Pharmacy Medical Necessity Policy

Antidiabetic Agents – Unified Formulary

Policy Number: 9.332
Version Number: 2.2
Version Effective Date: 1/1/2022

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

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, osmotic tablet) *	Metformin immediate-release tablet
Glumetza® (metformin extended-release, gastric tablet) *§	Metformin extended-release, XR tablet
Riomet® (metformin immediate-release solution) ≥ 13 years old*	Riomet® # (metformin immediate-release solution) < 13 years old
Riomet ER® (metformin solution extended-release suspension)	
Dipeptidyl peptidase-4 inhibitors (DPP-4)	

Drugs that require PA	No PA
Nesina® (alogliptin)† §	Januvia® (sitagliptin)
	Onglyza® (saxagliptin)
	Tradjenta® (linagliptin)
Glucagon Like Peptide-1 (GLP-1) Agonists	
Adlyxin® (lixisenatide)	Bydureon® (exenatide extended-release pen)
Bydureon BCise® (exenatide extended-release auto-injection)	Byetta® (exenatide) §
Ozempic® (semaglutide injection)	Trulicity® (dulaglutide) PD
Rybelsus® (semaglutide tablet)	Victoza® (liraglutide)
Sodium glucose cotransporter 2 (SGLT2) Inhibitors	
Steglatro® (ertugliflozin)	Farxiga® (dapagliflozin)
	Invokana® (canagliflozin)
	Jardiance® (empagliflozin)
Combination products	
Duetact® (glimepiride/pioglitazone) * §	Invokamet® (canagliflozin/metformin)
Glyxambi® (empagliflozin/linagliptin)	Invokamet XR® (canagliflozin/metformin extended-release)
Kazano® (alogliptin/metformin) †§	Janumet® (sitagliptin/metformin)
Oseni® (alogliptin/pioglitazone) †§	Janumet XR® (sitagliptin/metformin extended-release)
Qtern® (dapagliflozin/saxagliptin)	Jentadueto® (linagliptin/metformin)
Repaglinide/metformin	Jentadueto XR® (linagliptin/metformin extended-release)
Segluromet® (ertugliflozin/metformin)	Kombiglyze® XR (saxagliptin/metformin extended-release)
Soliqua® (insulin glargine/lixisenatide)	Synjardy® (empagliflozin/metformin)
Steglujan® (ertugliflozin/sitagliptin)	Synjardy XR® (empagliflozin/metformin extended-release)
Trijardy XR® (empagliflozin/Linagliptin/metformin extended-release)	Xigduo XR® (dapagliflozin/metformin extended-release)
Xultophy® (insulin degludec/liraglutide)	

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, a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class is required. 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, a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent is required.

Biguanides Approval Criteria:

Metformin extended-release tablet (generic Fortamet, brand Glumetza)	1. Member has a diagnosis of ONE of the following: a. Type 2 Diabetes Mellitus b. Gestational Diabetes; **AND** i. Member has had an inadequate response, adverse reaction, or contraindication to insulin c. Polycystic ovarian syndrome (PCOS); **AND** i. Member has oligomenorrhea related to PCOS

	(chart documentation required); **AND** 1. Member has had an inadequate response, adverse reaction, or contraindication to combined oral contraceptives; **OR** ii. Prescriber attests metformin is medically necessary for prevention of diabetes related to PCOS d. Prediabetes **AND** 2. Medical records documenting an inadequate response (at least 90 days of therapy) or adverse reaction, at the requested dose, to the metformin extended-release formulation available without prior authorization (e.g. generic Glucophage XR); **AND** 3. **Brand Glumetza request only:** Clinical rationale for the use of this Glumetza instead of other available metformin formulations.
Metformin immediate-release solution (generic Riomet) **for members 13 years of age and older** **Riomet ER** (metformin extended-release suspension)	1. Member has a diagnosis of ONE of the following: a. Type 2 Diabetes Mellitus b. Gestational Diabetes; **AND** i. Member has had an inadequate response, adverse reaction, or contraindication to insulin c. Polycystic ovarian syndrome (PCOS); **AND** i. Member has oligomenorrhea related to PCOS (chart documentation required); **AND** 1. Member has had an inadequate response, adverse reaction, or contraindication to combined oral contraceptives; **OR** ii. Prescriber attests metformin is medically necessary for prevention of diabetes related to PCOS d. Prediabetes **AND** 2. Member has ONE of the following: a. Medical necessity for a liquid formulation (e.g., inability to swallow oral medications); **OR** b. Medical records documenting an inadequate response despite 90 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) **AND** 3. **Riomet ER® requests only**: Medical records documenting an inadequate response despite 90 days of therapy with the immediate release metformin solution formulation have been provided
Duration of Authorization:	Prior authorization may be issued for **1 year.**

