Pharmacy Drug Policy & Procedure

Policy Name:	Diabetes Drug Therapies	Policy #:	546P

Purpose of the Policy

The purpose of this policy is to establish coverage criteria for Symlin (pramlintide), Byetta (exenatide), Bydureon BCise (exenatide extended release), Ozempic (semaglutide), Rybelsus (semaglutide), Trulicity (dulaglutide), Victoza (liraglutide), Mounjaro (tirzepatide), Januvia (sitagliptan), Janumet (sitagliptan-metformin), Janumet XR (sitagliptan-metformin XR), Onglyza (saxagliptin), Kombiglyze (saxagliptin-metformin); Kombiglzye XR (saxagliptin-metformin XR), Nesina (alogliptin benzoate), Oseni (alogliptin benzoate-pioglitazone), Kazano (alogliptin benzoate-metformin), Tradjenta (linagliptin), Jentadueto (linagliptin/metformin), Jentadueto XR (linagliptin/metformin), Farxiga (dapagliflozin), Xigduo (dapagliflozin-metformin), Xigduo XR (dapagliflozin- metformin ER), Qtern (dapagliflozin-saxagliptin), Invokana (canagliflozin), Invokamet (canagliflozin- metformin), Invokamet XR (canagluflozin-metformin), Jardiance (empagliflozin), and Synjardy (empagliflozin- metformin), Brenzavvy (bexagliflozin), Glyxambi (empagliflozin/linagliptin), Trijardy XR (empagliflozin-linagliptin-metformin), Steglatro (ertugliflozin), Steglujan (ertugliflozin-sitagliptin), Segluromet (ertugliflozin-metformin), Soliqua (insulin glargine-lixisenatide), Xultophy (insulin degludec-liraglutide), Novolin N (insulin NPH), Novolin R (insulin regular), Novolin 70/30, Novolog (insulin aspart), Novolog Mix 70/30, Apidra (insulin glulisine), Fiasp (insulin aspart), and Admelog (insulin lispro) for the treatment of diabetes mellitus.

Statement of the Policy

Health Alliance Medical Plans and Health Alliance Northwest will approve the use of the following diabetes medications when the following criteria have been met.

Criteria

1. Symlin (pramlintide) Step Edit

1.1 Symlin will be covered for members with documentation of failure to reach blood sugar control with mealtime insulin

1.2 Members with the following conditions will not be required to meet the step edit:

- Confirmed diagnosis of gastroparesis (delayed stomach empyting)
- Need for medications to stimulate gastrointestinal motility
- Poor compliance with current insulin regimen
- Poor compliance with prescribed self-blood glucose monitoring
- Recurrent severe hypoglycemia requiring assistance in the last 6 months
- Presence of hypoglycemia unawareness
- Pediatric patients

2. Glucagon-like peptide-1 (GLP- 1) and Glucose-Dependent Insulintropic Peptide (GIP) and Glucagon-like peptide-1

2.1 GLP-1 Agonists: Adlyxin, Byetta, Bydureon BCise, Ozempic, Rybelsus, Trulicity, and Victoza

2.2 GLP-1 and GIP Product: Mounjaro

2.3 Requested drug is being used for a Food and Drug Administration (FDA)-approved indication to improve glycemic control in patients with type 2 diabetes or reduce the risk of major cardiovascular events in adults with type 2 diabetes and established cardiovascular disease or multiple cardiovascular risk factors

- Medical necessity for coverage is only established for the Food and Drug Administration (FDA)-approved indications
- Off-label indications are otherwise excluded per the Excluded Drug List Policy

2.4 Drug is not being used solely for weight loss

2.5 One of the following criteria is met:

- Established ASCVD (coronary artery disease, cerebrovascular disease, or peripheral arterial disease OR identified as high risk for ASCVD as defined by one of the following
  - >/= 55 years old with coronary, carotid, or lower extremity artery stenosis > 50%
  - Left ventricular hypertrophy
- Inadequate response (defined as at least 30 days of therapy within the previous 180 days) at the maximally tolerated dose, contraindication or intolerance of metformin
- Inadequate response (defined as at least 30 days of therapy within the previous 180 days) at the maximally tolerated dose, contraindication or intolerance of a formulary insulin product

