



PCSK9 Inhibitors Prior Authorization with Quantity Limit Program Summary

POLICY REVIEW CYCLE

Effective Date
01-15-2026

Date of Origin

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Praluent	alirocumab subcutaneous solution auto-injector	150 MG/ML ; 75 MG/ML	M ; N ; O ; Y	N		
Repatha sureclick	evolocumab subcutaneous soln auto-injector	140 MG/ML	M ; N ; O ; Y	N		
Repatha pushtronex system	evolocumab subcutaneous soln cartridge/infusor	420 MG/3.5ML	M ; N ; O ; Y	N		
Repatha	evolocumab subcutaneous soln prefilled syringe	140 MG/ML	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
Repatha	evolocumab subcutaneous soln prefilled syringe	140 MG/ML	6	Syringes	28	DAYS			
Repatha sureclick	evolocumab subcutaneous soln auto-injector	140 MG/ML	6	Pens	28	DAYS			
Repatha pushtronex system	evolocumab subcutaneous soln cartridge/infusor	420 MG/3.5 ML	2	Cartridges	30	DAYS			
Praluent	alirocumab subcutaneous solution auto-injector	150 MG/ML ; 75 MG/ML	2	Pens	28	DAYS	1 package = 2mLs= 2 pens		

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
3935001000D5	Praluent	alirocumab subcutaneous solution auto-injector	150 MG/ML ; 75 MG/ML	1 package = 2mLs= 2 pens			

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Praluent	alirocumab subcutaneous solution auto-injector	150 MG/ML ; 75 MG/ML	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Repatha	evolocumab subcutaneous soln prefilled syringe	140 MG/ML	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Repatha pushtronex system	evolocumab subcutaneous soln cartridge/infusor	420 MG/3.5ML	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Repatha sureclick	evolocumab subcutaneous soln auto-injector	140 MG/ML	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods

CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Repatha	evolocumab subcutaneous soln prefilled syringe	140 MG/ML	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Repatha sureclick	evolocumab subcutaneous soln auto-injector	140 MG/ML	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Repatha pushtronex system	evolocumab subcutaneous soln cartridge/infusor	420 MG/3.5ML	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods
Praluent	alirocumab subcutaneous solution auto-injector	150 MG/ML ; 75 MG/ML	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; NM HIM Annual 2024 ; NM HIM Annual 2025 ; NM HIM Annual 2026 ; NM Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval	
PA	Preferred Target Agent(s)	Non-Preferred Target Agent(s)
	Repatha (evolocumab)	Praluent (alirocumab)

