BOSTON MEDICAL CENTER HEALTHNet PLAN

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WELL SENSE HEALTH PLAN

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Pharmacy Policy

Antidiabetic Agents – Unified Formulary

Policy Number: 9.332
Version Number: 1.2
Version Effective Date: 7/1/2021

Product Applicability	☐ **All Plan+ Products**
Well Sense Health Plan	**Boston Medical Center HealthNet Plan**
☐ New Hampshire Medicaid	☒ MassHealth ACO
	☒ MassHealth MCO
	☐ Qualified Health Plans/ConnectorCare/Employer Choice Direct
	☐ Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

Policy

Reference Table

Drugs that require PA	No PA
Biguanides	
Fortamet® (metformin extended-release) *	Glucophage® # (metformin)
Glumetza® (metformin extended-release) *	Glucophage® XR # (metformin extended-release)
Riomet® (metformin solution) ≥ 13 years old* §	Riomet® # (metformin solution) < 13 years old §
Riomet ER® (metformin solution extended-release)	
Dipeptidyl peptidase-4 inhibitors (DPP-4)	
Nesina® (alogliptin)†	Januvia® (sitagliptin)
	Onglyza® (saxagliptin)
	Tradjenta® (linagliptin)
Glucagon Like Peptide-1 (GLP-1) Agonists	
Bydureon BCise® (exenatide extended-release auto-injection)	Bydureon® (exenatide extended-release pen)

Drugs that require PA	No PA
Ozempic® (semaglutide injection)	Byetta® (exenatide) §
Rybelsus® (semaglutide tablet)	Trulicity® (dulaglutide) PD
	Victoza® (liraglutide)
Sodium glucose cotransporter 2 (SGLT2) Inhibitors	
Steglatro® (ertugliflozin)	Farxiga® (dapagliflozin)
	Invokana® (canagliflozin)
	Jardiance® (empagliflozin)
Combination products	
Glyxambi® (empagliflozin/linagliptin)	Invokamet® (canagliflozin/metformin)
Kazano® (alogliptin/metformin) †	Invokamet XR® (canagliflozin/metformin extended-release)
Segluromet® (ertugliflozin/metformin)	Janumet® (sitagliptin/metformin)
Soliqua® (insulin glargine/lixisenatide)	Janumet XR® (sitagliptin/metformin extended-release)
Xultophy® (insulin degludec/liraglutide)	Jentadueto® (linagliptin/metformin)
	Jentadueto XR® (linagliptin/metformin extended-release)
	Kombiglyze® XR (saxagliptin/metformin extended-release)
	Synjardy® (empagliflozin/metformin)
	Synjardy XR® (empagliflozin/metformin extended-release)
	Xigduo XR® (dapagliflozin/metformin extended-release)

This is a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.
*A-rated generic available. Both brand and A-rated generic require PA.
†Authorized generic available. Both brand and authorized generic require PA.
PD Preferred Drug. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Please note, for Trulicity® (dulaglutide) and GLP-1 receptor agonists, a trial with a preferred agent is not required prior to approval of a non-preferred agent.
§ Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.

Procedure

Approval Diagnosis:	• Type 2 Diabetes Mellitus (All agents)
Approval Criteria: *Biguanides: extended-release formulations* **Fortamet®** (metformin extended-release) * **Glumetza®** (metformin extended-release) * *A-rated generic available. Both brand and A-rated generic require PA.	Prescriber provides documentation of **ALL** of the following: 1. Appropriate diagnosis 2. Medical records documenting an inadequate response or adverse reaction despite 90 days of therapy with a generic metformin ER formulation at the requested dose that is AB-rated to Glucophage XR® (GSNs: 046574, 052080) 3. For requests for metformin extended-release (Glumetza®), clinical rationale for the use of this product instead of other available metformin formulations. 4. If request is for BRAND NAME Fortamet® or Glumetza®, the member must meet the above criteria and the prescriber must provide medical records documenting an inadequate response or adverse reaction to generic metformin extended release (as per the Brand Name Guideline)
Approval Criteria: *Biguanides: solution formulations* **Riomet®** (metformin	Prescriber provides documentation of **ALL** of the following: 1. Appropriate diagnosis 2. **ONE** of the following: a. Medical necessity for a liquid formulation (inability to swallow oral medications) b. Medical records documenting an inadequate response despite 90

