

Protocol for Glucagon-Like Peptide-1 Receptor Agonists for Type 2 Diabetes

January 2023

Adlyxin (lixisenatide)

Bydureon, Bydureon Bcise (exenatide Microspheres)

Byetta (exenatide)

Mounjaro (tirzepatide)

Ozempic (semaglutide)

Rybelsus (semaglutide)

Soliqua (insulin glargine/lixisenatide)

Trulicity (dulaglutide)

Victoza (liraglutide) – 10 years of age and older

Xultophy (insulin degludec/liraglutide)

Background:

The GLP-1RAs have been shown to significantly improve glycemic parameters and reduce body weight. These agents work by activating GLP-1 receptors in the pancreas, which leads to enhanced insulin release and reduced glucagon release-responses that are both glucose-dependent-with a consequent low risk for hypoglycemia.

Criteria for approval:

1. Diagnosis of type 2 diabetes mellitus; **AND**
2. Patient meets the age limit for requested product when appropriate; **AND**
3. Patient has/had suboptimal response to metformin therapy (for at least 3 months) or cannot use metformin for one of the following reasons:
 - a. Has a diagnosis of Crohn's disease, irritable bowel syndrome, or Ulcerative Colitis
 - b. Has severe renal impairment (eGFR below 45ml/min/1.73m²)
 - c. Intolerance to metformin therapy
 - d. Contraindication to metformin therapy
4. Will not be used concurrently with other GLP-1 (glucagon-like peptide-1) agonists
5. Documentation of HbA1C ≥ 7 measured within the past 6 months; **AND**
6. Medication is prescribed in accordance with Food and Drug Administration (FDA) established indication and dosing regimens or in accordance with medically appropriate off-label indication and dosing according to American Hospital Formulary Service, Micromedex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs (Lexicomp), national guidelines, or other peer-reviewed evidence

Continuation of therapy:

1. Patient has no contraindication for treatment

2. Medication is prescribed in accordance with Food and Drug Administration (FDA) established indication and dosing regimens or in accordance with medically appropriate off-label indication and dosing according to American Hospital Formulary Service, Micromedex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs (Lexicomp), national guidelines, or other peer-reviewed evidence

NOTE: There is a BOXED WARNING RISK OF THYROID C-CELL TUMORS. GLP-1 analogues are associated with thyroid cancer in patients with diabetes.

References:

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4. Mounjaro [package insert]. Lilly USA, LLC, Indianapolis, IN: May 2022.
5. Ozempic [package insert]. Novo Nordisk Inc.; Plainsboro, NJ: April 2021.
6. Rybelsus [package insert]. Novo Nordisk Inc.; Plainsboro, NJ: July 2021.
7. Soliqua [package insert]. Sanofi-Aventis U.S. LLC; Bridgewater, NJ: November 2016
8. Trulicity [package insert]. Eli Lilly and Company; Indianapolis, IN: April 2021.
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11. American Diabetes Association. Standard of Medical Care in Diabetes - 2021. Diabetes Care 2021;44 (Supplement 1).
12. Global Initiative for Asthma (GINA). Global Strategy For Asthma Management and Prevention, Global Initiative for Asthma (GINA) 2022. Available at www.ginasthma.org