GLP-1 (glucagon-like peptide-1) Agonists Prior Authorization with Quantity Limit Program Summary

POLICY REVIEW CYCLE

Effective Date **Date of Origin**
03-17-2025

FDA LABELED 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 • Bydureon BCise is an extended-release formulation of exenatide. It should not be used with other products containing the active ingredient exenatide.		4

Agent(s)	FDA Indication(s)	Notes	Ref#
	• 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 stroke) in adults with type 2 diabetes mellitus who have established cardiovascular disease or multiple cardiovascular risk factors Limitations of Use:		7

Agent(s)	FDA Indication(s)	Notes	Ref#
	• 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 (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 less than 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 PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
			M ; N ; O ; Y			

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Trulicity	dulaglutide soln auto-injector	0.75 MG/0.5ML ; 1.5 MG/0.5ML ; 3 MG/0.5ML ; 4.5 MG/0.5ML	M ; N ; O ; Y	N		
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		
Victoza	liraglutide soln pen-injector	18 MG/3ML ; 6 MG/ML	M ; N ; O ; Y	O ; Y		
Ozempic ; Rybelsus	semaglutide soln pen-inj ; semaglutide tab	1.5 MG ; 14 MG ; 2 MG/1.5ML ; 2 MG/3ML ; 3 MG ; 4 MG ; 4 MG/3ML ; 7 MG ; 8 MG/3ML ; 9 MG	M ; N ; O ; Y	N		
Mounjaro	tirzepatide soln auto-injector	10 MG/0.5ML ; 12.5 MG/0.5ML ; 15 MG/0.5ML ; 2.5 MG/0.5ML ; 5 MG/0.5ML ; 7.5 MG/0.5ML	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
			2	Pens	28	DAYS			
			2	Pens	180	DAYS			
Bydureon bcise	exenatide extended release susp auto-injector	2 MG/0.85 ML	4	Injections	28	DAYS			
Byetta	Exenatide Soln Pen-injector 10 MCG/0.04ML	10 MCG/0.04ML	1	Pen	30	DAYS			
Byetta	Exenatide Soln Pen-injector 5 MCG/0.02ML	5 MCG/0.02ML	1	Pen	30	DAYS			
Mounjaro	Tirzepatide Soln Pen-injector 10 MG/0.5ML	10 MG/0.5 ML	4	Pens	28	DAYS			
Mounjaro	Tirzepatide Soln Pen-injector 12.5 MG/0.5ML	12.5 MG/0.5 ML	4	Pens	28	DAYS			
Mounjaro	Tirzepatide Soln Pen-injector 15 MG/0.5ML	15 MG/0.5 ML	4	Pens	28	DAYS			
Mounjaro	Tirzepatide Soln Pen-injector 2.5 MG/0.5ML	2.5 MG/0.5 ML	4	Pens	180	DAYS			
Mounjaro	Tirzepatide Soln Pen-injector 5 MG/0.5ML	5 MG/0.5 ML	4	Pens	28	DAYS			
Mounjaro	Tirzepatide Soln Pen-injector 7.5 MG/0.5ML	7.5 MG/0.5 ML	4	Pens	28	DAYS			
Ozempic	Semaglutide Soln Pen-inj	2 MG/3ML	1	Pen	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
Ozempic	Semaglutide Soln Pen-inj	8 MG/3ML	1	Pen	28	DAYS			
Ozempic	Semaglutide Soln Pen-inj	4 MG/3ML	1	Pen	28	DAYS			
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			
Rybelsus	semaglutide tab	1.5 MG	30	Tablets	180	DAYS			
Rybelsus	semaglutide tab	4 MG	30	Tablets	30	DAYS			
Rybelsus	semaglutide tab	9 MG	30	Tablets	30	DAYS			
Rybelsus	Semaglutide Tab 14 MG	14 MG	30	Tablets	30	DAYS			
Rybelsus	Semaglutide Tab 3 MG	3 MG	30	Tablets	180	DAYS			
Rybelsus	Semaglutide Tab 7 MG	7 MG	30	Tablets	30	DAYS			
Trulicity	dulaglutide soln auto-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			
Victoza	liraglutide soln pen-injector	18 MG/3ML ; 6 MG/ML	3	Pens	30	DAYS			

