

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®	Liraglutide
Adlyxin®	Lixisenatide
Ozempic®	Semaglutide
Rybelsus®	Semaglutide
Mounjaro®	Tirzepatide

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

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

4. Is member currently on basal insulin and dose is 80 units or more per day? (Per the 2023 ADA guidelines, when A1c is $\geq 1.5\%$ 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)

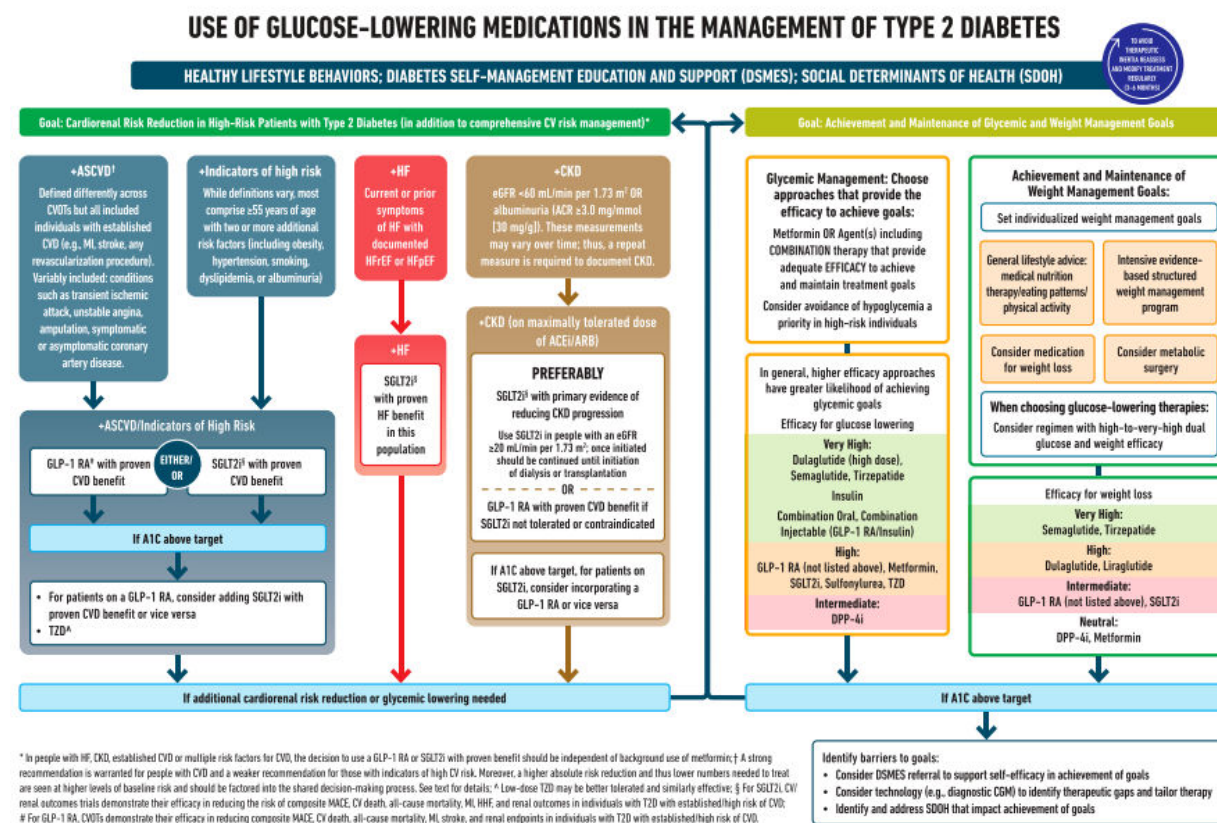
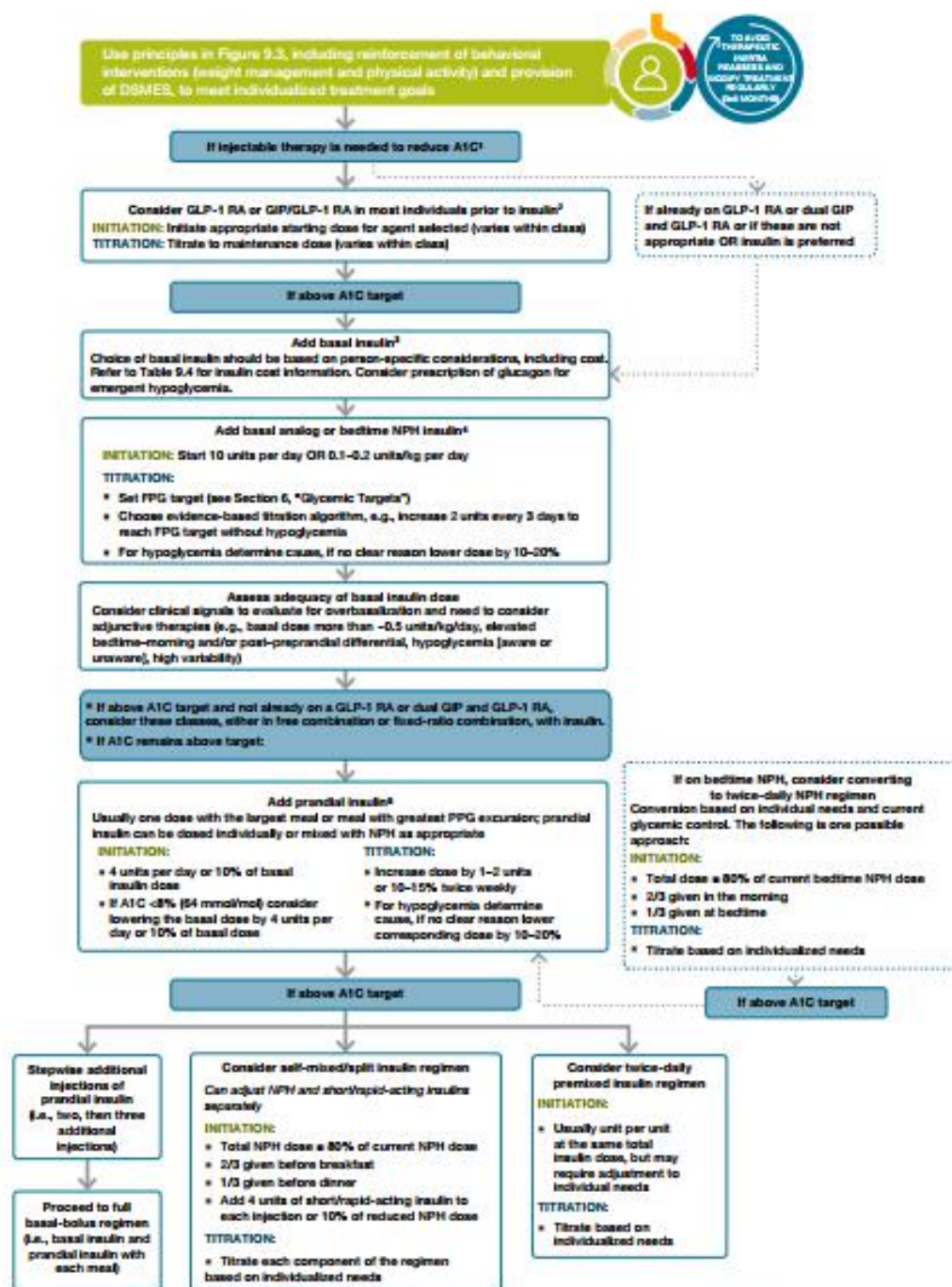


