

## Glucagon-like Peptide-1 (GLP-1) receptor agonist Policy Number: C5015-A

**CRITERIA EFFECTIVE DATES:**

ORIGINAL EFFECTIVE DATE	LAST REVIEWED DATE	NEXT REVIEW DATE
4/1/2014	10/30/2019	10/30/2020
J CODE	TYPE OF CRITERIA	LAST P&T APPROVAL
NA	RxPA	Q4 2019 20191030C5015-A

**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 1.5 mg/0.5 mL 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-LABELED 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

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:**

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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:**

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## **REFERENCES:**

1. Bydureon [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; 2018.
2. Bydureon BCise [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; 2018.
3. Byetta [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; 2015.
4. Ozempic [package insert]. Plainsboro, NJ: Novo Nordisk Inc; 2017.
5. Pharmacologic Approaches to Glycemic Treatment: Standards of Medical Care in Diabetes (DiabetesCare 2018; 41: S73-S85).
6. Saxenda [package insert]. Plainsboro, NJ: Novo Nordisk Inc; 2017.
7. Tanzeum [package insert]. Research Triangle Park, NC: GlaxoSmithKline LLC; 2017.
8. Trulicity [package insert]. Indianapolis, IN; Eli Lilly and Company; 2018.