

Phone: 541-269-7400 Fax: 541-269-7147



Glucagon-like Peptide-1 (GLP-1) Receptor Agonists and Glucose Dependent Insulinotropic Polypeptide (GIP) Receptor Agonist Drug Use Criteria

Created: December 2017

Reviewed: April 2019, October 2020, September 2021, August 2022, March 2023

Includes:

Byetta© Exenatide
Trulicity© Dulaglutide

Bydureon© Pen/Vial Exenatide Microspheres

Victoza©LiraglutideAdlyxin©LixisenatideOzempic©SemaglutideRybelsus©SemaglutideMounjaro©Tirzepatide

GUIDELINE FOR USE:

Initial Request:

- 1. Is the medication being used for treatment of Type 2 Diabetes Mellitus? *Use for chronic weight management alone is not a covered benefit on OHP.*
 - a. Yes: go to #2
 - b. If no and member is under 21 years of age, go to the EPSDT DUC.
 - c. If no and member is 21 years of age or older, deny as not meeting criteria. Medications for weight loss are not a covered benefit under the Oregon Health Plan. Off-label or experimental use of medication is not a covered benefit on Oregon Health Plan.
- 2. Has member tried and failed metformin for at least 90 days or have contraindications to metformin? * *Does fill history support dose optimization and adherence?* (Adherence is defined as Medication Possession Ratio (MPR) greater than or equal to 80% or no gaps between fills that exceed 5 days and dose optimization is 2000mg unless noted GI distress).
 - a. Yes: Go to #3
 - b. If no, deny as not meeting criteria. Please optimize dose of metformin.
- 3. Is the evidence of severe hyperglycemia (weight loss, hypertriglyceridemia, ketosis, polyuria, or polydipsia) or is the HgA1c >10%?
 - a. If yes, go to #4
 - b. If no, go to #5

Approved by Advanced Health Pharmacy and Therapeutics Committee 2/26/2018, 4/22/2019, 10/21/20, 10/13/2021, 8/10/2022, 6/14/2023

^{*}Saxenda and Wegovy are not a covered benefit on OHP as medications are approved for chronic weight management only.



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- 4. Is member currently on basal insulin and dose is 80 units or more per day? (Per the 2023 ADA guidelines, when A1c is ≥ 1.5% above glycemic target, many individuals will require dual-combination therapy or a more potent glucose-lowering agent to achieve target A1c).
 - a. If yes, approve up to 3 months.
 - b. If no, recommend a trial of basal insulin, unless there are contraindications.
- 5. Is HgA1c level >7.0%
 - a) If yes, approve up to 6 months.
 - c). If no, deny as criteria not met. Endocrinology consult is a covered benefit.

Renewal Request:

- 1. Is there clinical documentation supporting response to therapy including reduction in HgA1c?
 - a. If yes, approve for 6 fills.
 - b. If no, deny as not meeting criteria. Recommend changing treatment plan to optimize HgA1c reduction.

Rationale:

To promote cost-effective and safe step-therapy management for type 2 diabetes mellitus. To ensure optimization of least costly formulary alternatives including metformin and sulfonylureas prior to initiating therapy with more costly GLP-1 agonists. Adherence and dose optimization will be reviewed using prescription refill history for consideration of coverage for GLP-1 agonists. GLP-1 agonists will not be covered for weight loss as use of medications for weight loss is not a covered benefit on OHP. To ensure engagement with lifestyle modifications to optimize glycemic control from Type 2 diabetic patients.

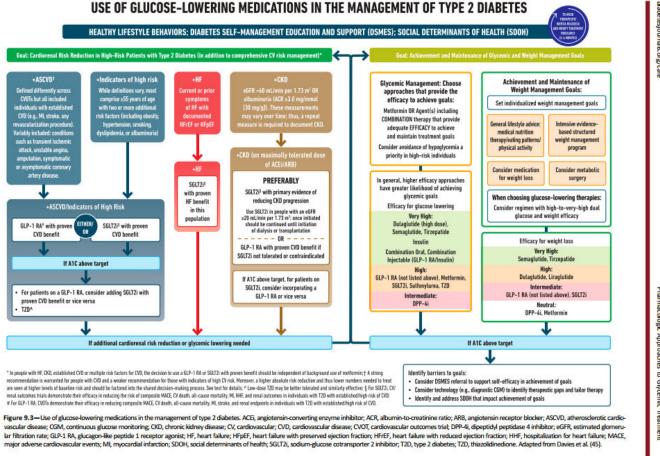
FDA Approved Indication:

These agents are add-on to lifestyle modifications such as diabetes education or dietary counseling to improve glycemic control in adults with Type 2 diabetes. Liraglutide is also indicated to reduce the risk of major adverse cardiovascular events in type diabetic adults with established cardiovascular disease. Dulaglutide has another indication of risk reduction of major cardiovascular events in adults with type 2 diabetes mellitus with cardiovascular disease or multiple cardiovascular risk factors. Semaglutide has an additional indication of risk reduction of major cardiovascular events in adults with type 2 diabetes mellitus and established cardiovascular disease.



