

Medical Policy



Title: Insulin Combination Agents (Soliqua, Xultophy)

- Prime Therapeutics will review Prior Authorization requests

Prior Authorization Form:

<https://www.bcbsks.com/CustomerService/Forms/pdf/PriorAuth-6058KS-ST.pdf>

Link to Drug List (Formulary):

http://www.bcbsks.com/CustomerService/PrescriptionDrugs/drug_list.shtml

Professional

Original Effective Date: September 1, 2017

Revision Date(s): September 1, 2017;
May 1, 2018

Current Effective Date: September 1, 2017

Institutional

Original Effective Date: September 1, 2017

Revision Date(s): September 1, 2017;
May 1, 2018

Current Effective Date: September 1, 2017

State and Federal mandates and health plan member contract language, including specific provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. To verify a member's benefits, contact [Blue Cross and Blue Shield of Kansas Customer Service](#).

The BCBSKS Medical Policies contained herein are for informational purposes and apply only to members who have health insurance through BCBSKS or who are covered by a self-insured group plan administered by BCBSKS. Medical Policy for FEP members is subject to FEP medical policy which may differ from BCBSKS Medical Policy.

The medical policies do not constitute medical advice or medical care. Treating health care providers are independent contractors and are neither employees nor agents of Blue Cross and Blue Shield of Kansas and are solely responsible for diagnosis, treatment and medical advice.

If your patient is covered under a different Blue Cross and Blue Shield plan, please refer to the Medical Policies of that plan.

DESCRIPTION

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 Drugs

- **Soliqua** (insulin glargine/lixisenatide)
- **Xultophy** (insulin degludec/liraglutide)

FDA Approved Indications and Dosage^{1,2}

Agent	Indication	Important limitations for use	Dosage and Administration
<p>Soliqua™ 100/33 (insulin glargine/lixisenatide)</p>	<p>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.</p>	<ul style="list-style-type: none"> • 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. 	<ul style="list-style-type: none"> • 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

Agent	Indication	Important limitations for use	Dosage and Administration
Xultophy® 100/3.6 (insulin degludec/liraglutide)	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)	<ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> ○ Persistently below 16 units, or ○ Over 50 units

POLICY

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
OR
2. The prescriber states the patient is using the requested agent AND is at risk if therapy is changed
OR
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. 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

RATIONALE**Guidelines**

Both the American Diabetes Association (ADA) and American Association of Clinical Endocrinologists (AACE) recommend metformin as the optimal non-insulin first-line drug in type II diabetes mellitus.^{3,4} Two-drug combinations should be used if metformin fails to achieve A1c target after approximately 3 months.^{3,4} The choice of the second agent (sulfonylurea, thiazolidinedione, dipeptidyl peptidase-4 inhibitors, sodium-glucose cotransporter 2 inhibitor, basal insulin, glucagon-like peptide 1 agonist).^{3,4}

REVISIONS

09-01-2017	Policy published 08-01-2017. Policy effective 09-01-2017.
05-01-2018	Description section updated
	Rationale section updated
	References updated

REFERENCES

1. Soliqua prescribing information. Sanofi-Aventis US LLC. September 2017.
2. Xultophy prescribing information. Novo Nordisk Inc. November 2016.
3. American Diabetes Association. Standards of medical care in diabetes-2017. Accessed 10/9/2017. Available at <https://professional.diabetes.org/content/clinical-practice-recommendations>.
4. Garber AJ, Abrahamson MB, Barzilay J, et al. Consensus statement by the American association of clinical endocrinologists and American college of endocrinology on the comprehensive type 2 diabetes management algorithm – 2017 executive summary. Accessed 10/9/2017. Available at <https://www.ace.com/publications/guidelines>.