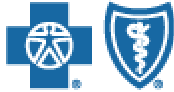

MASSACHUSETTS

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Pharmacy Medical Policy

Diabetes Step Therapy

Table of Contents

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Policy Number: 041

BCBSA Reference Number: None

Related Policies

None

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

Note: All requests for outpatient retail pharmacy for indications listed and not listed on the medical policy guidelines may be submitted to BCBSMA Clinical Pharmacy Operations by completing the Prior Authorization Form on the last page of this document. Physicians may also call BCBSMA Pharmacy Operations department at (800)366-7778 to request a prior authorization/formulary exception verbally. Patients must have pharmacy benefits under their subscriber certificates.

Please refer to the chart below for the formulary status of the medications affected by this policy.

Drug – Traditional Class	Formulary Information Standard Formulary Status
STEP 1	
• Generics in Alpha-Glucosidase Inhibitor class	Covered
• Generics in Biguanide class (Excluding ER generics of Fortamet & Glumetza)	
• Generics in Diabetic Combination (excluding Pioglitazone combinations) Medications class	
• Generics in D-Phenylalanine class	
• Generics in Meglitinide class	
• Generics in Sulfonylurea class	
• Formulary Injectable Insulin (Humulin, Humalog)	
STEP 2	
Actos ® (pioglitazone)	Prior Use of Step 1 Required
Afrezza ® (Insulin)	

Avandia ® (rosiglitazone)	
Duetact ™ (pioglitazone/glimepiride)	
Kerendia ® (finerenone**)**	
pioglitazone	
pioglitazone & glimepiride	
pioglitazone & metformin	
Riomet ER ™ (metformin Sol'n)	
STEP 3	
Actoplus Met ®** (pioglitazone / metformin)	Requires prior use of two step 2 medications.
Fortamet ®** (metformin)	
Glumetza ®** (metformin)	
metformin hydrochloride ER** (Generic of Glumetza ®)	
metformin hydrochloride** 625mg	
metformin hydrochloride Film-Coated ER** (Generic of Fortamet ®)	
Riomet ® (metformin solution)	

Drug –DPP4s	Formulary Information Standard Formulary Status
STEP 1	
• Generics in Alpha-Glucosidase Inhibitor class	Covered
• Generics in Biguanide class (Excluding ER generics of Fortamet & Glumetza)	
• Generics in Diabetic Combination (excluding Pioglitazone combinations) Medications class	
• Generics in Meglitinide class	
• Generics in Sulfonylurea class	
• Formulary Injectable Insulin (Humulin, Humalog)	
STEP 2	
Glyxambi® (empagliflozin / linagliptin)	Prior Use of Step 1 Required
Janumet™ (sitagliptin / metformin)	
Janumet™ **XR** (sitagliptin / metformin)	
Januvia™ (sitagliptin)	
Kombiglyze™ **XR (**saxagliptin / metformin)	
Onglyza™ (saxagliptin)	
Trijardy XR™ (empagliflozin / linagliptin & metformin)	
STEP 3	
Alogliptin**	Requires prior use of two step 2 medications.
Alogliptin & Metformin**	
Alogliptin & Pioglitazone**	
Jentadueto™** / XR (linagliptin / metformin)	
Kazano™** (alogliptin / metformin)	
Nesina™** (alogliptin)	
Oseni™** (alogliptin / pioglitazone)	
Qtern®** (dapagliflozin / saxagliptin) ++	
Steglujan™** (ertugliflozin and sitagliptin)++	
Tradjenta™** (Linagliptin)	

