



IL-31 Inhibitors Prior Authorization with Quantity Limit Program Summary

POLICY REVIEW CYCLE

Effective Date
03-15-2026

Date of Origin
11-14-2024

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Nemluvio	nemolizumab-ilto for subcutaneous auto-injector	30 MG	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
Nemluvio	nemolizumab-ilto for subcutaneous auto-injector	30 MG	1	Pen	28	DAYS			

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Nemluvio	nemolizumab-ilto for subcutaneous auto-injector	30 MG	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; 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 ; 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
Nemluvio	nemolizumab-iltto for subcutaneous auto-injector	30 MG	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; 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 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	<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. BOTH of the following: <ol style="list-style-type: none"> 1. ONE of the following: <ol style="list-style-type: none"> A. The patient has a diagnosis of prurigo nodularis (PN) and BOTH of the following: <ol style="list-style-type: none"> 1. The patient has ALL of the following features associated with PN: <ol style="list-style-type: none"> A. Presence of greater than or equal to 20 firm, nodular lesions AND B. Pruritus that has lasted for at least 6 weeks AND C. History and/or signs of repeated scratching, picking, or rubbing AND 2. ONE of the following: <ol style="list-style-type: none"> A. BOTH of the following: <ol style="list-style-type: none"> 1. ONE of the following: <ol style="list-style-type: none"> A. The patient has been diagnosed with stage four advanced, metastatic cancer and the requested agent is being used to treat the cancer OR B. The patient has been diagnosed with stage four advanced, metastatic cancer and the requested agent is being used to treat an associated condition related to stage four advanced metastatic cancer [chart notes required] AND 2. The use of the requested agent is consistent with best practices for the treatment of stage four advanced, metastatic cancer, or an associated

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	<p>condition; supported by peer-reviewed, evidence-based literature; and approved by the United States Food and Drug Administration OR</p> <p>B. The patient has ONE of the following:</p> <ol style="list-style-type: none"> 1. Has tried and had an inadequate response to ONE at least medium-potency topical corticosteroid used in the treatment of PN after at least a 2-week duration of therapy OR 2. Has an intolerance or hypersensitivity to ONE at least medium-potency topical corticosteroid used in the treatment of PN OR 3. Has an FDA labeled contraindication to ALL medium-, high-, and super-potency topical corticosteroids used in the treatment of PN OR <p>C. The patient’s medication history (excluding sample use) indicates use of a biologic immunomodulator agent or a systemic targeted synthetic small molecule drug (e.g., oral JAK inhibitor) that is FDA labeled or supported in compendia for the treatment of PN OR</p> <p>B. The patient has a diagnosis of moderate-to-severe atopic dermatitis (AD) AND BOTH of the following:</p> <ol style="list-style-type: none"> 1. ONE of the following: <ol style="list-style-type: none"> A. The patient has at least 10% body surface area involvement OR B. The patient has involvement of body sites that are difficult to treat with prolonged topical corticosteroid therapy (e.g., hands, feet, face, neck, scalp, genitals/groin, skin folds) OR C. The patient has an Eczema Area and Severity Index (EASI) score greater than or equal to 16 OR D. The patient has an Investigator Global Assessment (IGA) score greater than or equal to 3 AND 2. ONE of the following: <ol style="list-style-type: none"> A. The request is for a BCBS IL Fully Insured, ASO Cost/BBF, HIM, or Non-ERISA ASO/Self-insured Municipalities/Counties member OR B. The patient is currently being treated with the requested agent and the patient is currently stable on the requested agent [chart notes required] OR C. BOTH of the following [chart notes required]: <ol style="list-style-type: none"> 1. ONE of the following: <ol style="list-style-type: none"> A. The patient has tried and had an inadequate response to ONE at least medium-potency topical corticosteroid used in the treatment of AD after at least a 4-week duration of therapy OR B. ONE at least medium-potency topical corticosteroid used in the treatment of AD was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event OR

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	<ul style="list-style-type: none"> C. The patient has an intolerance or hypersensitivity to ONE at least medium-potency topical corticosteroid used in the treatment of AD OR D. The patient has an FDA labeled contraindication to ALL medium-, high-, and super-potency topical corticosteroids used in the treatment of AD OR E. ONE at least medium-potency topical corticosteroid used in the treatment of AD 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 OR F. ONE at least medium-potency topical corticosteroid used in the treatment of AD is not in the best interest of the patient based on medical necessity OR G. The patient has tried another prescription drug in the same pharmacologic class or with the same mechanism of action as ONE at least medium-potency topical corticosteroid used in the treatment of AD and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event AND <p>2. ONE of the following:</p> <ul style="list-style-type: none"> A. The patient has tried and had an inadequate response to ONE topical calcineurin inhibitor (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) used in the treatment of AD after at least a 6-week duration of therapy OR B. ONE topical calcineurin inhibitor used in the treatment of AD was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event OR C. The patient has an intolerance or hypersensitivity to ONE topical calcineurin inhibitor used in the treatment of AD OR

