

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

Sodium-Glucose Co-transporter-2 (SGLT2) Inhibitor Step Therapy

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

Medications	Status	Quantity Limit
Jardiance (empagliflozin)	Preferred	May be subject to quantity limit
Synjardy (empagliflozin/metformin)		
Synjardy XR (empagliflozin/metformin extended-release)		
Farxiga (dapagliflozin)	Non-Preferred	
Invokamet (canagliflozin and metformin)		
Invokamet XR (canagliflozin and metformin extended-release)		
Invokana (canagliflozin)		
Segluromet (ertugliflozin/metformin)		
Steglatro (ertugliflozin)		
Xigduo XR (dapagliflozin/metformin extended release)		

APPROVAL CRITERIA

Requests for Jardiance (empagliflozin), Synjardy (empagliflozin/metformin), or Synjardy XR (empagliflozin/metformin extended-release) 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 (AAACE/ACE 2019); **OR**
- II. Individual has a contraindication to metformin therapy.

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Requests for Farxiga (dapagliflozin), Invokamet (canagliflozin/metformin), Invokamet XR (canagliflozin and metformin extended-release), Invokana (canagliflozin), Segluromet (ertugliflozin/metformin), Steglatro (ertugliflozin), or Xigduo XR (dapagliflozin/metformin extended-release) 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 or intolerance to Jardiance (empagliflozin), Synjardy (empagliflozin/metformin) or Synjardy XR (empagliflozin/metformin extended-release);

OR

- IV. Farxiga (dapagliflozin) may be approved for an individual with New York Heart Association (NYHA) class II, III or IV heart failure symptoms when the following criteria are met (McMurray 2019):

- A. Individual has an ejection fraction of 40% or less; **AND**

- B. Individual will be taking Farxiga (dapagliflozin) in combination with a beta blocker **AND** an angiotensin-converting enzyme (ACE) inhibitor, angiotensin receptor blocker (ARB) or Entresto (sacubitril/valsartan) unless contraindicated or not tolerated;

OR

- V. Invokana (canagliflozin) may be approved for an individual with type 2 diabetes and diabetic nephropathy when the following criteria are met:

- A. Individual has albuminuria greater than 300 mg/day; **AND**

- B. If initiating therapy, individual has an eGFR greater than or equal to 30 mL/min/1.73 m² and less than 90 mL/min/1.73 m²; **AND**

- C. Individual will be taking Invokana (canagliflozin) in combination with an angiotensin-converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) unless contraindicated or not tolerated.

A SGLT2 inhibitor may **not** be approved for any of the following:

- I. Individual is requesting Invokana (canagliflozin), Invokamet (canagliflozin and metformin), or Invokamet XR (canagliflozin and metformin extended-release) and has a risk factor for lower limb amputation (including but not limited to history of prior amputation, peripheral vascular disease, neuropathy or diabetic foot ulcers); **OR**
- II. Individual is on dialysis; **OR**

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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- III. Individual is requesting Invokana (canagliflozin) with an eGFR less than 45 mL/min/1.73 m² unless individual is using to treat diabetic nephropathy; **OR**
- IV. Individuals is requesting Invokamet (canagliflozin and metformin), Invokamet XR (canagliflozin and metformin extended-release), Jardiance (empagliflozin), Synjardy (empagliflozin/metformin), Synjardy XR (empagliflozin/metformin extended-release), or Xigduo XR (dapagliflozin/metformin extended-release) with an eGFR less than 45 mL/min/1.73m²; **OR**
- V. Individual is requesting Farxiga (dapagliflozin) with an eGFR less than 30 mL/min/1.73 m²; **OR**
- VI. Individual is requesting Segluromet (ertugliflozin/metformin) or Steglatro (ertugliflozin) with an eGFR less than 60 mL/min/1.73 m²; **OR**
- VII. Individual is requesting for the 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 3, 2020.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
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. McMurray JJV, Solomon SD, Inzucchi SE, et al; DAPA-HF Trial Committees and Investigators. Dapagliflozin in Patients with Heart Failure and Reduced Ejection Fraction. *N Engl J Med*. 2019 Nov 21;381(21):1995-2008.
6. 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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