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

Reference Number: AZ.CP.PMN.14
Effective Date: 07.25.19
Last Review Date: 07.20
Line of Business: Arizona Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
The following agents contain a sodium-glucose co-transporter 2 (SGLT2) inhibitor and require prior authorization: canagliflozin (Invokana®), canagliflozin/metformin (Invokamet®, Invokamet® XR), dapagliflozin (Farxiga®), dapagliflozin/metformin (Xigduo® XR), dapagliflozin/saxagliptin (Qtern®), dapagliflozin/saxagliptin/metformin (Qternmet® XR), empagliflozin (Jardiance®), empagliflozin/linagliptin (Glyxambi®), empagliflozin/linagliptin/metformin (Trijardy™ XR), empagliflozin/metformin (Synjardy®, Synjardy® XR), ertugliflozin (Steglatro™), ertugliflozin/metformin (Segluromet™), and ertugliflozin/sitagliptin (Steglujan™).

AHCCCS preferred drugs in this class include Farxiga (dapagliflozin), Invokana (canagliflozin), Glyxambi (empagliflozin/linagliptin) and Jardiance (empagliflozin).

AHCCCS non-preferred drugs in this class include Invokamet and Invokamet XR (canagliflozin/metformin), Segluromet (ertugliflozin/metformin), Steglatro (ertugliflozin), Steglujan (ertugliflozin/sitagliptin), Synjardy and Synjardy XR (empagliflozin/metformin), empagliflozin/linagliptin/metformin (Trijardy™ XR), Qtern (dapagliflozin/saxagliptin), Qternmet XR (dapagliflozin/saxagliptin/metformin) and Xigduo XR (dapagliflozin/metformin.)

FDA approved indications
SGLT2 inhibitors are indicated as adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Farxiga, Invokana, and Jardiance are also indicated in adult patients with type 2 diabetes mellitus and established cardiovascular disease (or multiple cardiovascular risk factors [*Farxiga only*]) to:
- Reduce the risk of hospitalization for heart failure (HF) (Farxiga)
- Reduce the risk of major adverse cardiovascular events: cardiovascular death, nonfatal myocardial infarction, and nonfatal stroke (Invokana)
- Reduce the risk of cardiovascular death (Jardiance)

Invokana is additionally indicated to reduce the risk of end-stage kidney disease, doubling of serum creatinine, cardiovascular death, and hospitalization for HF in adults with type 2 diabetes mellitus and diabetic nephropathy with albuminuria > 300 mg/day.

Farxiga is also indicated to reduce the risk of CV death and hospitalization for HF in adults with heart failure with reduced ejection fraction (HFrEF) (New York Heart Association [NYHA] class II-IV).

Limitation(s) of use:
- SGLT2 inhibitors should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis.
- Qternmet XR initiation is intended only for patients currently taking metformin.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of Arizona Complete Health 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. Age ≥ 18 years;
3. Member meets one of the following (a or b):
   a. Failure of ≥ 3 consecutive months of metformin at a minimum daily dose of 1500mg, unless contraindicated or clinically significant adverse effects are experienced;
   b. HbA1c drawn within the past 3 months is ≥ 8.5%, and concurrent use of metformin at a minimum daily dose of 1500mg, unless contraindicated or clinically significant adverse effects are experienced;
4. Request meets one of the following (a, b, or c):
   a. Request is for a preferred SGLT2 inhibitor;
   b. Request is for a non-preferred SGLT2 inhibitor: failure of ≥ 3 consecutive months of all preferred SGLT2 inhibitors, unless contraindicated or clinically significant adverse effects are experienced;
   c. Request is for a non-preferred DPP-4 inhibitor/SGLT2 inhibitor combination therapy: failure of Glyxambi (empagliflozin/linagliptin);
5. Dose does not exceed the FDA approved maximum recommended dose (*see Section V*).