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			Commercial ; HIM 5 and 6 Tiers ; HIM 7 Tiers
Bydureon bcise	exenatide extended release susp auto-injector	2 MG/0.85ML	Commercial ; HIM 5 and 6 Tiers ; HIM 7 Tiers
Byetta	exenatide soln pen-injector	10 MCG/0.04ML ; 5 MCG/0.02ML	Commercial ; HIM 5 and 6 Tiers ; HIM 7 Tiers
Mounjaro	tirzepatide soln auto-injector	10 MG/0.5ML ; 12.5 MG/0.5ML ; 15 MG/0.5ML ; 2.5 MG/0.5ML ; 5 MG/0.5ML ; 7.5 MG/0.5ML	Commercial ; HIM 5 and 6 Tiers ; HIM 7 Tiers
Ozempic ; Rybelsus	semaglutide soln pen-inj ; semaglutide tab	1.5 MG ; 14 MG ; 2 MG/1.5ML ; 2 MG/3ML ; 3 MG ; 4 MG ; 4 MG/3ML ; 7 MG ; 8 MG/3ML ; 9 MG	Commercial ; HIM 5 and 6 Tiers ; HIM 7 Tiers
Trulicity	dulaglutide soln auto-injector	0.75 MG/0.5ML ; 1.5 MG/0.5ML ; 3 MG/0.5ML ; 4.5 MG/0.5ML	Commercial ; HIM 5 and 6 Tiers ; HIM 7 Tiers
Victoza	liraglutide soln pen-injector	18 MG/3ML ; 6 MG/ML	Commercial ; HIM 5 and 6 Tiers ; HIM 7 Tiers

CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			Commercial ; HIM 5 and 6 Tiers ; HIM 7 Tiers
			Commercial ; HIM 5 and 6 Tiers ; HIM 7 Tiers
Bydureon bcise	exenatide extended release susp auto-injector	2 MG/0.85ML	Commercial ; HIM 5 and 6 Tiers ; HIM 7 Tiers
Byetta	Exenatide Soln Pen-injector 10 MCG/0.04ML	10 MCG/0.04ML	Commercial ; HIM 5 and 6 Tiers ; HIM 7 Tiers
Byetta	Exenatide Soln Pen-injector 5 MCG/0.02ML	5 MCG/0.02ML	Commercial ; HIM 5 and 6 Tiers ; HIM 7 Tiers
Mounjaro	Tirzepatide Soln Pen-injector 10 MG/0.5ML	10 MG/0.5ML	Commercial ; HIM 5 and 6 Tiers ; HIM 7 Tiers
Mounjaro	Tirzepatide Soln Pen-injector 12.5 MG/0.5ML	12.5 MG/0.5ML	Commercial ; HIM 5 and 6 Tiers ; HIM 7 Tiers
Mounjaro	Tirzepatide Soln Pen-injector 15 MG/0.5ML	15 MG/0.5ML	Commercial ; HIM 5 and 6 Tiers ; HIM 7 Tiers
Mounjaro	Tirzepatide Soln Pen-injector 2.5 MG/0.5ML	2.5 MG/0.5ML	Commercial ; HIM 5 and 6 Tiers ; HIM 7 Tiers
Mounjaro	Tirzepatide Soln Pen-injector 5 MG/0.5ML	5 MG/0.5ML	Commercial ; HIM 5 and 6 Tiers ; HIM 7 Tiers
Mounjaro	Tirzepatide Soln Pen-injector 7.5 MG/0.5ML	7.5 MG/0.5ML	Commercial ; HIM 5 and 6 Tiers ; HIM 7 Tiers
Ozempic	Semaglutide Soln Pen-inj	8 MG/3ML	Commercial ; HIM 5 and 6 Tiers ; HIM 7 Tiers
Ozempic	Semaglutide Soln Pen-inj	2 MG/3ML	Commercial ; HIM 5 and 6 Tiers ; HIM 7 Tiers
Ozempic	Semaglutide Soln Pen-inj	4 MG/3ML	Commercial ; HIM 5 and 6 Tiers ; HIM 7 Tiers
Ozempic	Semaglutide Soln Pen-inj 0.25 or 0.5 MG/DOSE (2 MG/1.5ML)	2 MG/1.5ML	Commercial ; HIM 5 and 6 Tiers ; HIM 7 Tiers
Rybelsus	semaglutide tab	9 MG	Commercial ; HIM 5 and 6 Tiers ; HIM 7 Tiers
Rybelsus	semaglutide tab	4 MG	Commercial ; HIM 5 and 6 Tiers ; HIM 7 Tiers
Rybelsus	semaglutide tab	1.5 MG	Commercial ; HIM 5 and 6 Tiers ; HIM 7 Tiers
Rybelsus	Semaglutide Tab 14 MG	14 MG	Commercial ; HIM 5 and 6 Tiers ; HIM 7 Tiers
Rybelsus	Semaglutide Tab 3 MG	3 MG	Commercial ; HIM 5 and 6 Tiers ; HIM 7 Tiers
Rybelsus	Semaglutide Tab 7 MG	7 MG	Commercial ; HIM 5 and 6 Tiers ; HIM 7 Tiers
Trulicity	dulaglutide soln auto-injector	0.75 MG/0.5ML ; 1.5 MG/0.5ML ; 3 MG/0.5ML ; 4.5 MG/0.5ML	Commercial ; HIM 5 and 6 Tiers ; HIM 7 Tiers
Victoza	liraglutide soln pen-injector	18 MG/3ML ; 6 MG/ML	Commercial ; HIM 5 and 6 Tiers ; HIM 7 Tiers

