CRITERIA FOR INITIAL APPROVAL FOR ALL PRODUCTS: (must meet all of the following)

- Must be approved for the indication, age, and not exceed dosing limits listed in Table 1.
- For all agents listed, the preferred PDL drug, if applicable, which treats the PA indication, is required unless the patient meets the non-preferred PDL PA criteria.
- Patient must meet one of the following:
  - For glycemic control in patients with T2DM (must meet all of the following):
    - Prescriber must provide a prespecified HbA1c goal of one of the following: 6.5%, 7.0%, or 8.0%.\(^1\)
    - Patient must have a baseline HbA1c obtained in the past 6 months that is greater than the prespecified goal.
    - For HbA1c >10% or glucose level ≥300mg/dL, it is recommended (but not required) to initiate patients on an injectable therapy such as a GLP-1 RA or basal insulin.\(^1\)
  - Patient must meet one of the following:
    - History of clinical atherosclerotic cardiovascular disease (ASCVD) defined as having at least one of the following diagnoses:
      - Coronary heart disease
- For risk reduction in related comorbidities (SGLT2 inhibitors, GLP-1 receptor agonists, and SGLT2 or GLP-1 combination products with FDA indication for cardiovascular disease or chronic kidney disease (Table 1):
  - Patient must meet one of the following:\(^1\)
    - History of clinical atherosclerotic cardiovascular disease (ASCVD) defined as having at least one of the following diagnoses:
      - Coronary heart disease

BILLING CODE TYPE

For drug coverage and provider type information, see the KMAP Reference Codes webpage.

MANUAL GUIDELINES

Prior authorization will be required for all current and future dose forms available. All medication-specific criteria, including drug-specific indication, age, and dose for each agent is defined in Table 1 below.

- Canagliflozin (Invokana®)
- Canagliflozin/Metformin (Invokamet®, Invokamet® XR)
- Dulaglutide (Trulicity®)
- Dapagliflozin/Metformin (Xigduo XR®)
- Empagliflozin (Jardiance®)
- Empagliflozin/Metformin (Glyxambi®)
- Empagliflozin/Linagliptin (Qtern®)
- Empagliflozin/Metformin (Synjardy, Synjardy XR®)
- Ertugliiflozin (Steglatro®)
- Ertugliiflozin/Metformin (Segluromet®)
- Ertugliiflozin/Sitagliptin (Steglujan®)
- Exenatide (Bydureon®, Bydureon® BCise)
- Exenatide (Byetta®)
- Insulin Degludec/Liraglutide (Xultophy®)
- Insulin Glargine/Lixisenatide (Soliqua®)
- Liraglutide (Victoza®)
- Lixisenatide (Adlyxin®)
- Semaglutide Injection (Ozempic®)
- Semaglutide Oral (Rybelus®)
- Tirzepatide (Mounjaro®)
APPROVED PA Criteria

- Cerebrovascular disease (e.g. stroke, transient ischemic attack)
- Peripheral arterial disease
- Acute coronary syndromes (e.g. myocardial infarction, unstable angina)
- Arterial revascularization (e.g. coronary artery bypass graft)

- Diagnosis of chronic kidney disease
- Diagnosis of heart failure
- Indicators of high risk of developing ASCVD defined as:
  - Age ≥ 55 years with coronary, carotid or lower extremity artery stenosis > 50%
  - Left ventricular hypertrophy (LVH)
  - 10-year ASCVD risk ≥ 15%

LENGTH OF APPROVAL (INITIAL) FOR GLYCEMIC CONTROL: 6 months
LENGTH OF APPROVAL (INITIAL) TO REDUCE THE RISK OF CV EVENTS AND ESKD: Indefinite (no renewal required) 12 months

CRITERIA FOR RENEWAL FOR ALL PRODUCTS: (must meet one of the following)
- For glycemic control, documented improvement of HbA1c from pretreatment levels, defined by one of the following:
  - Reduction of HbA1c of at least 1% since the last approval.
  - Achievement or maintenance of therapeutic HbA1c goal as specified on the initial request.
- For risk reduction, no renewal is required.
- Patient must not exceed age and dosing limits listed in Table 1.