Module	Clinical Criteria for Approval
	<p>Initial Evaluation</p> <p>Target Agent(s) will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> 1. ONE of the following: <ol style="list-style-type: none"> A. The patient has a diagnosis of homozygous familial hypercholesterolemia (HoFH) AND ALL of the following: <ol style="list-style-type: none"> 1. A diagnosis of HoFH confirmed by ONE of the following: <ol style="list-style-type: none"> A. Genetic confirmation of bi-allelic pathogenic/likely pathogenic variants on different chromosomes at the <i>LDLR</i>, <i>Apo-B</i>, <i>PCSK9</i>, or <i>LDLRAP1</i> genes, or greater than or equal to 2 such variants at different loci OR B. History of untreated LDL-C greater than 400 mg/dL and ONE of the following: <ol style="list-style-type: none"> 1. Cutaneous or tendon xanthomas before 10 years of age OR 2. Untreated elevated LDL-C levels consistent with heterozygous FH in both parents, (or in digenic form, one parent may have normal LDL-C levels and the other may have LDL-C levels consistent with HoFH) AND 2. ONE of the following: <ol style="list-style-type: none"> A. Tried a high-intensity statin (e.g., atorvastatin 40-80 mg, rosuvastatin 20-40 mg daily) for 8 weeks and had an inadequate response OR B. An intolerance or hypersensitivity to ALL high-intensity statins OR C. An FDA labeled contraindication to ALL high-intensity statins OR B. BOTH of the following: <ol style="list-style-type: none"> 1. The patient has ONE of the following: <ol style="list-style-type: none"> A. A diagnosis of heterozygous familial hypercholesterolemia (HeFH) AND ONE of the following: <ol style="list-style-type: none"> 1. Genetic confirmation of one mutant allele at the <i>LDLR</i>, <i>Apo-B</i>, <i>PCSK9</i>, or <i>1/LDLRAP1</i> gene OR 2. Pre-treatment LDL-C greater than 190 mg/dL OR 3. Clinical manifestations of HeFH (e.g., cutaneous xanthomas, tendon xanthomas, corneal arcus) OR 4. "Definite" or "possible" familial hypercholesterolemia as defined by Simon Broome criteria OR 5. A Dutch Lipid Clinic Network Criteria score of greater than 5 OR 6. A treated LDL-C level greater than or equal to 100 mg/dL after statin treatment with or without ezetimibe OR B. A diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD) AND has ONE of the following: <ol style="list-style-type: none"> 1. Acute coronary syndrome OR 2. History of myocardial infarction OR 3. Stable or unstable angina OR 4. Coronary or other arterial revascularization OR 5. Stroke OR 6. Transient ischemic attack OR 7. Peripheral arterial disease, including aortic aneurysm, presumed to be of atherosclerotic origin OR C. A diagnosis of hyperlipidemia AND has ONE of the following: <ol style="list-style-type: none"> 1. Coronary artery calcium (CAC) score greater than or equal to 300 Agatston units OR 2. A pre-treatment LDL-C level greater than or equal to 190 mg/dL OR D. 20-29% 10-year ASCVD risk AND an LDL-C greater than or equal to 130 mg/dL while on a maximally tolerated statin OR E. 30-39% 10-year ASCVD risk AND an LDL-C greater than or equal to 100 mg/dL while on a maximally tolerated statin OR

Module	Clinical Criteria for Approval
	<p>F. At least a 40% 10-year ASCVD risk AND an LDL-C greater than or equal to 70 mg/dL while on a maximally tolerated statin AND</p> <p>2. ONE of the following:</p> <p>A. The patient has been adherent to high-intensity statin therapy (i.e., atorvastatin 40-80mg, rosuvastatin 20-40 mg daily) for at least 8 consecutive weeks AND ONE of the following:</p> <ol style="list-style-type: none"> 1. LDL-C level remains greater than or equal to 70 mg/dL after this statin therapy OR 2. Has not achieved a 50% reduction in LDL-C from this statin therapy OR 3. If the patient has ASCVD at very high risk, then the patient's LDL-C level remains greater than or equal to 55 mg/dL after this statin therapy OR <p>B. The patient is statin intolerant defined as experiencing ONE of the following:</p> <ol style="list-style-type: none"> 1. Statin-related rhabdomyolysis OR 2. Statin-related skeletal muscle symptoms (e.g., myopathy, myalgia) OR 3. Statin-related elevated hepatic transaminase OR <p>C. The patient has a hypersensitivity to atorvastatin and rosuvastatin OR</p> <p>D. The patient has an FDA labeled contraindication to atorvastatin and rosuvastatin OR</p> <p>C. The patient has another FDA labeled indication for the requested agent and route of administration OR</p> <p>D. The patient has an indication that is supported in compendia for the requested agent and route of administration AND</p> <p>2. If the patient has an FDA labeled indication, ONE of the following:</p> <ol style="list-style-type: none"> A. The patient's age is within FDA labeling for the requested indication for the requested agent OR B. There is support for using the requested agent for the patient's age for the requested indication AND <p>3. ONE of the following:</p> <ol style="list-style-type: none"> A. The requested agent is a preferred agent OR B. The requested agent is a non-preferred agent AND ONE of the following: <ol style="list-style-type: none"> 1. The request is for a BCBS IL Fully Insured, ASO Cost/BBF, HIM, or Non-ERISA ASO/Self-insured Municipalities/Counties member OR 2. The patient is currently being treated with the requested agent and the patient is currently stable on the requested agent [chart notes required] OR 3. The patient has ONE of the following [chart notes required]: <ol style="list-style-type: none"> A. Tried and had an inadequate response to ONE preferred agent OR B. An intolerance or hypersensitivity to ONE preferred agent OR C. An FDA labeled contraindication to ALL preferred agents OR 4. ONE preferred agent was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] OR 5. ONE preferred agent 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 ability to achieve or maintain reasonable functional ability in performing daily activities; OR cause an adverse reaction or cause physical or mental harm [chart notes required] OR 6. ONE preferred agent is not in the best interest of the patient based on medical necessity [chart notes required] OR 7. The patient has tried another prescription drug in the same pharmacologic class or with the same mechanism of action as ONE preferred agent and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] AND

