

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	NA

Sodium-Glucose Co-Transporter-2 (SGLT2) Inhibitor/Dipeptidyl Peptidase-4 (DPP-4) Inhibitor Combination Agents

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medication	Quantity Limit
Glyxambi (empagliflozin/linagliptin) Qtern (dapagliflozin/saxagliptin) Qternmet XR (dapagliflozin/saxagliptin/metformin) Steglujan (ertugliflozin/sitagliptin) Trijardy XR (empagliflozin/linagliptin/metformin extended-release)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for a SGLT2 inhibitor/DPP-4 inhibitor combination agent may be approved when the following criteria are met:

- I. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to metformin (AACE/ACE 2019);

OR

- II. Individual has a contraindication to metformin therapy;

AND

- III. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response to one preferred DPP-4 inhibitor*;

*Preferred DPP-4 inhibitors: Janumet, Janumet XR, Januvia

AND

- IV. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response to one preferred SGLT2 inhibitor**;

**Preferred SGLT2 inhibitors: Jardiance, Synjardy, Synjardy XR

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This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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AND

- V. Individual has had an adequate response (achieved glucose control) with a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) of a DPP-4 inhibitor and SGLT2 inhibitor at the same time;

AND

- VI. Documentation has been provided for why the combination agent is clinically necessary and not for convenience.

A SGLT2 inhibitor/DPP-4 inhibitor combination agent may not be approved for any of the following:

- I. Individual is requesting Glyxambi (empagliflozin/linagliptin), Qtern (dapagliflozin/saxagliptin), Qternmet XR (dapagliflozin/saxagliptin/metformin) or Trijardy XR (empagliflozin/linagliptin/metformin) with an eGFR less than 45 mL/min/1.73 m²; **OR**
- II. Individual is requesting Steglujan (ertugliflozin/sitagliptin) with an eGFR less than 60 mL/min/1.73 m²; **OR**
- III. Individual is on dialysis; **OR**
- IV. Individual is requesting for treatment of type 1 diabetes mellitus.

Key References:

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: January 28, 2020.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.

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3. 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 – 2019 Executive Summary. *Endocrine Practice*. 2019;25:69-100.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.
5. US Food and Drug Administration. FDA Drug Safety Communication: FDA revises warnings regarding use of the diabetes medicine metformin in certain patients with reduced kidney function. Last updated November 14, 2017. Available at <https://www.fda.gov/Drugs/DrugSafety/ucm493244.htm>. Accessed: January 2, 2020.

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