Drug –SGLT2s	Formulary Information Standard Formulary Status

STEP 1	
• Generics in Alpha-Glucosidase Inhibitor class	Covered
• Generics in Biguanide class (Excluding ER generics of Fortamet & Glumetza)	
• Generics in Diabetic Combination (excluding Pioglitazone combinations) Medications class	
• Generics in Meglitinide class	
• Generics in Sulfonylurea class	
• Formulary Injectable Insulin (Humulin, Humalog)	
STEP 2	
Farxiga ® (dapagliflozin)	Prior Use of Step 1 Required
Glyxambi ® (empagliflozin / linagliptin)	
Jardiance ® (empagliflozin)	
Synjardy ® (empagliflozin / metformin)	
Synjardy ® **XR** (empagliflozin / metformin)	
Trijardy XR ™ (empagliflozin / linagliptin & metformin)	
Xigduo ™ **XR** (dapagliflozin / metformin)	
STEP 3	
Invokamet ™** / XR (canagliflozin / metformin)	Requires prior use of two step 2 medications.
Invokana ™** (canagliflozin)	
Qtern ®** (dapagliflozin / saxagliptin) ++	
Steglatro ™** (ertugliflozin)	
Steglujan ™** (ertugliflozin and sitagliptin) ++	
Segluromet ™** (ertugliflozin and metformin)	

++ - The Step 3 Combination SGLT2 and DPP4 medications can be approved under either class Step.

Drug –GLP1s ± GIP	Formulary Information Standard Formulary Status
STEP 1	
• Generics in Alpha-Glucosidase Inhibitor class	Covered
• Generics in Biguanide class (Excluding ER generics of Fortamet & Glumetza)	
• Generics in Diabetic Combination (excluding Pioglitazone combinations) Medications class	
• Generics in Meglitinide class	
• Generics in Sulfonylurea class	
• Formulary Injectable Insulin (Humulin, Humalog)	
STEP 2	
Bydureon ™ (exenatide)	Prior use of Step 1 Required
Byetta ® (exenatide)	
Mounjaro ™ (tirzepatide)	
Trulicity® (dulaglutide)	
STEP 3	
Adlyxin ™** (lixisenatide)	Requires prior use of two step 2 medications.
Ozempic ®** (semaglutide for subcutaneous injection)	
Rybelsus ®** (semaglutide)	
Soliqua ™** (insulin glargine and lixisenatide)	
Victoza ®** (liraglutide)	
Xultophy ®** (insulin degludec / liraglutide)	

**Non formulary medications are covered when a formulary exception request is submitted to BCBSMA Pharmacy Operations and step criteria below are met.

We may cover the following antidiabetics listed in the chart above for new starts* in the following stepped approach:

*New start is defined as no previous paid claim for the requested medication within the past 130 days.

Step 1[1]**:** Formulary step 1 medications will be covered without prior authorization

Step 2[1]**:** Formulary step 2 medications may be covered when one of the following criteria is met:

- There must be evidence of a BCBSMA paid claim of a Step 1 drug within the previous 130 days or previous treatment.

OR

- There must be evidence of a BCBSMA paid claim by the patient of a Step 2 drug within the previous 130 days or previous treatment.

**Requests based exclusively on the use of samples will not meet coverage criteria for exception. Additional clinical information demonstrating medical necessity of the desired medication must be submitted by the requesting prescriber for review.

Step 3[1]**:** Non- Formulary step 3 medications may be covered when the following criteria is met:

- There must be evidence of BCBSMA paid claims by the patient of two different Step 2 drugs within the previous 130 days or previous treatment.
  OR
- There must be evidence of a BCBSMA paid claim by the patient of the Step 3 drug within the previous 130 days or previous treatment. If the Medication is Not Covered/Non-formulary the drug needs to meet requirements for a Formulary Exception for continued coverage.

NOTE: If a Provider submits a request and BCBSMA issues an approval for a step medication, the authorization will be granted for up to two (2) years. If the Member has claims history verifying a fill of a formulary step 1 or formulary step 2 medication within the past 130 days, and no break in coverage, then formulary step 2 medications will continue to pay at point of sale. If the Member has claims history verifying a fill of a formulary step 2 or formulary step 3 medication within the past 130 days, and no break in coverage, then formulary step 3 medications will continue to pay at point of sale. Non-formulary (not covered) medications within a step policy will not have any automation and a paper, electronic or phone call is required.

