



Louisiana

Sodium-Glucose Co-Transporter-2 (SGLT-2) Inhibitors and Combination Products

Policy # 00385

Original Effective Date: 08/21/2013

Current Effective Date: 01/01/2019

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- Benefits are available in the member's contract/certificate, and
- Medical necessity criteria and guidelines are met.

SGLT-2 Inhibitors, SGLT-2 Inhibitor/Metformin Combination Products

Based on review of available data, the Company may consider Invokana^{™‡} (canagliflozin), Invokamet^{™‡} (canagliflozin/metformin), or Invokamet XR (canagliflozin/metformin extended release) to be **eligible for coverage** when the below patient selection criterion is met:

Patient Selection Criteria

Coverage eligibility will be considered for Invokana (canagliflozin), Invokamet (canagliflozin/metformin), or Invokamet XR (canagliflozin/metformin extended release) when the below patient selection criterion is met:

- There is clinical evidence or patient history that suggests the use of Farxiga^{™‡} (dapagliflozin), Jardiance^{®‡} (empagliflozin), Steglatro^{™‡} (ertugliflozin), Synjardy^{®‡} (empagliflozin/metformin), Synjardy XR (empagliflozin/metformin extended release), Xigduo XR^{™‡} (dapagliflozin/metformin extended release), or Segluromet^{™‡} (ertugliflozin/metformin) will be ineffective or cause an adverse reaction to the patient.

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of Invokana (canagliflozin), Invokamet (canagliflozin/metformin), or Invokamet XR (canagliflozin/metformin extended release) when there is an absence of clinical evidence or patient history that suggests the use of Farxiga (dapagliflozin), Jardiance (empagliflozin), Steglatro (ertugliflozin), Synjardy (empagliflozin/metformin), Synjardy XR (empagliflozin/metformin extended release), Xigduo XR (dapagliflozin/metformin extended release), or Segluromet (ertugliflozin/metformin) will be ineffective or cause an adverse reaction to the patient to be **not medically necessary**.**

SGLT-2/DPP4 (Dipeptidyl Peptidase 4) Inhibitor Combination Products

Based on review of available data, the Company may consider Qtern (dapagliflozin/saxagliptin) or Steglujan (ertugliflozin/sitagliptin) to be **eligible for coverage** when the below patient selection criterion is met:

Patient Selection Criterion

Coverage eligibility will be considered for Qtern (dapagliflozin/saxagliptin) or Steglujan (ertugliflozin/sitagliptin) when the below patient selection criterion is met:

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- There is clinical evidence or patient history that suggests the use of Glyxambi (empagliflozin/linagliptin) will be ineffective or cause an adverse reaction to the patient.

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of Qtern (dapagliflozin/saxagliptin) or Steglujan (ertugliflozin/sitagliptin) when there is an absence of clinical evidence or patient history that suggests the use of Glyxambi (empagliflozin/linagliptin) will be ineffective or cause an adverse reaction to the patient to be **not medically necessary**.**

Schematic

Class	Preferred	Non-Preferred
SGLT-2 Inhibitors, SGLT-2 Inhibitor/Metformin Combination Products	Farxiga Jardiance Steglatro Synjardy Synjardy XR Xigduo XR Segluromet	Invokana Invokamet Invokamet XR
SGLT-2 Inhibitor/DPP4 Inhibitor Combination Products	Glyxambi	Qtern Steglujan

Background/Overview

SGLT-2 inhibitors are indicated as an adjunct to diet and exercise to improve glycemic control in patients with type 2 diabetes mellitus. SGLT-2, expressed in the proximal renal tubules, is responsible for the majority of the reabsorption of filtered glucose from the tubular lumen. The inhibition of SGLT-2 reduces reabsorption of filtered glucose and lowers the renal threshold for glucose, and thereby increases urinary glucose excretion.

The active ingredients in the non-preferred products have not been studied head to head versus the preferred products and therefore no superiority claims can be made between preferred and non-preferred products.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

All of these products are indicated for the treatment of type 2 diabetes mellitus.

