SmartPA Criteria Proposal

Drug/Drug Class:	Glucagon-Like Peptide -1 (GLP-1) Receptor Agonists & Combination Agents PDL Edit
First Implementation Date:	October 7, 2010
Proposed Date:	June 17, 2021
Prepared For:	MO HealthNet
Prepared By:	MO HealthNet/Conduent
Criteria Status:	☐Existing Criteria ☒Revision of Existing Criteria ☐New Criteria

Executive Summary

Purpose: The MO HealthNet Pharmacy Program will implement a state-specific preferred drug list.

Why Issue Selected: Type 2 diabetes mellitus is a significant health problem associated with excessive morbidity and mortality. As the prevalence of this metabolic disorder is rapidly increasing and as older treatments fail to stabilize the disease in many participants, prevention and control are considered key objectives. Metformin is still the cornerstone of type 2 diabetes mellitus treatment however many patients will require an additional agent(s). According to the ADA, several classes can be considered as add-on therapy, including the glucagon-like peptide-1 (GLP-1) receptor agonists. Selection of a specific agent should be based on drug-specific characteristics (e.g., adverse events, weight gain, hypoglycemia risk, cost) and patient preferences. Based on differences in cardiovascular risk/benefit and weight gain among the GLP-1 receptor agonists, patients with certain compelling indications might benefit from a specific agent in the class. For patients with established atherosclerotic cardiovascular disease, Victoza® (liraglutide), Trulicity® (dulaglutide) and injectable Ozempic® (semaglutide) have all demonstrated cardiovascular benefit and are preferred, as they are FDA-approved for cardiovascular disease reduction. For patients with a compelling need for weight loss, semaglutide is associated with the largest weight reduction. GLP-1 receptor agonists have a similar safety profile with gastrointestinal disorders being the most common adverse effect. All GLP-1 receptor agonists, except Adlyxin® (lixisenatide), Byetta® (exenatide) **and Soliqua® (insulin glargine/lixisenatide)** have a boxed warning regarding the risk of thyroid tumors. Dual therapy with insulin and a GLP-1 receptor agonist can be considered if patients cannot meet their HbA1c goals with basal insulin or a GLP-1 receptor agonist alone. No significant efficacy or safety differences have been noted between Xultophy® (insulin degludec/liraglutide) and Soliqua® (insulin glargine/lixisenatide).

Total program savings for the PDL classes will be regularly reviewed.

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Program-Specific Information:	Preferred Agents	Non-Preferred Agents
	• Bydureon® • Byetta® • Trulicity® • Victoza®	• Adlyxin® • Bydureon Bcise® • Ozempic® • Rybelsus® • Soliqua® • Xultophy®

Type of Criteria: ☐ **Increased risk of ADE** ☒ **Preferred Drug List** ☐ **Appropriate Indications** ☐ **Clinical Edit**

Data Sources: ☐ **Only Administrative Databases** ☒ **Databases + Prescriber-Supplied**

Setting & Population

- Drug class for review: Glucagon-Like Peptide -1 (GLP-1) Receptor Agonists & Combination Agents
- Age range: All appropriate MO HealthNet participants aged 10 years and older

Approval Criteria

- Participants aged 18 years or older **AND**
- Adequate therapeutic trial of metformin in the past year **AND**
- Failure to achieve desired therapeutic outcomes with trial on 3 or more preferred agents
  - Documented trial period of preferred agents
  - Documented ADE/ADR to preferred agents **AND**
- For Rybelsus: documented therapeutic trial of Ozempic in the past year
- For Victoza: participants aged 10 years or older
- For Soliqua and Xultophy: documented therapeutic trial on 2 or more preferred long acting insulins

Denial Criteria

- Lack of adequate trial on required preferred agents
- Therapy will be denied if all approval criteria are not met
- For exenatide: documented diagnosis of End Stage Renal Disease (ESRD) or severe renal impairment (creatinine clearance <30 mL/min)
- Claim exceeds maximum dosing limitation for the following:

Drug Description	Generic Equivalent	Maximum Dosing Limitation
BYDUREON BCISE 2 MG	EXENATIDE	3.4 mL per 28 days
BYETTA 5 MCG DOSE PEN	EXENATIDE	1.2 mL per 28 days
BYETTA 10 MCG DOSE PEN	EXENATIDE	2.4 mL per 28 days
RYBELSUS 3 MG TABLET	SEMAGLUTIDE	1 tablet per day
RYBELSUS 7 MG TABLET	SEMAGLUTIDE	1 tablet per day
RYBELSUS 14 MG TABLET	SEMAGLUTIDE	1 tablet per day
OZEMPIC 0.25-0.5 MG DOSE PEN	SEMAGLUTIDE	1.5 mL per 28 days
OZEMPIC 1 MG DOSE PEN (2 MG/1.5 ML)	SEMAGLUTIDE	3 mL per 28 days
OZEMPIC 1 MG/DOSE PEN (4 MG/3 ML)	SEMAGLUTIDE	3 mL per 28 days
TRULICITY 0.75 MG/0.5 ML PEN	DULAGLUTIDE	0.5 mL per 7 days
TRULICITY 1.5 MG/0.5 ML PEN	DULAGLITIDE	0.5 mL per 7 days
TRULICITY 3 MG/0.5 ML PEN	DULAGLITIDE	0.5 mL per 7 days
TRULICTY 4.5 MG/0.5 ML PEN	DULAGLITIDE	0.5 mL per 7 days

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VICTOZA 18 MG/3 ML PEN	LIRAGLUTIDE	0.3 mL per day

Required Documentation

Laboratory Results:	☐	Progress Notes:	☐
MedWatch Form:	☐	Other:	☐

Disposition of Edit

Denial: Exception Code "0160" (Preferred Drug List)
Rule Type: PDL

Default Approval Period

1 year

References

1. Drug Effectiveness Review Project – Drug Class Review Newer Diabetes Medications and Combinations. Center for Evidence-Based Policy, Oregon Health & Science University; February 2011; updated July 2016.
2. Evidence-Based Medicine and Fiscal Analysis: "GLP-1 Receptor Agonists and Combinations – Therapeutic Class Review", Conduent Business Services, L.L.C., Richmond, VA; June 2021.
3. Evidence-Based Medicine Analysis: "Antidiabetic Mimetics (GLP-1 Receptor Agonist)", UMKC-DIC; April 2021.
4. Evidence-Based Medicine Analysis: "Antidiabetic Combination Agents – Oral and Injectable", UMKC-DIC; March 2020.
5. American Diabetes Association (ADA). Standards of Medical Care in Diabetes – 2021. *Diabetes Care.* 2021;44(suppl 1): S1-S232.
6. USPDI, Micromedex; 2021.
7. Facts and Comparisons eAnswers (online); 2021 Clinical Drug Information, LLC.

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