solution) ≥ 13 years old§ **Riomet ER®** (metformin extended-release solution) § Brand Preferred over generic equivalents. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.	days of therapy with the metformin tablet formulation, or an allergic reaction or adverse reaction to the metformin tablet formulation that is not class specific (i.e. nausea, diarrhea) 3. If the request is for Riomet ER®, medical records documenting an inadequate response despite 90 days of therapy with the immediate release metformin solution formulation
Approval Criteria: *Combination Products (excluding GLP-1/insulin products)* **Glyxambi®** (empagliflozin/linagliptin), **Kazano®** (alogliptin/metformin)†, **Segluromet®** (ertugliflozin/ metformin) †Authorized generic available. Both brand and authorized generic require PA.	Prescriber provides documentation of the following: 1. Appropriate diagnosis 2. **ONE** of the following: a. Inadequate response (defined as at least 90 days of therapy within a 120-day time period) to metformin used in combination with at least one of the non-metformin agents in the requested combination‡ b. **BOTH** of the following: i. Adverse reaction or contraindication to metformin ii. Inadequate response (defined as at least 90 days of therapy within a 120-day time period) to at least one of the non-metformin agents in the requested combination‡ c. **BOTH** of the following: i. Inadequate response (defined as at least 90 days of therapy within a 120-day time period), adverse reaction or contraindication to metformin‡ ii. Adverse reaction to at least one of the non-metformin agents in the requested combination 3. If the request is for BRAND NAME Kazano®, the member must meet the above criteria and provide medical records documenting an inadequate response or adverse reaction to the therapeutically equivalent generic formulation *Notes:* ‡*Prescriber documentation on the PA form of failed 90-day trial of combination metformin and one of the non-metformin agents in the requested formulation is sufficient for approval (regardless of claims history). If dates of therapy are not noted on the PA, please be sure to verify claims history for 90 days of combination therapy.*
Approval Criteria: *DPP-IV inhibitors* **Nesina®** (alogliptin)†	Prescriber provides documentation of the following: 1. Appropriate diagnosis 2. **ONE** of the following: a. Inadequate response (defined as at least 90 days of therapy within a 120-day time period) to metformin used in combination with **ONE** of the following ‡*:*

†Authorized generic available. Both brand and authorized generic require PA.	i. Januvia® (sitagliptin) ii. Onglyza® (saxagliptin) iii. Tradjenta® (linagliptin) b. **BOTH** of the following: 1. Adverse reaction or contraindication to metformin 2. Inadequate response (defined as at least 90 days of therapy within a 120-day time period) to **ONE** of the following‡: i. Januvia® (sitagliptin) ii. Onglyza® (saxagliptin) iii. Tradjenta® (linagliptin) c. **BOTH** of the following: 1. Inadequate response (defined as at least 90 days of therapy within a 120-day time period), adverse reaction or contraindication to metformin‡ 2. Adverse reaction to **ONE** of the following: i. Januvia® (sitagliptin) ii. Onglyza® (saxagliptin) iii. Tradjenta® (linagliptin) d. **BOTH** of the following: 1. Inadequate response (defined as at least 90 days of therapy within a 120-day time period), adverse reaction or contraindication to metformin‡ 2. Contraindication to **ALL** of the following: i. Januvia® (sitagliptin) ii. Onglyza® (saxagliptin) iii. Tradjenta® (linagliptin) 2. If requested quantity exceeds 1 tablet/day, clinical rationale for exceeding FDA-approved dosing schedule *Notes:* ‡*Prescriber documentation on the PA form of failed 90-day trial of combination metformin and a DPP-IV is sufficient for approval (regardless of claims history). If dates of therapy are not noted on the PA, please be sure to verify claims history for 90 days of combination therapy.*
Approval Criteria: *GLP-1 agonists and combination products* **Bydureon Bcise®** (exenatide extended-release auto-injection), **Ozempic®** (semaglutide injection), **Rybelsus®** (semaglutide tablet),	Prescriber provides documentation of the following: 1. Appropriate diagnosis 2. **ONE** of the following: a. Inadequate response (defined as at least 90 days of therapy within a 120-day time period) to metformin used in combination with **ONE** of the following‡§*:* a. Bydureon® (exenatide extended-release pen) b. Byetta® (exenatide) c. Trulicity® (dulaglutide) d. Victoza® (liraglutide) b. **BOTH** of the following: a. Adverse reaction or contraindication to metformin

