

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

Created: December 2017

Updated: April 2019, October 2020, September 2021, August 2022, March 2023, June 2023, April 2024, June 2024

Includes:

Byetta ®	<i>Exenatide</i>
Trulicity ®	<i>Dulaglutide</i>
Bydureon ® Pen/Vial	<i>Exenatide Microspheres</i>
Victoza ®	<i>Liraglutide</i>
Adlyxin ®	<i>Lixisenatide</i>
Ozempic ®	<i>Semaglutide</i>
Rybelsus®	<i>Semaglutide</i>
Mounjaro®	<i>Tirzepatide</i>

**Saxenda (liraglutide) and Zepbound (tirzepatide) are not a covered benefit on OHP as medications are approved for chronic weight management only.*

**Wegovy has a different pathway to coverage (please see Wegovy DUC)*

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 #3
 - b. If no and member is 20 years of age or younger, go to the Medications for Weight Management DUC.
 - c. If no and member is 21 years of age or older, go to #2
2. Is the request for Wegovy?
 - a. Yes, go to Wegovy DUC.
 - b. No, Deny as not meeting criteria. Medications for weight loss are not a covered benefit for adults per Guideline Note 5.
3. 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 #4

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, 6/26/2023, 4/10/2024, 6/12/2024

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- b. If no, deny as not meeting criteria. Please optimize dose of metformin for at least 90 days.
 4. Is the evidence of severe hyperglycemia (weight loss, hypertriglyceridemia, ketosis, polyuria, or polydipsia) or is the HgA1c >10%?
 - a. If yes, go to #5
 - b. If no, go to #6
 5. 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, is the medication being used for CV risk reduction.
 - i. If yes, approve for up to 6 months.
 - ii. If no, recommend a trial of basal insulin, unless there are contraindications.
 6. 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 if member is not at goal or 12 fills if member is at goal and on maintenance therapy.
 - 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 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.

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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.

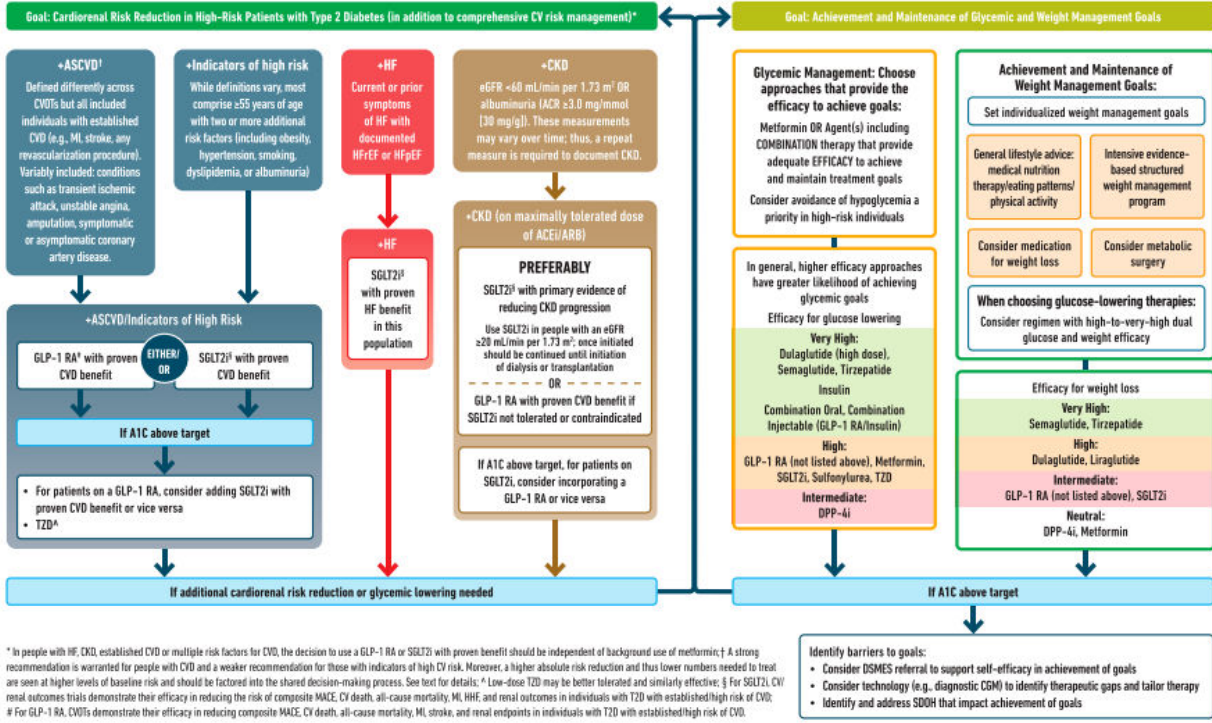
References:

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 3/2024.
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)

