

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

Program	Prior Authorization
Medication	<p>Preferred: Soliqua (insulin glargine/lixisenatide)</p> <p>Non-Preferred: Kultophy (insulin degludec/liraglutide)</p>
Markets in Scope	Arizona, California, Florida-CHIP, Hawaii, Maryland, Nevada, New Mexico, New York, New York EPP, Ohio, Rhode Island, Washington, New Jersey, Louisiana
Issue Date	4/2017
Pharmacy and Therapeutics Approval Date	2/2018
Effective Date	4/2018

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, inadequately controlled on basal insulin (less than 60 units daily) or lixisenatide.

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.

Kultophy, 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 inadequately controlled on basal insulin (less than 50 units daily) or liraglutide (less than or equal to 1.8mg daily).

2. Coverage Criteria:

A. Soliqua

1. Initial Authorization

a. **Soliqua** will be approved based on **both** 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), Tanzeum (albiglutide), Victoza (liraglutide), Bydureon (exenatide extended-release), Byetta (exenatide)]
 - ii. Basal insulin (e.g. insulin glargine, insulin degludec, insulin detemir)

Authorization will be issued for 12 months

2. Reauthorization

- a. **Soliqua** will be approved for continuation of therapy based on the following criterion:
 - 1) Documentation of positive clinical response to Soliqua therapy

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), Tanzeum (albiglutide), Victoza (liraglutide), Bydureon (exenatide extended-release), Byetta (exenatide)]
 - 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. References:

1. Soliqua prescribing information. Sanofi-aventis U.S. LLC. Bridgewater, NJ. October 2017.
2. Xultophy prescribing information. Novo Nordisk. Bagsvaerd, Denmark. November 2016.

Program	Prior Authorization – Combination Basal Insulin/GLP-1 Receptor Agonist
Change Control	
Date	Change
4/2017	New program.
2/2018	Annual review. Updated references.