



Commercial/Healthcare Exchange Step Criteria

Effective: April 2010

Step Therapy Name: Preferred GLP-1 inhibitors (Incretin Mimetics)

Step 1 Agent(s): Cycloset, Acarbose, Glyset, Miglitol, Precose, Fortamet, Glucophage/XR, Glumetza, metformin/ER, Riomet, Oseni, alogliptin-pioglitazone, alogliptin, Januvia, Nesina, Onglyza, Tradjenta, Amaryl, Chlorpropamide, glimepiride, glipizide/XL/ER, Glucotrol/XL, glyburide, Glynase, nateglinide, Prandin, repaglinide, Starlix, tolazamide, tolbutamide, Glyxambi, Qtern, Steglujan, Actoplus Met/XR, Avandamet, pioglitazone-metformin, Duetact, pioglitazone-glimepride, alogliptin-metformin, Janumet/XR, Jentadueto/XR, Kazano, Kombiglyze XR, glipizide-metformin, Glucovance, glyburide-metformin, repaglinide-metformin, Actos, Avandia, pioglitazone, Admelog/Solostar, Afrezza, Apidra, Basaglar, Fiasp, Humalog (all), Humulin (all), Insulin lispro, Lantus, Levemir, Myxredlin, Novolin (all), Novolog (all), Toujeo, Tresiba

Step 2 Agent(s): Bydureon, Byetta, Victoza, Ozempic, Rybelsus, Trulicity, Mounjaro

Medication/Class Description:

GLP-1 is produced from the proglucagon gene in L-cells of the small intestine and is secreted in response to food intake. GLP-1 binds to specific GLP-1 receptors expressed in various tissues including pancreatic beta cells, pancreatic ducts, gastric mucosa, etc. GLP-1 exerts its main effect by stimulating glucose-dependent insulin release from the pancreatic islets. It has also been shown to slow gastric emptying, inhibit inappropriate post-meal glucagon release, and thereby reduce food intake. Exenatide administration results in decreases in hemoglobin A1c (HbA1c) by approximately 0.5% to 1% (immediate release) or 1.5% to 1.9% (ER). Liraglutide administration results in decreases in hemoglobin A1c by approximately 1%. Due to the effects of GLP-1 on slowed gastric emptying and appetite centers in the brain, therapy with GLP-1 receptor agonists is associated with weight loss, even among patients without significant nausea and vomiting.

Required Medical Information:

1. Diagnosis
2. History of previous therapy tried/failed
3. Current therapy regimen
4. Hgb A1C value(s)

Age Restrictions:

1. Byetta, Mounjaro, Ozempic, Rybelsus, and Trulicity: 18 years of age and older
2. Bydureon and Victoza: 10 years of age and older

Prescriber Restrictions: None

Coverage Duration: 12 months

Exceptions for Stepped Medications

1. Member has history of failure of a Step 1 agent, defined as:

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- a. Failure to decrease Hemoglobin A1C; **OR**
2. Member has intolerance to a Step 1 agent, defined as (but not limited to):
 - a. Allergic reaction; **OR**
 - b. Adverse drug reactions; **OR**
3. Member is currently stable on Step 2 agent; **AND**
4. Change in therapy deemed medically unsafe, defined as (but not limited to):
 - a. High potential for bodily harm; **OR**
 - b. High potential for poor therapeutic outcomes

References:

1. Product Information: TANZEUM(TM) subcutaneous injection, albiglutide subcutaneous injection. GlaxoSmithKline (per FDA), Research Triangle Park, NC, 2015.
2. Product Information: TRULICITY(TM) subcutaneous injection, dulaglutide subcutaneous injection. Eli Lilly and Company (per manufacturer), Indianapolis, IN, 2014.
3. Product Information: Victoza(R) subcutaneous injection solution, liraglutide rDNA origin subcutaneous injection solution. Novo Nordisk Inc. (per FDA), Plainsboro, NJ, 2015.
4. Product Information: BYDUREON(R) subcutaneous extended-release injection suspension, exenatide subcutaneous extended-release injection suspension. AstraZeneca Pharmaceuticals LP (per FDA), Wilmington, DE, 2015.
5. Product Information: BYETTA(R) subcutaneous injection, exenatide subcutaneous injection. AstraZeneca Pharmaceuticals LP (per FDA), Wilmington, DE, 2015.
6. Product Information: ADLYXIN subcutaneous injection, lixisenatide subcutaneous injection. Sanofi-Aventis (per FDA), Bridgewater, NJ, 2016
7. Product Information: OZEMPIC(R) subcutaneous injection, semaglutide subcutaneous injection. Novo Nordisk Inc (per manufacturer), Plainsboro, NJ, 2017.
8. Product Information: RYBELSUS(R) oral tablets, semaglutide oral tablets. Novo Nordisk Inc (per manufacturer), Plainsboro, NJ, 2019.
9. Product Information: MOUNJARO(TM) subcutaneous injection, tirzepatide subcutaneous injection. Lilly USA LLC (per FDA), Indianapolis, IN, 2022.

Revision History:

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	Update	New Template; Addition of Rybelsus CCI P&T Review History: 4/10, 9/10, 12/10, 12/11, 10/12, 10/13, 11/15, 2/16, 11/16, 2/17, 5/17, 5/18, 5/19 CCI Revision Record: 12/10, 3/12, 11/12, 4/14, 6/14, 11/14, 11/16, 2/17, 5/17, 1/18, 5/18, 5/19	All	12/9/2019

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2	Update	Added Trulicity to Step 2 agent	Step 2 Agent(s)	03/2020
3	Update	Updates made to reflect FDA approved age restrictions for Bydureon and Victoza to 10 years of age and older	Age Restrictions	03/2022
4	Update	Added Mounjaro to Step 2 Agents and Age Restrictions	Step 2 Agents, Age Restrictions	8/1/2022
5	Update	Added Diagnosis to Required Medical Information	Required Medical Information	9/27/2022