



MASSACHUSETTS

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Pharmacy Medical Policy Diabetes Step Therapy

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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. Physicians may also submit requests for retail pharmacy exceptions via the web using Express PA which can be found on the BCBSMA provider portal or directly on the web at <https://provider.express-path.com>. 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		
<ul style="list-style-type: none"> • Generics in Alpha-Glucosidase Inhibitor class • 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) 	Covered	

STEP 2	
Actoplus Met® (pioglitazone / metformin)	Prior Use of Step 1 Required
Actoplus Met® XR (pioglitazone / metformin)	
Actos® (pioglitazone)	
Afrezza® (Insulin)	
Avandamet® (rosiglitazone / metformin)	
Avandia® (rosiglitazone)	
Duetact™ (pioglitazone/glimepiride)	
Pioglitazone	
Pioglitazone & Glimepiride	
Pioglitazone & Metformin	
Prandin® (repaglinide)	
STEP 3	
Fortamet®** (metformin)	
Glucophage®** (metformin)	
Glucophage® XR** (metformin)	
Glumetza®** (metformin)	
Metformin hydrochloride ER** (Generic of Glumetza®)	
Metformin hydrochloride Film-Coated ER** (Generic of Fortamet®)	

Drug –DPP4s	Formulary Information	
	Standard	
	Formulary Status	
STEP 1		
<ul style="list-style-type: none"> Generics in Alpha-Glucosidase Inhibitor class 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) 	Covered	
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)		
STEP 3		
Alogliptin**	Prior use of Step 1 and Step 2 Required	
Alogliptin & Metformin**		
Alogliptin & Pioglitazone**		
Jentadueto™** (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		
<ul style="list-style-type: none"> Generics in Alpha-Glucosidase Inhibitor class 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) 	Covered	
STEP 2		
Glyxambi® (empagliflozin / linagliptin)	Prior Use of Step 1 Required	
Invokamet™ (canagliflozin / metformin)		
Invokana™ (canagliflozin)		
Jardiance® (empagliflozin)		
Synjardy® (empagliflozin / metformin)		
Synjardy® XR (empagliflozin / metformin)		
STEP 3		
Farxiga®** (dapagliflozin)	Prior Use of Step 1 Required	
Qtern®** (dapagliflozin / saxagliptin)**		
Steglatro™** (ertugliflozin)		
Steglujan™** (ertugliflozin and sitagliptin)**		
Segluromet™** (ertugliflozin and metformin)		
Xigduo™ XR** (dapagliflozin / metformin)		

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

Drug –GLP1s	Formulary Information	
	Standard	
	Formulary Status	
STEP 1		
<ul style="list-style-type: none"> Generics in Alpha-Glucosidase Inhibitor class 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) 	Covered	
STEP 2		
Bydureon™ (exenatide)	Prior use of Step 1 Required	
Byetta® (exenatide)		
Trulicity® (dulaglutide)		
STEP 3		
Adlyxin™** (lixisenatide)	Prior use of Step 2 Required	
Ozempic®** (semaglutide for subcutaneous injection)		
Soliqua™** (insulin glargine and lixisenatide)		
Tanzeum** (albiglutide)		

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 1¹: Formulary step 1 medications will be covered without prior authorization

Step 2¹: Formulary step 2 medications may be covered when one of the following criteria is met:

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

OR

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

**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 3¹: Non- Formulary step 3 medications may be covered when the following criteria is met:

- There must be evidence of a BCBSMA paid claim or physician documented use by the patient of a Step 1 drug within the previous 130 days.
AND
- There must be evidence of a BCBSMA paid claim or physician documented use by the patient of a Step 2 drug within the previous 130 days.
OR
- There must be evidence of a BCBSMA paid claim by the patient of a Step 3 drug within the previous 130 days.

