

<b>POLICY NAME</b>	Diabetes Drug Therapies	<b>POLICY #</b>	546P
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## Criteria

### Symlin (pramlintide) Step Edit

- ☐ 1.1 Symlin will be covered for members with documentation of failure to reach blood sugar control with mealtime insulin
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- ☐ 1.2 Members with the following conditions will not be required to meet the step edit:
    - Confirmed diagnosis of gastroparesis (delayed stomach emptying)
    - 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 Statement of the Policy

## Glucagon-like peptide-1 (GLP- 1) and Glucose-Dependent Insulinotropic Peptide (GIP) and Glucagon-like peptide-1

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

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- ☐ **2.2** GLP-1 and GIP Product: Mounjaro

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- ☐ **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

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- ☐ **2.4** Drug is not being used solely for weight loss

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- ☐ **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
  - $\geq 55$  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
  - Requirement does not apply to State of Illinois members with diabetes and weight loss benefit per legislative mandate

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- ☐ **2.6** Coverage of Victoza (liraglutide) require previous trial with TWO of the following:
  - Mounjaro
  - Byetta or Bydureon
  - Ozempic or Rybelsus
  - Trulicity

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- ☐ **2.7** Quantity Limits as listed below

## 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

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

- ☐ **4.1** Non-preferred Products: Onglyza, Kombiglyze, Kombiglyze XR, Nesina, Oseni, Kazano, alogliptin, alogliptin-pioglitazone, alogliptin-metformin
- ☐ **4.2** 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
- ☐ **4.3** 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
- ☐ **4.4** Quantity Limit as listed below

## Sodium Glucose Co-Transporter 2 Inhibitors (SGLT-2) Preferred Product Step Edit

- ☐ **5.1** Preferred SGLT-2 products fall into two groups:
  - Group 1: Farxiga, Xigduo XR
  - Group 2: Jardiance, Synjardy
- ☐ **5.2** 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:
  - $\geq 55$  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
- ☐ **5.3** Quantity Limit as listed below
- ☐ **5.4** See SGLT2 Non-Diabetes Indications policies for coverage outside of this indication

## Sodium Glucose Co-Transporter 2 Inhibitors (SGLT-2) Non-Preferred Product Prior Authorization

- ☐ **6.1** Non-preferred products include: Invokana, Invokamet, Invokamet XR, Steglatro, Segluromet, Brenzavvy, Bexagliflozin
- ☐ **6.2** 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
- ☐ **6.3** Pharmacy claims showing at least a 90-day supply of at least one Group 2 SGLT-2 product in the previous

**days**

- ☐ **6.4** Quantity Limit as listed below

## SGLT-2/DPP-4 Combination Products Prior Authorization

- ☐ **7.1** Coverage of SGLT-2/DPP-4 combination products require the following:
  - Products include: Glyxambi, Trijardy XR, Steglujan, Qtern
- ☐ **7.2** Pharmacy claims showing at least a 90 day supply of Farxiga or Xigduo XR in the previous 180 days
- ☐ **7.3** Pharmacy claims showing at least a 90 day supply of Jardiance or Synjardy in the previous 180 days
- ☐ **7.4** Quantity Limit as listed below

## Long Acting Insulin/GLP-1 Combination Products Prior Authorization

- ☐ **8.1** 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)

## Medical Necessity for Immediate Dual Therapy Requirements

- ☐ **9.1** New diagnosis of Type 2 diabetes mellitus
- ☐ **9.2** A1c is greater than or equal to 9%
- ☐ **9.3** Second drug being requested will be used in combination with metformin or a sulfonylurea unless there is a contraindication to both
- ☐ **9.4** Immediate addition of a third product used with metformin AND any antidiabetic drug that doesn't require preauthorization is excluded.
- ☐ **9.5** 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
- ☐ **9.6** Use of in-class preferred formulary products is required
  - Example: Tradjenta or Januvia; Farxiga or Jardiance
- ☐ **9.7** Quantity limits as listed below
- ☐ **9.8** Addition of a third drug will require pharmacy claims showing member has used dual therapy for at least 3 months

## Non-Preferred Insulin Step-Edit

- ☐ **10.1** 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
- ☐ **10.2** Pharmacy claims showing at least 3 months use of a preferred insulin, OR
- ☐ **10.3** Notes from provider which show previous trial and failure, intolerance, or contraindication to a preferred insulin product

## Definitions

- ☐ **12.1** 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