Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 7/31/2018**
Policy Number:	**Effective Date: 01/2018** **Revision Date: 07/18/2018**
Policy Name:	**HC Approval Date:**

Type of Submission – Check all that apply:

- ☐ **New Policy**
- ☐ **Revised Policy***
- ☐ **Annual Review – No Revisions**
- ☐ **Attestation of HC PARP Policy –** *This option should only be used during Readiness Review for Community HealthChoices. The policy must be identical to the PARP approved policy for the HealthChoices Program, with the exception of revisions/clarifications adding the term "Community HealthChoices" to the policy.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

This policy is being retired and replaced by the following policy:

PA.CP.PST.19 Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors

Name of Authorized Individual (Please type or print): **Francis G. Grillo, MD**	**Signature of Authorized Individual:**

Clinical Policy: Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors

Reference Number: PA.CP.PPA.24
Effective Date: 01/18
Last Review Date: 11/17 Revision Log
Line of Business: Medicaid

Description
The following are sodium-glucose co-transporter 2 (SGLT2) inhibitors requiring prior authorization: *PDL*: empagliflozin (Jardiance®); *non-PDL*: canagliflozin (Invokana®), canagliflozin/metformin (Invokamet®, Invokamet® XR), dapagliflozin (Farxiga®), dapagliflozin/metformin (Xigduo® XR), empagliflozin/linagliptin (Glyxambi®), and empagliflozin/metformin (Synjardy®, Synjardy® XR).

FDA Approved Indication(s)
SGLT2 inhibitors are indicated as adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Jardiance is also indicated to reduce the risk of cardiovascular death in adult patients with type 2 diabetes mellitus and established cardiovascular disease.

Limitation of use: SGLT2 inhibitors should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis.

Policy/Criteria
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of Pennsylvania Health and Wellness® that SGLT2 inhibitors are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria
A. Type 2 Diabetes Mellitus (must meet all)**:**
1. Diagnosis of type 2 diabetes mellitus;
2. Member meets one of the following (a or b):
   a. Failure of ≥ 3 consecutive months of metformin at doses ≥ 2000 mg/day, unless contraindicated or clinically significant adverse effects are experienced;
   b. Both i and ii:
      i. HbA1c drawn within the past 3 months is > 7%;
      ii. Failure of ≥ 3 consecutive months of metformin at doses ≥ 1500 mg/day, unless contraindicated or clinically significant adverse effects are experienced;
3. If request is for a non-PDL SGLT2 inhibitor, member meets one of the following (a or b):
   a. For Glyxambi: Failure of ≥ 3 consecutive months of a PDL SGLT2 inhibitor OR a PDL dipeptidyl peptidase-4 (DPP-4) inhibitor at up to maximally indicated doses, unless all are contraindicated or clinically significant adverse effects are experienced;

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b. For all other non-PDL SGLT2 inhibitors: Failure of ≥ 3 consecutive months of a PDL SGLT2 inhibitor at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;

4. Dose does not exceed the FDA approved maximum recommended dose.

Approval duration: 12 months

B. Other diagnoses/indications

1. Refer to PA.CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

Authorization is automatically renewed if there is a claims history of ≥ 90 day supply of the requested agent in the last 120 days

A. Type 2 Diabetes Mellitus (must meet all)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met initial approval criteria; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. If request is for a dose increase, new dose does not exceed the FDA approved maximum recommended dose.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via health plan benefit and documentation supports positive response to therapy; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to PA.CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – PA.CP.PMN.53 or evidence of coverage documents;

B. Type 1 diabetes mellitus.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

AACE: American Association of Clinical Endocrinologists
ACE: American College of Endocrinology
ADA: American Diabetes Association
DPP-4: dipeptidyl peptidase-4
FDA: Food and Drug Administration
GLP-1: glucagon-like peptide 1
HbA1c: glycated hemoglobin
PDL: preferred drug list
SGLT2: sodium-glucose co-transporter

Appendix B: General Information

- A double-blind, placebo-controlled dose-response trial by Garber et al. found the maximal efficacy of metformin to occur at doses of 2000 mg. However, the difference in

adjusted mean change in HbA1c between the 1500 and 2000 mg doses was 0.3%, suggesting that the improvement in glycemic control provided by the additional 500 mg may be insufficient when HbA1c is > 7%.

