Commercial/Healthcare Exchange PA Criteria

Effective: March 2008

Prior Authorization: Diabetic Oral Medications

Products Affected:
Combinations: Actoplus Met XR, Duetact, Kazano, Kombiglyze XR, Segluromet, Xigduo XR,
DPP4's: Nesina, Onglyza
SGLT2's: Farxiga, Steglatro

Medication Description: These agents are approved for the treatment of Type 2 diabetes in combination with other agents or alone as an adjunct to diet and exercise to improve glycemic control.

Covered Uses:

1. All of these agents are approved for the treatment of Type 2 diabetes in combination with other agents or alone as an adjunct to diet and exercise to improve glycemic control.
2. Farxiga:
    a. To reduce the risk of hospitalization for heart failure in adults with type 2 diabetes mellitus and established CV disease or multiple CV risk factors.
    b. In addition to indications in diabetes, Farxiga is indicated for the following indications in patients with and without diabetes:
        i. Heart failure, to reduce the risk of CV death and hospitalization for heart failure (HHF) in adults with heart failure with reduced ejection fraction (New York Heart Association [NYHA] class II through IV).
        ii. Chronic kidney disease, to reduce the risk of sustained estimated glomerular filtration rate (eGFR) decline, end-stage kidney disease, CV death, and hospitalization for heart failure in adults with chronic kidney disease at risk of progression.

Exclusion Criteria:

1. Actoplus Met XR –
    A. Hypersensitivity to metformin, pioglitazone, or any component of the product
    B. Acute or chronic metabolic acidosis, including diabetic ketoacidosis, with or without coma
    C. NYHA Class III or IV heart failure
    D. Severe renal impairment (estimated GFR below 30 mL/min/1.73 m^2, end stage renal disease, or dialysis
    E. Pregnancy
    F. Alcohol abuse

2. Duetact –
    A. Hypersensitivity to sulfonamide derivatives

B. Hypersensitivity to pioglitazone, glimepiride or any other component of the product
C. NYHA Class III or IV heart failure
D. Acute or chronic metabolic acidosis, including diabetic ketoacidosis, with or without coma
E. Active liver disease, as seen by increased serum transaminase levels

3. Kazano -
   A. Serious hypersensitivity (e.g., anaphylaxis, angioedema, or severe cutaneous reaction) to alogliptin, metformin, or any component of the product
   B. Acute or chronic metabolic acidosis, including diabetic ketoacidosis with or without coma
   C. Severe renal impairment (estimated GFR below 30 mL/min/1.73 m^2, end stage renal disease, or dialysis
   D. Alcohol abuse
   E. Hepatic impairment
   F. Pregnant

4. Kombiglyze XR -
   A. Hypersensitivity to metformin hydrochloride
   B. Serious hypersensitivity reaction to saxagliptin alone or in combination with metformin hydrochloride (e.g., anaphylaxis, angioedema, or exfoliative skin conditions)
   C. Acute or chronic metabolic acidosis, including diabetic ketoacidosis, with or without coma
   D. Severe renal impairment (estimated GFR below 30 mL/min/1.73 m^2, end stage renal disease, or dialysis
   E. Alcohol abuse
   F. Hepatic impairment
   G. Pregnant

5. Segluromet -
   A. Acute or chronic metabolic acidosis, including diabetic ketoacidosis, with or without coma
   B. Serious hypersensitivity to ertugliflozin, metformin, or any component of the product; reactions such as anaphylaxis or angioedema have occurred
   C. Severe renal impairment (eGFR below 30 mL/min/1.73 m^2, end stage renal disease, or dialysis
   D. Alcohol abuse
   E. Hepatic impairment
   F. Pregnant

6. Xigduo XR -
   A. Acute or chronic metabolic acidosis, including diabetic ketoacidosis, with or without coma
   B. Serious hypersensitivity to dapagliflozin (e.g., anaphylactic reactions, angioedema) or hypersensitivity to metformin hydrochloride
   C. Severe renal impairment (estimated GFR below 30 mL/min/1.73 m^2, end stage renal disease, or dialysis
   D. Alcohol abuse
   E. Hepatic impairment
   F. Pregnant

7. Nesina -

A. Serious hypersensitivity reaction to alogliptin or any component of the product, such as anaphylaxis, angioedema or severe cutaneous adverse reactions