References:

- 1. American Diabetes Association (ADA). Standards of Medical Care in Diabetes 2023. Diabetes Care 2022 Dec; 46(Supplement 1): S140-S157.
- 2. Byetta Prescribing Information. Revised 6/2021.
- 3. Trulicity Prescribing Information. Revised 9/2020.
- 4. Bydureon Prescribing Information. Revised 12/2020.
- 5. Victoza Prescribing Information. Revised 11/2020.
- 6. Adlyxin Prescribing Information. Revised 7/2021.
- 7. Ozempic Prescribing Information. Revised 4/2021.
- 8. Wegovy Prescribing Information. Revised 6/2021.
- 9. Saxenda Prescribing Information. Revised 12/2020.
- 10. Mounjara Prescribing Information. Revised 5/2022.
- 11. Guideline Note 5, Obesity and Overweight (Medications for weight loss are not a covered benefit of OHP)



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5150 Pharmacologic Approaches to Glycemic Treatment Diabetes Care Volume 46, Supplement 1, January 2023 If injectable therapy is needed to reduce A1C1 Consider GLP-1 RA or GIP/GLP-1 RA in most individuals prior to insulin² If already on GLP-1 RA or dual GIP INITIATION: Initiate appropriate starting dose for agent selected (varies within class) TITRATION: Titrate to maintenance dose (varies within class) and GLP-1 RA or if these are not appropriate OR insulin is preferred If above A1C target Add basel insulin³ Choice of basel insulin should be based on person-specific considerations, including cor Refer to Table 9.4 for insulin cost information. Consider preacription of glucagon for Add basal analog or bedtime NPH insuling INTUATION: Start 10 units per day OR 0.1-0.2 units/kg per day TITRATION: Set FPG target (see Section 6, "Glycomic Targets") ence-based Stration algorithm, e.g., increase 2 units every 3 days to reach FPG target without hypoglycemia For hypoglycemia determine cause, if no clear reason lower dose by 10-20%. Assess adequacy of basel insulin does Consider clinical signals to evaluate for overbassitudion and need to consider adjunctive therapies (e.g., basel does more than -0.5 unita/lightsy, elevated bedtime-morning and/or post-preprandial differential, hypoglycemia [aware or unaware), high variability) If above A1C target and not already on a GLP-1 RA or dust GP and GLP-1 RA, consider these classes, either in tree combination or fixed-ratio combination, with it. If on bedtime NPH, consider converting to twice-daily NPH regimen based on individual needs and current Add prancial insuling Usually one dose with the largest most or most with greatest PPG excursion; prantial insulin can be dosed incluidually or mixed with NPH as appropriate glycemic control. The following is one possible approach INITIATION: TITRATION-INITIATION 4 units per day or 10% of basel insulin doss Increase dose by 1–2 units or 10–15% builds weekly. . Total dose a 80% of current bedtime NPH dose 2/3 given in the morning
 1/3 given at bedtime ■ A1C <8% (64 mmgl/mg) consider * For hypoglycemia determine cause, if no clear reason low TITRATION ponding does by 10-20% COM Titrate based on individualized needs If above A1C target If above A1C target lanoitibbs salv Consider self-mixed/split insulin regimen or twice-daily Can adjust NPM and short/rapid-acting insulins MITIATION (i.e., two, then three additional INITIATION: Usually unit per unit. * Total NPH dose a 80% of current NPH dose 2/3 given before breakfast require adjustment to individual needs 1/3 given before dinner Add 4 units of short/rapid-acting insulin to each injection or 10% of reduced NPH dose Proceed to full TITRATIONS basal-bolus regimen (i.e., basal insulin and Titrate based on inclividualized needs prancial insulin with Titrate each component of the regimen based on individualized needs

Consider insulin as the first injectable if evidence of organing catabolism, symptoms of hyperglycemia are present, when A1C levels ()-10% (bit menoith) are very high, or a diagnosis of type 1 diabetes in a possibility.
 When selecting GLP-1 RA, consider includual perference, A1C leveling, weight-investing effect, or frequency of injection. If CVD is present, consider GLP-1 RA with proven CVD benefit. One or injectible GLP-1 RA are appropriate.

1. For people on GLP-1 RA and basel insulin comi or use of a fixed-ratio combination product (ClegLim or Kitat.ini).

 Consider switching from evening NPH to a based areas of the individual develops bypoglycentia and/or bequently torgets to administer NPH in the evening and would be better mar with an axis, close of a long-acting based standing. 5. If acting prantial insulin to 19%, consider initiation of a self-mixed or premixed insulin regimen to decrease the number of injections requ

Figure 9.4—Intensifying to injectable therapies in type 2 diabetes. DSMES, diabetes self-management education and support; FPG, fasting plasma glucose; GLP-1 RA, glucagon-like peptide 1 receptor agonist; max, maximum; PPG, postprandial glucose. Adapted from Davies et al. (43).