

# SmartPA Criteria Proposal

<b>Drug/Drug Class:</b>	Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors & Combination Agents PDL Edit
<b>First Implementation Date:</b>	October 2, 2014
<b>Proposed Date:</b>	June 18, 2020
<b>Prepared For:</b>	MO HealthNet
<b>Prepared By:</b>	MO HealthNet/Conduent
<b>Criteria Status:</b>	<input checked="" type="checkbox"/> Existing Criteria <input type="checkbox"/> Revision of Existing Criteria <input type="checkbox"/> 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
		<ul style="list-style-type: none"> <li>• Invokamet®</li> <li>• Invokamet® XR</li> <li>• Segluromet™</li> <li>• Steglatro™</li> <li>• Synjardy® XR</li> <li>• Trijardy® XR</li> <li>• Xigduo® XR</li> </ul>

Type of Criteria:  Increased risk of ADE  
 Appropriate Indications

Preferred Drug List  
 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

## Approval Criteria

- For first claim only:
  - Documented diagnosis of Diabetes Mellitus Type 2 in the past 2 years **AND**
  - Documented trial of metformin in the past year **AND**
- 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

- Lack of adequate trial on required preferred agents
- Therapy will be denied if no approval criteria are met
- 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:



## Required Documentation

Laboratory Results:   
MedWatch Form:

Progress Notes:   
Other:

## Disposition of Edit

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

## Default Approval Period

1 year

## References

1. Lippincott, Williams, Wilkins. PDR Electronic Library, Montvale NJ; 2020.
2. USPDI, Micromedex; 2020.
3. Facts and Comparisons eAnswers (online); 2020 Clinical Drug Information, LLC.
4. 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; April 2020.
5. Evidence-Based Medicine Analysis: “Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors”, UMKC-DIC; April 2020.
6. Evidence-Based Medicine Analysis: “Antidiabetic Combination Agents – Oral and Injectable”, UMKC-DIC; March 2020.
7. Invokana [package insert]. Titusville, NJ: Janssen Pharmaceuticals; 2020.
8. Farxiga [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; 2020.
9. Jardiance [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc; 2020.
10. Steglatro [package insert]. Whitehouse Station, NJ: Merck Sharp & Dohme; 2020.
11. 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.

### *SmartPA PDL Proposal Form*

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