MASSACHUSETTS

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Pharmacy Medical Policy
Diabetes Step Therapy

Table of Contents

Policy Number: 041

BCBSA Reference Number: N/A

Related Policies

- Quality Care Dosing guidelines may apply and can be found in Medical Policy #**621B**
- Heart Failure and Hypertrophic Cardiomyopathy Medical Policy #**063**
- Drugs for Weight Loss Medical Policy #**572**

Prior Authorization Information

Policy	☐ Prior Authorization ☒ Step Therapy ☒ Quantity Limit	Reviewing Department	**Pharmacy Operations:** Tel: 1-800-366-7778 Fax: 1-800-583-6289
		Policy Effective Date	**5/2024**
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 is a comprehensive policy covering step therapy and quantity limit requirements for oral anti-diabetic medications.

This step therapy policy applies to members utilizing the below medications for the treatment of diabetes. Coverage of medications listed below that are FDA-approved for non-diabetic indications can be found in the related medical policies listed above.

Policy

Length of Approval	24 months
Formulary Status	All requests must meet the Step Therapy requirement and for non-covered medications, 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.
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.

Traditional Anti-diabetic Medications

Coverage for traditional anti-diabetic medications may be may be considered **MEDICALLY NECESSARY** when **ALL** of the following criteria are met:

1. Documented diagnosis of Type 2 Diabetes Mellitus, **AND**
2. Meet the step therapy requirements described below.

Drug	Formulary Status (BCBSMA Commercial Plan)	Step Requirement
Step 1		
Generics in Alpha-Glucosidase Inhibitor class (e.g., acarbose)	Covered	Covered with no requirements
Generics in Biguanide class (e.g., metformin); Excluding ER generics of Fortamet & Glumetza	Covered	
Generics in Diabetic Combination (e.g., glyburide-metformin); Excluding Pioglitazone combinations) Medications class	Covered	
Generics in D-Phenylalanine class (e.g., Nateglinide)	Covered	
Generics in Meglitinide class (e.g., Repaglinide)	Covered	
Generics in Sulfonylurea class (e.g., glyburide)	Covered	
Formulary Injectable Insulin (e.g., Humulin, Humalog)	Covered, QCD	
Step 2		
Actos ® (pioglitazone)	ST, QCD	Requires prior use of ONE step 1 medication OR history of prior use of any step 2 medication in this table within the previous 130 days. See below for prior use criteria.
Afrezza ® (Insulin)	ST	
Avandia ® (rosiglitazone)	ST, QCD	
Kerendia ® (finerenone)	ST, QCD	
pioglitazone	ST, QCD	
pioglitazone & glimepiride	ST	
pioglitazone & metformin	ST, QCD	
Riomet ER ™ (metformin Solution)	ST	

Step 3		
Actoplus Met ® (pioglitazone / metformin)	NFNC, QCD	Requires prior use of TWO step 2 medications OR history of prior use of a step 3 medication in this table within the previous 130 days. See below for prior use criteria.
Duetact ® (pioglitazone and glimepiride)	ST	
Fortamet ® (metformin)	NFNC	
Glumetza ® (metformin)	NFNC	
Glynase ® (glyburide)	ST	
metformin hydrochloride ER (Generic of Glumetza ®)	NFNC	
metformin hydrochloride 625mg	NFNC	
metformin hydrochloride Film-Coated ER (Generic of Fortamet ®)	NFNC	
Riomet ® (metformin solution)	ST	

QCD - Quality Care Dosing (quantity limits policy #621B); ST – Step Therapy, NFNC – Non-Formulary Non-Covered

Dipeptidyl Peptidase-4 (DPP-4) Inhibitors

Coverage of DPP-4 inhibitors may be may be considered **MEDICALLY NECESSARY** when **ALL** of the following criteria are met:

1. Documented diagnosis of Type 2 Diabetes Mellitus, **AND**
2. Meet the step therapy requirements described below.

Drug	Formulary Status (BCBSMA Commercial Plan)	Step Requirement
Step 1		
Generics in Alpha-Glucosidase Inhibitor class (e.g., acarbose)	Covered	Covered with no requirements
Generics in Biguanide class (e.g., metformin); Excluding ER generics of Fortamet & Glumetza	Covered	
Generics in Diabetic Combination (e.g., glyburide-metformin); Excluding Pioglitazone combinations) Medications class	Covered	
Generics in D-Phenylalanine class (e.g., Nateglinide)	Covered	
Generics in Meglitinide class (e.g., Repaglinide)	Covered	
Generics in Sulfonylurea class (e.g., glyburide)	Covered	
Formulary Injectable Insulin (e.g., Humulin, Humalog)	Covered, QCD	
Step 2		
Glyxambi ® (empagliflozin / linagliptin)	ST, QCD	Requires prior use of ONE step 1 medication OR history of prior use of any step 2 medication in this table within the previous 130 days. See below for prior use criteria.
Janumet ™ (sitagliptin / metformin)	ST	
Janumet ™ XR (sitagliptin / metformin)	ST	
Januvia ™ (sitagliptin)	ST	
saxagliptin	ST	

saxagliptin/metformin	ST	
Trijardy XR ™ (empagliflozin / linagliptin & metformin)	ST, QCD	
Step 3		
Alogliptin	NFNC	Requires prior use of TWO step 2 medications OR history of prior use of a step 3 medication in this table within the previous 130 days. See below for prior use criteria.
Alogliptin & Metformin	NFNC	
Alogliptin & Pioglitazone	NFNC	
Jentadueto ™/ XR (linagliptin / metformin)	NFNC	
Kazano ™ (alogliptin / metformin)	NFNC	
Kombiglyze ™ XR (saxagliptin / metformin)	NFNC	
Nesina ™ (alogliptin)	NFNC	
Onglyza ™ (saxagliptin)	NFNC	
Oseni ™ (alogliptin / pioglitazone)	NFNC	
Qtern ® (dapagliflozin / saxagliptin)	NFNC, QCD	
Steglujan ™ (ertugliflozin and sitagliptin)	NFNC, QCD	
Tradjenta ™ (Linagliptin)	NFNC	
Zituvio ® (sitagliptin)	NFNC	

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Sodium-Glucose Cotransporter-2 (SGLT2) Inhibitors

Coverage of SGLT2 inhibitors may be may be considered **MEDICALLY NECESSARY** when **ALL** of the following criteria are met:

1. Documented diagnosis of Type 2 Diabetes Mellitus, **AND**
2. Meet the step therapy requirements described below.

Drug	Formulary Status (BCBSMA Commercial Plan)	Step Requirement
Step 1		
Generics in Alpha-Glucosidase Inhibitor class (e.g., acarbose)	Covered	Covered with no requirements.
Generics in Biguanide class (e.g., metformin); Excluding ER generics of Fortamet & Glumetza	Covered	
Generics in Diabetic Combination (e.g., glyburide-metformin); Excluding Pioglitazone combinations) Medications class	Covered	
Generics in D-Phenylalanine class (e.g., Nateglinide)	Covered	
Generics in Meglitinide class (e.g., Repaglinide)	Covered	
Generics in Sulfonylurea class (e.g., glyburide)	Covered	
Formulary Injectable Insulin (e.g., Humulin, Humalog)	Covered, QCD	

Step 2		
Farxiga ® (dapagliflozin)	ST, QCD	Requires prior use of ONE step 1 medication OR history of prior use of any step 2 medication in this table within the previous 130 days. See below for prior use criteria.
Glyxambi ® (empagliflozin / linagliptin)	ST, QCD	
Jardiance ® (empagliflozin)	ST, QCD	
Synjardy ® (empagliflozin / metformin)	ST, QCD	
Synjardy ® XR (empagliflozin / metformin)	ST, QCD	
Trijardy XR ™ (empagliflozin / linagliptin & metformin)	ST, QCD	
Xigduo ™ XR (dapagliflozin / metformin)	ST, QCD	
Step 3		
Brenzavvy ™ (bexagliflozin)	NFNC, QCD	Requires prior use of TWO step 2 medications OR history of prior use of a step 3 medication in this table within the previous 130 days. See below for prior use criteria.
dapagliflozin	NFNC, QCD	
dapagliflozin /metformin	NFNC, QCD	
Invokamet ™/ XR (canagliflozin / metformin)	NFNC, QCD	
Invokana ™ (canagliflozin)	NFNC, QCD	
Qtern ® (dapagliflozin / saxagliptin)	NFNC, QCD	
Steglatro ™ (ertugliflozin)	NFNC, QCD	
Steglujan ™ (ertugliflozin and sitagliptin)	NFNC, QCD	
Segluromet ™ (ertugliflozin and metformin)	NFNC, QCD	