- Per the American Diabetes Association (ADA) and American Association of Clinical Endocrinologists and American College of Endocrinology (AACE/ACE) 2017 guidelines:
  - Metformin is recommended for all patients with type 2 diabetes. Monotherapy is recommended for most patients; however:
    - Starting with dual therapy (i.e., metformin plus another agent, such as a sulfonylurea, thiazolidinedione, DPP-4 inhibitor, SGLT2 inhibitor, glucagon-like peptide 1 [GLP-1] receptor agonist, or basal insulin) may be considered for patients with baseline HbA1c ≥ 9% per the ADA (≥ 7.5% per the AACE/ACE).
    - Starting with combination injectable therapy (i.e., with GLP-1 receptor agonist or insulin) may be considered for patients with baseline HbA1c ≥ 10% per the ADA (≥ 9% if symptoms are present per the AACE/ACE).
  - If the target HbA1c is not achieved after approximately 3 months of monotherapy, dual therapy should be initiated. If dual therapy is inadequate after 3 months, triple therapy should be initiated. Finally, if triple therapy fails to bring a patient to goal, combination injectable therapy should be initiated. Each non-insulin agent added to initial therapy can lower HbA1c by 0.9-1.1%.

V. Dosage and Administration

Drug	Dosing Regimen	Maximum Dose
PDL		
Jardiance (empagliflozin)	10 mg once daily	25 mg/day
Non-PDL		
Farxiga (dapagliflozin)	5 mg once daily	10 mg/day
Glyxambi (empagliflozin/linagliptin)	10/5 mg once daily	25/5 mg/day
Invokamet (canagliflozin/metformin)	One 50/500 mg tablet twice daily	300/2000 mg/day
Invokamet XR (canagliflozin/metformin)	Two 50/500 mg tablets once daily	300/2000 mg/day
Invokana (canagliflozin)	100 mg once daily	300 mg/day
Synjardy (empagliflozin/metformin)	Individualized dose twice daily	25/2000 mg/day
Synjardy XR (empagliflozin/metformin)	Individualized dose once daily	25/2000 mg/day
Xigduo XR (dapagliflozin/metformin)	Individualized dose once daily	10/2000 mg/day

VI. Product Availability

Drug	Availability
PDL	
Jardiance (empagliflozin)	Tablets: 10 mg, 25 mg
Non-PDL	
Farxiga (dapagliflozin)	Tablets: 5 mg, 10 mg
Glyxambi (empagliflozin/linagliptin)	Tablets: 10/5 mg, 25/5 mg

Invokamet (canagliflozin/metformin)	Tablets: 50/500 mg, 50/1000 mg, 150/500 mg, 150/1000 mg
Invokamet XR (canagliflozin/metformin)	Tablets: 50/500 mg, 50/1000 mg, 150/500 mg, 150/1000 mg
Invokana (canagliflozin)	Tablets: 100 mg, 300 mg
Synjardy (empagliflozin/metformin)	Tablets: 5/500 mg, 5/1000 mg, 12.5/500 mg, 12.5/1000 mg
Synjardy XR (empagliflozin/metformin)	Tablets: 5/1000 mg, 10/1000 mg, 12.5/1000 mg, 25/1000 mg
Xigduo XR (dapagliflozin/metformin)	Tablets: 5/500 mg, 5/1000 mg, 10/500 mg, 10/1000 mg

VII. References

1. American Diabetes Association. Standards of medical care in diabetes—2017. Diabetes Care. 2017; 40(suppl 1): S1-S135.
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12. Garber AJ, Abrahamson MJ, Barzilay, JI, et al. Consensus statement by the American Association of Clinical Endocrinologists and American College of Endocrinology on the comprehensive type 2 diabetes management algorithm – 2017 executive summary. Endocr Pract. 2017; 23(2): 207-238.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
This policy is being retired and replaced by the following policy: **PA.CP.PST.19 Sodium-Glucose Co-Transporter 2 (SGLT2) Inhibitors**	7/18	

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