BlueCross BlueShield Federal Employee Program

MYCAPSSA (octreotide)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Mycapssa (octreotide acetate) exerts pharmacological actions similar to the natural hormone somatostatin, but is a more potent inhibitor of growth hormone (GH), glucagon, and insulin than somatostatin. Like somatostatin, it also suppresses luteinizing hormone (LH) response to gonadotropin-releasing hormone (GnRH), decreases splanchnic blood flow, and inhibits release of serotonin, gastrin, vasoactive intestinal peptide, secretin, motilin, and pancreatic polypeptide (1).

Regulatory Status

FDA-approved indication: Mycapssa is a somatostatin analog indicated for long-term maintenance treatment in acromegaly patients who have responded to or tolerated treatment with octreotide or lanreotide (1).

The maximum recommended dosage of Mycapssa is 80 mg daily. Once the maintenance dosage of Mycapssa is achieved, IGF-1 levels and the patient's signs and symptoms should be monitored monthly or as indicated (1).

Mycapssa therapy should be withdrawn periodically to assess disease activity. If IGF-1 levels increase and signs and symptoms recur, Mycapssa therapy should be resumed (1).

Mycapssa has warnings regarding: cholelithiasis; hyperglycemia and hypoglycemia; thyroid function abnormalities; cardiac function abnormalities; and decreased Vitamin B_{12} levels and abnormal Schilling's Tests (1).

There is a potential for unintended pregnancy with premenopausal women as the therapeutic benefits of a reduction in GH levels and normalization of IGF-1 concentration in acromegalic females treated with octreotide may lead to improved fertility (1).

The safety and effectiveness of Mycapssa in pediatric patients have not been established (1).

Summary

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Mycapssa (octreotide acetate) exerts pharmacological actions similar to the natural hormone somatostatin, but is a more potent inhibitor of growth hormone (GH), glucagon, and insulin than somatostatin. Like somatostatin, it also suppresses luteinizing hormone (LH) response to gonadotropin-releasing hormone (GnRH), decreases splanchnic blood flow, and inhibits release of serotonin, gastrin, vasoactive intestinal peptide, secretin, motilin, and pancreatic polypeptide. The safety and effectiveness of Mycapssa in pediatric patients less than 18 years of age have not been established (1).

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

References

1. Mycapssa [package insert]. Scotland, UK: MW Encap Ltd.; March 2022.