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5.30.024

Section:	Prescription Drugs	**Effective Date:**	January 1, 2025
Subsection:	Endocrine and Metabolic Drugs	**Original Policy Date:**	September 11, 2009
Subject:	Zorbtive	**Page:**	1 of 5

Last Review Date: December 13, 2024

Zorbtive

Description

Zorbtive (somatropin)

Background
Zorbtive (somatropin) is a human growth hormone (hGH) produced by recombinant DNA technology. Zorbtive is approved for use in the treatment of short bowel syndrome (SBS) in patients who are on a specialized diet. SBS is a rare, serious and potentially life-threatening condition that follows extensive surgical removal of portions of the small intestine as a treatment for acute or chronic disorders of the intestine. Removal of a large portion of the bowel results in impaired absorption of nutrients. Currently the standard treatment for SBS involves careful management of dietary intake and hydration, or where appropriate, a process referred to as parenteral nutrition in which patients are fed through an intravenous tube. On rare occasions, surgical transplant of the intestine may also be performed for this condition (1).

Intestinal mucosa contains receptors for growth hormone and for insulin-like growth factor-1 (IGF-1), which is known to mediate many of the cellular actions of growth hormone. Thus, the actions of growth hormone on the gut may be direct or mediated via the local or systemic production of IGF-1. In human clinical studies, the administration of growth hormone has been shown to enhance the transmucosal transport of water, electrolytes, and nutrients (1).

The potential for misuse or abuse of Zorbtive is high since it is the same medication used for growth hormone deficiencies. Growth hormones misuse is prevalent with athletes and body builders and among those seeking its purported anti-aging and weight loss effects (2).

Regulatory Status
FDA-approved indication: Zorbtive is a recombinant human growth hormone indicated for the treatment of short bowel Syndrome in patients receiving specialized nutritional support (1).

Specialized nutritional support may consist of a high carbohydrate, low-fat diet, adjusted for individual patient requirements and preferences. Nutritional supplements may be added according to the discretion of the treating physician. Zorbtive therapy should be used in conjunction with optimal management of Short Bowel Syndrome. Optimal management of Short Bowel Syndrome may include dietary adjustments, enteral feedings, parenteral nutrition, and fluid and micronutrient supplements, as needed (1).

Patients should be informed that allergic reactions are possible and that prompt medical attention should be sought if an allergic reaction occurs. Zorbtive is contraindicated in patients with acute critical illness, active malignancy, and diabetic retinopathy (1).

Recombinant human growth hormone (r-hGH) has been associated with acute pancreatitis. The use of somatropin has been associated with cases of new onset impaired glucose intolerance. New onset type 2 diabetes mellitus and exacerbation of preexisting diabetes mellitus have been reported in patients receiving somatropin. Some patients developed diabetic ketoacidosis and diabetic coma. In some patients, these conditions improved when somatropin was discontinued, while in others the glucose intolerance persisted. Some patients required initiation or adjustment of anti-diabetic treatment while on somatropin. Patients with other risk factors for glucose intolerance should be monitored closely during Zorbtive therapy (1).

Safety and effectiveness of Zorbtive in pediatric patients less than 18 years of age have not been established (1).

Related policies
Gattex, Growth Hormone Adult, Growth Hormone Pediatric, Serostim

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Zorbtive may be considered **medically necessary** if the conditions indicated below are met.

Zorbtive may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:
Short bowel syndrome (SBS)

AND ALL of the following:

1. Patient is currently receiving optimal management of short bowel syndrome including specialized nutritional support.
2. Absence of acute critical illness due to complications following open heart or abdominal surgery, multiple accidental trauma or acute respiratory failure
3. Absence of active malignancy
4. Absence of active proliferative or severe non-proliferative diabetic retinopathy
5. **NOT** being used in combination with another somatropin agent

Prior – Approval *Renewal* Requirements

Same as above

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 4 weeks per 365 days

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Zorbtive (somatropin) is a human growth hormone (hGH) produced by recombinant DNA technology. Intestinal mucosa contains receptors for growth hormone and for insulin-like growth factor-1 (IGF-1), which is known to mediate many of the cellular actions of growth hormone. Zorbtive is FDA approved for the treatment of short bowel syndrome in patients receiving specialized nutritional support (1). The potential for misuse or abuse of Zorbtive is high since it is the same medication used for growth hormone deficiencies. Growth hormone misuse is prevalent with athletes and body builders and among those seeking its purported anti-aging and weight loss effects (2). Safety and effectiveness of Zorbtive in pediatric patients less than 18 years of age have not been established (1).

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

References

1. Zorbtive [package insert]. Rockland, MA: EMD Serono, Inc.; September 2019.
2. Growth Hormone: Use and Abuse; Journal of Clinical Endocrinology and Metabolism - Volume 94, Issue 6 (June 2009).

Policy History

Date	Action
August 2009	New policy
June 2010	Corrected the ICD coding
June 2012	Revision of the addition of indicators of effectiveness
December 2012	Annual editorial review and reference update
September 2013	Annual editorial review
December 2014	Annual editorial review and reference update Added to criteria: No concurrent use with another somatropin
September 2015	Annual editorial review and reference update
September 2016	Annual editorial review and reference update Policy number changed from 5.08.24 to 5.30.24
December 2017	Annual editorial review and reference update
September 2018	Annual review and reference update
December 2019	Annual review
December 2020	Annual review and reference update
March 2021	Annual editorial review Added requirement “Absence of active proliferative or severe non-proliferative diabetic retinopathy” and changed “NO active neoplasia” to

	"Absence of active malignancy" to align with package insert and Related Policy (Serostim)
December 2021	Annual review
December 2022	Annual review. Changed policy number to 5.30.024
December 2023	Annual review
December 2024	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 13, 2024 and is effective on January 1, 2025.