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:	July 18, 2023
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. 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
• Byetta® • Trulicity® • Victoza®	• 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
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
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
OZEMPIC 0.25-0.5 MG DOSE PEN	SEMAGLUTIDE	1.5 mL per 28 days
OZEMPIC 0.25-0.5 MG DOSE PEN (2 MG/3 ML)	**SEMAGLUTIDE**	**3 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
OZEMPIC 2 MG DOSE PEN (8 MG/3 ML)	**SEMAGLUTIDE**	**3 mL per 28 days**
RYBELSUS 14 MG TABLET	SEMAGLUTIDE	1 tablet per day
RYBELSUS 3 MG TABLET	SEMAGLUTIDE	1 tablet per day
RYBELSUS 7 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**

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 and Fiscal Analysis: “Therapeutic Class Review: ENDOCRINE AND METABOLIC AGENTS: Antihyperglycemic, GLP-1 Receptor Agonists and Combinations”, Gainwell Technologies; Last updated April 26, 2023.
- Evidence-Based Medicine Analysis: “GLP-1 Receptor Agonists”, UMKC-DIC; February 2023.
- American Diabetes Association (ADA). Standards of Care in Diabetes – 2023. *Diabetes Care.* 2022;46(suppl 1): S1-S291.
- USPDI, Micromedex; 2023.
- Clinical Pharmacology [online]. Tampa (FL): Elsevier. 2023.