LENGTH OF APPROVAL FOR GLYCEMIC CONTROL (RENEWAL):
- 12 months if the patient is at HbA1c goal.
- 6 months if the patient is not at goal, but has at least a 1% further reduction in HbA1c since the last approval.

FOR DRUGS THAT HAVE A CURRENT PA REQUIREMENT, BUT NOT FOR THE NEWLY APPROVED INDICATIONS OR DOSAGES, FOR OTHER FDA-APPROVED INDICATIONS, AND FOR CHANGES TO AGE REQUIREMENTS NOT LISTED WITHIN THE PA CRITERIA:
- The PA request will be reviewed based upon the following package insert information: Indication, Age, Dose, and any pre-requisite treatment requirements for that indication.

LENGTH OF APPROVAL (INITIAL AND RENEWAL): 12 months

Table 1. FDA-approved indications, age and dosing limits for Type 2 Diabetes Mellitus (T2DM) Agents.3-24

<table>
<thead>
<tr>
<th>Agents</th>
<th>Indication(s)</th>
<th>Age</th>
<th>Dosing Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glucagon-Like Peptide-1 (GLP-1) Receptor Agonists</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dulaglutide (Trulicity®)</td>
<td>Adjunct to diet and exercise to improve glycemic control in T2DM (noninsulin dependent)</td>
<td>≥ 10 years</td>
<td>4.5 mg SQ weekly</td>
</tr>
<tr>
<td></td>
<td>Risk reduction of major cardiovascular (CV) events in adults with T2DM and established CV disease</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exenatide (Bydureon®, Bydureon® BCise)</td>
<td>Adjunct to diet and exercise to improve glycemic control in T2DM (noninsulin dependent)</td>
<td>≥ 10 years</td>
<td>2 mg SQ weekly</td>
</tr>
<tr>
<td>Exenatide (Byetta®)</td>
<td>Adjunct to diet and exercise to improve glycemic control in T2DM (noninsulin dependent)</td>
<td>≥ 18 years</td>
<td>10 mcg SQ twice daily</td>
</tr>
<tr>
<td>Liraglutide (Victoza®)</td>
<td>Adjunct to diet and exercise to improve glycemic control in T2DM (noninsulin dependent)</td>
<td>≥ 10 years</td>
<td>1.8 mg SQ once daily</td>
</tr>
<tr>
<td>PA Criteria</td>
<td>Risk reduction of major CV events in adults with T2DM and established CV disease</td>
<td>≥ 18 years</td>
<td>20 mcg SQ once daily</td>
</tr>
<tr>
<td>-------------</td>
<td>--------------------------------------------------------------------------------</td>
<td>------------</td>
<td>---------------------</td>
</tr>
<tr>
<td>Lixisenatide (Adlyxin®)</td>
<td>Adjunct to diet and exercise to improve glycemic control in T2DM (noninsulin dependent)</td>
<td>≥ 18 years</td>
<td>2 mg SQ once weekly</td>
</tr>
<tr>
<td>Semaglutide (Ozempic®)</td>
<td>Adjunct to diet and exercise to improve glycemic control in T2DM (noninsulin dependent)</td>
<td>≥ 18 years</td>
<td>14 mg orally once daily</td>
</tr>
<tr>
<td>Semaglutide (Rybelsus®)</td>
<td>Adjunct to diet and exercise to improve glycemic control in T2DM (noninsulin dependent)</td>
<td>≥ 18 years</td>
<td>15 mg SQ weekly</td>
</tr>
</tbody>
</table>

**Glucose-dependent insulinotropic polypeptide (GIP)/GLP-1 Receptor Agonist**

| Tirzepatide (Mounjaro®) | Adjunct to diet and exercise to improve glycemic control in T2DM (noninsulin dependent) | ≥ 18 years | 15 mg SQ weekly |