Rationale/Source

Based on a review of the available data and in the absence of any of the caveats mentioned, there is no advantage of using Invokana (canagliflozin), Invokamet (canagliflozin/metformin), or Invokamet XR

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(canagliflozin/metformin extended release) over Farxiga (dapagliflozin), Jardiance (empagliflozin), Steglatro (ertugliflozin), Synjardy (empagliflozin/metformin), Synjardy XR (empagliflozin/metformin extended release), Xigduo XR (dapagliflozin/metformin extended release), or Segluromet (ertugliflozin/metformin). Based on a review of the available data and in the absence of any of the caveats mentioned, there is no advantage of using Qtern (dapagliflozin/saxagliptin) or Steglujan (ertugliflozin/sitagliptin) over Glyxambi (empagliflozin/linagliptin).

References

1. Invokana [package insert]. Janssen Pharmaceuticals, Inc. Titusville, NJ.
2. Farxiga [package insert], Bristol Myers Squibb. Princeton, NJ.
3. Xigduo XR tablets [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; October 2014.
4. Invokamet tablets [prescribing information]. Titusville, NJ: Janssen; August 2014.
5. Jardiance tablets [prescribing information]. Ridgefield, CT and Indianapolis, IN: Boehringer Ingelheim Pharmaceuticals, Inc and Eli Lilly and Company; August 2014.
6. SGLT-2 Step Therapy Policy. Express Scripts. Updated 06/2105.
7. Synjardy/XR [package insert]. Boehringer Ingelheim, Eli Lilly and Company. Ridgefield, Connecticut and Indianapolis, Indiana. Updated 7/2016.
8. Steglatro [package insert]. Merck. Whitehouse Station, New Jersey. Updated 12/2017.
9. Segluromet [package insert]. Merck. Whitehouse Station, New Jersey. Updated 12/2017.
10. Steglujan [package insert]. Merck. Whitehouse Station, New Jersey. Updated 12/2017.
11. Qtern [package insert]. Astra Zeneca. Wilmington, Delaware. Updated February 2017.

Policy History

Original Effective Date: 08/21/2013

Current Effective Date: 01/01/2019

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|------------|---|
| 08/07/2013 | Medical Policy Committee review |
| 08/21/2013 | Medical Policy Implementation Committee approval. New Pharmacy step-therapy policy. |
| 08/07/2014 | Medical Policy Committee review |
| 08/20/2014 | Medical Policy Implementation Committee approval. Added new drugs (Farxiga) and empagliflozin (Jardiance) to the description of the included products that may be eligible for coverage. |
| 08/06/2015 | Medical Policy Committee review |
| 08/19/2015 | Medical Policy Implementation Committee approval. Added new drugs (canagliflozin/metformin (Invokamet), and dapagliflozin/metformin extended release (Xigduo XR) to the description of the included products that may be eligible for coverage. |
| 08/04/2016 | Medical Policy Committee review |
| 08/17/2016 | Medical Policy Implementation Committee approval. Added a new brand, Synjardy, to the policy. |
| 10/06/2016 | Medical Policy Committee review |
| 10/19/2016 | Medical Policy Implementation Committee approval. Chose preferred products in this class (Invokana, Invokamet, Invokamet XR, Jardiance, Synjardy). |
| 08/03/2017 | Medical Policy Committee review |
| 08/23/2017 | Medical Policy Implementation Committee approval. Removed the PA and PA/step sections to revert this back to a step only policy. |
| 07/05/2018 | Medical Policy Committee review |
| 07/11/2018 | Medical Policy Implementation Committee approval. Added Steglujan, Steglatro, Segluromet, and Qtern to the policy. |
| 09/06/2018 | Medical Policy Committee review |

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09/19/2018 Medical Policy Implementation Committee approval. Removed generic before brand step therapy. Changed Invokana, Invokamet, and Invokamet XR to non-preferred.

Next Scheduled Review Date: 09/2019

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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