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	<ul style="list-style-type: none"> D. The patient has an FDA labeled contraindication to ALL topical calcineurin inhibitors used in the treatment of AD OR E. ONE topical calcineurin inhibitor used in the treatment of AD 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 OR F. ONE topical calcineurin inhibitor used in the treatment of AD is not in the best interest of the patient based on medical necessity OR G. The patient has tried another prescription drug in the same pharmacologic class or with the same mechanism of action as ONE topical calcineurin inhibitor used in the treatment of AD and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event OR <ul style="list-style-type: none"> D. The patient's medication history (excluding sample use) indicates use of a biologic immunomodulator agent or a systemic targeted synthetic small molecule drug (e.g., oral JAK inhibitor) that is FDA labeled or supported in compendia for the treatment of AD OR C. The patient has another FDA labeled indication for the requested agent and route of administration AND <ul style="list-style-type: none"> 2. If the patient has an FDA labeled indication, then ONE of the following: <ul 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 OR B. The patient has another indication that is supported in compendia for the requested agent and route of administration AND <ul style="list-style-type: none"> 2. If the patient has a diagnosis of moderate-to-severe atopic dermatitis (AD), then ALL of the following: <ul style="list-style-type: none"> A. BOTH of the following: <ul style="list-style-type: none"> 1. The patient is currently treated with topical emollients and practicing good skin care AND 2. The patient will continue the use of topical emollients and good skin care practices in combination with the requested agent AND B. ONE of the following: <ul style="list-style-type: none"> 1. BOTH of the following:

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	<p>A. The patient is currently treated with at least a low-potency topical corticosteroid OR a topical calcineurin inhibitor (e.g., Elidel/pimecrolimus, Protopic/tacrolimus) AND</p> <p>B. The patient will continue topical corticosteroid OR topical calcineurin inhibitor therapy in combination with the requested agent OR</p> <p>2. The patient has been treated with the requested agent for at least 16 consecutive weeks AND BOTH of the following:</p> <p>A. The patient's atopic dermatitis has sufficiently improved AND</p> <p>B. Based on disease activity, concurrent topical therapies (e.g., topical corticosteroid, topical calcineurin inhibitor) have been tapered and discontinued OR</p> <p>3. The patient has an intolerance, hypersensitivity, or FDA labeled contraindication to ALL topical corticosteroids AND topical calcineurin inhibitors AND</p> <p>C. ONE of the following:</p> <p>1. The patient is initiating therapy with the requested agent OR</p> <p>2. The patient has been treated with the requested agent for less than 16 consecutive weeks OR</p> <p>3. The patient has been treated with the requested agent for at least 16 consecutive weeks AND ONE of the following:</p> <p>A. The requested dose is 30 mg every 8 weeks OR</p> <p>B. The requested dose is 30 mg every 4 weeks AND ONE of the following:</p> <p>1. The patient has NOT achieved clear or almost clear skin OR</p> <p>2. There is support for continued therapy at the requested dose of 30 mg every 4 weeks AND</p> <p>3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., allergist, dermatologist, immunologist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis AND</p> <p>4. ONE of the following (please refer to "Agents NOT to be used Concomitantly" table):</p> <p>A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) OR</p> <p>B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following:</p> <p>1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent AND</p> <p>2. There is support for the use of combination therapy (submitted copy of clinical trials, phase III studies, or guidelines required) AND</p> <p>5. The patient does NOT have any FDA labeled contraindications to the requested agent</p> <p>Compendia Allowed: AHFS, DrugDex 1, 2a, or 2b level of evidence, or NCCN 1, 2a, or 2b recommended use</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> <p>1. The request is for a BCBS MT Fully Insured or MT HIM member AND</p> <p>A. The patient is under the age of 18 years old AND</p>

