



Pharmacy Medical Policy

Diabetes Step Therapy - Second Step Agents

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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.

Standard Formulary	
Drug/Class	Formulary Status
STEP 1	
<ul style="list-style-type: none">Generics in Alpha-Glucosidase Inhibitor class	Covered
<ul style="list-style-type: none">Generics in Biguanide class	
<ul style="list-style-type: none">Generics in Diabetic Combination Medications class	
<ul style="list-style-type: none">Generics in D-Phenylalanine class	
<ul style="list-style-type: none">Generics in Meglitinide class	
<ul style="list-style-type: none">Generics in Sulfonylurea class	
<ul style="list-style-type: none">Generics in Thiazolidinedione class	
<ul style="list-style-type: none">Insulin	
STEP 2	

<ul style="list-style-type: none"> • Actoplus Met® • Actoplus Met® XR • Actos® • Avandamet® • Avandaryl® • Avandia® • Duetact™ • Invokana™ • Janumet™ • Janumet™ XR • Januvia™ • Kombiglyze™ XR • Onglyza™ • Pioglitazone • Pioglitazone/glimepiride • Pioglitazone/metformin 	Prior Use of Step 1 Required
STEP 3	
<ul style="list-style-type: none"> • Farxiga®** • Fortamet®** • Glucophage®** • Glucophage® XR** • Glumetza®** • Jentadueto™** • Kazano™** • Nesina™** • Oseni™** • Tradjenta™** 	Prior use of Step 1 or Step 2 Required

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

We 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 will 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 will 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
Clinical Pharmacy Department
One Enterprise Drive
Quincy, MA 02171
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
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.
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

1. American Diabetes Association Position Statement. Standards of Medical Care in Diabetes – 2007. Diabetes Care 2007; 30 (1): S4-S41.
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.
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.

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.

Request for Outpatient Retail Pharmacy Prior Authorization for Second Line Agents for Diabetes (#041)
Fax to: Clinical Pharmacy Program (800) 583-6289
Phone Authorization (800)366-7778 or Web: <https://provider.express-path.com>
To ensure that we can confirm your request (required by NCQA), please be sure to include your fax number.

Patient Information (REQUIRED)																																																	
Name																																																	
BCBSMA ID Number																																																	
Is the patient a BCBSMA employee?	Yes No																																																
If yes, please fax request to: (617) 246-4013																																																	
Date of Birth																																																	
Patient's Diagnosis																																																	
Physician Information (REQUIRED)																																																	
Name																																																	
Medical Specialty																																																	
BCBSMA Provider number/NPI Number																																																	
Telephone Number																																																	
Fax Number																																																	
Is this fax number 'secure' for PHI receipt/transmission per HIPAA requirements? (circle one) Yes No																																																	
Contact Name (if different from physician)																																																	
Please select one of the three following sections to complete, depending on the nature of your request for the above-named patient.																																																	
Outpatient Retail Pharmacy Prior Authorization Request																																																	
Drug name:																																																	
Previous treatment failure (excluding samples) within the previous 130 days (please check all that apply):																																																	
Oral Agents: <table border="0"> <tbody> <tr> <td>ActoplusMetTM /XR</td> <td>DuetactTM</td> <td>Glyset[®]</td> <td>Micronase[®]</td> </tr> <tr> <td>Actos[®]</td> <td>Farxiga[®]</td> <td>InvokanaTM</td> <td>NesinaTM</td> </tr> <tr> <td>Amaryl[®]</td> <td>FortametTM</td> <td>JanumetTM</td> <td>OnglyzaTM</td> </tr> <tr> <td>Avandamet[®]</td> <td>glimepiride</td> <td>JanumetTM XR</td> <td>OseniTM</td> </tr> <tr> <td>pioglitazone/metformin</td> <td>glipizide</td> <td>JanuviaTM</td> <td>pioglitazone</td> </tr> <tr> <td>Avandaryl[®]</td> <td>Glucophage[®]</td> <td>JentaduetoTM</td> <td>Prandin[®]</td> </tr> <tr> <td>Avandia[®]</td> <td>Glucophage[®] XR</td> <td>KazanoTM</td> <td>Precose[®]</td> </tr> <tr> <td>chlorpropamide</td> <td>Glucotrol[®]</td> <td>KombiglyzeTM XR</td> <td>RiometTM</td> </tr> <tr> <td>DiaBeta[®]</td> <td>Glucotrol[®] XL</td> <td>MetaglipTM</td> <td>Starlix[®]</td> </tr> <tr> <td>Diabinese[®]</td> <td>Glucovance[®]</td> <td>metformin</td> <td>tolazamide</td> </tr> <tr> <td></td> <td>glyburide</td> <td>metformin/glipizide</td> <td>tolbutamide</td> </tr> <tr> <td></td> <td>Glynase[®] PresTab[®]</td> <td>metformin/glyburide</td> <td>TradjentaTM</td> </tr> </tbody> </table>		ActoplusMet TM /XR	Duetact TM	Glyset [®]	Micronase [®]	Actos [®]	Farxiga [®]	Invokana TM	Nesina TM	Amaryl [®]	Fortamet TM	Janumet TM	Onglyza TM	Avandamet [®]	glimepiride	Janumet TM XR	Oseni TM	pioglitazone/metformin	glipizide	Januvia TM	pioglitazone	Avandaryl [®]	Glucophage [®]	Jentadueto TM	Prandin [®]	Avandia [®]	Glucophage [®] XR	Kazano TM	Precose [®]	chlorpropamide	Glucotrol [®]	Kombiglyze TM XR	Riomet TM	DiaBeta [®]	Glucotrol [®] XL	Metaglip TM	Starlix [®]	Diabinese [®]	Glucovance [®]	metformin	tolazamide		glyburide	metformin/glipizide	tolbutamide		Glynase [®] PresTab [®]	metformin/glyburide	Tradjenta TM
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Drug name, strength and quantity requested:																																																	
Clinical reason for override (please specify)																																																	
Prescriber Signature:	Date:																																																