HARVARD PILGRIM HEALTH CARE
RECOMMENDED MEDICATION REQUEST GUIDELINES

INSULIN/INCRETIN MIMETIC COMBINATION PRODUCTS

Generic	Brand	HICL	GCN	Exception/Other
INSULIN DEGLUDEC, LIRAGLUTIDE	XULTOPHY	41880		
INSULIN GLARGINE, LIXISENATIDE	SOLIQUA	43944		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for a patient with Type 2 Diabetes?

   If yes, continue to #2.
   If no, do not approve. Please use status code #238 and the denial text provided.
   DENIAL TEXT: Per your health plan's Insulin/Incretin Mimetic Combination Products guideline, this medication is only covered when prescribed for the treatment of Type 2 Diabetes. Your provider did not indicate that you have this diagnosis and therefore your request was not approved.

2. Does the patient meet one of the following conditions?
   - Inadequately controlled on combination therapy with a long-acting insulin (e.g., Lantus, Levemir, Toujeo, Tresiba), and an incretin mimetic (e.g., liraglutide, exenatide, dulaglutide, etc.)
   - Stable on combination therapy with the individual active ingredients, e.g.,
     - Insulin degludec (Tresiba) and liraglutide (Victoza) if the request is for Xultophy or
     - Insulin glargine (Lantus, Basaglar) and lixisenatide (Adlyxin) if the request is for Soliqua

   If yes, continue to #3.
   If no, do not approve. Please use status code #238 and the denial text provided.
   DENIAL TEXT: Per your health plan's Insulin/Incretin Mimetic Combination Products guideline, this medication is only covered if you meet one of the following conditions: 1). Inadequately controlled on combination therapy with a long-acting insulin (such as Lantus or Toujeo) and a incretin mimetic (such as liraglutide (Victoza), exenatide (Byetta), dulaglutide (Trulicity), **OR** 2). Stable on combination therapy with the individual active ingredients, **[insulin degludec (Tresiba) and liraglutide (Victoza) or insulin glargine (Lantus) and lixisenatide (Adlyxin)]**. Your provider did not indicate that you meet one of these conditions, and therefore your request was not approved.

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INSULIN/INCRETIN MIMETIC COMBINATION PRODUCTS

INITIAL CRITERIA (CONTINUED)

3. Does the requested daily dose fall within one of the following dosing parameters?
   - Soliqua: 15 units (15 units insulin glargine and 5 mcg lixisenatide) to 60 units (60 units insulin glargine and 20 mcg lixisenatide)
   - Xultophy: 16 units (16 units insulin degludec and 0.58 mg liraglutide) to 50 units (50 units insulin degludec and 1.8 mg liraglutide)

   If yes, continue to #4.
   If no, do not approve. Please use status code #238 and the denial text provided.
   DENIAL TEXT (Soliqua): Per your health plan's Insulin/Incretin Mimetic Combination Products guideline, Soliqua is only covered if the daily dose is between 15 units and 60 units. Your provider did not indicate that your dose meets this condition, and therefore your request was not approved.

   DENIAL TEXT (Xultophy): Per your health plan's Insulin/Incretin Mimetic Combination Products guideline, Xultophy is only covered if the daily dose is between 16 units and 50 units. Your provider did not indicate that your dose meets this condition, and therefore your request was not approved.

4. **Approve for 24 months by HICL.** Please use status code #057.
   Requests for products on formulary with a restriction, please use the approval text provided.
   APPROVAL TEXT: Your request for **[Soliqua, Xultophy]** has been approved for a 24-month period.
   Requests for products not on formulary, please use the approval text provided.

   APPROVAL TEXT: Your request for **[Soliqua, Xultophy]** has been approved for 24 months at your highest cost-share tier. Refer to your Harvard Pilgrim ID card for the amount you pay for drugs on that tier.

RENEWAL CRITERIA

1. Is the request for a patient with Type 2 Diabetes?

   If yes, continue to #2.
   If no, do not approve. Please use status code #238 and the denial text provided.
   DENIAL TEXT: Per your health plan's Insulin/Incretin Mimetic Combination Products guideline, this medication is only covered when prescribed for the treatment of Type 2 Diabetes. Your provider did not indicate that you have this diagnosis and therefore your request was not approved.

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RENEWAL CRITERIA (CONTINUED)

2. Did the provider indicate the patient has shown improvement or is stable on the requested medication?

   If yes, **approve for 24 months by HICL.** Please use status code #057 and the approval text provided.
   Requests for products on formulary with a restriction, please use the approval text provided.
   APPROVAL TEXT: Your request for **[Soliqua, Xultophy]** has been approved for a 24-month period.

   Requests for products not on formulary, please use the approval text provided.
   APPROVAL TEXT: Your request for **[Soliqua, Xultophy]** has been approved for 24 months at your highest cost-share tier. Refer to your Harvard Pilgrim ID card for the amount you pay for drugs on that tier.

   If no, do not approve. Please use status code #238 and the denial text provided.
   DENIAL TEXT: Per your health plan's Insulin/Incretin Mimetic Combination Products guideline, authorization for renewal requires you have shown improvement or that you are stable on the requested medication. Your provider did not indicate that your symptoms have improved or you are stable on the medication and therefore your request was not approved.

RATIONALE

To ensure appropriate use of the combination long-acting insulin and incretin mimetic products for the treatment of type 2 diabetes.

FDA APPROVED INDICATIONS

- Soliqua is a combination of a long-acting human insulin analog with a glucagon-like peptide-1 (GLP-1) receptor agonist 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.
- Xultophy is a combination of insulin degludec, a long-acting human insulin analog, and liraglutide, a glucagon-like peptide 1 (GLP-1) receptor agonist, 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 1.8 mg daily).

REFERENCES

- Soliqua [prescribing information]. Sanofi-Aventis U.S. LLC. Bridgewater, NJ. November 2016.
- Xultophy [prescribing information]. Novo Nordisk A/S. Bagsvaerd, Denmark. November 2016

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