Soliqua® (insulin glargine/lixisenatide), **Xultophy**® (insulin degludec/liraglutide)	b. Inadequate response (defined as at least 90 days of therapy within a 120-day time period) to **ONE** of the following‡§: a. Bydureon® (exenatide extended-release pen) b. Byetta® (exenatide) c. Trulicity® (dulaglutide) d. Victoza® (liraglutide) c. **BOTH** of the following: a. Inadequate response (defined as at least 90 days of therapy within a 120-day time period), adverse reaction or contraindication to metformin‡ b. Adverse reaction to **ONE** of the following§: a. Bydureon® (exenatide extended-release pen) b. Byetta® (exenatide) c. Trulicity® (dulaglutide) d. Victoza® (liraglutide) d. **BOTH** of the following: a. Inadequate response (defined as at least 90 days of therapy within a 120-day time period), adverse reaction or contraindication to metformin‡ b. Contraindication to **ALL** of the following§: 1. Bydureon® (exenatide extended-release pen) 2. Byetta® (exenatide) 3. Trulicity® (dulaglutide) 4. Victoza® (liraglutide) 3. If requested quantity exceeds quantity limits, clinical rationale for exceeding FDA-approved dosing schedule* *Notes:* • **For the quantity limit listed above, a 30 day supply should consist of:* o *One carton of four 2 mg autoinjectors (Bydureon Bcise®)* o *Two pens of 2 mg/1.5 mL or one pen of 4mg/3mL (Ozempic®)* o *1 tablet/day (Rybelsus®)* o *Six prefilled pens (Soliqua®)* o *One carton of five prefilled pens (Xultophy®)* • ‡*Prescriber documentation on the PA form of failed 90-day trial of combination metformin and a GLP-1 is sufficient for approval (regardless of claims history). If dates of therapy are not noted on the PA, please be sure to verify claims history for 90 days of combination therapy.* • *§ Requests for Rybelsus® (semaglutide tablet) may be approved in patients without a trial of a GLP-1 agonist if it is documented that the member is not a candidate for injectable formulations and if an alternative second line agent is used in combination with metformin (e.g., DPP-IV, SGLT2, TZD, sulfonylurea or insulin) in place of the GLP-1 agonist in 2a to 2d above.*
Approval Criteria: *SGLT2 inhibitors*	Prescriber provides documentation of the following: 1. Appropriate diagnosis 2. **ONE** of the following: a. Inadequate response (defined as at least 90 days of therapy