**Long-Acting Insulins/Glucagon-Like Peptide-1 (GLP-1) Receptor Agonists**

| Insulin Degludec/Liraglutide (Xultophy®) | Adjunct to diet and exercise to improve glycemic control in T2DM (noninsulin dependent) | ≥ 18 years | 50 units/1.8 mg SQ once daily |
| Insulin Glargine/Lixisenatide (Soliqua®) | Adjunct to diet and exercise to improve glycemic control in T2DM (noninsulin dependent) | ≥ 18 years | 60 units/20 mcg SQ once daily |

**Sodium-Glucose Cotransporter 2 (SGLT2) Inhibitors – Single Agents**

<p>| Canagliflozin (Invokana®) | Adjunct to diet and exercise to improve glycemic control in T2DM (noninsulin dependent) | ≥ 18 years | 300 mg orally once daily |
| Dapagliflozin (Farxiga®) | Adjunct to diet and exercise to improve glycemic control in T2DM (noninsulin dependent) | ≥ 18 years | 10 mg orally once daily |</p>
<table>
<thead>
<tr>
<th>Drug/Combination</th>
<th>Description</th>
<th>Age</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Empagliflozin (Jardiance®)</strong></td>
<td>Adjunct to diet and exercise to improve glycemic control in T2DM (noninsulin dependent)</td>
<td>≥ 18 years</td>
<td>25 mg orally once daily</td>
</tr>
<tr>
<td><strong>Empagliflozin/Linagliptin (Glyxambi®)</strong></td>
<td>Risk reduction of CV mortality in adults with T2DM and established CV disease</td>
<td>≥ 18 years</td>
<td>5 mg/25 mg orally once daily</td>
</tr>
<tr>
<td><strong>Empagliflozin/Linagliptin (Glyxambi®)</strong></td>
<td>To reduce the risk of CV death and hospitalization for heart failure in adults with heart failure</td>
<td>≥ 18 years</td>
<td>5 mg/25 mg orally once daily</td>
</tr>
<tr>
<td><strong>Ertugliflozin (Steglatro®)</strong></td>
<td>Adjunct to diet and exercise to improve glycemic control in T2DM</td>
<td>≥ 18 years</td>
<td>15 mg orally once daily</td>
</tr>
<tr>
<td><strong>Canagliflozin/Metformin (Invokamet®, Invokamet® XR)</strong></td>
<td>Adjunct to diet and exercise to improve glycemic control in T2DM (noninsulin dependent)</td>
<td>≥ 18 years</td>
<td>100 mg/2,000 mg orally once daily</td>
</tr>
<tr>
<td><strong>Canagliflozin/Metformin (Invokamet®, Invokamet® XR)</strong></td>
<td>Risk reduction of CV events in adults with T2DM and established CV disease</td>
<td>≥ 18 years</td>
<td>100 mg/2,000 mg orally once daily</td>
</tr>
<tr>
<td><strong>Canagliflozin/Metformin (Invokamet®, Invokamet® XR)</strong></td>
<td>Risk reduction of ESKD, doubling of serum creatinine, CV death, and hospitalization for heart failure in adults with T2DM and diabetic nephropathy with urinary albumin excretion &gt;300 mg/day</td>
<td>≥ 18 years</td>
<td>100 mg/2,000 mg orally once daily</td>
</tr>
<tr>
<td><strong>Dapagliflozin/Metformin (Xigduo XR®)</strong></td>
<td>Adjunct to diet and exercise to improve glycemic control in T2DM (noninsulin dependent)</td>
<td>≥ 18 years</td>
<td>10 mg/2,000 mg orally once per day</td>
</tr>
<tr>
<td><strong>Dapagliflozin/Metformin (Xigduo XR®)</strong></td>
<td>Risk reduction of hospitalization for heart failure in patients with T2DM and established CV disease or multiple CV risk factors or multiple CV risk factors</td>
<td>≥ 18 years</td>
<td>10 mg/2,000 mg orally once per day</td>
</tr>
<tr>
<td><strong>Dapagliflozin/Metformin (Xigduo XR®)</strong></td>
<td>Reduce the risk of CV death and hospitalization for heart failure in adults with heart failure with reduced ejection fraction (NYHA class II-IV) in those without T2DM</td>
<td>≥ 18 years</td>
<td>10 mg/2,000 mg orally once per day</td>
</tr>
<tr>
<td><strong>Dapagliflozin/Saxagliptin (Qtern®)</strong></td>
<td>Adjunct to diet and exercise to improve glycemic control in T2DM (noninsulin dependent)</td>
<td>≥ 18 years</td>
<td>5 mg/10 mg orally once daily</td>
</tr>
<tr>
<td><strong>Empagliflozin/Linagliptin (Glyxambi®)</strong></td>
<td>Adjunct to diet and exercise to improve glycemic control in T2DM (noninsulin dependent)</td>
<td>≥ 18 years</td>
<td>25 mg/5 mg orally once per day</td>
</tr>
</tbody>
</table>
Empagliflozin/Linagliptin/Metformin (Trijardy XR®)

