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:	September 15, 2022
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 additional therapy. According to the American Diabetes Association (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 FDA-approved for cardiovascular disease 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. Mounjaro™ (tirzepatide), the most recently FDA-approved product in the class, is the first dual glucose-dependent insulinotropic polypeptide (GIP) receptor and GLP-1 receptor agonist.

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

Program-Specific Information:

Preferred Agents	Non-Preferred Agents
• Bydureon® • Byetta® • Trulicity® • Victoza®	• Adlyxin® • Bydureon BCise® • **Mounjaro™** • 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

Approval Criteria

- For preferred agents:
  - Adequate therapeutic trial of metformin in the past year **OR**
  - **Prior history with a GLP-1 agonist in the past 3 months**
- For non-preferred agents:
  - **Documented diagnosis of type 2 diabetes mellitus in the past year 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 Mounjaro: failure to achieve goal A1c despite documented 6 month therapeutic trial of Ozempic utilized at a maximum tolerated dose in the past year**
  - For Rybelsus: documented therapeutic trial of Ozempic in the past year
  - 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
- For exenatide: documented diagnosis of End Stage Renal Disease (ESRD) or severe renal impairment (creatinine clearance < 30 mL/min)
- Therapy will be denied if all approval criteria are not met
- 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**~~
MOUNJARO 2.5 MG/0.5 ML PEN	**TIRZEPATIDE**	**2 mL per 28 days**
MOUNJARO 5 MG/0.5 ML PEN	**TIRZEPATIDE**	**2 mL per 28 days**
MOUNJARO 7.5 MG/0.5 ML PEN	**TIRZEPATIDE**	**2 mL per 28 days**
MOUNJARO 10 MG/0.5 ML PEN	**TIRZEPATIDE**	**2 mL per 28 days**
MOUNJARO 12.5 MG/0.5 ML PEN	**TIRZEPATIDE**	**2 mL per 28 days**
MOUNJARO 15 MG/0.5 ML PEN	**TIRZEPATIDE**	**2 mL per 28 days**
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
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
~~**TRULICITY 0.75 MG/0.5 ML PEN**~~	~~**DULAGLUTIDE**~~	~~**0.5 mL per 7 days**~~
~~**TRULICITY 1.5 MG/0.5 ML PEN**~~	~~**DULAGLUTIDE**~~	~~**0.5 mL per 7 days**~~
~~**TRULICITY 3 MG/0.5 ML PEN**~~	~~**DULAGLUTIDE**~~	~~**0.5 mL per 7 days**~~

~~TRULICITY 4.5 MG/0.5 ML PEN~~	~~DULAGLUTIDE~~	~~0.5 mL per 7 days~~
~~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

- Evidence-Based Medicine Analysis: "Antidiabetic Mimetics (GLP-1 Receptor Agonist)", UMKC-DIC; March 2022.
- 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.
- American Diabetes Association (ADA). Standards of Medical Care in Diabetes – 2021. *Diabetes Care.* 2021;44(suppl 1): S1-S232.
- USPDI, Micromedex; 2022.
- Facts and Comparisons eAnswers (online); 2022 Clinical Drug Information, LLC.