8. Onglyza -
   A. Hypersensitivity reaction to saxagliptin (e.g., anaphylaxis, angioedema, or exfoliative skin conditions), serious

9. Farxiga -
   A. Serious hypersensitivity reaction (e.g., anaphylactic reaction or angioedema) to dapagliflozin propanediol
   B. Severe renal impairment (estimated GFR below 30 mL/min/1.73 m^2, end stage renal disease or dialysis

10. Steglatro -
    A. Hypersensitivity to ertugliflozin or any component of the product; reactions such as angioedema have occurred
    B. Severe renal impairment (estimated GFR below 30 mL/min/1.73 m^2, end stage renal disease, or dialysis

Required Medical Information:
1. Diagnosis
2. Previous medications tried/failed

Prescriber Restriction: None

Age Restriction: 18 years of age and older

Coverage Duration: 12 months

Other Criteria:

Initial Approval Criteria

NOTE: All of the following drugs require a diagnosis of diabetes mellitus type 2:

DRUG	Requirements
Actoplus Met XR	Metformin
Duetact	Metformin
Farxiga	Metformin **AND** one of the following: Invokana Invokamet Jardiance Synjardy

Kazano	Metformin **AND** one of the following: Januvia Janumet/XR Jentadueto Tradjenta
Kombiglyze XR / Saxaliptan-Metformin ER	Metformin **AND** one of the following: Januvia Janumet/XR Jentadueto Tradjenta
Nesina	Metformin **AND** one of the following: Januvia Janumet/XR Jentadueto Tradjenta
Onglyza / Saxagliptan	Metformin **AND** one of the following: Januvia Janumet/XR Jentadueto Tradjenta
Segluromet	Metformin **AND** one of the following: Invokana Invokamet Jardiance Synjardy
Steglatro	Metformin **AND** one of the following: Invokana Invokamet Jardiance Synjardy
Xigduo XR	Metformin **AND** one of the following: Invokana Invokamet Jardiance Synjardy

References:

1. Nathan DM, Buse JB, Davidson MB, et al. Management of hyperglycemia on type 2 diabetes: a consensus algorithm for the initiation and adjustment of therapy. Diabetes Care 2006;29:1963-72.
2. Actoplus Met XR full prescribing information. Deerfield, IL. Takeda Pharmaceuticals.
3. Duetact full prescribing information. Deerfield IL. Takeda Pharmaceuticals.
4. Glumetza full prescribing information. Menlo Park, CA. DepoMed Inc.

5. Fortamet full prescribing information. Atlanta, GA. Sciele Pharma Inc.
6. Oseni full prescribing information. Deerfield, IL. Takeda Pharmaceuticals.
7. Kazano full prescribing information. Deerfield, IL. Takeda Pharmaceuticals.
8. Xigduo XR, full prescribing information, Wilmington, DE, AstraZeneca Pharmaceuticals
9. Kombiglyze XR full prescribing information. Princeton, NJ. Bristol-Myers Squibb Company.
10. Nesina full prescribing information. Deerfield, IL. Takeda Pharmaceuticals.
11. Onglyza full prescribing information. Princeton, NJ. Bristol-Myers Squibb Company.
12. Farxiga full prescribing information. Princeton, NJ. Bristol-Myers Squibb Company.
13. GoodRx.com/blog/metformin-vs-metformin-mod-vs-osm-whats-the-difference/
14. Steglatro full prescribing information. Whitehouse Station, NJ. Merck & Co, Inc.
15. Steglurometfull prescribing information. Whitehouse Station, NJ. Merck & Co, Inc.
16. Steglujan full prescribing information. Whitehouse Station, NJ. Merck & Co, Inc.
17. Qtern full prescribing information. Wilmington, DE. AstraZeneca Pharmaceuticals LP.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	Transferred Policy from old CCI Template	Previous Revision History: 9/08, 12/09, 12/10, 5/11, 12/11, 9/12, 3/13, 4/13, 10/13, 2/14, 6/14, 10/14, 2/15, 7/15, 9/15, 5/16, 8/16, 11/16, 2/17, 5/17, 11/17, 1/18, 5/18, 9/18, 11/18, 5/19, 1/1/2020 – removed Oseni, please see separate Oseni Policy, 1/23/2020 – removed Qtern and Steglujan, please see separate policies for both, 2/20/2020 – removed Fortamet, Glumetza, Riomet, Metformin oral solution, please see separate Metformin Extended Release and Riomet policies P&T Review History:3/08, 6/08, 9/08, 9/09, 9/10, 12/11, 10/13, 10/14, 2/16, 8/16, 11/16, 2/17, 5/17, 11/17,5/18, 5/19	All	9/25/2023
2	Update	Added Farxiga: a. To reduce the risk of hospitalization for heart failure in adults with type 2 diabetes mellitus and established CV disease or multiple CV risk factors. b. In addition to indications in diabetes, Farxiga is indicated for the following indications in patients with and without diabetes: i. Heart failure, to reduce the risk of CV death and hospitalization for heart failure (HHF) in adults with heart failure with reduced ejection fraction (New York Heart Association [NYHA] class II through IV). ii. Chronic kidney disease, to reduce the risk of sustained estimated glomerular filtration rate (eGFR) decline, end-stage kidney disease, CV death, and hospitalization for heart failure in adults with chronic	Covered Uses	9/26/2023