Steglatro® (ertugliflozin)	within a 120-day time period) to metformin used in combination with **ONE** of the following‡*:* a. Farxiga® (dapagliflozin) b. Invokana® (canagliflozin) c. Jardiance® (empagliflozin) b. **BOTH** of the following: a. Adverse reaction or contraindication to metformin b. Inadequate response (defined as at least 90 days of therapy within a 120-day time period) to **ONE** of the following‡: a. Farxiga® (dapagliflozin) b. Invokana® (canagliflozin) c. Jardiance® (empagliflozin) c. **BOTH** of the following: a. Inadequate response (defined as at least 90 days of therapy within a 120-day time period), adverse reaction or contraindication to metformin‡ b. Adverse reaction to **ONE** of the following: a. Farxiga® (dapagliflozin) b. Invokana® (canagliflozin) c. Jardiance® (empagliflozin) d. **BOTH** of the following: a. Inadequate response (defined as at least 90 days of therapy within a 120-day time period), adverse reaction or contraindication to metformin‡ b. Contraindication to **ALL** of the following: 1. Farxiga® (dapagliflozin) 2. Invokana® (canagliflozin) 3. Jardiance® (empagliflozin) 3. If requested quantity exceeds 1 tablet/day, clinical rationale for exceeding FDA-approved dosing schedule *Notes:* ‡*Prescriber documentation on the PA form of failed 90-day trial of combination metformin and an insulin, sulfonylurea, pioglitazone, a DPP-IV, an SGLT2 or exenatide is sufficient for approval (regardless of claims history). If dates of therapy are not noted on the PA, please be sure to verify claims history for 90 days of combination therapy.*
Denial Criteria:	Cases that do not meet the approval criteria will be denied. If a request is denied and the prescriber has additional clinical documentation, a **new** prior authorization request must be submitted.
Brand Preferred over Generic:	• In addition to any prior authorization requirements that may be listed above, generic medications listed below have Brand name products that are included on the MassHealth Brand Name Preferred Over Generic List. Requests for generic versions require a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent prior to approval: o metformin solution

Duration of Authorization:	Prior authorization may be issued for **1 year.**
Recertification Criteria:	Resubmission by prescriber will infer a positive response to therapy and requests can be recertified for **1 year.** **Handling recertification requests with PA criteria change:** If a member was approved for a PA requiring agent prior to the changes implemented on 1/1/21, the member must meet the new criteria for recertification.

Appendix:

Stability

Stability on a PA requiring agent is not rationale for approval. Compelling requests may be reviewed case by case by clinical review.

Grandfathering

N/A

Additional Information

Point of Sale (POS) Criteria

Criteria:

1. Claims for alogliptin/metformin, Glyxambi®, metformin ER (Fortamet®, Glumetza®), and Riomet ER will usually reject at the pharmacy as prior authorization required.
2. Claims for metformin solution for those members <13 years of age will usually process and pay at the pharmacy. Claims for metformin solution for members ≥13 years of age will usually reject at the pharmacy as prior authorization required.
3. Claims for alogliptin, Bydureon Bcise, Ozempic®, Rybelsus®, Soliqua, Steglatro®, and Xultophy will usually process and pay at the pharmacy for members that have a history of a diagnosis of DM-2 AND there is a history of metformin and a second less costly agent (see below) for a total of 90 days of each agent within the last 120 day time period. Quantity limits also apply as noted below.
    a. Less costly agent (LCA) as noted below:
        1. For Bydureon Bcise®, Ozempic®, Rybelsus®, Soliqua® or Xultophy, LCA are: Bydureon®, Byetta®, Trulicity® or Victoza®
        2. For alogliptin, LCA are: Januvia®, Onglyza® or Tradjenta®
        3. For Steglatro®, LCA are: Farxiga®, Invokana® or Jardiance®
    b. Quantity limits as noted below:
        - Quantity limit of 1 tablet/day (30 tablets/month) applies to alogliptin, and Rybelsus®
        - Quantity limit of four autoinjectors/month applies to Bydureon Bcise®
        - Quantity limit of two pens of 2 mg/1.5 mL/month or one pen of 4mg/3ml/month applies to Ozempic®
        - Quantity limit of six 3 mL pens/month applies to Soliqua
        - Quantity limit of five 3 mL pens/month applies to Xultophy

Responsibility and Accountability

Policy History

Original Approval Date	Original Effective Date	Policy Owner	Approved by
12/1/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date**	**Approved by**
12/1/2020	Created policy for MH Partial Unified Formulary	1/1/2021	P&T Committee
1/20/2021	Updated policy to reflect PUF changes as of 9/29/20	1/20/2021	P&T Committee
5/13/2021	Updated policy to reflect 3/1/21 changes from MH, added POS criteria	7/1/2021	P&T Committee
5/13/2021	Updated policy to reflect 4/15/21 changes from MH. New formulation of Ozempic (4mg/3mL) in both PA and POS criteria	7/1/2021	P&T Committee

Next Review Date

2021

Other Applicable Policies

References

Reference to Applicable Laws and Regulations, if Any