Approval duration: 12 months

B. Heart Failure (must meet all)**:**
1. Diagnosis of HFrEF of NYHA Class II, III, or IV;
2. Request is for Farxiga;
3. Prescribed by or in consultation with a cardiologist;
4. Age ≥ 18 years;
5. Left ventricular ejection fraction (LVEF) is ≤ 40%;
6. Member does not have a diagnosis of type 1 diabetes mellitus;

7. Member is currently receiving standard HF drug therapy at target doses for ≥ 4 weeks including both of the following (a and b) unless all are contraindicated or clinically significant adverse effects are experienced:
   a. Angiotensin converting enzyme inhibitor, angiotensin receptor blocker, or Entresto®;
   b. Beta blocker;
8. Dose does not exceed 10 mg (1 tablet) per day.

Approval duration: 12 months

C. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): AZ.CP.PMN.53 for Arizona Medicaid.

II. Continued Therapy

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

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Request meets one of the following (a, b, or c):
   a. Request is for a preferred SGLT2 inhibitor;
   b. Request is for a non-preferred SGLT2 inhibitor: history of failure of ≥ 3 consecutive months of all preferred SGLT2 inhibitors, unless contraindicated or clinically significant adverse effects are experienced;
   c. Request is for a non-preferred DPP-4 inhibitor/SGLT2 inhibitor combination therapy: history of failure of Glyxambi (empagliflozin/linagliptin);
3. Member is responding positively to therapy;
4. Documentation of continued metformin therapy (unless contraindicated);
5. If request is for a dose increase, the new dose does not exceed the FDA approved maximum recommended dose (*see Section V*).

Approval duration: 12 months

B. Heart Failure (must meet all)**:**

1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Farxiga for HFrEF and has received this medication for at least 30 days;
2. Request is for Farxiga;
3. Member is responding positively to therapy;
4. If request is for a dose increase, new dose does not exceed 10 mg (1 tablet) per day.

Approval duration: 12 months

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

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or

2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): AZ.CP.PMN.53 for Arizona Medicaid.

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 policies – AZ.CP.PMN.53 for Arizona Medicaid.

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
ER: extended-release
FDA: Food and Drug Administration
GLP-1: glucagon-like peptide-1
HbA1c: glycated hemoglobin
IR: immediate-release
SGLT2: sodium-glucose co-transporter 2

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Metformin (Fortamet®, Glucophage®, Glucophage® XR, Glumetza®)	Regular-release (Glucophage): 500 mg PO BID or 850 mg PO QD; increase as needed in increments of 500 mg/week or 850 mg every 2 weeks Extended-release: • Fortamet, Glumetza: 1,000 mg PO QD; increase as needed in increments of 500mg/week • Glucophage XR: 500 mg PO QD; increase as needed in increments of 500 mg/week	Regular-release: 2,550 mg/day Extended-release: • Fortamet: 2,500 mg/day • Glucophage XR, Glumetza: 2,000 mg/day
Farxiga (dapagliflozin propanediol)	Initial, 5 mg PO QD, may increase to 10 mg PO QD	10 mg/day
Invokana (canagliflozin)	Initial, 100 mg PO QD, may increase to 300 mg PO QD	300 mg/day
Glyxambi (empagliflozin/linagliptin)	Initial, empagliflozin 10 mg/linagliptin 5 mg PO QD, may increase to empagliflozin 25 mg/linagliptin 5 mg PO QD	Empagliflozin 25 mg/linagliptin 5 mg

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Jardiance (empagliflozin)	Initial, 10 mg PO QD, may increase to 25 mg PO QD	25 mg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s):
  - History of serious hypersensitivity reaction to the requested drug product
  - Moderate to severe renal impairment*, end-stage renal disease, or dialysis
    *Minimum degree of renal impairment varies per agent; refer to individual prescribing information
  - Metabolic acidosis, including diabetic ketoacidosis (metformin-containing products only)
- Boxed warning(s): lactic acidosis (*metformin-containing products only*), lower limb amputation (*Invokana only*)

