MASSACHUSETTS

Blue Cross Blue Shield of Massachusetts is an Independent Licensee of the Blue Cross and Blue Shield Association

Pharmacy Medical Policy

Glucagon-like Peptide-1 (GLP-1) Receptor Agonists and Related Drugs for the Treatment of Type 2 Diabetes

Table of Contents

Policy Number: 056

BCBSA Reference Number: N/A

Related Policies

- Drugs for Weight Loss Medical Policy #572
- Quality Care Dosing guidelines may apply and can be found in Medical Policy #621B

Prior Authorization Information

Policy	☒ Prior Authorization ☐ Step Therapy ☒ Quantity Limit ☐ Administrative	Reviewing Department	**Pharmacy Operations:** Tel: 1-800-366-7778 Fax: 1-800-583-6289
		Policy Effective Date	**1/2025**
Pharmacy (Rx) or Medical (MED) benefit coverage	☒ Rx ☐ MED	**To request for coverage:** Providers may call, fax, or mail the attached form (Formulary Exception/Prior Authorization form) to the address below. **Blue Cross Blue Shield of Massachusetts** **Pharmacy Operations Department** 25 Technology Place Hingham, MA 02043 Tel: 1-800-366-7778 Fax: 1-800-583-6289 **Individual Consideration for the atypical patient:** Policy for requests that do not meet clinical criteria of this policy, see section labeled Individual Consideration	
Policy applies to Commercial Members: • Managed Care (HMO and POS), • PPO and Indemnity • MEDEX with Rx plan • Managed Major Medical with Custom BCBSMA Formulary • Comprehensive Managed Major Medical with Custom BCBSMA Formulary • Managed Blue for Seniors with Custom BCBSMA Formulary **Policy does NOT apply to**: • Medicare Advantage			

Summary

This policy applies to members utilizing the below GLP-1 or GIP/GLP-1 receptor agonist medications for the treatment of type 2 diabetes mellitus. Coverage of medications listed below that are FDA-approved for non-diabetic indications can be found in the related medical policy listed above.

Drug	Formulary Status (BCBSMA Commercial Plan)	Step Requirement
Preferred		
Liraglutide AG	PA, QCD	See below for PA criteria.
Mounjaro™ (tirzepatide)	PA, QCD	
Ozempic ® (subcutaneous injection)	PA, QCD	
Rybelsus ® (semaglutide oral)	PA, QCD	
Trulicity ® (dulaglutide)	PA, QCD	
Non-Preferred		
Adlyxin ™ (lixisenatide)	NFNC, PA, QCD	See below for PA criteria.
Bydureon ™ (exenatide)	NFNC, PA, QCD	
Byetta ® (exenatide)	NFNC, PA, QCD	
Soliqua ™ (insulin glargine / lixisenatide)	NFNC, PA, QCD	
Victoza ® (liraglutide)	NFNC, PA, QCD	
Xultophy ® (insulin degludec / liraglutide)	NFNC, PA, QCD	

QCD - Quality Care Dosing (quantity limits policy #621B); NFNC – Non-formulary-Not Covered

Policy

Length of Approval	12 months
Formulary Status	For non-covered medications, in addition to the prior authorization criteria, the member **must** also have had a previous treatment failure with, or contraindication to, **at least two** covered formulary alternatives when available. See section on individual consideration for more information if you require an exception to any of these criteria requirements for an atypical patient.
Criteria Documentation	Provider **must** submit supporting documentation (e.g., chart notes, lab results or other clinical information) to show that member has met all approval criteria
Member cost share consideration	A higher non-preferred cost share may be applied if an exception request is approved for coverage of a non-preferred or a non-formulary/non-covered drug.

Mounjaro, Ozempic, Rybelsus, Trulicity, and Liraglutide

Requests for a covered GLP-1 or GLP-1/GIP receptor agonist for the treatment of type 2 diabetes mellitus may be considered **MEDICALLY NECESSARY** when **ALL** of the following criteria are met:

1. Member meets one of the following:
   a. Age 10 years or older for Trulicity, and Liraglutide, **OR**
   b. Age 18 years or older for Ozempic, Rybelsus or Mounjaro,

   AND

2. Requested drug is not being prescribed for concurrent use with another GLP-1 or GLP-1/GIP receptor agonist,

   AND

3. Has an ICD 10 or documented diagnosis of Type 2 Diabetes Mellitus confirmed by any one of the following:
   a. HbA1C > 6.5%, **OR**
   b. Fasting plasma glucose (FPG) ≥ 126 mg/dL post 8-hour fast, **OR**
   c. 2-hour plasma glucose ≥200 mg/dL during a 75-g oral glucose tolerance test (OGTT), **OR**

d. Random plasma glucose ≥ 200 mg/dL with presence of classic symptoms of hyperglycemia (polyuria, polydipsia, polyphagia), **OR**
e. Documented ICD-10 code for Type 2 Diabetes.

