289 LaClair Coos Bay OR 97420
Phone: 541-269-7400 Fax: 541-269-7147

Sodium-Glucose CoTransporter-2 Inhibitors (SGLT-2 Inhibitors) Drug Use Criteria

Created: August 2020
Reviewed: September 30, 2020, October 2020, September 2021, January 2022

Includes:

Invokana©	**Canagliflozin**
Invokamet XR©	Canagliflozin/Metformin HCI
Invokamet©	Canagliflozin/Metformin HCI
Farxiga©	**Dapagliflozin Propanediol**
XigduoXR©	Dapagliflozin/Metformin HCI
Qtern©	Dapagliflozin/Saxagliptin HCI
Jardiance©	**Empagliflozin**
Glyxambi©	Empagliflozin/Linagliptin
Synjardy XR©	Empagliflozin/Metformin HCI
Synjardy©	Empagliflozin/Metformin HCI
Steglatro©	**Ertugliflozin Pidolate (Preferred for glycemic control)**
Segluromet©	Ertugliflozin/Metformin
Steglujan©	Ertugliflozin/Sitagliptin
Trijardy XR©	Empaglifozin/Linagliptin/Metformin

(Bolded items are preferred agents)

GUIDELINE FOR USE:

Initial Request:

1. Is this a request for renewal of a previously approved prior authorization?
   a) Yes: Go the Renewal Criteria
   b) No: Go to #2

Drug Name	Risk Reduction for major CV events in T2DM and established CV disease	Risk Reduction of end-stage kidney disease in patients with T2DM and diabetic nephropathy with albuminuria >300mg/day	Risk Reduction of eGFR decline and end-stage kidney disease CV death and hospitalization for HF in patients with CKD at risk of progression	HF risk reduction in patients with T2DM and established CV disease or multiple CV risk factors	HF risk reduction in patients with HFrEF (NYHA Class II-IV)

AdvancedHealth
Bridging the Future of Healthcare

289 LaClair Coos Bay OR 97420
Phone: 541-269-7400 Fax: 541-269-7147

Invokana (canagliflozin)	**X**	**X**			
Farxiga (dapagliflozin)			**X**	**X**	**X**
Jardiance (empagliflozin)	**X**				**X**
Steglatro (ertugliflozin)					

*Abbreviations: CKD- chronic kidney disease; CV- Cardiovascular; eGFR- estimated glomerular filtration rate; HF- heart failure; HFrEF- heart failure with reduced ejection fraction; NYHA- New York Heart Association; T2DM- Type 2 Diabetes Mellitus

2. Does the member qualify for the requested therapy based on the diagnoses and requirements in Table 1?
   a) Yes: Go to #5
   b) No: Go to #3

3. Does the member have T2DM and an A1c >9%?
   a) Yes: Deny as not meeting criteria. SGLT-2 Inhibitors aren't recommended due to inferior glycemic efficacy and the potential for increasing symptoms from polyuria. Recommend basal insulin and prandial insulin.
   b) No: Go to #4.

4. Does the patient have T2DM and has tried and failed metformin and another oral glucose lowering agent, have contraindications to these treatments or is the request for use of a SGLT-2 inhibitor with metformin and an oral glucose lowering agent? (Please document dose optimization, medication adherence, and/or clinical contraindications, if any e.g., heart failure). *For dose optimization of oral glucose lowering agents, has member trialed maximum dose supported by manufacturer labeling or highest tolerated dose? For dose optimization of basal insulin, has member trialed at least 80 units per day of basal insulin?*
   a) Yes: go to question #5
   b) No and not on basal insulin: Deny and recommend trial of metformin, other oral glucose lowering agents (sulfonylurea, pioglitazone, or alogliptin), or basal insulin (Semglee).
   c). No and on basal insulin: Go to #5

5. Is the request for the following treatments (including combination products) with an associated estimated glomerular filtration rate (eGFR):
   - Canagliflozin and eGFR <30 mL/min/ 1.73 m2, or
   - Empagliflozin and eGFR <30 mL/min/1.73 m2, or
   - Dapagliflozin and eGFR <25 mL/min/1.73 m2, or
   - Ertugliflozin and eGFR <60 mL/min/1.73 m2?

289 LaClair Coos Bay OR 97420
Phone: 541-269-7400 Fax: 541-269-7147

*Additional manufacturer labeling information will be used on an individual basis.

a) Yes: Deny as criteria not met. Use is not recommended per manufacturing labeling.
b) No: Approve for 3 months. Please submit follow-up chart note evaluating response to treatment, including HgA1c level after treatment was initiated.

Renewal Request:

1. Does member still meet initial criteria?
   a). Yes: Go to #2
   b). No: Deny as not meeting criteria.

2. Has the patient been adherent to therapy and if applicable, has HgA1c been reduced by 0.5% for T2DM?
   a) Yes: approve for 6 months.
   b) No: deny as criteria not met.

Rationale:
To promote value within step therapy management and evidence-based standard of care. To ensure optimization of least costly formulary alternatives including metformin, other oral glucose lowering agents and basal insulin prior to initiating therapy with more costly SGLT-2 inhibitors. Adherence and dose optimization will be reviewed using prescription refill history for consideration of coverage for SGLT-2 inhibitors.