3	Update	***Added exclusion criteria*** 1. Actoplus Met XR – A. Hypersensitivity to metformin, pioglitazone, or any component of the product B. Acute or chronic metabolic acidosis, including diabetic ketoacidosis, with or without coma C. NYHA Class III or IV heart failure D. Severe renal impairment (estimated GFR below 30 mL/min/1.73 m^2, end stage renal disease, or dialysis E. Pregnancy F. Alcohol abuse 2. Duetact – A. Hypersensitivity to sulfonamide derivatives B. Hypersensitivity to pioglitazone, glimepiride or any other component of the product C. NYHA Class III or IV heart failure D. Acute or chronic metabolic acidosis, including diabetic ketoacidosis, with or without coma E. Active liver disease, as seen by increased serum transaminase levels 3. Kazano A. Serious hypersensitivity (e.g., anaphylaxis, angioedema, or severe cutaneous reaction) to alogliptin, metformin, or any component of the product B. Acute or chronic metabolic acidosis, including diabetic ketoacidosis with or without coma C. Severe renal impairment (estimated GFR below 30 mL/min/1.73 m^2, end stage renal disease, or dialysis D. Alcohol abuse E. Hepatic impairment F. Pregnant 4. Kombiglyze XR A. Hypersensitivity to metformin hydrochloride B. Serious hypersensitivity reaction to saxagliptin alone or in combination with metformin hydrochloride (e.g., anaphylaxis, angioedema, or exfoliative skin conditions) C. Acute or chronic metabolic acidosis, including diabetic ketoacidosis, with or without coma D. Severe renal impairment (estimated GFR below 30 mL/min/1.73 m^2, end stage renal disease, or dialysis E. Alcohol abuse F. Hepatic impairment G. Pregnant 5. Segluromet A. Acute or chronic metabolic acidosis, including diabetic ketoacidosis, with or without coma B. Serious hypersensitivity to ertugliflozin, metformin, or any component of the product; reactions such as anaphylaxis or angioedema have occurred C. Severe renal impairment (eGFR below 30 mL/min/1.73 m^2, end stage renal disease, or dialysis D. Alcohol abuse E. Hepatic impairment F. Pregnant 6. Xigduo XR A. Acute or chronic metabolic acidosis, including diabetic ketoacidosis, with or without coma B. Serious hypersensitivity to dapagliflozin (e.g., anaphylactic reactions, angioedema) or hypersensitivity to metformin hydrochloride C. Severe renal impairment (estimated GFR below 30 mL/min/1.73 m^2, end stage renal disease, or dialysis D. Alcohol abuse E. Hepatic impairment F. Pregnant 7. Nesina A. Serious hypersensitivity reaction to alogliptin or any component of the product, such as anaphylaxis, angioedema or severe cutaneous adverse reaction 8. Onglyza A. Hypersensitivity reaction to saxagliptin (e.g., anaphylaxis, angioedema, or exfoliative skin conditions), serious 9. Farxiga A. Serious hypersensitivity reaction (e.g., anaphylactic reaction or angioedema) to dapagliflozin propanediol B. Severe renal impairment (estimated GFR below 30 mL/min/1.73 m^2, end stage renal disease or dialysis 10. Steglatro A. Hypersensitivity to ertugliflozin or any component of the product; reactions such as angioedema have occurred B. Severe renal impairment (estimated GFR below 30 mL/min/1.73 m^2, end stage renal disease, or dialysis	Exclusion Criteria	9/27/2023