Combination Products (excluding GLP-1/insulin products) Approval Criteria:

Duetact® - Brand Preferred (glimepiride/pioglitazone) **Glyxambi®** (empagliflozin/linagliptin) **Kazano® - Brand Preferred** (alogliptin/metformin) **Oseni® - Brand Preferred** (alogliptin/pioglitazone) **Qtern®** (dapagliflozin/saxagliptin) repaglinide/metformin **Segluromet®** (ertugliflozin/ metformin) **Steglujan®** (ertugliflozin/sitagliptin) **Trijardy XR®** (empagliflozin/linagliptin/ metformin extended-release)	1. Member has a diagnosis of Type 2 Diabetes Mellitus; **AND** 2. Member has had **ONE** of the following: a. An 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; **OR** b. **BOTH** of the following: i. An adverse reaction or contraindication to metformin; **AND** ii. An 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; **OR** c. **BOTH** of the following: i. An inadequate response (defined as at least 90 days of therapy within a 120-day time period), adverse reaction or contraindication to metformin; **AND** ii. An adverse reaction to at least one of the non-metformin agents in the requested combination 3. **Trijardy XR requests only:** Clinical rationale for the use of the combination product instead of the commercially-available separate agents has been provided.
Duration of Authorization:	Prior authorization may be issued for **1 year.**

DPP-IV Inhibitors Approval Criteria:

Nesina® - Brand Preferred (alogliptin)	1. Member has a diagnosis of Type 2 Diabetes Mellitus; **AND** 2. The member meets **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 *:* i. Januvia® (sitagliptin) ii. Onglyza® (saxagliptin) iii. Tradjenta® (linagliptin) **OR** b. **BOTH** of the following: 1. Adverse reaction or contraindication to metformin; **AND** 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) **OR** 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; **AND** 2. Adverse reaction to **ONE** of the following: i. Januvia® (sitagliptin) ii. Onglyza® (saxagliptin) iii. Tradjenta® (linagliptin) **OR** 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) **AND** 3. If requested quantity exceeds 1 tablet/day, clinical rationale for exceeding FDA-approved dosing schedule
Duration of Authorization:	Prior authorization may be issued for **1 year.**

GLP-1 Agonist and Combination Product Approval Criteria:

Adlyxin® (lixisenatide) **Bydureon BCise®** (exenatide extended-release auto-injection) **Ozempic®** (semaglutide injection) **Rybelsus®** (semaglutide tablet) **Soliqua®** (insulin glargine/lixisenatide) **Xultophy®** (insulin degludec/liraglutide)	1. Member has one of the following diagnosis: a. Type 2 Diabetes Mellitus; **OR** b. **For requests for Adlyxin, Bydureon BCise, Ozempic, or Rybelsus only:** Prediabetes **AND** 2. Member has **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) **OR** b. **BOTH** of the following: a. Adverse reaction or contraindication to metformin; **AND** 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) **OR** 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; **AND** b. Adverse reaction to **ONE** of the following: a. Bydureon® (exenatide extended-release pen) b. Byetta® (exenatide) c. Trulicity® (dulaglutide) d. Victoza® (liraglutide) **OR** 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; **AND** b. Contraindication to **ALL** of the following§: 1. Bydureon® (exenatide extended-release pen) 2. Byetta® (exenatide) 3. Trulicity® (dulaglutide) 4. Victoza® (liraglutide) **OR** e. **For Rybelsus requests only: BOTH** of the following: a. Documentation that the member is not a candidate for injectable formulations including documentation of needle-phobia; **AND** b. Documentation that an alternative second line agent (e.g., DPP-IV, SGLT2, TZD, sulfonylurea, or insulin) is used in combination with metformin in place of the GLP-1 agonist preferred agents (e.g. Bydureon, Byetta, Trulicity, and/or Victoza) **AND** 3. If requested quantity exceeds quantity limits, clinical rationale for exceeding FDA-approved dosing schedule
Duration of Authorization:	Prior authorization may be issued for **1 year.**