AND

4. Meets ONE of the following%% verified by claim or documented clinical history:
   a. History of antidiabetic medication use such as Insulin, sulfonylureas, metformin, SGLT-2 inhibitor (flozins), DPP-IV inhibitor (gliptins) or other, **OR**
   b. History of intolerance, contraindication, clinically significant adverse effects, or inadequate response to metformin, **OR**
   c. ICD 10 diagnosis code or documentation of Chronic Kidney Disease (CKD) **OR** established atherosclerotic cardiovascular disease†† (ASCVD) **OR** at least two risk factors for ASCVD** if the request is for Trulicity.
   d. ICD 10 diagnosis code or documentation of established atherosclerotic cardiovascular disease†† (ASCVD) if the request is for Ozempic or Liraglutide.

%% - per the American Diabetes Association (ADA) and American Association of Clinical Endocrinologists and American College of Endocrinology (AACE/ACE) guidelines

†† - ASCVD: Coronary Heart Disease (myocardial infarction, angina, coronary artery disease); Cerebrovascular Disease, (e.g., transient ischemic attack, ischemic stroke); Peripheral Artery Disease; Aortic Atherosclerotic Disease

*** - ASCVD risk factors: Dyslipidemia, Hypertension, Current tobacco use, Obesity/Overweight*

Adlyxin, Bydureon, Byetta, Soliqua, Victoza, and Xultophy

Requests for a covered GLP-1 or GLP-1/GIP receptor agonist may be may be considered **MEDICALLY NECESSARY** when **ALL** of the following criteria are met:

1. Member meets one of the following:
   a. Age 10 years or older for Bydureon, and Victoza**, OR**
   b. Age 18 years or older for Adlyxin, Byetta, Soliqua, and Xultophy,

AND

2. Requested drug is not being prescribed for concurrent use with another GLP-1 or GLP-1/GIP receptor agonist,

AND

3. Has an ICD 10 or documented diagnosis of Type 2 Diabetes Mellitus confirmed by any one of the following:
   a. HbA1C > 6.5%, **OR**
   b. Fasting plasma glucose (FPG) ≥ 126 mg/dL post 8-hour fast, **OR**
   c. 2-hour plasma glucose ≥200 mg/dL during a 75-g oral glucose tolerance test (OGTT), **OR**
   d. Random plasma glucose ≥ 200 mg/dL with presence of classic symptoms of hyperglycemia (polyuria, polydipsia, polyphagia), **OR**
   e. Documented ICD-10 code for Type 2 Diabetes.

AND

4. Meets ONE of the following%% verified by claim or clinical history:
   a. History of antidiabetic medication use such as Insulin, sulfonylureas, metformin, SGLT-2 inhibitor (flozins), DPP-IV inhibitor (gliptins) or other, **OR**
   b. History of intolerance, contraindication, clinically significant adverse effects, or inadequate response to metformin
   c. ICD 10 diagnosis code or documentation of established atherosclerotic cardiovascular disease†† (ASCVD) if the request is for Victoza.

AND

5. Documented trial or inadequate response, intolerance, or contraindication to at least TWO (2) covered GLP-1/GLP-1-related formulary alternatives (see formulary drug table above).

%% - per the American Diabetes Association (ADA) and American Association of Clinical Endocrinologists and American College of Endocrinology (AACE/ACE) guidelines

†† - ASCVD: Coronary Heart Disease (myocardial infarction, angina, coronary artery disease); Cerebrovascular Disease, (e.g., transient ischemic attack, ischemic stroke); Peripheral Artery Disease; Aortic Atherosclerotic Disease.

*** - ASCVD risk factors: Dyslipidemia, Hypertension, Current tobacco use, Obesity/Overweight*

Provider Documentation Requirements

Documentation from the provider to support a reason preventing trial of formulary alternative(s) must include the name and strength of alternatives tried and failed (if alternatives were tried, including dates if available) and specifics regarding the treatment failure. Documentation to support clinical basis preventing switch to formulary alternative should also provide specifics around clinical reason.

