Glucagon-like Peptide-1 (GLP-1) Agonists Step Therapy with Quantity Limit Program Summary

This program applies to Medicaid.

Step Therapy only applies to the MN Medicaid Preferred Drug List (PDL) preferred drugs: Byetta, Bydureon pens, Bydureon BCise, Ozempic, and Victoza.

The BCBS MN Step Therapy Supplement applies to this program for Medicaid.

POLICY REVIEW CYCLE

Effective Date	Date of Origin
07-01-2024	07-01-2027

FDA APPROVED INDICATIONS AND DOSAGE

Agent(s)	FDA Indication(s)	Notes	Ref#
Adlyxin® (lixisenatide) Subcutaneous injection	Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitations of Use: • Has not been studied in patients with chronic pancreatitis or a history of unexplained pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis • Should not be used in patients with type 1 diabetes • Has not been studied in patients with gastroparesis and is not recommended in patients with gastroparesis.		8
Bydureon® (exenatide) Subcutaneous injection	Adjunct to diet and exercise to improve glycemic control in adults and pediatric patients aged 10 years and older with type 2 diabetes mellitus. Limitations of Use: • Not recommended as first-line therapy for patients inadequately controlled on diet and exercise • Is not indicated for use in patients with type 1 diabetes mellitus • Bydureon is an extended-release formulation of exenatide and should not be used with other products containing the active ingredient exenatide. • Has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis.		3
Bydureon BCise® (exenatide) Subcutaneous injection	Adjunct to diet and exercise to improve glycemic control in adults and pediatric patients aged 10 years and older with type 2 diabetes mellitus. Limitations of Use: • Not recommended as first-line therapy for patients inadequately controlled on diet and exercise. • Is not indicated for use in patients with type 1 diabetes mellitus		4

Agent(s)	FDA Indication(s)	Notes	Ref#
	• Bydureon BCise is an extended-release formulation of exenatide. It should not be used with other products containing the active ingredient exenatide. • Has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis.		
Byetta® (exenatide) Subcutaneous injection	Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Limitations of Use: • Should not be used for the treatment of type 1 diabetes. • Has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis.		1
Mounjaro® (tirzepatide) Subcutaneous injection	An adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus Limitations of Use • Has not been studied in patients with a history of pancreatitis • Is not indicated for use in patients with type 1 diabetes mellitus		11
Ozempic® (semaglutide) Subcutaneous injection	Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus To reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes mellitus and established cardiovascular disease Limitations of Use: • Has not been studied in patients with a history of pancreatitis. Consider another antidiabetic therapy • Not for treatment of type 1 diabetes mellitus		5
Rybelsus® (semaglutide) Tablet	Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus Limitations of Use: • Not recommended as first-line therapy for patients who have inadequate glycemic control on diet and exercise • Has not been studied in patients with a history of pancreatitis • Not indicated for use in patients with type 1 diabetes mellitus		6
Trulicity® (dulaglutide) Subcutaneous injection	Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. To reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal		7

Agent(s)	FDA Indication(s)	Notes	Ref#
	stroke) in adults with type 2 diabetes mellitus who have established cardiovascular disease or multiple cardiovascular risk factors Limitations of Use: • Has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in these patients • Not for treatment of type 1 diabetes • Not recommended in patients with severe gastrointestinal disease, including severe gastroparesis.		
Victoza® (liraglutide) Subcutaneous injection	Adjunct to diet and exercise to improve glycemic control in patients 10 years and older with type 2 diabetes mellitus. To reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease Limitations of Use: • Should not be used in patients with type 1 diabetes mellitus. • Contains liraglutide and should not be coadministered with other liraglutide containing products		2

See package insert for FDA prescribing information: https://dailymed.nlm.nih.gov/dailymed/index.cfm