SGLT2 Inhibitors Approval Criteria:

Steglatro® (ertugliflozin)	1. Member has a diagnosis of Type 2 Diabetes Mellitus; **AND** 2. Member has **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. Farxiga® (dapagliflozin) b. Invokana® (canagliflozin) c. Jardiance® (empagliflozin) **OR** b. **BOTH** of the following: a. Adverse reaction or contraindication to metformin; **AND** 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) **OR** 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; **AND** b. Adverse reaction to **ONE** of the following: a. Farxiga® (dapagliflozin) b. Invokana® (canagliflozin) c. Jardiance® (empagliflozin) **OR** 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; **AND** b. Contraindication to **ALL** of the following: 1. Farxiga® (dapagliflozin) 2. Invokana® (canagliflozin) 3. Jardiance® (empagliflozin) **AND** 3. If requested quantity exceeds 1 tablet/day, clinical rationale for exceeding FDA-approved dosing schedule
Duration of Authorization:	Prior authorization may be issued for **1 year.**

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
9/27/2021	Updated policy to reflect changes from MH (dated 8/3/2021). Riomet IR is no longer brand preferred.	12/1/2021	P&T Committee

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date**	**Approved by**
10/1/2021	Updated policy to reflect 1/1/2022 UPPL updates: Guideline updated to include seven new agents to UPPL. These include the following: Adlyxin® (lixisenatide), Duetact® (glimepiride/pioglitazone), Oseni® (alogliptin/pioglitazone), Qtern® (dapagliflozin/saxagliptin), repaglinide/metformin, Steglujan® (ertugliflozin/sitagliptin), and Trijardy XR® (empagliflozin/linagliptin/ metformin extended-release). Guideline updated to include GLP-1 agonists requiring PA to allow for approval of requests for members with prediabetes based on published consensus guideline. Additionally, GLP-1 agonists was updated to clarify that members with needle-phobia can be reviewed using the same guidance as those with a contraindication to injectable formulations. Off-label metformin requests for the following indications: gestational diabetes, PCOS, and prediabetes were added to criteria. Glumetza®, Kazano®, and Nesina® are now brand preferred.	1/1/2022	P&T Committee

Next Review Date

5/2022

Other Applicable Policies

References

1. Adlyxin (lixisenatide) [prescribing information]. Sanofi-Aventis: Bridgewater, NJ; July 2021
2. American Diabetes Association. Standards of Medical Care in Diabetes – 2021. Diabetes Care. 2021 Jan;44(Supplement 1);S1-S232.
3. Bydureon (exenatide extended-release) [prescribing information]. AstraZeneca Pharmaceuticals: Wilmington, DE; July 2021.
4. Bydureon BCise (exenatide extended-release) [prescribing information]. AstraZeneca Pharmaceuticals: Wilmington, DE; December 2020.
5. Byetta (exenatide) [prescribing information]. AstraZeneca Pharmaceuticals: Wilmington, DE; February 2020.
6. Duetact (glimepiride/pioglitazone) [prescribing information]. Takeda Pharmaceuticals: Lexington, MA; June 2020.
7. Farxiga (dapagliflozin) [prescribing information]. AstraZeneca Pharmaceuticals: Wilmington, DE; April 2021.
8. Fortamet (metformin extended-release) [prescribing information]. Shinogi Pharmaceuticals: Florham Park, NJ; March 2021.
9. Glucophage/Glucophage XR (metformin/metformin extended-release) [prescribing information]. Bristol-Myers Squibb: Princeton, NJ; December 2019.
10. Glumetza (metformin extended-release) [prescribing information]. Salix Pharmaceuticals: Bridgewater, NJ; August 2019.
11. Invokamet (canagliflozin/metformin) [prescribing information]. Janssen Pharmaceuticals, Inc.: Titusville, NJ; August 2020.
12. Invokamet XR (canagliflozin/metformin extended-release) [prescribing information]. Janssen Pharmaceuticals, Inc.: Titusville, NJ; August 2020.
13. Invokana (canagliflozin) [prescribing information]. Janssen Pharmaceuticals, Inc.: Titusville, NJ; August 2020.
14. Janumet (sitagliptin/metformin) [prescribing information]. Merck and Co: Whitehouse Station, NJ: June 2021.
15. Janumet XR (sitagliptin/metformin extended-release) [prescribing information]. Merck and Co: Whitehouse Station, NJ; June 2021.
16. Januvia (sitagliptin) [prescribing information]. Merck and Co: Whitehouse Station, NJ; December 2020.
17. Jardiance (empagliflozin) [prescribing information]. Boehringer Ingelheim Pharmaceuticals, Inc.: Ridgefield, CT; August 2021.
18. Jentadueto (linagliptin/metformin) [prescribing information]. Boehringer Ingelheim: Ridgefield, CT; March 2020.
19. Jentadueto XR (linagliptin/metformin extended-release) [prescribing information]. Boehringer Ingelheim: Ridgefield, CT; October 2021.
20. Kazano (alogliptin/metformin) [prescribing information]. Takeda Pharmaceuticals: Deerfield, IL; July 2020.
21. Kombiglyze XR (saxagliptin/metformin extended-release) [prescribing information]. AstraZeneca Pharmaceuticals: Wilmington, DE; October 2019.