We do not cover drugs listed in the above chart unless the above step therapy criteria are met.

For the treatment of atherosclerotic cardiovascular disease (ACVD), Chronic Kidney Disease (CKD), & Heart Failure (HF)

We may cover **Farxiga** and or **Jardiance** when **ALL** of the following criteria is met:

Requires the use of a beta blocker **OR** an Angiotensin-Converting Enzyme (ACE) inhibitors **OR** an Angiotensin receptor blockers (ARB)

If the above conditions can be met with BCBSMA paid claims data, the Medication will adjudicate without the need for step or prior authorization.

NOTE: If a Provider submits a request and BCBSMA issues an approval for a step medication, the authorization will be granted for up to two (2) years. If the Member has claims history verifying a fill of a formulary step 1 or formulary step 2 medication within the past 130 days, and no break in coverage, then formulary step 2 medications will continue to pay at point of sale. If the Member has claims history verifying a fill of a formulary step 2 or formulary step 3 medication within the past 130 days, and no break in coverage, then formulary step 3 medications will continue to pay at point of sale. Non-formulary (not covered) medications within a step policy will not have any automation and a paper, electronic or phone call is required.

Individual Consideration

All our medical policies are written for the majority of people with a given condition. Each policy is based on medical science. For many of our medical policies, each individual's unique clinical circumstances may be considered in light of current scientific literature. Physicians may send relevant clinical information for individual patients for consideration to:

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

Prior Authorization Information

Outpatient

For services described in this policy, see below for products where prior authorization **IS REQUIRED** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is **required**.
Commercial PPO and Indemnity	Prior authorization is **required**.

Policy History

Date	Action
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.

References

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2. Januvia™ [package insert]. Whitehouse Station, NJ: Merck &Co., Inc. February 2013.
3. Janumet™ [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.: September 2013.
4. JanumetXR™ [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.: February 2013.
5. Jentadueto™ [package insert]. Inc.: Ridgefield, CT; 06877; Boehringer Ingelheim; August 2013.
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7. Actoplus Met® [package insert]. Deerfield, IL: Takeda Pharmaceuticals, Inc.: 2009.
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19. Invokana™[package insert]. Titusville, NJ: Takeda Pharmaceuticals, Inc.: 2013.
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22. Jardiance® [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.: 2014
23. Farxiga™ [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP.: 2014
24. Xigduo™XR [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP.: 2014
25. Afrezza® [package insert]. Bridgewater, NJ: Sanofi-Aventis U.S. LLC.: 2015
26. Glyxambi® [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.: Aug 2015
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40. Rybelsus® [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; Sept 2019.
41. Kerendia® [package insert]. Leverkusen, Germany: Bayer AG.; July 2021.
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Endnotes

1. Based on the recommendations of the BCBSMA Pharmacy and Therapeutics Committee meeting on 2/13/2007 and 9/11/2007.
2. First line oral hypoglycemic agents include: Alpha-Glucosidase Inhibitors (Glyset® and Precose®), Biguanides (Fortamet™, Glucophage®, Glucophage®XR, metformin and metformin solution), Meglitinide Derivatives (Prandin®and Starlix®), Sulfonylureas (Amaryl®, chlorpropamide, Diaβeta®, Diabinase®, glimepiride, glipizide, Glucotrol®, Glucotrol®XL, glyburide, Glynase® PresTab®, Micronase®, tolazamide and tolbutamide) , and combination products (Glucovance®, Metaglip™, metformin/glipizide and metformin/glyburide).
3. Based on the recommendations of the BCBSMA Pharmacy and Therapeutics Committee meeting on 2/12/2008.
4. Based on the recommendations of the BCBSMA Pharmacy and Therapeutics Committee meeting on 9/15/2009.
5. Based on the recommendations of the BCBSMA Pharmacy and Therapeutics Committee meeting on 4/9/2013.

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