CLINICAL RATIONALE

Diabetes Mellitus	The American Diabetes Association (ADA) recommends the following guidelines:(9,10) • Healthy lifestyle behaviors, diabetes self-management education and support, avoidance of clinical inertia, and social determinants of health should be considered in the glucose-lowering management of type 2 diabetes. Pharmacologic therapy should be guided by person-centered treatment factors, including comorbidities and treatment goals. • In adults with type 2 diabetes and established/high risk of atherosclerotic cardiovascular disease, heart failure, and/or chronic kidney disease, the treatment regimen should include agents that reduce cardiorenal risk. • Pharmacologic approaches that provide adequate efficacy to achieve and maintain treatment goals should be considered, such as metformin or other agents, including combination therapy. • Weight management is an impactful component of glucose-lowering management in type 2 diabetes. The glucose-lowering treatment regimen should consider approaches that support weight management goals. • Metformin should be continued upon initiation of insulin therapy (unless contraindicated or not tolerated) for ongoing glycemic and metabolic benefits. A Early combination therapy can be considered in some individuals at treatment initiation to extend the time to treatment failure. • The early introduction of insulin should be considered if there is evidence of ongoing catabolism (weight loss), if symptoms of hyperglycemia are present, or when A1C levels (>10% [86 mmol/mol]) or blood glucose levels (greater or equal to 300 mg/dL) are very high. • A person-centered approach should guide the choice of pharmacologic agents. Consider the effects on cardiovascular and renal comorbidities, efficacy,

	hypoglycemia risk, impact on weight, cost and access, risk for side effects, and individual preferences. • Among individuals with type 2 diabetes who have established atherosclerotic cardiovascular disease or indicators of high cardiovascular risk, established kidney disease, or heart failure, a sodium–glucose cotransporter 2 inhibitor and/or glucagon-like peptide 1 receptor agonist with demonstrated cardiovascular disease benefit is recommended as part of the glucose-lowering regimen and comprehensive cardiovascular risk reduction, independent of A1C and in consideration of person-specific factors. • In adults with type 2 diabetes, a glucagon-like peptide 1 receptor agonist is preferred to insulin when possible. • An A1C level of greater than or equal to 6.5% is recommended for most nonpregnant adults, if it can be achieved safely. Glucose targets should be individualized with consideration for life expectancy, disease duration, presence or absence of micro- and macrovascular complications, cardiovascular disease (CVD) risk factors, comorbid conditions, and risk for hypoglycemia, as well as a person's cognitive and psychological status. • Adopt less stringent glycemic goals (A1C 7% to 8%) in persons with a history of severe hypoglycemia, hypoglycemia unawareness, limited life expectancy, advanced renal disease, extensive comorbid conditions, or long-standing DM in which the A1C goal has been difficult to attain despite intensive efforts, so long as the person remains free of hyperglycemia-associated symptoms. Healthy lifestyle behaviors, diabetes self-management, education, and support, avoidance of clinical inertia, and social determinants of health should be considered in the glucose-lowering management of type 2 diabetes. Pharmacologic therapy should be guided by person-centered treatment factors, including comorbidities and treatment goals. Pharmacotherapy should be started at the time type 2 diabetes is diagnosed unless there are contraindications. Pharmacologic approaches that provide the efficacy to achieve treatment goals should be considered, such as metformin or other agents, including combination therapy, that provide adequate efficacy to achieve and maintain treatment goals. In adults with type 2 diabetes and established/high risk of atherosclerotic cardiovascular disease (ASCVD), heart failure (HF), and/or chronic kidney disease (CKD), the treatment regimen should include agents that reduce cardiorenal risk. Pharmacologic approaches that provide the efficacy to achieve treatment goals should be considered, specified as metformin or agent(s), including combination therapy, that provide adequate efficacy to achieve and maintain treatment goals. In general, higher-efficacy approaches have greater likelihood of achieving glycemic goals, with the following considered to have very high efficacy for glucose lowering: the GLP-1 RAs dulaglutide (high dose) and semaglutide, the gastric inhibitory peptide (GIP) and GLP-1 RA tirzepatide, insulin, combination oral therapy, and combination injectable therapy. Weight management is an impactful component of glucose-lowering management in type 2 diabetes. The glucose-lowering treatment regimen should consider approaches that support weight management goals, with very high efficacy for weight loss seen with semaglutide and tirzepatide. Metformin is effective and safe, is inexpensive, and may reduce risk of cardiovascular events and death. Metformin is available in an immediate-release form for twice-daily dosing or as an extended-release form that can be given once daily. Compared with sulfonylureas, metformin as first-line therapy has beneficial effects on A1C, weight, and cardiovascular mortality. For people with type 2 diabetes and established ASCVD or indicators of high ASCVD risk, HF, or CKD, an SGLT2 inhibitor and/or GLP-1 RA with demonstrated CVD benefit is recommended as part of the glucose-lowering regimen independent of A1C, independent of metformin use and in consideration of person-specific factors. For people without established ASCVD, indicators of high ASCVD risk, HF, or CKD, medication choice is guided by efficacy in support of individualized glycemic and weight management goals,