Appendix D: 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 2,000 mg. However, the difference in adjusted mean change in HbA1c between the 1,500 and 2,000 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 2019 American Diabetes Association (ADA) and 2017 American Association of Clinical Endocrinologists and American College of Endocrinology (AACE/ACE) 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, dipeptidyl peptidase-4 inhibitor, sodium-glucose co-transporter inhibitor, GLP-1 receptor agonist, or basal insulin) may be considered for patients with baseline HbA1c ≥ 1.5% above their target per the ADA (≥ 7.5% per the AACE/ACE). According to the ADA, a reasonable HbA1c target for many non-pregnant adults is < 7%.
    - Starting with combination injectable therapy (i.e., with GLP-1 receptor agonist or insulin) may be considered for patients with baseline HbA1c ≥ 10% or ≥ 2% above their target 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 0.7-1%.
- Although Invokana is currently the only SGLT2 inhibitor with a labeled indication for diabetic nephropathy, Farxiga and Jardiance have also demonstrated renal protective

effects. The 2019 ADA guidelines recommend SGLT2 inhibitors be considered when treating type 2 diabetic patients with renal concerns, noting that Farxiga, Jardiance, and Invokana all confer renal benefit, with no preference for one over the other

- Farxiga DECLARE-TIMI 58: The cardiorenal secondary composite outcome (sustained decline of at least 40% in eGFR to less than 60 mL/min/1.73 m2, end stage renal disease (ESRD), or death from renal or cardiovascular causes) was significantly reduced with Farxiga compared to placebo (HR 0.76, 95% CI 0.67-0.87; p < 0.0001); excluding death from cardiovascular causes, the HR for the renal-specific outcome was 0.53 (95% CI 0.43-0.66; p < 0.0001). There was a 46% reduction in sustained decline in eGFR by at least 40% to less than 60 mL/min/1.73 m2 (120 [1.4% vs 221 [2.6%]; HR 0.54 [95% CI 0.43-0.67]; p < 0.0001). The risk of ESRD or renal death was also lower in the Farxiga group than in the placebo group (11 [0.1%] vs 27 [0.3%]; HR 0.41 [95% CI 0.20-0.82]; p = 0.012).
- Jardiance EMPA-REG Outcome: Analysis of secondary outcomes yielded a reduction of risk for incident of or worsening nephropathy (HR 0.61 [95% CI 0.53-0.70]), progression to urine albumin to creatinine ratio (UACR) > 300 mg/g (HR 0.62 [95% CI 0.54-0.72]), composite consisting doubling of serum creatinine, initiation of renal replacement therapy, and death from ESRD (HR 0.54 [95% CI 0.40-0.75]).
- Examples of cardiovascular risk factors may include but are not limited to: chronic kidney disease, dyslipidemia, hypertension, obesity, a family history of premature coronary disease, smoking, and presence of albuminuria.
- According to the ADA, ASCVD includes coronary heart disease, cerebrovascular disease, or peripheral arterial disease presumed to be of atherosclerotic origin.
- Although Farxiga and Invokana are the only SGLT2 inhibitors with labeled indications for reducing the risk of HHF, Jardiance has also been shown to reduce the risk of HHF. The 2019 ADA guidelines acknowledge Farxiga along with Jardiance and Invokana as agents which reduce the risk of HHF, without a preference for one agent over the other. Any of the three can be used in T2DM patients with established HF; however, the guidelines recommend only Jardiance or Invokana for patients with established ASCVD.
- Jardiance EMPA-REG Outcome, patients with established ASCVD: The primary outcome (composite of death from CV causes, nonfatal MI, or non-fatal stroke) was reduced with Jardiance compared to placebo (HR 0.86, 95% CI 0.74 – 0.99; p = 0.04). Analysis of secondary outcomes yielded a reduction in hospitalization for heart failure when treated with Jardiance compared to placebo (HR 0.65, 95% CI 0.50 – 0.85; p = 0.002).
- Invokana CANVAS Program, patients with established ASCVD or multiple ASCVD risk factors: The primary outcome (composite of death from CV causes, nonfatal MI or nonfatal stroke) was reduced with Invokana compared to placebo (HR 0.86, 95% CI 0.75 – 0.97; p = 0.02). Analysis of secondary outcomes yielded a reduction in hospitalization for heart failure when treated with Invokana compared to placebo (HR 0.67, 95% CI 0.52 – 0.87).

