I. Medication Description

Incretin mimetics are synthetic analogues of the gut hormone glucagon-like peptide-1 (GLP-1). GLP-1 enhances insulin secretion; it increases glucose-dependent insulin synthesis and in vivo secretion of insulin from pancreatic beta cells in the presence of elevated glucose. In addition to increases in insulin secretion and synthesis, GLP-1 suppresses glucagon secretion, slows gastric emptying, reduces food intake, and promotes beta-cell proliferation.

Insulins and their analogs lower blood glucose by stimulating peripheral glucose uptake, especially by skeletal muscle and fat, and by inhibiting hepatic glucose production. Insulin also inhibits lipolysis and proteolysis, and enhances protein synthesis.

II. Position Statement

Coverage is determined through a prior authorization process with supporting clinical documentation for every request.

III. Policy

Coverage is provided when the following criteria are met:

- Member is at least 18 years of age AND
- Medication is used for the treatment of type II diabetes AND
- Medication is used in combination with diet and exercise AND

For the coverage of Soliqua, patient has failed to achieve desired glucose control despite prior use of:

- Metformin (unless contraindicated) AND
- One of the following:
  - Basal insulin (less than 60 units daily) OR
  - Lixisenatide (less than 20 mcg daily)

For the coverage of Xultophy, patient has failed to achieve desired glucose control despite prior use of:

- Metformin (unless contraindicated) AND
- One of the following:
  - Basal insulin (less than 50 units daily) OR
  - Liraglutide (less than or equal to 1.8 mg daily)

IV. Quantity Limitations

- Soliqua is covered at up to 5 prefilled pens per month.
• Xultophy is covered at up to 5 prefilled pens per month.
• Additional quantities of either medication may be reviewed for approval if requested to accommodate dosing needs.

V. Coverage Duration

Coverage may be granted for 12 months and may be renewed.

VI. Coverage Renewal Criteria

Coverage can be renewed based upon the following criteria:
• Stabilization of disease or in absence of disease progression AND
• Absence of unacceptable toxicity from the drug

VII. Billing/Coding Information

Available as:
• Soliqua 100 units insulin glargine, 33 mcg lixisenatide/ml, 3 ml pens
• Xultophy 100 units insulin degludec, 3.6 mg liraglutide/ml, 3 ml pens

VIII. Summary of Policy Changes

• 4/10/17: new policy
• 7/13/17: coverage criteria clarified in accordance with FDA-approved prescribing information
• 5/1/18: coverage criteria updated to specify required metformin trial; coverage duration changed to 12 months; updated available products

IX. References


The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.

The preceding policy applies only to members for whom the above named pharmacy benefit medications are included on their covered formulary. Members with closed formulary benefits are subject to trying all appropriate formulary alternatives before a coverage exception for a non-formulary medication will be considered.

The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.