	avoidance of side effects (particularly hypoglycemia and weight gain), cost/access, and individual preferences.(10) The American Diabetes Association (ADA) and the American Association of Clinical Endocrinologists (AACE) recommend glucagon-like peptide 1 receptor agonists (GLP-1) as an add-on therapy to oral agents and in combination with insulin for the treatment of diabetes. Current guidelines by the ADA and AACE do not support combination therapy of GLP-1 and dipeptidyl peptidase 4 inhibitors (DPP-4) due to lack of added clinical benefit. The mechanism of action by which GLP-1 and DPP-4 medications control blood glucose is by targeting the body's incretin system. GLP-1 agonists act as "incretin mimetics" and DPP-4 inhibitors prevent the breakdown of endogenous incretin. Unlike endogenous incretin, GLP-1 is not broken down by the DPP-4 enzyme. Therefore, using these medications at the same time yields no additional benefit due to the simliar mechanism of action. (10,12,13)

Safety	Bydureon, Bydureon BCise, Mounjaro, Ozempic, Rybelsus, Trulicity, and Victoza all share the same boxed warning and contraindications:(2-7,11)
	
	• Causes thyroid C-cell tumors at clinically relevant exposures in rats. It is unknown whether these agents cause thyroid C-cell tumors, including medullary thyroid carcinoma (MTC) in humans, as the human relevance of induced rodent thyroid C-cell tumors has not been determined.
	• Contraindicated in:
	  ○ Patients with a personal or family history of MTC or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2).
	  ○ Prior serious hypersensitivity reaction to the active ingredient or any of the product components
	
	Adlyxin and Byetta are contraindicated in patients with severe hypersensitivity to the active product ingredient or any component. (1,8)

REFERENCES

Number	Reference
1	Byetta prescribing information. AstraZeneca Pharmaceuticals, Inc. December 2022.
2	Victoza prescribing information. Novo Nordisk A/S. July 2023.
3	Bydureon prescribing information. AstraZeneca Pharmaceuticals, Inc. December 2022.
4	Bydureon BCise prescribing information. AstraZeneca Pharmaceuticals, Inc. December 2022.
5	Ozempic prescribing information. Novo Nordisk. September 2023.
6	Rybelsus prescribing information. Novo Nordisk A/S. January 2022.
7	Trulicity prescribing information. Eli Lilly and Company. November 2022.
8	Adlyxin prescribing information. Sanofi-Aventis US. LLC. June 2022.
9	American Diabetes Association. 6. Glycemic Targets: Standards of Care in Diabetes-2024. Diabetes Care. 2024 Jan;47(Suppl 1):S97-S1https://doi.org/10.2337/dc24-S00610.
10	American Diabetes Association. 9. Pharmacologic Approaches to Glycemic Treatment: Standards of Care in Diabetes-2023. Diabetes Care 1 January 2023; 47 (Supplement_1): S158–S178. https://doi.org/10.2337/dc23-S009.
11	Mounjaro prescribing information. Lilly, USA. June 2023.
12	Nauck, Michael A. Addition of dipeptidyl peptidase-4 inhibitor, sitagliptin, to ongoing therapy with the glucagon-like peptide-1 receptor agonist liraglutide: A randomized controlled trial in patients with type 2 diabetes. Diabetes Obesity and Metabolism. (2):200-207. dom-pubs.onlinelibrary.wiley.com/doi/10.1111/dom.12802.
13	Blonde, L., Umpierrez, G. et. al., 2022 Clinical Practice Guideline for Development of a Diabetes Mellitus Comprehensive Care Plan. October 2022. 28(10): 923-1049. https://doi.org/10.1016/j.eprac.2022.08.002.
14	American Diabetes Association. Understanding A1C. https://diabetes.org/about-diabetes/a1c.