Adjunct to diet and exercise to improve glycemic control in T2DM (noninsulin dependent)

- Risk reduction of CV mortality in adults with T2DM and established CV disease

≥ 18 years

25 mg/5 mg/2,000 mg orally per day

Empagliflozin/Metformin (Synjardy)

Adjunct to diet and exercise to improve glycemic control in T2DM (noninsulin dependent)

≥ 10 years

25 mg/2,000 mg orally per day

Empagliflozin/Metformin (Synjardy, Synjardy XR®)

Adjunct to diet and exercise to improve glycemic control in T2DM (noninsulin dependent)

- Risk reduction of CV mortality in adults with T2DM and established CV disease

To reduce the risk of CV mortality and hospitalization for heart failure in adults, with T2DM and heart failure

≥ 18 years

25 mg/2,000 mg orally per day

Ertugliflozin/Metformin (Segluromet®)

Adjunct to diet and exercise to improve glycemic control in T2DM (noninsulin dependent)

≥ 18 years

15 mg/2,000 mg orally per day

Ertugliflozin/Sitagliptin (Steglujan®)

Adjunct to diet and exercise to improve glycemic control in T2DM (noninsulin dependent)

≥ 18 years

15 mg/100 mg orally once per day

Notes:

- The early introduction of insulin should be considered if there is evidence of ongoing catabolism (weight loss), if symptoms of hyperglycemia are present, or when HbA1C levels (>10% [86 mmol/mol]) or blood glucose levels (≥300 mg/dL [16.7 mmol/L]) are very high.¹

- Qternmet® XR was FDA-approved in May 2019, but has not been marketed to date.

References:


3. Trulicity (dulaglutide) [prescribing information]. Indianapolis, IN: Eli Lilly and Company; December 2022.

4. Bydureon BCISE (exenatide) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals; December 2022.

5. Byetta (exenatide) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; December 2022.


13. Invokamet (canagliflozin/metformin), Invokamet® XR (canagliflozin and metformin hydrochloride extended-release tablets) [prescribing information]. Titusville, NJ: Janssen Pharmaceuticals Inc; October 2022.


15. Xigduo XR (dapagliflozin/metformin) [prescribing information]. Wilmington, DE: AstraZeneca; October 2022.

16. Qtern (dapagliflozin/saxagliptin) [prescribing information]. Wilmington, DE; AstraZeneca Pharmaceuticals; October 2022.

17. Jardiance (empagliflozin) [prescribing information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals Inc; October-June 2023.

18. Glyxambi (empagliflozin/linagliptin) [prescribing information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc; October 2022.
PA Criteria

19. Trijardy XR (empagliflozin, linagliptin, and metformin) [prescribing information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals Inc; October 2022.
20. Synjardy (empagliflozin/metformin) Synjardy XR (empagliflozin/metformin) [prescribing information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals Inc; February-June 2023.
23. Steglujan (ertugliflozin/sitagliptin) [prescribing information]. Whitehouse Station, NJ; Merck Sharp & Dohme Corp: October 2022.
24. Mounjaro (tirzepatide) [prescribing information]. Indianapolis, IN; Eli Lilly and Company: September 2022.