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

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

Managed Care Authorization Instructions

- Physicians may call BCBSMA Pharmacy Operations department to request a review for prior authorization for patients who do not meet the step-therapy criteria at the point of sale. Pharmacy Operations: (800) 366-7778
- Physicians may also fax or mail the attached form to the address above. The Formulary Exception/Prior Authorization form is included as part of this document for physicians to submit for patients who do not meet the step therapy criteria at the point of sale.
- Physicians may also submit requests for retail pharmacy exceptions via the web using Express PAtH which can be found on the BCBSMA provider portal or directly on the web at <https://provider.express-path.com>.

PPO and Indemnity Authorization Instructions

- Physicians may call BCBSMA Pharmacy Operations department to request a review for prior authorization for patients who do not meet the step-therapy criteria at the point of sale.
Pharmacy Operations: (800) 366-7778
- Physicians may also fax or mail the attached form to the address above. The Formulary Exception/Prior Authorization form is included as part of this document for physicians to submit for patients who do not meet the step therapy criteria at the point of sale.
- Physicians may also submit requests for retail pharmacy exceptions via the web using Express PATH which can be found on the BCBSMA provider portal or directly on the web at <https://provider.express-path.com>.

Policy History

Date	Action
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 Jentaduo™.
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.
11/2010	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

- American Diabetes Association Position Statement. Standards of Medical Care in Diabetes – 2007. Diabetes Care 2007; 30 (1): S4-S41.
- 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. Jentaduo™ [package insert]. Inc.: Ridgefield, CT; 06877; Boehringer Ingelheim; August 2013.
6. Actos® [package insert]. Deerfield, IL: Takeda Pharmaceuticals, Inc.: 2009.
7. Actoplus Met® [package insert]. Deerfield, IL: Takeda Pharmaceuticals, Inc.: 2009.
8. Duetact® [package insert]. Deerfield, IL: Takeda Pharmaceuticals, Inc.: 2009.
9. Avandia® [package insert]. Research Triangle Park, NC: GlaxoSmithKline: 2008.
10. Avandaryl® [package insert]. Research Triangle Park, NC: GlaxoSmithKline: 2008.
11. Avandamet® [package insert]. Research Triangle Park, NC: GlaxoSmithKline: 2008.
12. Onglyza™ [package insert]. Princeton, NJ: Bristol-Myers Squibb: 2009.
13. Kombiglyze™ XR [package insert]. Princeton, NJ: Bristol-Myers Squibb: 2010.
14. Tradjenta™ [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc. 2011.
15. Duetact® [package insert]. Deerfield, IL: Takeda Pharmaceuticals, Inc.: 2009.
16. Nesina™ [package insert]. Deerfield, IL: Takeda Pharmaceuticals, Inc.: 2013.
17. Kazano™ [package insert]. Deerfield, IL: Takeda Pharmaceuticals, Inc.: 2013.
18. Oseni™ [package insert]. Deerfield, IL: Takeda Pharmaceuticals, Inc.: 2013.
19. Invokana™ [package insert]. Titusville, NJ: Takeda Pharmaceuticals, Inc.: 2013.
20. Glucophage®/XR [package insert]. Princeton, NJ: Bristol-Myers Squibb Company.:Jan 2009.
21. Fortamet® [package insert]. Florham Park, NJ: Shionogi Inc.: April 2012.
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
27. Byetta® injection [package insert]. San Diego, CA: Amylin Pharmaceuticals, Inc.; October 2009.
28. Victoza® injection [package insert]. Princeton, NJ: NovoNordisk; January 2010.
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30. 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
31. 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.
32. 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
33. Tanzeum™ injection [package insert]. Wilmington, DE: GlaxoSmithKline LLC.; 2014
34. Trulicity™ [package insert]. Indianapolis, IN: Eli Lilly and Company; 3/2015
35. Xultophy® injection [package insert]. Princeton, NJ: NovoNordisk; Nov 2016
36. Ozempic® injection [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; Dec 2017.
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

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 Riomet™), Meglitinide Derivatives (Prandin®and Starlix®), Sulfonylureas (Amaryl®, chlorpropamide, DiaBeta®, Diabinese®, 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.com/common/en_US/medical_policies/023%20E%20Form%20medication%20prior%20auth%20instruction%20prn.pdf