UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Combination Basal Insulin/GLP-1 Receptor Agonist

Program	Prior Authorization
Medication	**Preferred:** Soliqua (insulin glargine/lixisenatide) **Non-Preferred:** Xultophy (insulin degludec/liraglutide)
Markets in Scope	Arizona, California, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	4/2017
Pharmacy and Therapeutics Approval Date	8/2020
Effective Date	10/2020

1. Background:

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

If a member has a prescription for a basal insulin (e.g. insulin glargine), a GLP-1 receptor agonist (e.g. lixisenatide) or Soliqua in their claims history in the past 12 months, the claim for Soliqua will automatically process.

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

2. Coverage Criteria:

A. Soliqua

1. Soliqua will be approved based on the following:

a. Inadequately controlled on **one** of the following

1) GLP-1 receptor agonist [e.g. Adlyxin (lixisenatide), Trulicity (dulaglutide), Victoza (liraglutide), Bydureon (exenatide extended-release), Byetta (exenatide)]

-OR-

2) Basal insulin (e.g. insulin glargine, insulin degludec, insulin detemir)

Authorization will be issued for 12 months

B. Xultophy

1. Initial Authorization

a. **Xultophy** will be approved based on **all** of the following:

1) Diagnosis of type 2 diabetes mellitus

-AND-

2) Inadequately controlled on **one** of the following

i. GLP-1 receptor agonist [e.g. Adlyxin (lixisenatide), Trulicity (dulaglutide), Victoza (liraglutide), Bydureon (exenatide extended-release), Byetta (exenatide)]

-OR-

ii. Basal insulin (e.g. insulin glargine, insulin degludec, insulin detemir)

-AND-

3) History of failure, intolerance, or contraindication to Soliqua.

Authorization will be issued for 12 months

2. Reauthorization

a. **Xultophy** will be approved for continuation of therapy based on the following criterion:

1) Documentation of positive clinical response to Xultophy therapy

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Soliqua [package insert]. Bridgewater, NJ: Sanofi-aventis U.S. LLC.; November 2019.
2. Xultophy [package insert]. Bagsvaerd, Denmark: Novo Nordisk Inc.; November 2019.
3. American Diabetes Association. Standards of Medical Care in Diabetes—2019. *Diabetes Care* 2020; 43 (Supplement 1)

Program	Prior Authorization – Combination Basal Insulin/GLP-1 Receptor Agonist
Change Control	
Date	Change
4/2017	New program.
2/2018	Annual review. Updated references.
7/2019	Annual review. Updated references. Removed Tanzeum from criteria. Updated indication of Soliqua and Xultophy in background information.
7/2020	Annual review. Removed diagnosis check and reauthorization criteria from Soliqua since it is setup as step therapy. Added Additional Clinical Rules and updated references.