2.6 Quantity Limits as listed below

3. Dipeptidyl Peptidase IV (DPP-4) *Preferred* Product Step-Edit

3.1 Preferred DPP-4 products fall into two groups:

- Group 1: Tradjenta, Jentadueto, Jentadueto XR
- Group 2: Januvia, Janumet, Janumet XR

3.2 Pharmacy claims history showing that the member has filled at least a 90-day supply of metformin in the previous 180 days, or documentation of intolerance or contraindication to metformin; OR

3.3 Pharmacy claims showing at least a 90-day supply of a formulary insulin product in the previous 180 days

3.4 Quantity Limit as listed below

5 Dipeptidyl Peptidase IV (DPP-4) *Non-Preferred* Product Prior Authorization

5.1 Non-preferred Products: Onglyza, Kombiglyze, Kombiglyze XR, Nesina, Oseni, Kazano, alogliptin, alogliptin-pioglitazone, alogliptin-metformin

5.2 Documented failure of at least one product listed in Group 1, with claims history that indicates that the member has filled at least a 90 day supply of metformin in the previous 180 days, AND

5.3 Documented failure of at least one product listed in Group 2, with claims history that indicates that the member has filled at least a 90 day supply within the previous 180 days

5.4 Quantity Limit as listed below

6. Sodium Glucose Co-Transporter 2 Inhibitors (SGLT-2) *Preferred* Product Step Edit

6.1 Preferred SGLT-2 products fall into two groups:

- Group 1: Farxiga, Xigduo XR
- Group 2: Jardiance, Synjardy

6.2 One of the following criteria is met:

- Established ASCVD (coronary artery disease, cerebrovascular disease, or peripheral arterial disease OR identified as high risk for ASCVD as defined by one of the following:
  - ≥ 55 years old with coronary, carotid, or lower extremity stenosis > 50%

- Left ventricular hypertrophy
- Pharmacy claims history indicating that the member has filled at least a 90-day supply of metformin within the previous 180 days, or documentation showing intolerance or contraindication to metformin
- Pharmacy claims showing at least a 90 day supply of a formulary insulin product within the previous 180 days

6.3 Quantity Limit as listed below
6.4 See SGLT2 Non-Diabetes Indications policies for coverage outside of this indication

7. Sodium Glucose Co-Transporter 2 Inhibitors (SGLT-2) *Non-Preferred* Product Prior Authorization

7.1 Non-preferred products include: Invokana, Invokamet, Invokamet XR, Steglatro, Segluromet, Brenzavvy, Bexagliflozin
7.2 Pharmacy claims showing at least a 90-day supply use of at least one Group 1 SGLT-2 product in the previous 180 days, AND
7.3 Pharmacy claims showing at least a 90-day supply of at least one Group 2 SGLT-2 product in the previous 180 days
7.4 Quantity Limit as listed below

8. SGLT-2/DPP-4 Combination Products Prior Authorization

8.1 Coverage of SGLT-2/DPP-4 combination products require the following:
- Products include: Glyxambi, Trijardy XR, Steglujan, Qtern

8.2 Pharmacy claims showing at least a 90 day supply of Farxiga or Xigduo XR in the previous 180 days
8.3 Pharmacy claims showing at least a 90 day supply of Jardiance or Synjardy in the previous 180 days
8.4 Quantity Limit as listed below

9. Long Acting Insulin/GLP-1 Combination Products Prior Authorization

9.1 Coverage of long-acting insulin/GLP-1 products, Soliqua and Xultophy, require documented failure with one of the following:
- Pharmacy claims showing at least a 90 day supply of a GLP-1 product within the previous 180 days
- Pharmacy claims showing at least a 90 day supply of a long acting basal insulin product within the previous 180 days (ex. Lantus, Levemir, Tresiba)

10. Medical Necessity for Immediate Dual Therapy Requirements

10.1 New diagnosis of Type 2 diabetes mellitus
10.2 A1c is greater than or equal to 9%
10.3 Second drug being requested will be used in combination with metformin or a sulfonylurea unless there is a contraindication to both
10.4 Immediate addition of a third product used with metformin AND any antidiabetic drug that doesn't require preauthorization is excluded.
10.5 Immediate addition of a third product to combination products which include metformin or any other combination antidiabetic product that doesn't require preauthorization is excluded
10.6 Use of in-class preferred formulary products is required
- Example: Tradjenta or Januvia; Farxiga or Jardiance

