UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

<table>
<thead>
<tr>
<th>Program Number</th>
<th>2015 P 3018-6</th>
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</thead>
<tbody>
<tr>
<td>Program</td>
<td>Step Therapy – Diabetes Medications</td>
</tr>
<tr>
<td>Medication</td>
<td>Farxiga (dapagliflozin), Invokana (canagliflozin), Januvia (sitagliptin), Janumet(sitagliptin/metformin immediate-release), Janumet XR (sitagliptin/metformin extended-release), Jardiance (empagliflozin), Trulicity (dulaglutide), Xigduo XR (dapagliflozin/metformin extended-release)</td>
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<tr>
<td>Effective Date</td>
<td>7/1/2015; Oxford only: 7/1/2015</td>
</tr>
</tbody>
</table>

1. **Background:**

   Farxiga (dapagliflozin), Invokana (canagliflozin), Januvia (sitagliptin), Jardiance (empagliflozin), Tradjenta (linagliptin), Onglyza (saxagliptin) and Nesina (alogliptin) are indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

   Janumet (sitagliptin/metformin), Janumet XR (sitagliptin/metformin extended-release) are indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both sitagliptin and metformin/metformin extended-release is appropriate.

   Jentadueto (linagliptin/metformin) is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both linagliptin and metformin is appropriate.

   Kazano (alogliptin/metformin) is indicated as an adjunct to diet and exercise in patients to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both alogliptin and metformin is appropriate.

   Kombiglyze XR (saxagliptin/metformin extended-release) is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both saxagliptin and metformin is appropriate.

   Invokamet (canagliflozin/metformin), Xigduo XR (dapagliflozin/metformin extended-release) are sodium-glucose co-transporter 2 (SGLT2) inhibitors and biguanide combination medications indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus who are not adequately controlled on a regimen containing metformin or a SGLT-2 inhibitor or in patients already being treated with both a SGLT-2 inhibitor and metformin.

   Bydureon (exenatide extended-release), Byetta (exenatide), Tanzeum (albiglutide), Trulicity (dulaglutide), and Victoza (liraglutide) are glucagon-like peptide-1 (GLP-1) receptor agonists indicated as adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

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If a member has a prescription for metformin, a sulfonylurea, or a thiazolidinedione and has a prescription for Invokana or Jardiance in the claims history within the previous 12 months, the claim for Invokana, Farxiga or Jardiance will automatically process. Members currently on Invokana or Jardiance as documented in claims history will be allowed to continue on their current therapy. Members new to therapy will be required to meet the coverage criteria below.

2. **Coverage Criteria:**

<table>
<thead>
<tr>
<th><strong>A. Januvia</strong></th>
<th>will be approved based on the following criterion:</th>
</tr>
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<tbody>
<tr>
<td>1. History of a three month trial* resulting in a therapeutic failure, contraindication, or intolerance to <strong>all</strong> of the following (list reason for therapeutic failure, contraindication, or intolerance):</td>
<td></td>
</tr>
</tbody>
</table>
| a. Nesina (alogliptin)  
| b. Tradjenta (linagliptin)  
| c. Onglyza (saxagliptin) |
| **Authorization will be issued for 60 months.** |

<table>
<thead>
<tr>
<th><strong>B. Janumet and Janumet XR</strong></th>
<th>will be approved based on the following criterion:</th>
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<tbody>
<tr>
<td>1. History of a three month trial* resulting in a therapeutic failure, contraindication, or intolerance to <strong>all</strong> of the following (list reason for therapeutic failure, contraindication, or intolerance):</td>
<td></td>
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</tbody>
</table>
| a. Kazano (alogliptin/metformin immediate-release)  
| b. Jentadueto (linagliptin/metformin immediate-release)  
| c. Kombiglyze XR (saxagliptin/metformin extended-release) |
| **Authorization will be issued for 60 months.** |

<table>
<thead>
<tr>
<th><strong>C. Invokana and Jardiance</strong></th>
<th>will be approved based on <strong>one</strong> of the following criteria:</th>
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<tbody>
<tr>
<td>1. History of failure, contraindication or intolerance to <strong>one</strong> of the following:</td>
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</tbody>
</table>
| a. Metformin  
| b. Sulfonylurea (e.g. glimepiride)  
| c. Thiazolidinedione (e.g. pioglitazone) |
| **-OR-** |
| 2. **Both** of the following: |
| a. Currently on therapy with Invokana or Jardiance and is requesting continuation of the same therapy. |
AND-

b. **One** of the following:

   (1) Has **not** received a manufacturer supplied sample at no cost as a means to establish as a current user of Invokana or Jardiance.

-OR-

(2) **Both** of the following:

   i. Has received a manufacturer supplied sample at no cost as a means to establish as a current user of Invokana or Jardiance

-AND-

   ii. History of failure, contraindication, or intolerance to **one** of the following:

   - Metformin
   - Sulfonylurea (e.g. glimepiride)
   - Thiazolidinedione (e.g. rosiglitazone)

**Authorization will be issued for 60 months.**

**D. Farxiga** will be approved based on the following criteria:

1. History of a three month trial* resulting in therapeutic failure, contraindication or intolerance to **both** of the following:
   a. **One** of the following
      i. Metformin
      ii. Sulfonylurea (e.g. glimepiride)
      iii. Thiazolidinedione (e.g. pioglitazone)

      -AND-

   b. **Both** of the following
      i. Invokana (canagliflozin)
      ii. Jardiance (empagliflozin)

      **Authorization will be issued for 60 months.**

**E. Xigduo XR** will be approved based on the following criterion:

1. History of a three month trial* resulting in therapeutic failure, contraindication or
intolerance to Invokamet (canagliflozin/metformin)

Authorization will be issued for 60 months.

F. Trulicity will be approved based on the following criteria:

1. History of a three month trial* resulting in a therapeutic failure, contraindication, or intolerance to two of the following (list reason for therapeutic failure, contraindication, or intolerance):
   a. Bydureon (exenatide extended-release)
   b. Byetta (exenatide)
   c. Tanzeum (albiglutide)
   d. Victoza (liraglutide)

Authorization will be issued for 60 months.

* For Connecticut and Kentucky business, only a 30 day trial will be required.

3. Additional Clinical Rules:
   - Supply limits may be in place.

4. References:
20. American Diabetes Association; Executive Summary: Standards of Medical Care in Diabetes 2012, Diabetes Care 2012:35:S4-S10.

<table>
<thead>
<tr>
<th>Program</th>
<th>Step Therapy – Diabetes Medication</th>
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<tbody>
<tr>
<td><strong>Change Control</strong></td>
<td></td>
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<tr>
<td>Date</td>
<td>Change</td>
</tr>
<tr>
<td>12/2013</td>
<td>New program</td>
</tr>
<tr>
<td>4/2014</td>
<td>Added Farxiga to criteria.</td>
</tr>
<tr>
<td>8/2014</td>
<td>Criteria updated to require metformin, sulfonylurea or a thiazolidinedione plus Invokana prior to approving Farxiga. Grandfathering removed for Farxiga. Added DPP-4 step therapy and renamed to Diabetes step therapy program.</td>
</tr>
<tr>
<td>11/2014</td>
<td>Added Jardiance, Invokamet, Xigduo XR to criteria.</td>
</tr>
<tr>
<td>1/2015</td>
<td>Added GLP-1’s to criteria</td>
</tr>
<tr>
<td>4/2015</td>
<td>Modified to require Trulicity as the only step 2 agent</td>
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