

Glucagon-Like Peptide-1 (GLP-1) Receptor Agonist/Long-Acting Insulin Combination Agent Step Therapy

Override(s)	Approval Duration
Prior Authorization	1 year

Medications	Quantity Limit
Soliqua Pen (insulin glargine/lixisenatide)	May be subject to quantity limit
Xultophy Pen (insulin degludec/liraglutide)	

APPROVAL CRITERIA

Requests for Soliqua (insulin glargine/lixisenatide) or Xultophy (insulin degludec/liraglutide) may be approved when the following criteria are met:

- I. Individual has had a trial and inadequate response or intolerance to metformin (AACE 2023). Medication samples/coupons/discount cards are excluded from consideration as a trial.; **OR**
- II. Individual has a contraindication to metformin therapy [including but not limited to, renal insufficiency (eGFR is less than 45mL/minute/1.73 m²)];

AND

- III. Individual has had a trial and inadequate response to one preferred GLP-1 receptor agonist or GIP receptor-GLP-1 receptor agonist (preferred GLP-1 receptor agonists/GIP receptor-GLP-1 receptor agonist: Ozempic, Rybelsus, Trulicity, liraglutide – generic Victoza, Mounjaro). Medication samples/coupons/discount cards are excluded from consideration as a trial.; **OR**
- IV. Individual has had a trial and inadequate response to one preferred long-acting insulin agent [preferred long-acting insulin agents: Lantus/Lantus SoloStar]. Medication samples/coupons/discount cards are excluded from consideration as a trial.

Requests for a GLP-1 receptor agonist/long-acting insulin combination agent may not be approved for the following:

- I. Individual is using in combination with another GLP-1 receptor agonist (including but not limited to Saxenda, Wegovy, Zepbound, Mounjaro, Adlyxin, Bydureon BCise, Byetta, Ozempic, Rybelsus, Trulicity or Victoza); **OR**

- II. Individual is using in combination with a DPP4 inhibitor (including but not limited to Janumet/XR, Januvia, Jentadueto/XR, Kazano, Kombiglyze XR, Nesina, Onglyza, Oseni, Sitagliptin, Tradjenta, Zituvio, Zituvimet, Glyxambi, Qtern, Steglujan or Trijardy XR.).

Key References:

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: April 2, 2024.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc. Updated periodically.
4. Samson SL, Vellanki P, Blonde L, et. al. American Association of Clinical Endocrinologists (AACE) Consensus Statement: Comprehensive Type 2 Diabetes Management Algorithm – 2023 Update. *Endocrine Practice*. 2023;29:305-340.
5. US Food and Drug Administration. FDA Drug Safety Communication: FDA revises warnings regarding use of the diabetes medicine metformin in certain patients with reduced kidney function. Last updated: November 14, 2017. Available at <https://www.fda.gov/Drugs/DrugSafety/ucm493244.htm>. Accessed: March 31, 2024.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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