BlueCross BlueShield of Illinois
BlueCross BlueShield of Montana
BlueCross BlueShield of New Mexico
BlueCross BlueShield of Oklahoma
BlueCross BlueShield of Texas

GLP-1 (glucagon-like peptide-1) Agonists Step Therapy with Quantity Limit Program Summary

POLICY REVIEW CYCLE

Effective Date **Date of Origin**
09-23-2024

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
	Exenatide Extended Release for Susp Pen-injector 2 MG		M ; N ; O ; Y			
	Tirzepatide Soln Pen-injector		M ; N ; O ; Y			
	Tirzepatide Soln Pen-injector		M ; N ; O ; Y			
	Tirzepatide Soln Pen-injector		M ; N ; O ; Y			
	Tirzepatide Soln Pen-injector		M ; N ; O ; Y			
	Tirzepatide Soln Pen-injector		M ; N ; O ; Y			
	Tirzepatide Soln Pen-injector		M ; N ; O ; Y			
Adlyxin	lixisenatide soln pen-injector	20 MCG/0.2ML	M ; N ; O ; Y	N		
Adlyxin starter pack	Lixisenatide Pen-inj Starter Kit 10 MCG/0.2ML & 20 MCG/0.2ML	10 & 20 MCG/0.2ML	M ; N ; O ; Y	N		
Bydureon bcise	Exenatide Extended Release Susp Auto-Injector 2 MG/0.85ML	2 MG/0.85ML	M ; N ; O ; Y	N		
Byetta	Exenatide Soln Pen-injector 10 MCG/0.04ML	10 MCG/0.04ML	M ; N ; O ; Y	N		
Byetta	Exenatide Soln Pen-injector 5 MCG/0.02ML	5 MCG/0.02ML	M ; N ; O ; Y	N		
Mounjaro	tirzepatide soln pen-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		
Ozempic	semaglutide soln pen-inj	2 MG/1.5ML ; 2 MG/3ML ; 4 MG/3ML ; 8 MG/3ML	M ; N ; O ; Y	N		
Rybelsus	semaglutide tab	14 MG ; 3 MG ; 7 MG	M ; N ; O ; Y	N		
Rybelsus	Semaglutide Tab 3 MG	3 MG	M ; N ; O ; Y	N		
Trulicity	dulaglutide soln pen-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		
Victoza	liraglutide soln pen-injector	18 MG/3ML	M ; N ; O ; Y	M		

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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
	Exenatide Extended Release for Susp Pen-injector 2 MG		4	Pens	28	DAYS			
	Exenatide For Inj Extended Release Susp 2 MG		4	Vials	28	DAYS			
	Tirzepatide Soln Pen-injector		4	Syringes	180	DAYS			
Adlyxin	lixisenatide soln pen-injector	20 MCG/0.2 ML	6	mLs	28	DAYS			
Adlyxin starter pack	Lixisenatide Pen-inj Starter Kit 10 MCG/0.2ML & 20 MCG/0.2ML	10 & 20 MCG/0.2 ML	6	mLs	180	DAYS			
Bydureon bcise	Exenatide Extended Release Susp Auto-Injector 2 MG/0.85ML	2 MG/0.85 ML	4	Pens	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	Syringes	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	DAY			
Ozempic	Semaglutide Soln Pen-inj	2 MG/3ML	1	Pen	28	DAYS			
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	14 MG ; 3 MG ; 7 MG	30	Tablets	30	DAYS			
Rybelsus	Semaglutide Tab 3 MG	3 MG	30	Tablets	180	DAYS			

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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
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			
Victoza	liraglutide soln pen-injector	18 MG/3ML	3	Pens	30	DAYS			
Victoza	Liraglutide Soln Pen-injector 18 MG/3ML (6 MG/ML)	18 MG/3ML	3	Pens	30	DAYS			

CLIENT SUMMARY – STEP THERAPY

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
	Exenatide Extended Release for Susp Pen-injector 2 MG		HIM Annual 2023
	Tirzepatide Soln Pen-injector		HIM Annual 2023
	Tirzepatide Soln Pen-injector		HIM Annual 2023
	Tirzepatide Soln Pen-injector		HIM Annual 2023
	Tirzepatide Soln Pen-injector		HIM Annual 2023
	Tirzepatide Soln Pen-injector		HIM Annual 2023
	Tirzepatide Soln Pen-injector		HIM Annual 2023
Adlyxin	lixisenatide soln pen-injector	20 MCG/0.2ML	HIM Annual 2023
Adlyxin starter pack	Lixisenatide Pen-inj Starter Kit 10 MCG/0.2ML & 20 MCG/0.2ML	10 & 20 MCG/0.2ML	HIM Annual 2023
Bydureon bcise	Exenatide Extended Release Susp Auto-Injector 2 MG/0.85ML	2 MG/0.85ML	HIM Annual 2023
Byetta	Exenatide Soln Pen-injector 10 MCG/0.04ML	10 MCG/0.04ML	HIM Annual 2023
Byetta	Exenatide Soln Pen-injector 5 MCG/0.02ML	5 MCG/0.02ML	HIM Annual 2023
Mounjaro	tirzepatide soln pen-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	HIM Annual 2023
Ozempic	semaglutide soln pen-inj	2 MG/1.5ML ; 2 MG/3ML ; 4 MG/3ML ; 8 MG/3ML	HIM Annual 2023
Rybelsus	semaglutide tab	14 MG ; 3 MG ; 7 MG	HIM Annual 2023
Rybelsus	Semaglutide Tab 3 MG	3 MG	HIM Annual 2023
Trulicity	dulaglutide soln pen-injector	0.75 MG/0.5ML ; 1.5 MG/0.5ML ; 3 MG/0.5ML ; 4.5 MG/0.5ML	HIM Annual 2023
Victoza	liraglutide soln pen-injector	18 MG/3ML	HIM Annual 2023

CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
	Exenatide Extended Release for Susp Pen-injector 2 MG		HIM Annual 2023
	Exenatide For Inj Extended Release Susp 2 MG		HIM Annual 2023
	Tirzepatide Soln Pen-injector		HIM Annual 2023

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Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Adlyxin	lixisenatide soln pen-injector	20 MCG/0.2ML	HIM Annual 2023
Adlyxin starter pack	Lixisenatide Pen-inj Starter Kit 10 MCG/0.2ML & 20 MCG/0.2ML	10 & 20 MCG/0.2ML	HIM Annual 2023
Bydureon bcise	Exenatide Extended Release Susp Auto-Injector 2 MG/0.85ML	2 MG/0.85ML	HIM Annual 2023
Byetta	Exenatide Soln Pen-injector 10 MCG/0.04ML	10 MCG/0.04ML	HIM Annual 2023
Byetta	Exenatide Soln Pen-injector 5 MCG/0.02ML	5 MCG/0.02ML	HIM Annual 2023
Mounjaro	Tirzepatide Soln Pen-injector 10 MG/0.5ML	10 MG/0.5ML	HIM Annual 2023
Mounjaro	Tirzepatide Soln Pen-injector 12.5 MG/0.5ML	12.5 MG/0.5ML	HIM Annual 2023
Mounjaro	Tirzepatide Soln Pen-injector 15 MG/0.5ML	15 MG/0.5ML	HIM Annual 2023
Mounjaro	Tirzepatide Soln Pen-injector 2.5 MG/0.5ML	2.5 MG/0.5ML	HIM Annual 2023
Mounjaro	Tirzepatide Soln Pen-injector 5 MG/0.5ML	5 MG/0.5ML	HIM Annual 2023
Mounjaro	Tirzepatide Soln Pen-injector 7.5 MG/0.5ML	7.5 MG/0.5ML	HIM Annual 2023
Ozempic	Semaglutide Soln Pen-inj	8 MG/3ML	HIM Annual 2023
Ozempic	Semaglutide Soln Pen-inj	2 MG/3ML	HIM Annual 2023
Ozempic	Semaglutide Soln Pen-inj	4 MG/3ML	HIM Annual 2023
Ozempic	Semaglutide Soln Pen-inj 0.25 or 0.5 MG/DOSE (2 MG/1.5ML)	2 MG/1.5ML	HIM Annual 2023
Rybelsus	semaglutide tab	14 MG ; 3 MG ; 7 MG	HIM Annual 2023
Rybelsus	Semaglutide Tab 3 MG	3 MG	HIM Annual 2023
Trulicity	dulaglutide soln pen-injector	0.75 MG/0.5ML ; 1.5 MG/0.5ML ; 3 MG/0.5ML ; 4.5 MG/0.5ML	HIM Annual 2023
Victoza	liraglutide soln pen-injector	18 MG/3ML	HIM Annual 2023
Victoza	Liraglutide Soln Pen-injector 18 MG/3ML (6 MG/ML)	18 MG/3ML	HIM Annual 2023

STEP THERAPY CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
1-Step	**Target Agent(s)** will be approved when BOTH 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 has been treated with the requested agent within the past 90 days **OR** B. The prescriber states the patient is currently being treated with the requested agent **AND** the patient is currently stable on the requested agent **OR** C. The patient has tried and had an inadequate response to ONE or more of the following antidiabetic agents; an agent containing metformin or insulin **OR** D. ONE or more of the following antidiabetic agents; an agent containing metformin or insulin was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event **OR** E. The patient has an intolerance or hypersensitivity to ONE of the following antidiabetic agents; an agent containing metformin or insulin **OR** F. 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** G. The patient has an FDA labeled contraindication to metformin **AND** insulin **OR** H. ONE or more of the following antidiabetic agents; an agent containing metformin or insulin is expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug; OR cause a significant barrier to the patient's adherence of care; OR worsen a comorbid condition; OR decrease the patient's

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Module	Clinical Criteria for Approval
	ability to achieve or maintain reasonable functional ability in performing daily activities; OR cause an adverse reaction or cause physical or mental harm **OR** I. ONE or more of the following antidiabetic agents; an agent containing metformin or insulin is not in the best interest of the patient based on medical necessity **OR** J. The patient has tried another prescription drug in the same pharmacologic class or with the same mechanism of action as the one or more of the following antidiabetic agents; an agent containing metformin or insulin and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event **OR** K. The requested agent is medically necessary and appropriate for the patient **Length of approval:** 12 months NOTE: If Quantity Limit program also applies, please refer to Quantity Limit documents.

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: A. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** B. 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: A. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** B. There is support for therapy with a higher dose for the requested indication **Length of Approval:** 12 months

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