22. Nesina (alogliptin) [prescribing information]. Takeda Pharmaceuticals: Deerfield, IL; July 2020.
23. Onglyza (saxagliptin) [prescribing information]. AstraZeneca Pharmaceuticals: Wilmington, DE; October 2019.
24. Oseni (alogliptin/pioglitazone) [prescribing information]. Takeda Pharmaceuticals: Deerfield, IL; July 2020.
25. Ozempic (semaglutide) [prescribing information]. Novo Nordisk: Plainsboro, NJ; April 2021.
26. Qtern (dapagliflozin/saxagliptin) [prescribing information]. AstraZeneca Pharmaceuticals: Wilmington, DE; January 2020.
27. Riomet (metformin) [prescribing information]. Sun Pharmaceutical Industries: Cranbury, NJ; December 2018.
28. Riomet ER (metformin extended-release) [prescribing information]. August 2019. Sun Pharmaceutical Industries: Cranbury, NJ; November 2019.
29. Rybelsus (semaglutide) [prescribing information]. Novo Nordisk: Plainsboro, NJ; April 2021.
30. Segluromet (ertugliflozin/metformin) [prescribing information]. Merck and Co: Whitehouse Station, NJ; September 2021.
31. Soliqua (insulin glargine/lixisenatide) [prescribing information]. Sanofi-Aventis: Bridgewater, NJ; July 2021.
32. Steglatro (ertugliflozin) [prescribing information]. Merck and Co: Whitehouse Station, NJ; September 2021.
33. Steglujan (ertugliflozin/sitagliptin) [prescribing information]. Merck and Co: Whitehouse Station, NJ; September 2021.
34. Synjardy (empagliflozin/metformin) [prescribing information]. Boehringer Ingelheim Pharmaceuticals, Inc.: Ridgefield, CT; June 2021.
35. Synjardy XR (empagliflozin/metformin extended-release) [prescribing information]. Boehringer Ingelheim Pharmaceuticals, Inc.: Ridgefield, CT; June 2021.
36. Tradjenta (linagliptin) [prescribing information]. Boehringer Ingelheim Pharmaceuticals, Inc.: Ridgefield, CT; March 2020.
37. Trijardy XR (empagliflozin/linagliptin/metformin extended-release) [prescribing information]. Boehringer Ingelheim Pharmaceuticals, Inc.: Ridgefield, CT; June 2021.
38. Trulicity (dulaglutide) [prescribing information]. Eli Lilly: Indianapolis, IN; April 2021.
39. Victoza (liraglutide) [prescribing information]. Novo Nordisk: Plainsboro, NJ; November 2020.
40. Xigduo XR (dapagliflozin/metformin extended-release) [prescribing information]. AstraZeneca Pharmaceuticals: Wilmington, DE; January 2020.
41. Xultophy (insulin degludec/liraglutide) [prescribing information]. Novo Nordisk: Plainsboro, NJ; November 2019.

Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the

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Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.