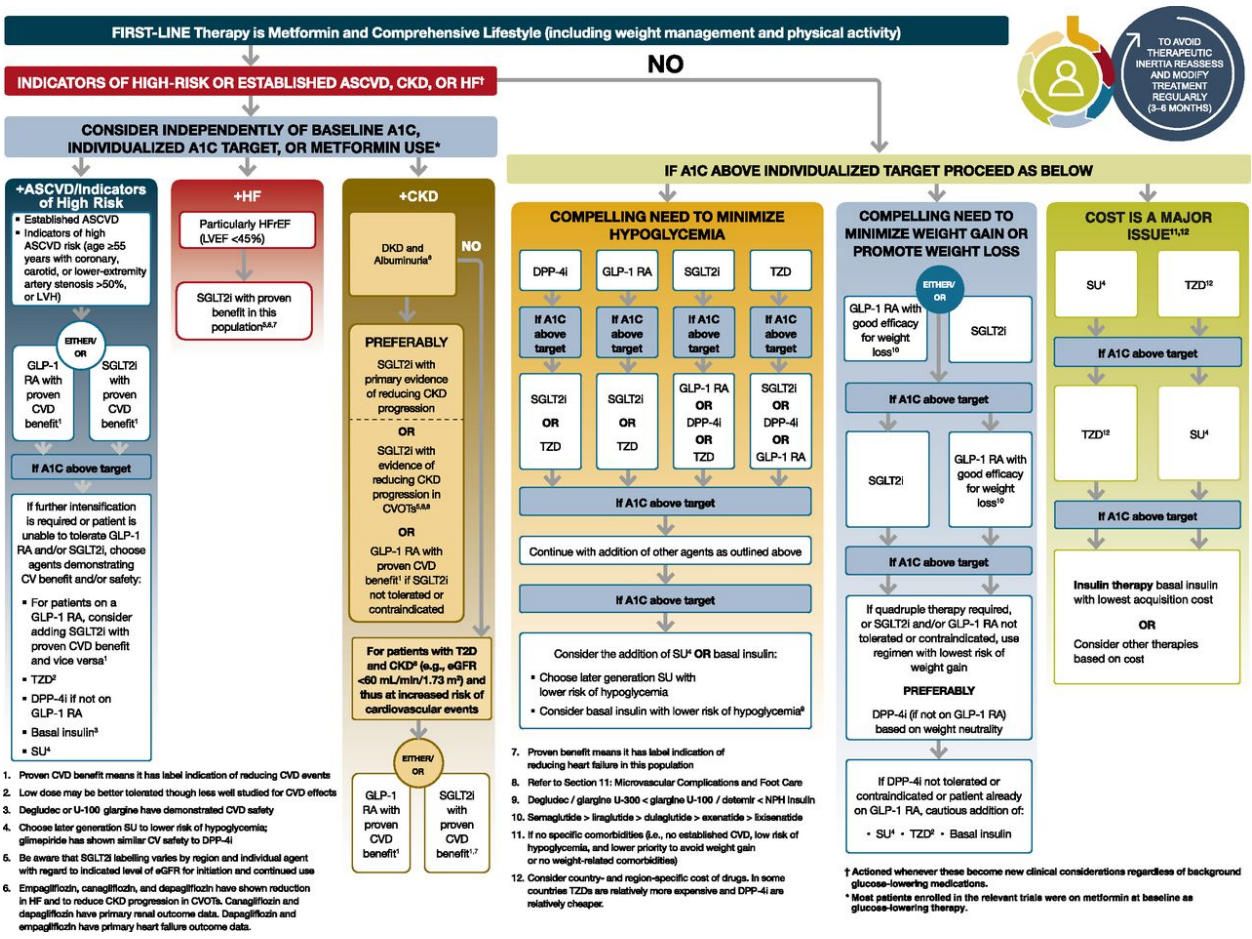
FDA Approved Indication:

As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus for all products. See Table 1 for medication specific indications.

References:

1. American Diabetes Association (ADA). Standards of Medical Care in Diabetes – 2021. Diabetes Care 2021 Jan; 44(Supplement 1): S111-S124.
2. Invokana Prescribing Information. Revised 8/2020.
3. Invokamet XR Prescribing Information. Revised 8/2020.
4. Invokamet Prescribing Information. Revised 8/2020.
5. Farxia Prescribing Information. Revised 4/2021.
6. XigduoXR Prescribing Information. Revised 1/2020.
7. Qtern Prescribing Information. Revised 1/2020.
8. Jardiance Prescribing Information. Revised 8/2021.
9. Glyxambi Prescribing Information. Revised 6/2021.
10. Synjardy XR Prescribing Information. Revised 6/2021.
11. Synjardy Prescribing Information. Revised 6/2021.

12. Steglatro Prescribing Information. Revised 9/2021.
13. Segluromet Prescribing Information. Revised 9/2021.
14. Steglujan Prescribing Information. Revised 9/2021.
15. Trijardy Prescrbing Information. Revised 6/2021.
16. UpToDate: Management of persistent hyperglycemia in type 2 diabetes mellitus. Last updated: January 18, 2022. Accessed January 27, 2022.



Glucose-lowering medication in type 2 diabetes: 2021 ADA Professional Practice Committee (PPC) adaptation of Davies et al. (35) and Buse et al. (36).