**Prior Authorization Criteria**

**Glucagon-like Peptide-1 (GLP-1) receptor agonist**

**Policy Number: C5015-A**

<table>
<thead>
<tr>
<th>CRITERIA EFFECTIVE DATES:</th>
</tr>
</thead>
<tbody>
<tr>
<td>ORIGINAL EFFECTIVE DATE</td>
</tr>
<tr>
<td>4/1/2014</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>J CODE</th>
<th>TYPE OF CRITERIA</th>
<th>LAST P&amp;T APPROVAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>NA</td>
<td>RxPA</td>
<td>Q4 2019 20191030C5015-A</td>
</tr>
</tbody>
</table>

**PRODUCTS AFFECTED:**
Adlyxin (lixisenatide), Bydureon (exanatide), Byetta (exenatide), Ozempic (semaglutide), Tanzeum (albiglutide), Trulicity (dulaglutide), Victoza (liraglutide)

**DRUG CLASS:**
Incretin Mimetic Agents, (GLP-1 Receptor Agonists)

**ROUTE OF ADMINISTRATION:**
Subcutaneous

**PLACE OF SERVICE:**
Retail Pharmacy

**AVAILABLE DOSAGE FORMS:**
Bydureon BCSISE: 2mg in 0.85mL single dose auto injector
Bydureon: Single-dose 2mg vial or pen
Byetta: 250mcg/mL: 5mcg per dose, 60 doses, 1.2mL prefilled pen OR 10mcg per dose, 60 doses, 2.4mL prefilled pen
Ozempic: Pen, 2mg/1.5mL: 0.25mg or 0.5mg per injection OR 1mg per injection
Tanzeum: 30 mg or 50 mg in a single-dose Pen
Trulicity: 0.75mg/0.5mL OR 1.5mg/0.5mL solution in a single-dose pen
Victoza: 18gm/3ml 2 pen box or 3 pen box

**FDA-APPROVED USES:**
indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus in multiple clinical settings

**COMPENDIAL APPROVED OFF-LABEL USES:**

**COVERAGE CRITERIA: INITIAL AUTHORIZATION**

**DIAGNOSIS:** type 2 diabetes mellitus

**REQUIRED MEDICAL INFORMATION:**

A. **TYPE 2 DIABETES MELLITUS:**
1. Documentation of diagnosis of type 2 diabetes mellitus AND
2. Documentation member will be using the requested drug as an adjunct to diet and exercise to improve glycemic control with a diagnosis of Type 2 diabetes mellitus AND
3. (a) Documentation showing current hemoglobin A1c between 7% and 9% in the past 90 days. OR
   (b) If A1C is >9%, documentation that if patient was symptomatic, insulin use was
Prior Authorization Criteria

started prior to the addition of a GLP-1 agent. OR (c) Patient is currently using insulin and has not achieved adequate glycemic control (HbA1c > 7% after 3 continuous months of receiving maximal daily doses) despite current treatment

4. (a) Documentation of a trial, failure or intolerance to at least (i) metformin AND (ii) sulfonyurea OR TZD AND (iii) DPP4 OR SGLT2 OR
(b) Patient has a claims history OR Chart note documentation of a historical utilization to a DPP4, SGLT2 or GLP1 AND

5. Documentation showing adequate trial and failure or intolerance to preferred formulary GLP-1 agonist agent. (Failure is defined as not achieving expected A1C lowering while adherent to therapy.)

DURATION OF APPROVAL:
Initial Authorization: 6 months, Continuation of Therapy: 9 months

QUANTITY:
Bydureon, Tanzeum: 4 pens per 28 days, Byetta: 1 pen per month (30 days), Ozempic: 3 mL per 28 days, Trulicity: 2mL per 28 days, Victoza: 9mL per 30 days

PRESCRIBER REQUIREMENTS:
No requirements

AGE RESTRICTIONS:
18 years of age and older

GENDER:
Male and female

CONTINUATION OF THERAPY:
A. TYPE 2 DIABETES MELLITUS:
   1. Patient continues to meet initial criteria AND
   2. Documentation or refill history showing member compliance to therapy AND
   3. If on therapy at least 3 months, documentation showing hemoglobin A1c is <7.0% or has improved from baseline while compliant to therapy.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses are considered experimental/investigational and therefore, will follow Molina's Off-Label policy. For use in type 1 diabetes or diabetic ketoacidosis. Concurrent use with another GLP-1 agonist medicine. History of pancreatitis, severe renal impairment (creatinine clearance less than 30mL per minute), end stage renal disease, personal or family history of medullary thyroid carcinoma (MTC), Multiple Endocrine Neoplasia syndrome type 2 (MEN2)

OTHER SPECIAL CONSIDERATIONS:
If A1C is over 10%, insulin should be started. Response to maximized insulin therapy should be assessed before starting an addition agent such as GLP-1 agonist. Saxenda indicated for chronic weight management (weight loss) and is considered benefit exclusion under most plans.

BACKGROUND:
Molina Healthcare, Inc. confidential and proprietary © 2018
This document contains confidential and proprietary information of Molina Healthcare and cannot be reproduced, distributed or printed without written permission from Molina Healthcare. This page contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with Molina Healthcare.
Prior Authorization Criteria

The intent of the GLP-1 (glucagon-like peptide-1) Agonists criteria is to ensure appropriate selection of patients based on product labeling, and/or clinical guidelines, and/or clinical studies. Appropriate patients for exenatide or liraglutide therapy are those who are concurrently receiving or have tried metformin, a sulfonylurea, an oral combination product containing metformin or a sulfonylurea, or insulin.

The criteria and step edit allows continuation of therapy when patients have been receiving albiglutide, dulaglutide, exenatide or liraglutide. Patients without prerequisite agents in claims history or those who are unable to take a prerequisite agent due to documented intolerance, FDA labeled contraindication, or hypersensitivity will be reviewed when patient-specific documentation has been provided.

APPENDIX:

REFERENCES:

5. Pharmacologic Approaches to Glycemic Treatment: Standards of Medical Care in Diabetes (DiabetesCare 2018; 41: S73-S85).