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Farxiga (dapagliflozin)	5 mg PO QD	10 mg/day

Indication	Dosing Regimen	Maximum Dose
Glyxambi (empagliflozin/linagliptin)	One 10/5 mg tablet PO QD	25/5 mg/day
Invokamet (canagliflozin/metformin)	One 50/500 mg tablet PO BID	300/2,000 mg/day
Invokamet XR (canagliflozin/metformin)	Two 50/500 mg tablets PO QD	300/2,000 mg/day
Invokana (canagliflozin)	100 mg PO QD	300 mg/day
Jardiance (empagliflozin)	10 mg PO QD	25 mg/day
Qtern (dapagliflozin/saxagliptin)	One 5/5 mg tablet PO QD	10/5 mg/day
Qternmet XR (dapagliflozin/saxagliptin/metformin)	Individualized dose PO QD	10/5/2,000 mg/day
Steglatro (ertugliflozin)	Individualized dose PO QD	15 mg/day
Steglujan (ertugliflozin/sitagliptin)	One 5/100 mg tablet PO QD	15/100 mg/day
Synjardy (empagliflozin/metformin)	Individualized dose PO BID	25/2,000 mg/day
Synjardy XR (empagliflozin/metformin)	Individualized dose PO QD	25/2,000 mg/day
Trijardy XR (empagliflozin/linagliptin/ metformin)	Individualized dose PO QD	25/5/2,000 mg/day
Xigduo XR (dapagliflozin/metformin)	Individualized dose PO QD	10/2,000 mg/day

VI. Product Availability

Drug Name	Availability
Farxiga (dapagliflozin)	Tablets: 5 mg, 10 mg
Glyxambi (empagliflozin/linagliptin)	Tablets: 10/5 mg, 25/5 mg
Invokamet (canagliflozin/metformin)	Tablets: 50/500 mg, 50/1,000 mg, 150/500 mg, 150/1,000 mg
Invokamet XR (canagliflozin/metformin)	Tablets: 50/500 mg, 50/1,000 mg, 150/500 mg, 150/1,000 mg
Invokana (canagliflozin)	Tablets: 100 mg, 300 mg
Jardiance (empagliflozin)	Tablets: 10 mg, 25 mg
Qtern (dapagliflozin/saxagliptin)	Tablets: 5/5 mg, 10/5 mg
Qternmet XR (dapagliflozin/saxagliptin/metformin)	Tablets: 2.5/2.5/1,000 mg, 5/2.5/1,000 mg, 5/5/1000 mg, 10/5/1,000 mg
Steglatro (ertugliflozin)	Tablets: 5 mg, 15 mg
Steglujan (ertugliflozin/sitagliptin)	Tablets: 5/100 mg, 15/100 mg
Synjardy (empagliflozin/metformin)	Tablets: 5/500 mg, 5/1,000 mg, 12.5/500 mg, 12.5/1,000 mg
Synjardy XR	Tablets: 5/1,000 mg, 10/1,000 mg, 12.5/1,000 mg,

Drug Name	Availability
(empagliflozin/metformin)	25/1,000 mg
Trijardy XR (empagliflozin/linagliptin/ metformin)	Tablets: 5/2.5/1,000 mg, 10/5/1,000 mg, 12.5/2.5/1,000 mg, 25/5/1,000 mg
Xigduo XR (dapagliflozin/metformin)	Tablets: 2.5/1,000 mg, 5/500 mg, 5/1,000 mg, 10/500 mg, 10/1,000 mg

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Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	07.25.19	08.19
Added criterion for history of failure of preferred SGLT2 inhibitors for Continued Therapy	10.7.19	10.19
1Q 2020 annual review: policy updated to include Invokana's new FDA indication: diabetic nephropathy and Farxiga's new FDA indication: reduction in risk of hospitalization due to HF in patients with established cardiovascular disease or with multiple cardiovascular risk factors; criteria modified to allow Jardiance for diabetic nephropathy/HF as supported by ADA guidelines/published data (Farxiga and Invokana are not allowed due to formulary status); clarified that established cardiovascular disease can mean ASCVD or HF; added criteria to allow Invokana for patients with multiple cardiovascular risk factors as supported by CANVAS Program trials; references reviewed and updated.	02.2020	01.2020
Criteria added for Farxiga's new FDA indication: heart failure with reduced ejection fraction. Added Trijardy XR dosing information and product availability; references reviewed and updated.	07.10.20	07.20

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health

plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.