QCD - Quality Care Dosing (quantity limits policy #621B); ST – Step Therapy, NFNC – Non-Formulary Non-Covered

Glucagon-like Peptide-1 (GLP-1) Agonists & Glucose-dependent Insulinotropic Polypeptide (GIP)

Coverage of GLP-1 / GIP inhibitors may be may be considered **MEDICALLY NECESSARY** when **ALL** of the following criteria are met:

1. Documented diagnosis of Type 2 Diabetes Mellitus, **AND**
2. Meet the step therapy requirements described below.

Drug	Formulary Status (BCBSMA Commercial Plan)	Step Requirement
Step 1		
Generics in Alpha-Glucosidase Inhibitor class (e.g., acarbose)	Covered	Covered with no requirements.

Generics in Biguanide class (e.g., metformin); Excluding ER generics of Fortamet & Glumetza	Covered	
Step 1 Continued		
Generics in Diabetic Combination (e.g., glyburide-metformin); Excluding Pioglitazone combinations) Medications class	Covered	Covered with no requirements.
Generics in D-Phenylalanine class (e.g., Nateglinide)	Covered	
Generics in Meglitinide class (e.g., Repaglinide)	Covered	
Generics in Sulfonylurea class (e.g., glyburide)	Covered	
Formulary Injectable Insulin (e.g., Humulin, Humalog)	Covered, QCD	
Step 2		
Mounjaro™ (tirzepatide)*****	ST, QCD	Requires prior use of ONE step 1 medication OR history of prior use of any step 2 medication in this table within the previous 130 days. See below for prior use criteria.
Ozempic ® (semaglutide for subcutaneous injection)	ST, QCD	
Rybelsus ® (semaglutide oral)	ST, QCD	
Trulicity ® (dulaglutide)	ST, QCD	
Victoza ® (liraglutide)	ST, QCD	
Step 3		
Adlyxin ™ (lixisenatide)	NFNC, QCD	Requires prior use of TWO step 2 medications OR history of prior use of a step 3 medication in this table within the previous 130 days. See below for prior use criteria.
Bydureon ™ (exenatide)	NFNC, QCD	
Byetta ® (exenatide)	NFNC, QCD	
Soliqua ™ (insulin glargine and lixisenatide)	NFNC, QCD	
Xultophy ® (insulin degludec / liraglutide)	NFNC, QCD	

QCD - Quality Care Dosing (quantity limits policy #621B); ST – Step Therapy, NFNC – Non-Formulary Non-Covered
**** - This medication requires specifically a trial with Metformin.***

Prior Use of 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.

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.

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 formulary alternatives or to show if step therapy criteria has been met. 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 preferred formulary medications or that step therapy criteria has been met.

Policy History

Date	Action
5/2024	Clarified coding for Glynase ® and Duetact ®.
3/2024	Updated to add Zituvio ® (sitagliptin) to Step 3 in the DPP-4 table and added AG of Farxiga and Xigduo to Step 3 of the SGLT2 table.

