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5.30.048

Section:	Prescription Drugs	**Effective Date:**	July 1, 2026
Subsection:	Endocrine and Metabolic Agents	**Original Policy Date:**	May 19, 2017
Subject:	Insulin GLP-1 Combinations	**Page:**	1 of 5

Last Review Date: June 11, 2026

Insulin GLP-1 Combinations

Description

Soliqua (insulin glargine and lixisenatide), Xultophy (insulin degludec and liraglutide)

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).

Limitations of Use: (1-2)

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
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).

Related policies
Afrezza, GLP-1 Agonists, Metformin, SGLT2 Inhibitors, SGLT2 Step Policy, Trijardy XR

Policy

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

Soliqua and Xultophy may be considered **medically necessary** if the conditions indicated below are met.

Soliqua and Xultophy may be considered **investigational** for all other indications.

Prior-Approval Requirements

*Patients who have filled at least one ≥90-day supply of long-acting insulin **AND** GLP-1 agonist in the past 180 days are exempt from these PA requirements.*

Age 18 years of age or older

Diagnosis

Patient must have the following:

Type 2 diabetes mellitus (DM)

AND ALL of the following:

1. Inadequate treatment response, intolerance, or contraindication to metformin monotherapy
2. Inadequate treatment response to the use of a GLP-1 receptor agonist and long-acting insulin separately
3. Patient must have a HbA1c > 7.0%
4. **NOT** used for the treatment of diabetic ketoacidosis (DKA)
5. **NO** dual therapy with other long-acting insulins
6. **NO** dual therapy with other glucagon-like peptide-1 (GLP-1) receptor agonists (e.g., Mounjaro, Rybelsus, Saxenda, Wegovy)

AND the following for **Xultophy** only:

1. Prescriber agrees to monitor for signs and symptoms of thyroid tumors

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Type 2 diabetes mellitus (DM)

AND ALL of the following:

1. Patient's HbA1c has improved to ≤ 7.0% **OR** HbA1c has decreased by at least 1.5% from baseline

2. **NOT** used for the treatment of diabetic ketoacidosis (DKA)
3. **NO** dual therapy with other long-acting insulins
4. **NO** dual therapy with other glucagon-like peptide-1 (GLP-1) receptor agonists (e.g., Mounjaro, Rybelsus, Saxenda, Wegovy)

AND the following for **Xultophy** only:

1. Prescriber agrees to monitor for signs and symptoms of thyroid tumors

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

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; March 2026.

2. Xultophy [prescribing information]. Plainsboro, NJ: Novo Nordisk Inc; October 2025.

Policy History

Date	Action
May 2017	Addition to PA
June 2017	Annual review
July 2017	Removal of the inadequate treatment response, intolerance, or contraindication to one of the medications from the following categories: sulfonylurea, thiazolidinedione (TZD), DPP-4 inhibitor, SGLT2 inhibitor
September 2017	Annual review
June 2018	Annual editorial review and reference update
September 2018	Addition of patients who have filled at least one ≥ 90-day supply of long-acting insulin and GLP-1 agonist in the past 180 days are exempt from these PA requirements
November 2018	Annual review
December 2019	Annual editorial review and reference update
December 2020	Annual review and reference update
June 2021	Annual review and reference update
June 2022	Annual review and reference update
December 2022	Annual review. Moved Soliqua to FE + PA only. Changed policy number to 5.30.048
June 2023	Annual review and reference update
September 2023	Annual review and reference update
June 2024	Annual review and reference update. Per SME, allowed option for renewal for patient to meet a 1.5% reduction in A1c from baseline
September 2024	Annual review
June 2025	Annual review and reference update
June 2026	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 11, 2026 and is effective on July 1, 2026.