USE OF GLUCOSE-LOWERING MEDICATIONS IN THE MANAGEMENT OF TYPE 2 DIABETES



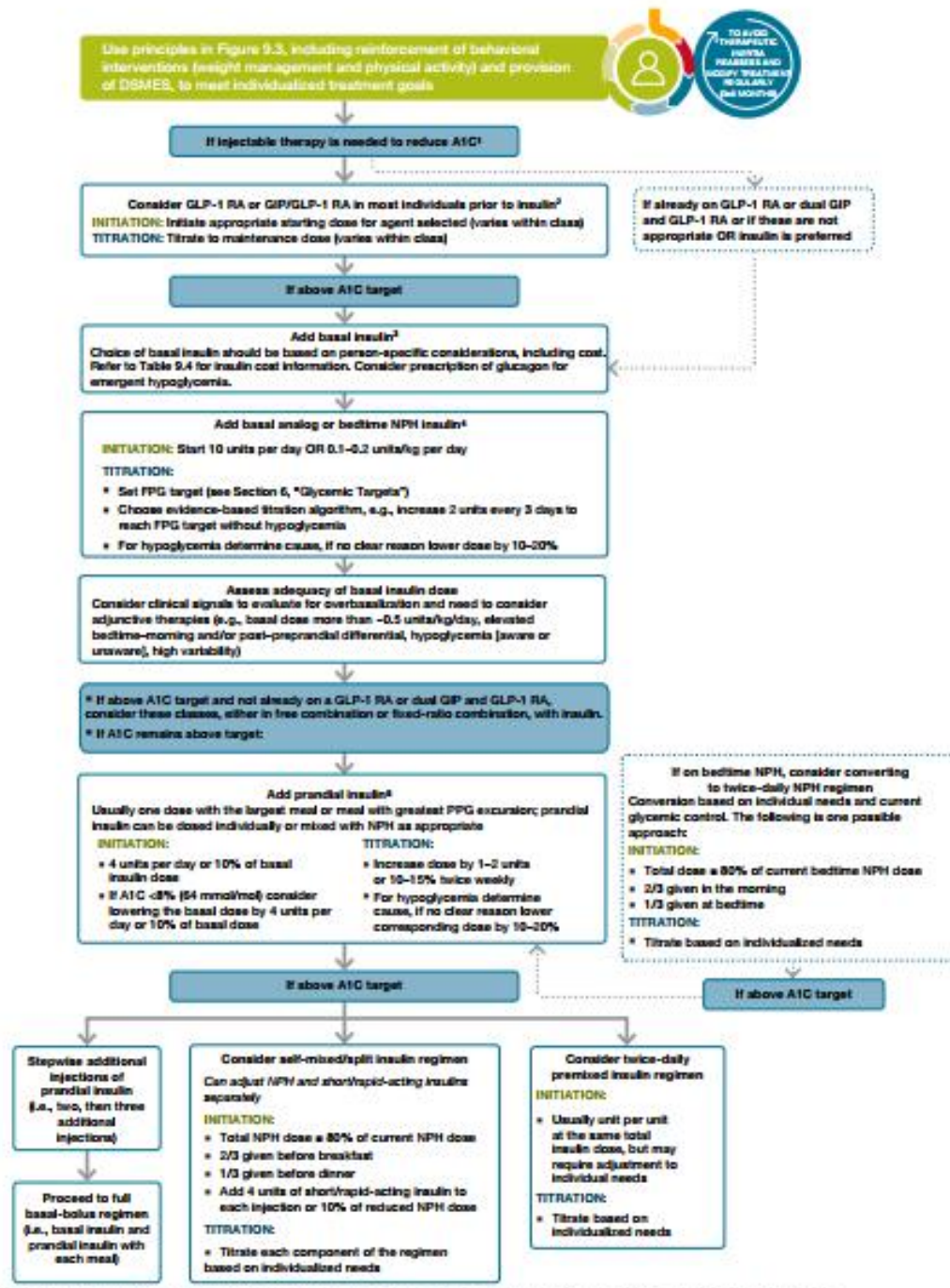
HEALTHY LIFESTYLE BEHAVIORS; DIABETES SELF-MANAGEMENT EDUCATION AND SUPPORT (DSMES); SOCIAL DETERMINANTS OF HEALTH (SDOH)



* In people with HF, CKD, established CVD or multiple risk factors for CVD, the decision to use a GLP-1 RA or SGLT2i with proven benefit should be independent of background use of metformin. † A strong recommendation is warranted for people with CVD and a weaker recommendation for those with indicators of high CV risk. Moreover, a higher absolute risk reduction and thus lower numbers needed to treat are seen at higher levels of baseline risk and should be factored into the shared decision-making process. See text for details. ‡ Low-dose TZD may be better tolerated and similarly effective. § For SGLT2i, CV renal outcomes trials demonstrate their efficacy in reducing the risk of composite MACE, CV death, all-cause mortality, MI, HFrEF, and renal outcomes in individuals with T2D with established/high risk of CVD. ¶ For GLP-1 RA, CVOTs demonstrate their efficacy in reducing composite MACE, CV death, all-cause mortality, MI, stroke, and renal endpoints in individuals with T2D with established/high risk of CVD.

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; CV, cardiovascular; 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).

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1. Consider insulin as the first injectable if evidence of ongoing catabolism, symptoms of hyperglycemia are present, when A1C levels (>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 (DegLira or Kiazulix).
 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).