POLICY AGENT SUMMARY STEP THERAPY

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Bydureon bcise	exenatide extended release susp auto-injector	2 MG/0.85ML	M ; N ; O ; Y	N		
Byetta	exenatide soln pen-injector	10 MCG/0.04ML ; 5 MCG/0.02ML	M ; N ; O ; Y	N		
Ozempic	semaglutide soln pen-inj	2 MG/1.5ML ; 2 MG/3ML ; 4 MG/3ML ; 8 MG/3ML	M ; N ; O ; Y	N		
Victoza	liraglutide soln pen-injector	18 MG/3ML	M ; N ; O ; Y	N		

POLICY AGENT SUMMARY QUANTITY LIMIT

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
Adlyxin	Lixisenatide Soln Pen-injector 20 MCG/0.2ML (100 MCG/ML)	20 MCG/0.2 ML	2	Pens	28	DAYS	The patient must have a diagnosis of type 2 diabetes mellitus		
Adlyxin starter pack	Lixisenatide Pen-inj Starter Kit 10 MCG/0.2ML & 20 MCG/0.2ML	10 & 20 MCG/0.2 ML	2	Pens	180	DAYS	The patient must have a diagnosis of type 2 diabetes mellitus		
Bydureon bcise	Exenatide Extended Release Susp Auto-Injector 2 MG/0.85ML	2 MG/0.85 ML	4	Injection Devices	28	DAYS	The patient must have a diagnosis of type 2 diabetes mellitus		
Byetta	Exenatide Soln Pen-injector 10 MCG/0.04ML	10 MCG/0.0 4ML	1	Pen	30	DAYS	The patient must have a diagnosis of type 2 diabetes mellitus		
Byetta	Exenatide Soln Pen-injector 5 MCG/0.02ML	5 MCG/0.0 2ML	1	Pen	30	DAYS	The patient must have a diagnosis of type 2 diabetes mellitus.		
Mounjaro	Tirzepatide Soln Pen-injector	2.5 MG/0.5 ML	4	Pens	180	DAYS			
Mounjaro	Tirzepatide Soln Pen-injector	5 MG/0.5 ML	4	Pens	28	DAYS			
Mounjaro	Tirzepatide Soln Pen-injector	7.5 MG/0.5 ML	4	Pens	28	DAYS			

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
Mounjaro	Tirzepatide Soln Pen-injector	10 MG/0.5 ML	4	Pens	28	DAYS			
Mounjaro	Tirzepatide Soln Pen-injector	12.5 MG/0.5 ML	4	Pens	28	DAYS			
Mounjaro	Tirzepatide Soln Pen-injector	15 MG/0.5 ML	4	Pens	28	DAYS			
Ozempic	Semaglutide Soln Pen-inj	8 MG/3ML	1	Pen	28	DAYS	The patient must have a diagnosis of type 2 diabetes mellitus.		
Ozempic	Semaglutide Soln Pen-inj	4 MG/3ML	1	Pen	28	DAYS	The patient must have a diagnosis of type 2 diabetes mellitus		
Ozempic	Semaglutide Soln Pen-inj 0.25 or 0.5 MG/DOSE (2 MG/1.5ML)	2 MG/1.5 ML	1	Pen	28	DAYS	The patient must have a diagnosis of type 2 diabetes mellitus		
Rybelsus	Semaglutide Tab 14 MG	14 MG	30	Tablets	30	DAYS	The patient must have a diagnosis of type 2 diabetes mellitus.		
Rybelsus	Semaglutide Tab 3 MG	3 MG	30	Tablets	180	DAYS	The patient must have a diagnosis of type 2 diabetes mellitus		
Rybelsus	Semaglutide Tab 7 MG	7 MG	30	Tablets	30	DAYS	The patient must have a diagnosis of type 2 diabetes mellitus.		
Trulicity	dulaglutide soln pen-injector	0.75 MG/0.5 ML ; 1.5 MG/0.5 ML ; 3 MG/0.5 ML ; 4.5 MG/0.5 ML	4	Pens	28	DAYS	The patient must have a diagnosis of type 2 diabetes mellitus		
Victoza	liraglutide soln pen-injector	18 MG/3ML	3	Pens	30	DAYS	The patient must have a diagnosis of type 2 diabetes mellitus.		