Figure 9.3—Use of glucose-lowering medications in the management of type 2 diabetes. ACEi, angiotensin-converting enzyme inhibitor; ACR, albumin-to-creatinine ratio; ARB, angiotensin receptor blocker; ASCVD, atherosclerotic cardiovascular disease; CGM, continuous glucose monitoring; CKD, chronic kidney disease; CVD, cardiovascular disease; CVOT, cardiovascular outcomes trial; DPP-4i, dipeptidyl peptidase 4 inhibitor; eGFR, estimated glomerular filtration rate; GLP-1 RA, glucagon-like peptide 1 receptor agonist; HF, heart failure; HFpEF, heart failure with preserved ejection fraction; HFrEF, heart failure with reduced ejection fraction; HHF, hospitalization for heart failure; MACE, major adverse cardiovascular events; MI, myocardial infarction; SDOH, social determinants of health; SGLT2i, sodium-glucose cotransporter 2 inhibitor; TZD, type 2 diabetes; TZD, thiazolidinedione. Adapted from Davies et al. (45).



1. Consider insulin as the first injectable if evidence of ongoing catabolism, symptoms of hyperglycemia are present, when A1C levels ($\geq 10\%$ [86 mmol/mol]) or blood glucose levels (≥ 300 mg/dL [16.7 mmol/L]) are very high, or a diagnosis of type 1 diabetes is a possibility.
2. When selecting GLP-1 RA, consider individual preference, A1C lowering, weight-lowering effect, or frequency of injection. If CVD is present, consider GLP-1 RA with proven CVD benefit. Oral or injectable GLP-1 RA are appropriate.
3. For people on GLP-1 RA and basal insulin combination, consider use of a fixed-ratio combination product (Dewelins or Vilaris).
4. Consider switching from evening NPH to a basal analog if the individual develops hypoglycemia and/or frequently forgets to administer NPH in the evening and would be better managed with an AAM dose of a long-acting basal insulin.
5. If adding prandial insulin to NPH, consider initiation of a self-mixed or premixed insulin regimen to decrease the number of injections required.

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).

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