10.7 Quantity limits as listed below
10.8 Addition of a third drug will require pharmacy claims showing member has used dual therapy for at least 3 months

11. Non-Preferred Insulin Step-Edit

11.1 Coverage of non-preferred insulin products requires:
- Non-preferred insulin products include: Novolin N, Novolin R, Novolin 70/30, Novolog, Novolog Mix 70/30, Admelog, Fiasp, and Apidra

11.2 Pharmacy claims showing at least 3 months use of a preferred insulin, OR
11.3 Notes from provider which show previous trial and failure, intolerance, or contraindication to a preferred insulin product

12. Approval time frames

12.1 Approval period of 12 months

13. Definitions

13.1 Contraindication to metformin based on:

- Kidney dysfunction
- Concurrent active or progressive liver disease
- Active alcohol abuse
- History of acute lactic acidosis while taking metformin or chronic lactic acidosis
- Unstable or acute heart failure

14. Quantity limits

Product	Amount per 30 days	Amount per 90 days
Byetta 5mcg	1 box, or 1.2ml	3 boxes or 3.6ml
Byetta 10mcg	1 box or 2.4ml	3 boxes or 7.2ml
Bydureon BCise	3.4ml (per 28 days)	10.2ml (per 84 days)
Mounjaro	2ml (per 28 days)	6ml (per 84 days)
Ozempic	1.5ml or 3ml (per 28 days)	4.5ml or 9ml (per 84 days)
Rybelsus	30 tablets	90 tablets
Trulicity	2ml (per 28 days)	6ml (per 84 days)
Victoza 2 Pack	6ml	18ml
Victoza 3 pack	9ml	27ml
Tradjenta 5mg	30 tablets	90 tablets
Jentadueto	60 tablets	180 tablets
Jentadueto XR 2.5-1000	60 tablets	180 tablets
Jentadueto XR 5-1000	30 tablets	90 tablets
Januvia	30 tablets	90 tablets
Janumet	60 tablets	180 tablets
Janumet XR 50-500, 100-1000	30 tablets	90 tablets
Janumet XR 50-1000	60 tablets	180 tablets
Onglyza	30 tablets	90 tablets
Kombiglyze XR 2.5-1000mg	60 tablets	180 tablets
Kombiglyze XR 5-500mg, 5-1000mg	30 tablets	90 tablets
Nesina	30 tablets	90 tablets
Oseni	30 tablets	90 tablets
Kazano	60 tablets	180 tablets
Invokana	30 tablets	90 tablets
Invokamet/Invokamet XR	60 tablets	180 tablets
Jardiance	30 tablets	90 tablets
Synjardy	60 tablets	180 tablets
Farxiga	30 tablets	90 tablets
Xigduo XR 5-500mg, 10-500mg, 10-1000mg	30 tablets	90 tablets

Xigduo XR 5-1000mg	60 tablets	180 tablets
Steglatro	30 tablets	90 tablets
Segluromet	60 tablets	180 tablets
Brenzavvy/Bexagliflozin	30 tablets	90 tablets
Glyxambi	30 tablets	90 tablets
Trijardy XR 5-2.5-1000mg, 12.5-2.5-1000mg	60 tablets	180 tablets
Trijardy XR 10-5-1000mg, 25-5-1000mg	30 tablets	90 tablets
Steglujan	30 tablets	90 tablets
Qtern	30 tablets	90 tablets

HCPCS Codes

References

1. American Diabetes Association Professional Practice Committee; 9. Pharmacologic Approaches to Glycemic Treatment: Standards of Care in Diabetes—2024. Diabetes Care 1 January 2024; 47 (Supplement_1): S158–S178.

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DISCLAIMER
This Medical Policy has been developed as a guide for determining medical necessity. The process of medical necessity review also entails review of the most recent literature and physician review. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care. Health Alliance encourages input from providers when developing and implementing medical policies. Benefit determinations are based on applicable contract language in the member's Policy/ Subscription Certificate/ Summary Plan Description. This Medical Policy does not guarantee coverage. There may be a delay between the revision of this policy and the posting on the web. Please contact the Health Alliance Customer Service Department at 1-800-851-3379 for verification of coverage.