Prior Use Criteria

The plan uses prescription claim records to support criteria for prior use within previous 130 days or the trial and failure of formulary alternatives when available. Additional documentation will be required from the provider when historic prescription claim data is either not available or the medication fill history fails to establish criteria for prior use or trial and failure of formulary alternatives. Documentation will also be required to support any clinical reasons preventing the trial and failure of formulary alternatives. Please see the section on documentation requirements for more information.

Individual Consideration (For Atypical Patients)

Our medical policies are written for most people with a given condition. Each policy is based on peer reviewed clinical evidence. We also take into consideration the needs of atypical patient populations and diagnoses.

If the coverage criteria outlined is unlikely to be clinically effective for the prescribed purpose, the health care provider may request an exception to cover the requested medication based on an individual's unique clinical circumstances. This is also referred to as "individual consideration" or an "exception request."

Some reasons why you may need us to make an exception include: therapeutic contraindications; history of adverse effects; expected to be ineffective or likely to cause harm (physical, mental, or adverse reaction).

To facilitate a thorough and prompt review of an exception request, we encourage the provider to include additional supporting clinical documentation with their request. This may include:

- Clinical notes or supporting clinical statements.
- The name and strength of formulary alternatives tried and failed (if alternatives were tried) and specifics regarding the treatment failure, if applicable.
- Clinical literature from reputable peer reviewed journals.
- References from nationally recognized and approved drug compendia such as American Hospital Formulary Service® Drug Information (AHFS-DI), Lexi-Drug, Clinical Pharmacology, Micromedex or Drugdex®; and
- References from consensus documents and/or nationally sanctioned guidelines.

Providers may call, fax or mail relevant clinical information, including clinical references for individual patient consideration, to:

Blue Cross Blue Shield of Massachusetts
Pharmacy Operations Department
25 Technology Place
Hingham, MA 02043
Phone: 1-800-366-7778
Fax: 1-800-583-6289

We may also use prescription claims records to establish prior use of metformin. We will require the provider to share additional information when prescription claims data is either not available or the medication fill history fails to establish use of other.

Policy History

Date	Action
1/2025	Updated to move Victoza to Non-Formulary, Non-Covered (NFNC) and move liraglutide (Authorized Generic of Victoza) to Preferred brand.
10/2024	Updated to add the Authorized Generic Liraglutide to the policy as NFNC.
7/2024	New PA policy created for GLP-1 and GIP/GLP-1 receptor agonists

Forms

To request prior authorization using the Massachusetts Standard Form for Medication Prior Authorization Requests (eForm), click the link below:

https://www.bluecrossma.org/medical-policies/sites/g/files/csphws2091/files/acquiadam-assets/023%20E%20Form%20medication%20prior%20auth%20instruction%20prn.pdf

OR

Print and fax, Massachusetts Standard Form for Medication Prior Authorization Requests #434

References

1. American Diabetes Association. Standards of medical care in diabetes – 2022. *Diabetes Care*. 2022;45(Suppl. 1):S1-S264.
2. Byetta® injection [package insert]. San Diego, CA: Amylin Pharmaceuticals, Inc.; October 2009.
3. Victoza® injection [package insert]. Princeton, NJ: NovoNordisk; January 2010.
4. Garber A, Henry R, Ratner R, et al; for the LEAD-3 (Mono) study group. Liraglutide versus glimeperide monotherapy for type 2 diabetes (LEAD-3 mono): a randomized, 52-week, phase III, double-blind, parallel-treatment trial. *Lancet*. 2009;373:473-481.
5. Nauck M, Frid A, Hermansen K, et al; for the LEAD-2 study group. Efficacy and safety comparison of liraglutide, glimeperide, and placebo, all in combination with metformin, in type 2 diabetes. *Diabetes Care*. 2009;32:84-90
6. Buse JB, Rosenstock J, Sesti G, et al; for the LEAD-6 study group. Liraglutide once a day versus exenatide twice a day for type 2 diabetes: a 26-week randomized, parallel-group, multinational, open-label trial (LEAD-6). *Lancet*. 2009;374:39-47.
7. Rodbard HW, Davidson JA, Garber AJ, et al. Statement by an American Association of Clinical Endocrinologists/American College of Endocrinology Consensus Panel of Type 2 Diabetes Mellitus: an algorithm for glycemic control. *Endocr Pract.* 2009;15(6):540-559
8. Trulicity™ [package insert]. Indianapolis, IN: Eli Lily and Company; 3/2015
9. Xultophy® injection [package insert]. Princeton, NJ: NovoNordisk; Nov 2016
10. Rybelsus® [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; Sept 2019.
11. Mounjaro™ [package insert]. Indianapolis, IN: Eli Lily and Company; 5/2022