant bradycardia, high-grade heart block, or concomitant use of drugs associated with bradycardia, should be carefully monitored (1).

As the pharmacological activity of Signifor mimics that of somatostatin, inhibition of pituitary hormones, other than ACTH, may occur. Monitoring of pituitary function (e.g., TSH/free T4) should occur prior to initiation of therapy with Signifor and should be repeated periodically during treatment. If hypocortisolism occurs, consider a temporary dose reduction or interruption of treatment with Signifor, as well as temporary, exogenous glucocorticoid replacement therapy (1).

Cholelithiasis has been frequently reported. Ultrasonic examination of the gallbladder before, and at 6- to 12-month intervals during Signifor therapy is recommended (1).

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

Summary

Signifor is a somatostatin analog indicated for the treatment of adult 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. Signifor is associated with QT prolongation, elevated liver tests, and cholelithiasis. The safety and efficacy of Signifor in pediatric patients have not been studied (1).

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

References

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