BlueCross BlueShield
Federal Employee Program

INSULIN GLP-1 COMBINATIONS
Soliqua* (insulin glargine and lixisenatide), Xultophy (insulin degludec and liraglutide)

*Non-covered medications must go through prior authorization and the formulary exception process

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Soliqua and Xultophy are injectable antidiabetic agents containing a long-acting human insulin analog (insulin glargine or degludec) and glucagon-like peptide-1 (GLP-1) receptor agonists (lixisenatide or liraglutide). Soliqua and Xultophy are indicated for adults with type 2 diabetes mellitus who have had a suboptimal response to other diabetic agents. Long-acting insulin acts via specific membrane-bound receptors on the liver, skeletal muscle, and adipose tissue to regulate metabolism of carbohydrates, proteins, and fats. GLP-1 receptor agonists effects post-prandial blood glucose by binding to the same receptors as endogenous hormone incretin leading to increased glucose-dependent insulin secretion, decreased inappropriate glucagon release, and slowed gastric emptying (1-2).

Regulatory Status

FDA-approved indications:

Soliqua

Soliqua is a combination of a long-acting human insulin analog with a glucagon-like peptide-1 (GLP-1) receptor agonist indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus (1).

Xultophy

Xultophy is a combination of insulin degludec, a long-acting human insulin analog, and liraglutide, a glucagon-like peptide 1 (GLP-1) receptor agonist, indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus (2).

<u>Limitations of Use: (1-2)</u>

1. Not for treatment of type 1 diabetes mellitus or diabetic ketoacidosis
2. Not recommended for use in combination with any other product containing a GLP-1 receptor agonists or basal insulin
3. Not recommended for use in patients with gastroparesis
4. Has not been studied in people taking short-acting (prandial) insulin

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5. Has not been studied in patients with a history of unexplained pancreatitis

Xultophy has a boxed warning and contraindication in patients with a personal or family history of medullary thyroid carcinoma (MTC) or in patients with Multiple Endocrine Neoplasia syndrome type 2 are at high risk of treatment duration-dependent thyroid C-cell tumors. Routine monitoring of serum calcitonin or using thyroid ultrasound is of uncertain value for early detection of MTC. Significantly elevated serum calcitonin may indicate MTC and patients with MTC usually have calcitonin values >50 ng/L. If serum calcitonin is measured and found to be elevated, the patient should be further evaluated. Patients with thyroid nodules noted on physical examination or neck imaging should also be further evaluated (2).

The safety and effectiveness of Soliqua and Xultophy have not been established in patients under 18 years of age (1-2).

Summary

Soliqua and Xultophy are injectable combination products indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. The two active ingredients in Soliqua and Xultophy work to control fasting and post-prandial glucose by regulating carbohydrate metabolism. Long-acting insulin acts via specific membrane-bound receptors on the liver, skeletal muscle, and adipose tissue. GLP-1 receptor agonists bind to the same receptors as endogenous hormone incretin leading to increased glucose-dependent insulin secretion, decreased inappropriate glucagon release, and slowed gastric emptying. The safety and effectiveness of Soliqua and Xultophy have not been established in patients under 18 years of age (1-2).

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

References

1. Soliqua [prescribing information]. Bridgewater, NJ: Sanofi-Aventis US LLC; September 2023.

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2. Xultophy [prescribing information]. Plainsboro, NJ: Novo Nordisk Inc; July 2023.