ADDITIONAL QUANTITY LIMIT INFORMATION

Wildcard	Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Additional QL Information	Targeted NDCs When Exclusions Exist	Effective Date	Term Date
2717005600D230	Adlyxin	Lixisenatide Soln Pen-injector 20 MCG/0.2ML (100 MCG/ML)	20 MCG/0.2 ML	The patient must have a diagnosis of type 2 diabetes mellitus			
2717005600F420	Adlyxin starter pack	Lixisenatide Pen-inj Starter Kit 10 MCG/0.2ML & 20 MCG/0.2ML	10 & 20 MCG/0.2 ML	The patient must have a diagnosis of type 2 diabetes mellitus			
2717002000D420	Bydureon bcise	Exenatide Extended Release Susp Auto-Injector 2 MG/0.85ML	2 MG/0.85 ML	The patient must have a diagnosis of type 2 diabetes mellitus			
2717002000D240	Byetta	Exenatide Soln Pen-injector 10 MCG/0.04ML	10 MCG/0.0 4ML	The patient must have a diagnosis of type 2 diabetes mellitus			
2717002000D220	Byetta	Exenatide Soln Pen-injector 5 MCG/0.02ML	5 MCG/0.0 2ML	The patient must have a diagnosis of type 2 diabetes mellitus.			
2717007000D225	Ozempic	Semaglutide Soln Pen-inj	8 MG/3ML	The patient must have a diagnosis of type 2 diabetes mellitus.			
2717007000D222	Ozempic	Semaglutide Soln Pen-inj	4 MG/3ML	The patient must have a diagnosis of type 2 diabetes mellitus			
2717007000D210	Ozempic	Semaglutide Soln Pen-inj 0.25 or 0.5 MG/DOSE (2 MG/1.5ML)	2 MG/1.5 ML	The patient must have a diagnosis of type 2 diabetes mellitus			
27170070000330	Rybelsus	Semaglutide Tab 14 MG	14 MG	The patient must have a diagnosis of type 2 diabetes mellitus.			
27170070000310	Rybelsus	Semaglutide Tab 3 MG	3 MG	The patient must have a diagnosis of type 2 diabetes mellitus			
27170070000320	Rybelsus	Semaglutide Tab 7 MG	7 MG	The patient must have a diagnosis of type 2 diabetes mellitus.			
2717001500D2	Trulicity	dulaglutide soln pen-injector	0.75 MG/0.5 ML ; 1.5 MG/0.5 ML ; 3 MG/0.5 ML ; 4.5 MG/0.5 ML	The patient must have a diagnosis of type 2 diabetes mellitus			
27170050	Victoza	liraglutide soln pen-injector	18 MG/3ML	The patient must have a diagnosis of type 2 diabetes mellitus.			