Module	Clinical Criteria for Approval
	<p>4. The patient will NOT be using the requested agent in combination with another PCSK9 agent AND</p> <p>5. The patient does NOT have any FDA labeled contraindications to the requested agent</p> <p>Compendia Allowed: AHFS, or DrugDex 1, 2a, or 2b level of evidence</p> <p>Length of Approval:</p> <p>BCBSOK: 36 months</p> <p>ALL other plans: 12 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p> <p>The requested agent will also be approved when ONE of the following is met:</p> <ol style="list-style-type: none"> 1. The request is for a BCBS MT Fully Insured or MT HIM member AND <ol style="list-style-type: none"> A. The patient is under the age of 18 years old AND B. The patient does NOT have any FDA labeled contraindications to the requested agent AND C. The patient has an indication that is supported in TWO articles from major peer-reviewed professional medical journals [e.g., Journal of American Medical Association (JAMA), New England Journal of Medicine (NEJM), Lancet] as generally safe and effective. Accepted study designs may include, but are not limited to, randomized, double blind, placebo controlled clinical trials. NOTE: Case studies are not acceptable [journal articles required] AND D. There is support for an age in the patient's given age bracket in TWO articles from major peer-reviewed professional medical journals as generally safe and effective. The age brackets are: 1. infancy (birth up to, but not including, 2 years of age), 2. childhood (2 years of age through 11 years of age), 3. adolescence (12 years of age through 17 years of age). Accepted study designs may include, but are not limited to, randomized, double blind, placebo controlled clinical trials. NOTE: Case studies are not acceptable [journal articles required] OR 2. The request is for a BCBS NM Fully Insured or NM HIM member and ALL of the following: <ol style="list-style-type: none"> A. The patient does NOT have any FDA labeled contraindications to the requested agent AND B. The requested indication is a rare disease AND C. ONE of the following: <ol style="list-style-type: none"> 1. The patient has another FDA labeled indication for the requested agent and route of administration OR 2. The patient has another indication that is supported in compendia for the requested agent and route of administration OR 3. ALL of the following: <ol style="list-style-type: none"> A. The member resides in Ohio AND B. The plan is Fully Insured or HIM Shop (SG) AND C. The patient does NOT have any FDA labeled contraindications to the requested agent AND D. ONE of the following: <ol style="list-style-type: none"> 1. The patient has another FDA labeled indication for the requested agent and route of administration OR 2. The patient has another indication that is supported in compendia for the requested agent and route of administration OR 3. The prescriber has submitted TWO articles from major peer-reviewed professional medical journals [e.g., Journal of American Medical Association (JAMA), New England Journal of Medicine (NEJM), Lancet] supporting the proposed use(s) as generally safe and effective. Accepted study designs may include, but are not limited to, randomized, double