1/2024	Updated to add saxagliptin/metformin to Step 2 in the DPP-4 table
10/2023	Updated to add saxagliptin to Step 2 in the DPP-4 table and Brenzavvy ™ to step 3 in the SGLT2 table.
9/2023	Reformatted policy. Updated IC section to align with 118E MGL § 51A.
7/2023	Reformatted Policy.
1/2023	Updated to add Ozempic ®, Rybelsus ® and Victoza ® to preferred and to move Onglyza Kombiglyze ®, Byetta ®, and Bydureon ™ to non-covered.
8/2022	Updated to add Mounjaro to Step 2 of the GLP table and Metformin 625mg to the Step 3 Traditional table in the policy.
4/2022	Updated to clarify Actoplus Met® coding as non-preferred.
1/2022	Updated to add Trijardy XR™ to Step two in SGLT2 & DPP4 tables
10/2021	Updated to include Kerendia ® as step 2 drug and also added an ASCVD automation to Jardiance ® and Farxiga ®.
4/2021	Updated to remove Avandamet as FDA discontinued marketing.
10/2020	Updated to make Farxiga® & Xigduo™ XR step 2 and to move Invokana™ & Invokamet™/XR to step 3.
6/2020	Updated to include Trijardy™ XR to the policy.
2/2020	Updated to add Rybelsus® to Step 3
1/2020	Updated Step 3 criteria to require two step 2 medications prior to an approval.
9/2019	Updated to revise Step Criteria.
1/2019	Updated to add Glyxambi® to Step 2 and to make Victoza® Not Covered.
5/2018	Updated to Include Ozempic, Steglatro, Steglujan, and Segluromet.
1/2018	Updated to include Class specific tables inside of the policy plus merged in policy #282 GLP1s.
4/2017	Added Alogliptin and Alogliptin/Metformin Authorized generics to Step 3.
1/2017	Added Synjardy to Step 2.
3/2016	Added metformin hydrochloride ER to step 3 & added Standard PA form.
12/2015	Updated to include Glyxambi®
8/2015	Updated to add Afrezza® to step2.
1/2015	Updated to include Xigduo™XR on Step 3.
11/2014	Updated to include Jardiance® as step 2.
8/2014	Update Step 1 for Pioglitazone combinations exception.
6/2014	Updated to include Farxiga on Step 3.
3/2014	Updated policy to add Step 1 classes section and Step 3 drugs section and added standard step language.
1/2014	Pioglitazone/glimepiride, Nesina™, Oseni™, Kazano™, Invokana™ to step 2. Updated ExpressPAth language.
8/2012	Updated 8/12 to include coverage criteria for pioglitazone/metformin, pioglitazone, Janumet™ XR and Jentadueto™.
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
7/2011	Updated to include coverage criteria for new FDA approved medication Tradjenta™.
5/2011	Reviewed - Medical Policy Group - Pediatrics and Endocrinology. No changes to policy statements.
3/2011	Updated to include coverage criteria for new FDA approved medication Kombiglyze™ XR.
112010	Updated to include coverage criteria for new FDA approved product Actoplus Met® XR.
3/2010	Updated to include coverage criteria for new FDA approved product Onglyza™.
2/2010	Reviewed - Medical Policy Group - Psychiatry and Ophthalmology. No changes to policy statements.
1/2010	Policy updated to include coverage criteria for Thiazolidinediones to include: Actoplus Met, Actos. Avandamet, Avandaryl, Avandia, Duetact.
9/2009	Policy updated to change 180 day look back period to 130 days, add sample language and to remove Medicare Part D criteria from Medical Policy.

2/2009	Reviewed - Medical Policy Group - Psychiatry and Ophthalmology. No changes to policy statements.
3/2008	Updated to include Janumet™ as part of step therapy policy for all formularies.
1/1/2008	New policy, effective 1/1/2008, describing covered and non-covered indications.

Forms

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

Massachusetts Standard Form for Medication Prior Authorization Requests #434

References

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37. Steglatro ™ [package insert]. Whitehouse Station, NJ: Merck &Co., Inc. Dec 2017
38. Steglujan ™ [package insert]. Whitehouse Station, NJ: Merck &Co., Inc. Feb 2018
39. Segluromet ™ [package insert]. Whitehouse Station, NJ: Merck &Co., Inc. Dec 2017
40. Rybelsus ® [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; Sept 2019.
41. Kerendia ® [package insert]. Leverkusen, Germany: Bayer AG.; July 2021.
42. Mounjaro ™ [package insert]. Indianapolis, IN: Eli Lily and Company; 5/2022
43. Zituvio ® [package insert]. Ahmedabad, India: Zydus Lifesciences Ltd.; November 2023.

To request prior authorization using the Massachusetts Standard Form for Medication Prior Authorization Requests (eForm), click the link below:
http://www.bluecrossma.org/medical-policies/sites/g/files/csphws2091/files/acquiadam-assets/023%20E%20Form%20medication%20prior%20auth%20instruction%20prn.pdf