AllCare CCO - Prior Authorization Criteria Summary:

Criteria number: 027.5

Criteria title: Approval criteria for GLP-1 receptor agonists

Date of origin: 10/08/2013

Classification: Class Specific

Date of Last Review: 07/26/2022

Drug Class: GLP-1 RA

Date of Next Review: 07/25/2024

References:

- Oregon Health Authority, Department of Medical Assistance, OAR 410-120-0250 (3)
- Oregon Medicaid Pharmaceutical Services Prior Authorization Criteria
- Byetta [package insert]. San Diego, CA: Amylin Pharmaceuticals Inc; 2009.
- Xultophy: Prescribing Information. Bagsvaerd, Denmark : Novo Nordisk, 2016.
- Soliqua: Prescribing Information. Bridgewater, NJ : Sanofi-Aventis , 2016.
- Adlyxin: Prescribing Information. Bridgewater, New Jersey. : Sanofi, 2016.
- Victoza: Prescribing Information. Bagsvaerd, Denmark. : Novo Nordisk, 2017.
- GLP-1 receptor agonists for individualized treatment of type 2 diabetes mellitus. Meier, J.J. 2012, Nat Rev Endocrinol , Vol. 8, pp. 728-742.
- GLP-1 receptor agonists: a review of head-to-head clinical studies. Trujillo, J, Nuffer, W, Ellis, S. 2015, Ther Adv Endocrinol Metab, Vol. 6, pp. 19-28.
- Benefits and Harms of Once-Weekly Glucagon-like Peptide-1 Receptor A Systematic Review and Network Meta-analysis. Zaccardi, Francesco, et al. 164, 2016, Annals of Internal Medicine, pp. 102-113.
- A Network Meta-analysis Comparing Exenatide Once Weekly with Other GLP-1 Receptor Agonists for the Treatment of Type 2 Diabetes Mellitus. Kayaniyil S, Lozano-Ortega G, Bennett HA, et al. 7, 2016, Diabetes Ther, pp. 27-43.
- Garber AJ, Abrahamson MJ, Barzilay JI, et al. Consensus statement by the American Association of Clinical Endocrinologists and American College of Endocrinology on the comprehensive type 2 diabetes management algorithm – 2018 executive summary. Endo Pract. 2018;24(1):91-120.
- Riddle MC, et al. American Diabetes Association Standards of medical care in diabetes – 2018. J Clin App Res Ed. 2018; 41(1):1-172.
- Williams, J., & Nieuwsma, J. (2018). Glucagon-like peptide-1 receptor agonists for the treatment of type 2 diabetes mellitus. David M Nathan, MD (Ed.), UpToDate. Retrieved 3/25/2019

FDA approved indication: Diabetes Mellitus, type II

Purpose: To define the process for coverage of Glucagon-like peptide 1 receptor agonists (GLP1 RA) for treatment of Type II Diabetes Mellitus (DM)

Clinical Rationale: GLP-1 receptor antagonists are not considered as initial therapy for the majority of patients with type 2 diabetes. GLP-1 receptor agonists should not be initiated in a patient with a history of pancreatitis. Combination therapy with GLP1 RA and dipeptidyl peptidase-4 (DPP-4) inhibitors does not provide additive glucose-lowering effects, and thus, the combination should be avoided. While not prohibited by this policy, it should be noted that concurrent use of GLP1 RA with prandial insulin has not been studied.

Policy: Cover preferred formulary GLP1 RA for members with type II DM who have failed three oral medications from different drug classes, including metformin. Some of these medications are available with prior authorization (PA).

Non-preferred formulary agents require trial with one preferred agent prior to approval in addition to failure of three oral medications from different drug classes, including metformin.

For non-formulary agents, the member must have a documented trial of at least two formulary GLP1 RA agents (including at least one preferred agent) prior to approval in addition to failure of three oral medications from different drug classes, including metformin.

Quantity limits apply.

For GLP-1 RA/basal insulin combination agents, members must be established on basal insulin at doses less than 50 units/day and meet criteria for GLP1 RA single agents below.

Agents included in criteria:

Exenatide ER (Bydureon Bcise®)	Formulary, Pref	QL: 3.4/28 days
Exenatide ER (Bydureon®)	Formulary, Pref	QL: 4/28 days
Exenatide (Byetta®)	Formulary, Non-pref	QL: 2.4/30 days
Lixisenatide (Adlyxin®)	Formulary, Pref	QL: 6/28 days
Dulaglutide (Trulicity®)	Formulary, Non-pref	QL: 2/28 days
Semaglutide (Ozempic®)	Formulary, Non-pref	QL: 3/28day
Semaglutide (Rybelsus®)	Formulary, Non-pref	QL: 1/day
Tirzepatide (Mounjaro®)	Formulary, Non-pref	QL: 2/28 days

Approval criteria for GLP-1 RA:	**Met**	**Not Met**

Criteria #1:	Does the member have a diagnosis of type 2 diabetes mellitus	Go to #2	Deny
Criteria #2:	Is there documentation the member has used or has a contraindication to metformin	Go to #3	Deny
Criteria #3:	Is the request for a GLP1 RA agent listed above	preferred formulary: Go to #5 non-preferred formulary: Go to #4	Deny
Criteria #4:	Is this request to reduce the risk of cardiovascular events for a member with established cardiovascular disease* or multiple cardiovascular risk factors	Go to #5	Go to #6
Criteria #5:	Member has had adequate trial with (or documented contraindication to) formulary SGLT2 agent‡	Approve x12 months	Deny
Criteria #6:	for non-preferred agent, the member tried and failed at least one preferred agent	Approve x12 months	Deny

Renewal criteria for GLP-1 RA:		**Met**	**Not Met**
Renewal #1:	Did member meet PA criteria for initial criteria	Go to #2	Deny
Renewal #2:	Do recent chart notes support the continuation of the medication‡	Approve x1 year	Deny

Reviewed and approved by: Chief Medical Officer

Date: 08/25/2022