SmartPA Criteria Proposal

Drug/Drug Class:	Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors & Combination Agents PDL Edit
First Implementation Date:	October 2, 2014
Revised Date:	October 14, 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. Since 2015, the American Diabetes Association (ADA) Standards of Medical Care in Diabetes were updated to include the sodium-glucose co- transporter 2 (SGLT2) inhibitors in the management algorithm for type 2 diabetes mellitus. Although SGLT2 inhibitors are approved for monotherapy, metformin is still the preferred initial treatment, with the SGLT2 inhibitors added to the regimen if weight loss is also a goal. The most common side effects associated with these agents are urinary tract infections and female genital mycotic infections. Jardiance® (empagliflozin) was the first SGLT2 inhibitor to demonstrate benefit in reducing cardiovascular disease risk in persons with type 2 diabetes mellitus. It is believed that the beneficial effect of improving cardiovascular outcomes may be a class effect of the SGLT2 inhibitors. ADA guidelines favor Invokana® (canagliflozin), Jardiance® (empagliflozin), and Farxiga® (dapagliflozin) due to these agents' lower risks for heart failure and progression of chronic kidney disease. Dapagliflozin was recently approved by the FDA for use to reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure with reduced ejection fraction (NYHA class I to IV).

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

Program-Specific Information:

Preferred Agents	Non-Preferred Agents
• Farxiga® • Invokana® • Jardiance® • Synjardy®	• Invokamet® • Invokamet® XR • Segluromet® • Steglatro® • Synjardy® XR • Trijardy® XR • Xigduo® XR

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: Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors & Combination Agents
- Age range: All appropriate MO HealthNet participants aged 18 years or older

Approval Criteria

- ~~**For first claim only:**~~
  - ~~**Documented diagnosis of Diabetes Mellitus Type 2 AND**~~
  - ~~**Documented trial of metformin in the past year OR**~~
- ~~**For Farxiga only: Documented diagnosis of Heart Failure**~~
- Failure to achieve desired therapeutic outcomes with trial on 2 or more preferred agents
  - Documented trial period of preferred agents **OR**
  - Documented ADE/ADR to preferred agents

Denial Criteria

- Therapy will be denied if all approval criteria are not met
- Lack of adequate trial on required preferred agents
- ~~**For first claim only:**~~
  - ~~**Documented diagnosis of severe renal impairment or end stage renal disease OR**~~
  - ~~**Documented diagnosis of severe hepatic impairment**~~
- Claim exceeds maximum dosing limitation for the following:

Drug Description	Generic Equivalent	Max Dosing Limitation
FARXIGA 10 MG	DAPAGLIFLOZIN	1 tablet per day
FARXIGA 5 MG	DAPAGLIFLOZIN	2 tablets per day
INVOKANA 100 MG	CANAGLIFLOZIN	2 tablets per day
INVOKANA 300 MG	CANAGLIFLOZIN	1 tablet per day
JARDIANCE 10 MG	EMPAGLIFLOZIN	2 tablets per day
JARDIANCE 25 MG	EMPAGLIFLOZIN	1 tablet per day
STEGLATRO 15 MG	ERTUGLIFLOZIN	1 tablet per day
STEGLATRO 5 MG	ERTUGLIFLOZIN	2 tablets 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. USPDI, Micromedex; 2021.
2. Facts and Comparisons eAnswers (online); 2021 Clinical Drug Information, LLC.
3. Evidence-Based Medicine and Fiscal Analysis: “Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors and Combinations – Therapeutic Class Review”, Conduent Business Services, L.L.C., Richmond, VA; June 2021.
4. Evidence-Based Medicine Analysis: “Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors”, UMKC-DIC; March 2021.
5. Evidence-Based Medicine Analysis: “Antidiabetic Combination Agents – Oral and Injectable”, UMKC-DIC; March 2020.
6. Invokana [package insert]. Titusville, NJ: Janssen Pharmaceuticals; August 2020.
7. Farxiga [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; May 2020.
8. Jardiance [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc; January 2020.
9. Steglatro [package insert]. Whitehouse Station, NJ: Merck Sharp & Dohme; March 2021.
10. 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.