1. Background:
Byetta (exenatide), Ozempic (semaglutide), Rybelsus (semaglutide), and Trulicity (dulaglutide), are indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Bydureon BCise (exenatide extended-release), and Victoza (liraglutide) are indicated as an adjunct to diet and exercise to improve glycemic control in patients 10 years of age and older with type 2 diabetes mellitus. Ozempic, Trulicity and Victoza are also indicated to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease.

Mounjaro (tirzepatide) is a glucose-dependent insulinotropic polypeptide (GIP) receptor and glucagon-like peptide-1 (GLP-1) receptor agonist indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Bydureon BCise, Byetta, Mounjaro, Ozempic, Rybelsus, Trulicity and Victoza are only indicated for the treatment of type 2 DM and are not FDA approved for the treatment of weight loss.

2. Coverage Criteria:\textsuperscript{a,b}:

A. Authorization

1. **Bydureon BCise, Byetta, Mounjaro, Ozempic, Rybelsus, Trulicity or Victoza** will be approved based on one the following criteria:

   a. Submission of medical records (e.g., chart notes) confirming diagnosis of type 2 diabetes mellitus as evidenced by **one** of the following laboratory values

      1) A1C greater than or equal to 6.5%
      2) Fasting plasma glucose (FPG) greater than or equal to 126 mg/dL
      3) 2-hour plasma glucose (PG) greater than or equal to 200 mg/dL during oral glucose tolerance test
      4) Random plasma glucose \(\geq 200\) mg/dL in patient with classic symptoms of hyperglycemia or hyperglycemic crisis

   -OR-
b. For patients requiring ongoing treatment for type 2 diabetes mellitus (i.e., diagnosed greater than 2 years ago), submission of medical records (e.g. chart notes) confirming diagnosis of type 2 diabetes mellitus

\[a\] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

\[b\] Bydureon BCise, Byetta, Mounjaro, Ozempic, Rybelsus, Trulicity, Victoza are not FDA approved for the treatment of weight loss. Medications used for the purposes of weight loss are typically excluded from benefit coverage. Coverage is determined by the member’s prescription drug benefit plan.

**Authorization will be issued for 12 months.**

3. **Additional Clinical Programs:**
   - Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
   - Supply limits may be in place.

4. **References:**

<table>
<thead>
<tr>
<th>Program</th>
<th>Change Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>10/2020</td>
<td>New program.</td>
</tr>
<tr>
<td>3/2021</td>
<td>Administrative change to adjust Oxford effective date.</td>
</tr>
<tr>
<td>11/2021</td>
<td>Annual review. Updated references.</td>
</tr>
<tr>
<td>9/2022</td>
<td>Updated criteria to define accepted laboratory testing methodologies per treatment guidelines for diagnosis of diabetes and use is not solely for weight loss. Updated references. Added state mandate footnote.</td>
</tr>
</tbody>
</table>

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| 4/2024 | Added additional laboratory value. Removed that step therapy may be in place. Updated references. |