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval

Preferred Target Agent(s)	Non-Preferred Target Agent(s)
Bydureon (exenatide) **Mounjaro** (tirzepatide) **Ozempic** (semaglutide) **Rybelsus** (semaglutide) **Trulicity** (dulaglutide)	**Adlyxin** (lixisenatide) **Byetta** (exenatide) **Victoza**, **Liraglutide**

Module	Clinical Criteria for Approval

Target Agent(s) will be approved when ALL of the following are met:

1. The patient has a diagnosis of type 2 diabetes mellitus (Medical record documentation required) **AND**
2. ONE of the following:
   A. The requested agent is eligible for continuation of therapy AND ONE of the following:

Agents Eligible for Continuation of Therapy
Ozempic, Rybelsus, Trulicity, Mounjaro, Bydureon

      1. The patient has been treated with a preferred agent (starting on samples is not approvable) within the past 90 days **OR**
      2. The prescriber states the patient has been treated with a preferred agent within the past 90 days (starting on samples is not approvable) AND is at risk if therapy with a preferred agent is discontinued **OR**

   B. BOTH of the following:
      1. ONE of the following:
         A. The patient has tried and had an inadequate response to an agent containing metformin or insulin* **OR**
         B. The patient has an intolerance or hypersensitivity to metformin or insulin **OR**
         C. The patient has an FDA labeled contraindication to BOTH metformin AND insulin **OR**
         D. 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 **AND**
      2. ONE of the following:
         A. The requested agent is a preferred GLP-1 or GLP-1/GIP **OR**
         B. The agent is a non-preferred GLP-1 and TWO of the following* (medical record documentation of intolerance/contraindication to preferred GLP-1 required):
            1. The patient has tried and had an inadequate response after at least a 90 day trial of therapy, has an intolerance, has a hypersensitivity, or has an FDA labeled contraindication to semaglutide (Ozempic OR Rybelsus) **OR**
            2. The patient has tried and had an inadequate response after at least a 90 day trial of therapy, has an intolerance, has a hypersensitivity, or has an FDA labeled contraindication to dulaglutide (Trulicity) **OR**
            3. The patient has tried and had an inadequate response after at least a 90 day trial of therapy, has an intolerance, has a hypersensitivity, or has an FDA labeled contraindication to tirzepatide (Mounjaro) **AND**
3. The patient will NOT be using the requested agent in combination with a DPP-4 agent containing agent for the requested indication **AND**
4. The patient will NOT be using the requested agent in combination with another GLP-1 receptor agonist agent **AND**
5. If request is for weight loss, it is a benefit exclusion

Length of Approval: 12 months

Module	Clinical Criteria for Approval
	NOTE: If Quantity Limit program also applies, please refer to Quantity Limit criteria. * Step therapy requirement may not apply if the requested medication was previously approved by another health plan and documentation of a paid claim within the past 90 days is submitted

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	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. BOTH of the following: A. The patient has a diagnosis of type 2 diabetes mellitus **AND** B. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: 1. BOTH of the following: 1. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** 2. There is support for why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** 2. BOTH of the following: 1. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** 2. There is support for therapy with a higher dose for the requested indication **Length of Approval:** up to 12 months

