AdvancedHealth
Bridging the Future of Healthcare

289 LaClair Coos Bay OR 97420
Phone: 541-269-7400 Fax: 541-269-7789

Glucagon – like Peptide – 1 (GLP-1) Receptor Agonists Drug Use Criteria

Created: December 2017
Reviewed: April 2019, October 2020

Includes:

Byetta©(preferred GLP-1 agonist)	*Exenatide*
Trulicity©	*Dulaglutide*
Bydureon© Pen/Vial	*Exenatide Microspheres*
Victoza©	*Liraglutide*
Adlyxin©	*Lixisenatide*
Ozempic©	*Semaglutide*

(Highlighted agents are on formulary and aligned with Oregon Medicaid FFS Preferred Drug List).

GUIDELINE FOR USE:

Initial Request:

1. Is the medication being used for treatment of Type 2 Diabetes Mellitus?
    a. If yes, continue to 2
    b. If no, deny as not meeting criteria. Off label or experimental use of medication is not a covered benefit on Oregon Health Plan.
2. Has the patient tried and failed optimized doses of metformin and sulfonylurea therapy or have contraindications to these therapies? Prescription fill history will be monitored to ensure dose optimization and consistent filling of these medications for at least 3 months to support adherence to prescribed therapy. See below for guidance on initiating metformin therapy.
    a. If yes, go to 3
    b. If no, deny as not meeting criteria. Please optimize dose of metformin and/or sulfonylurea and ensure adherence to therapy.

3. Has the member tried and failed ONE of the thiazolidinediones such as formulary pioglitazone, (Unable to maintain or achieve goal A1c)?
    a) yes: continue to #4.
    b) no: do not approve. Deny and recommend trial of formulary pioglitazone.
4. Evaluate based on HbA1c
    a) Is HbA1c < 7.5%----------> If yes, do not approve.
    b) Is HbA1c > 7.5%----------> If yes, continue to #5
5. Is the request for Byetta, Victoza, Bydureon or Trulicity?
    a. If yes, go to 6
    b. If no, request if provider will change prescription to Byetta, Victoza, Bydureon, or Trulicity to align with FFS Preferred Drug List. If provider refuses to change to a preferred agent, continue to 6.

Approved by Advanced Health Pharmacy and Therapeutics Committee 2/26/2018, 4/22/2019, 10/21/20

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6. Is the patient currently taking basal insulin?
    a. If yes, go to 7.
    b. If no, deny as not meeting criteria and recommend initiating basal insulin.
7. Is the request for exenatide, liraglutide, or lixisendatide (including combination products) and patient is using insulin formulations other than basal insulin?
    a. If yes, deny as not meeting criteria. Concurrent use of short-acting insulin and GLP-1 agonist has not been studied and cannot be recommended. Experimental or off label use of medications is not a covered benefit on OHP.
    b. If no, go to 8.
    c. Is the request for semaglutide or dulaglutide, go to 8.
8. Does the patient have any contraindications to GLP-1 therapy?
    a. If yes, deny as not meeting criteria. Off-label use of medications is not a covered benefit on OHP.
    b. If no, go to 9
9. Is the requested dose of medication consistent with the FDA approved prescribing information?
    a. If yes, approve for 3 fills and request HgA1c and current chart note be submitted with renewal request for consideration of ongoing therapy.
    b. If no, deny as not meeting criteria. Experimental or off label use of medications is not a covered benefit on OHP.

Renewal Request:

1. Is there clinical documentation supporting response to therapy including reduction in HgA1c?
    a. If yes, approve for 12 fills.
    b. If no, deny as not meeting criteria. Recommend changing treatment plan to optimize HgA1c reduction.

Initiating Metformin:

Initiating Metformin

1.	Begin with low-dose metformin (500 mg) taken once or twice per day with meals (breakfast and/or dinner) or 850 mg once per day.
2.	After 5-7 days, if gastrointestinal side effects have not occurred, advance dose to 850 mg, or two 500 mg tablets, twice per day (medication to be taken before breakfast and/or dinner).
3.	If gastrointestinal side effects appear with increasing doses, decrease to previous lower dose and try to advance the dose at a later time.
4.	The maximum effective dose can be up to 1,000 mg twice per day. Modestly greater effectiveness has been observed with doses up to about 2,500 mg/day. Gastrointestinal side effects may limit the dose that can be used.

Nathan, et al. Medical management of hyperglycemia in Type 2 Diabetes: a consensus algorithm for the initiation and adjustment of therapy. *Diabetes Care*. 2008; 31;1-11.

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

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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. Dulaglitide 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.

Mechanism of Action and Dosing:

Glucagon-like peptide-1 receptor agonists are analogs of GLP-1 (an incretin hormone) which increases glucose-dependent insulin secretion, decreases inappropriate glucagon secretion, increases B-cell growth/replication, slows gastric emptying, and decreases food intake, which decreases hemoglobin A1c by approximately 1% to 1.5%.

Contraindications / Cautions:

- Hypersensitivity to GLP-1 receptor agonists or any components of the formulation
- Pregnancy
- Breastfeeding
- Personal or family history of medullary thyroid carcinoma / or patients with Multiple Endocrine Neoplasia Syndrome

References:

1. Antidiabetic Agents (excluding insulins). Drug Class Update. September 2017. Oregon State University Drug Use Research and Management Program. Oregon Health Authority. Available at: http://www.orpdl.org/durm/meetings/meetingdocs/2017_09_28/archives/2017_09_28_Diabetes_Class_Updates_2017.pdf.
2. Byetta Prescribing Information. Revised 10/2009.
3. Trulicity Prescribing Information. Revised 9/2020.
4. Bydureon Prescribing Information. Revised 4/2018.
5. Victoza Prescribing Information. Revised 8/2020.
6. Adlyxin Prescribing Information. Revised 1/2019.
7. Ozempic Prescribing Information. Revised 9/2020.
8. Guideline Note 5, Obesity and Overweight (Medications for weight loss are not a covered benefit of OHP)

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