## Insulin Combination Agents (Soliqua, Xultophy)
### Step Therapy and Quantity Limit
#### Program Summary

This program applies to FlexRx Open, GenRx Open, Health Insurance Marketplace, FocusRx and KeyRx.

This program is part of the Full and Lite step therapy program packages.

The BCBS MN Step Therapy Supplement also applies to this program for all Commercial/HIM lines of business.

### FDA APPROVED INDICATIONS AND DOSAGE\(^1,2\)

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| **Soliqua™ 100/33** (insulin glargine/lixisenatide) | 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. | • Has not been studied in patients with a history of pancreatitis Consider other antidiabetic therapies in patients with a history of pancreatitis.  
• Not recommended for use in combination with any other product containing lixisenatide or another GLP-1 receptor agonist  
• Not indicated for use in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis.  
• Has not been studied in patients with gastroparesis and is not recommended in patients with gastroparesis.  
• Has not been studied in combination with prandial insulin. | • In patients inadequately controlled on less than 30 units of basal insulin or on lixisenatide, the starting dosage is 15 units (15 units insulin glargine/5 mcg lixisenatide) given subcutaneously once daily.  
• In patients inadequately controlled on 30 to 60 units of basal insulin, the starting dosage is 30 units (30 units insulin glargine/10 mcg lixisenatide) given subcutaneously once daily.  
• Maximum daily dosage is 60 units (60 units of insulin glargine and 20 mcg of lixisenatide).  
• Use alternative antidiabetic products if patients require a Soliqua 100/33 daily dosage below 15 units or over 60 units |
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| **Xultophy® 100/3.6**        | 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 1.8 mg daily) | • Not recommended as first-line therapy for patients inadequately controlled on diet and exercise.  
• Has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis.  
• Not recommended for use in combination with any other product containing liraglutide or another GLP-1 receptor agonist.  
• Not for treatment of type 1 diabetes mellitus or diabetic ketoacidosis.  
• Has not been studied in combination with prandial insulin.  
• Recommended starting dosage is 16 units (16 units of insulin degludec and 0.58 mg of liraglutide) given subcutaneously once daily.  
• Maximum daily dosage is 50 units (50 units of insulin degludec and 1.8 mg of liraglutide).  
• Use alternative antidiabetic products if patients require a Xultophy 100/3.6 daily dosage:  
  o Persistently below 16 units, or  
  o Over 50 units. |
Insulin Combination Agents (Soliqua, Xultophy) Step Therapy

OBJECTIVE
The intent of the Insulin Combination Step Therapy (ST) program is to ensure appropriate selection of patients based on product labeling, and/or clinical guidelines, and/or clinical studies. The program will approve for patients who have tried an agent containing metformin and an agent containing either basal insulin or GLP-1. The step edit allows continuation of therapy. Patients without prerequisite agents in claims history or those who are unable to take a prerequisite agent due to documented intolerance, FDA labeled contraindication, or hypersensitivity will be reviewed when patient-specific documentation has been provided.

TARGET AGENTS
- Soliqua (insulin glargine/lixisenatide)
- Xultophy (insulin degludec/liraglutide)

PRIOR AUTHORIZATION CRITERIA FOR APPROVAL
Insulin Combination Agents will be approved when ONE of the following is met:

1. There is documentation that the patient is currently using the requested agent
2. The prescriber states the patient is using the requested agent AND is at risk if therapy is changed
3. BOTH of the following:
   a. ONE of the following:
      i. The patient’s medication history includes an agent containing metformin in the past 180 days
      OR
      ii. The patient has a documented intolerance, FDA labeled contraindication, hypersensitivity to metformin, or the patient has failed metformin therapy
   AND
   b. ONE of the following:
      i. The patient’s medication history includes the use of at least one of the agents included as a combination in the requested agent (e.g. basal insulin, GLP-1 for diabetes) in the past 180 days

Length of approval: 12 months

NOTE: If Quantity Limit program also applies, please refer to Quantity Limit documents.
Step Therapy Supplement

This program applies to FlexRx Closed, FlexRx Open, GenRx Closed, GenRx Open, Health Insurance Marketplace, FocusRx and KeyRx formularies.

Please note, this does not include or apply to quantity limit questions.

STEP THERAPY SUPPLEMENT

OBJECTIVE

The intent of the Step Therapy Supplement is to provide additional questions, to ensure compliance to MN Statute 62Q.184. These questions will apply if the step therapy component within a Prior Authorization or Step Therapy program is not able to be approved.

CONDITIONS FOR APPROVAL

The requested agent will be approved when ONE of the following are met:

1. The patient is currently being treated with the requested agent as indicated by ALL of the following:
   a. A statement by the prescriber that the patient is currently taking the requested agent
   AND
   b. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent
   AND
   c. The prescriber states that a change in therapy is expected to be ineffective or cause harm
   OR
2. The patient’s medication history include the required prerequisite/preferred agent(s) as indicated by:
   a. Evidence of a paid claim(s) within the past 999 days
   OR
   b. The prescriber has stated that the patient has tried the required prerequisite/preferred agent(s) in the past 999 days AND the required prerequisite/preferred agent(s) was discontinued due to lack of effectiveness or an adverse event
   OR
3. The prescriber has provided documentation that the required prerequisite/preferred agent(s) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm

Length of Approval: As per program specific criteria