CLIENT SUMMARY – STEP THERAPY

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Bydureon bcise	exenatide extended release susp auto-injector	2 MG/0.85ML	Medicaid
Byetta	exenatide soln pen-injector	10 MCG/0.04ML ; 5 MCG/0.02ML	Medicaid
Ozempic	semaglutide soln pen-inj	2 MG/1.5ML ; 2 MG/3ML ; 4 MG/3ML ; 8 MG/3ML	Medicaid
Victoza	liraglutide soln pen-injector	18 MG/3ML	Medicaid

CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Adlyxin	Lixisenatide Soln Pen-injector 20 MCG/0.2ML (100 MCG/ML)	20 MCG/0.2ML	Medicaid
Adlyxin starter pack	Lixisenatide Pen-inj Starter Kit 10 MCG/0.2ML & 20 MCG/0.2ML	10 & 20 MCG/0.2ML	Medicaid
Bydureon bcise	Exenatide Extended Release Susp Auto-Injector 2 MG/0.85ML	2 MG/0.85ML	Medicaid
Byetta	Exenatide Soln Pen-injector 10 MCG/0.04ML	10 MCG/0.04ML	Medicaid
Byetta	Exenatide Soln Pen-injector 5 MCG/0.02ML	5 MCG/0.02ML	Medicaid
Mounjaro	Tirzepatide Soln Pen-injector	15 MG/0.5ML	Medicaid
Mounjaro	Tirzepatide Soln Pen-injector	12.5 MG/0.5ML	Medicaid
Mounjaro	Tirzepatide Soln Pen-injector	5 MG/0.5ML	Medicaid
Mounjaro	Tirzepatide Soln Pen-injector	2.5 MG/0.5ML	Medicaid
Mounjaro	Tirzepatide Soln Pen-injector	7.5 MG/0.5ML	Medicaid
Mounjaro	Tirzepatide Soln Pen-injector	10 MG/0.5ML	Medicaid
Ozempic	Semaglutide Soln Pen-inj	8 MG/3ML	Medicaid
Ozempic	Semaglutide Soln Pen-inj	4 MG/3ML	Medicaid
Ozempic	Semaglutide Soln Pen-inj 0.25 or 0.5 MG/DOSE (2 MG/1.5ML)	2 MG/1.5ML	Medicaid
Rybelsus	Semaglutide Tab 14 MG	14 MG	Medicaid
Rybelsus	Semaglutide Tab 3 MG	3 MG	Medicaid
Rybelsus	Semaglutide Tab 7 MG	7 MG	Medicaid
Trulicity	dulaglutide soln pen-injector	0.75 MG/0.5ML ; 1.5 MG/0.5ML ; 3 MG/0.5ML ; 4.5 MG/0.5ML	Medicaid
Victoza	liraglutide soln pen-injector	18 MG/3ML	Medicaid

STEP THERAPY CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	TARGET AGENT(S) **Bydureon BCise™** (exenatide extended-release) **Byetta®** (exenatide) **Ozempic®** (semaglutide) **Victoza®** (liraglutide) **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has a diagnosis of type 2 diabetes mellitus **AND** 2. ONE of the following: A. The patient is currently being treated with the requested GLP-1 within the past 90 days **OR** B. The prescriber states the patient is currently being treated with the requested GLP-1 within the past 90 days AND is at risk if therapy is changed **OR** C. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** D. The patient's medication history includes use of one or more of the following: an agent containing metformin or insulin **OR**

Module	Clinical Criteria for Approval
	E. The prescriber has stated that the patient has tried insulin or an agent containing metformin AND ONE of the following: 1. Insulin or an agent containing metformin was discontinued due to lack of effectiveness or an adverse event **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over insulin or an agent containing metformin **OR** F. The patient has an intolerance or hypersensitivity to ONE of the following agents: metformin or insulin **OR** G. The patient has an FDA labeled contraindication to ALL of the following agents: metformin AND insulin **OR** H. The patient has a diagnosis of type 2 diabetes with/or at high risk for atherosclerotic cardiovascular disease, heart failure, and/or chronic kidney disease **OR** I. The prescriber has provided documentation that ALL of the following agents: metformin and insulin cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 3. The patient will NOT be using the requested agent in combination with another GLP-1 receptor agonist agent **Length of Approval:** 12 months NOTE: If Quantity Limit program also applies, please refer to Quantity Limit criteria.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL with PA	**Quantity limit for the Target Agent(s)** will be approved when ONE of the following is met: 1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** 3. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** C. There is support for therapy with a higher dose for the requested indication **Length of Approval:** up to 12 months