

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

Program	Prior Authorization
Medication	<p><b>Preferred:</b> Soliqua (insulin glargine/lixisenatide)</p> <p><b>Non-Preferred:</b> 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
<b>Change Control</b>	
Date	Change
4/2017	New program.
2/2018	Annual review. Updated references.