Module	Clinical Criteria for Approval
	<p>blind, placebo controlled clinical trials. NOTE: Case studies are not acceptable [journal articles required]</p> <p>Non-oncology compendia allowed: DrugDex level 1, 2A or 2B, AHFS-DI (narrative text must be supportive)</p> <p>Oncology compendia allowed: NCCN 1 or 2A, AHFS-DI (narrative text must be supportive), DrugDex level 1, 2A, or 2B, or Clinical Pharmacology (narrative text must be supportive), Lexi-Drugs evidence level A, peer-reviewed medical literature</p> <p>Length of Approval:</p> <p>BCBSOK: 36 months</p> <p>ALL other plans: 12 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p> <p>Renewal Evaluation</p> <p>Target Agent(s) will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> 1. The patient has been previously approved for therapy for a PCSK9 inhibitor through the plan's Prior Authorization process (Note: patients not previously approved for a PCSK9 Inhibitor will require initial evaluation review) AND 2. The patient has had clinical benefit with a PCSK9 inhibitor AND 3. If the patient has ASCVD, HeFH, or hyperlipidemia, then ONE of the following: <ol style="list-style-type: none"> A. Has been adherent to high-intensity statin therapy (i.e., atorvastatin 40-80mg, rosuvastatin 20-40 mg daily) OR B. Is statin intolerant defined as experiencing ONE of the following: <ol style="list-style-type: none"> 1. Statin-related rhabdomyolysis OR 2. Statin-related skeletal muscle symptoms (e.g., myopathy, myalgia) OR 3. Statin-related elevated hepatic transaminase OR C. Has a hypersensitivity to atorvastatin and rosuvastatin OR D. Has an FDA labeled contraindication to atorvastatin and rosuvastatin OR E. Does not require additional therapy as they have met their goal of therapy using a single agent PCSK9 inhibitor AND 4. ONE of the following: <ol style="list-style-type: none"> A. The requested agent is a preferred agent OR B. The requested agent is a non-preferred agent AND ONE of the following: <ol style="list-style-type: none"> 1. The request is for a BCBS IL Fully Insured, ASO Cost/BBF, HIM, or Non-ERISA ASO/Self-insured Municipalities/Counties member OR 2. The patient is currently being treated with the requested agent and the patient is currently stable on the requested agent [chart notes required] OR 3. The patient has ONE of the following [chart notes required]: <ol style="list-style-type: none"> A. Tried and had an inadequate response to ONE preferred agent OR B. An intolerance or hypersensitivity to ONE preferred agent OR C. An FDA labeled contraindication to ALL preferred agents OR 4. ONE preferred agent was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] OR 5. ONE preferred agent 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 ability to achieve or maintain reasonable functional ability in

Module	Clinical Criteria for Approval
	<p>performing daily activities; OR cause an adverse reaction or cause physical or mental harm [chart notes required] OR</p> <p>6. ONE preferred agent is not in the best interest of the patient based on medical necessity [chart notes required] OR</p> <p>7. The patient has tried another prescription drug in the same pharmacologic class or with the same mechanism of action as ONE preferred agent and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event [chart notes required] AND</p> <p>5. The patient will NOT be using the requested agent in combination with another PCSK9 agent AND</p> <p>6. The patient does NOT have any FDA labeled contraindications to the requested agent</p> <p>Length of Approval:</p> <p>BCBSOK: 36 months</p> <p>ALL other plans: 12 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.</p>

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	<p>Quantity Limit for the Target Agent(s) will be approved when ONE of the following is met:</p> <ol style="list-style-type: none"> 1. The requested quantity (dose) does NOT exceed the program quantity limit OR 2. The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: <ol style="list-style-type: none"> A. BOTH of the following: <ol style="list-style-type: none"> 1. The requested agent does NOT have a maximum FDA labeled dose for the requested indication AND 2. There is support for therapy with a higher dose for the requested indication OR B. BOTH of the following: <ol style="list-style-type: none"> 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 <p>Length of Approval: 12 months</p>