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	<p>B. The patient does NOT have any FDA labeled contraindications to the requested agent AND</p> <p>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</p> <p>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</p> <p>2. ALL of the following:</p> <p>A. The member resides in Ohio AND</p> <p>B. The plan is Fully Insured or HIM Shop (SG) AND</p> <p>C. The patient does NOT have any FDA labeled contraindications to the requested agent AND</p> <p>D. ONE of the following:</p> <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 blind, placebo controlled clinical trials. NOTE: Case studies are not acceptable [journal articles required] <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 the requested agent through the plan's Prior Authorization process [Note: patients not previously approved for the requested agent will require initial evaluation review] AND 2. The patient has had clinical benefit with the requested agent AND

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	<p>3. If the patient has a diagnosis of moderate-to-severe atopic dermatitis, then ALL of the following:</p> <ul style="list-style-type: none"> A. The patient will continue standard maintenance therapies (e.g., topical emollients, good skin care practices) in combination with the requested agent AND B. ONE of the following: <ul style="list-style-type: none"> 1. The patient will continue topical corticosteroid OR topical calcineurin inhibitor therapy in combination with the requested agent OR 2. The patient has been treated with the requested agent for at least 16 consecutive weeks AND BOTH of the following: <ul style="list-style-type: none"> A. The patient's atopic dermatitis has sufficiently improved AND B. Based on disease activity, concurrent topical therapies (e.g., topical corticosteroid, topical calcineurin inhibitor) have been tapered and discontinued OR 3. The patient has an intolerance, hypersensitivity, or FDA labeled contraindication to ALL topical corticosteroids AND topical calcineurin inhibitors AND C. ONE of the following: <ul style="list-style-type: none"> 1. The patient is initiating therapy with the requested agent OR 2. The patient has been treated with the requested agent for less than 16 consecutive weeks OR 3. The patient has been treated with the requested agent for at least 16 consecutive weeks AND ONE of the following: <ul style="list-style-type: none"> A. The requested dose is 30 mg every 8 weeks OR B. The requested dose is 30 mg every 4 weeks AND ONE of the following: <ul style="list-style-type: none"> 1. The patient has NOT achieved clear or almost clear skin OR 2. There is support for continued therapy at the requested dose of 30 mg every 4 weeks AND <p>4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., allergist, dermatologist, immunologist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis AND</p> <p>5. ONE of the following (please refer to "Agents NOT to be used Concomitantly" table):</p> <ul style="list-style-type: none"> A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) OR B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following: <ul style="list-style-type: none"> 1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent AND 2. There is support for use of combination therapy (submitted copy of clinical trials, phase III studies, or guidelines required) AND <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
QL	<p>Quantity Limit for the Target Agent(s) will be approved when ONE of the following is met:</p> <ul 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: <ul style="list-style-type: none"> A. The requested agent is Nemluvio for a diagnosis of prurigo nodularis AND ONE of the following:

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	<ol style="list-style-type: none"> 1. The patient weighs less than 90 kg AND BOTH of the following: <ol style="list-style-type: none"> A. The request is for an initial loading dose AND B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication OR 2. The patient weighs 90 kg or greater AND the requested quantity (dose) does NOT exceed 60 mg every 4 weeks OR <p>B. BOTH of the following:</p> <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 <p>C. BOTH of the following:</p> <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> <p><u>Note:</u> If approving initial loading dose for Nemluvio for atopic dermatitis or prurigo nodularis, approve quantity for loading dose for 1 month per FDA labeling followed by maintenance dose for the remainder of the length of approval. Maintenance dosing begins 4 weeks after patient receives the loading dose.</p>

CONTRAINDICATION AGENTS

Contraindicated as Concomitant Therapy
<p>Agents NOT to be used Concomitantly</p> <p>Abrilada (adalimumab-afzb) Actemra (tocilizumab) Adalimumab Adbry (tralokinumab-ldrm) Amjevita (adalimumab-atto) Arcalyst (rilonacept) Avsola (infliximab-axxq) Avtozma (tocilizumab-anoh) Benlysta (belimumab) Bimzelx (bimekizumab-bkzx) Cibinqo (abrocitinib) Cimzia (certolizumab) Cinqair (reslizumab) Cosentyx (secukinumab) Cyltezo (adalimumab-adbm) Dupixent (dupilumab) Ebglyss (lebrikizumab-lbkz) Enbrel (etanercept) Entyvio (vedolizumab) Fasenra (benralizumab) Hadlima (adalimumab-bwwd) Hulio (adalimumab-fkjp) Humira (adalimumab) Hyrimoz (adalimumab-adaz) Idacio (adalimumab-aacf) Ilaris (canakinumab) Ilumya (tildrakizumab-asmn) Imuldosa (ustekinumab-srlf) Inflectra (infliximab-dyyb)</p>

Contraindicated as Concomitant Therapy

Infliximab
Kevzara (sarilumab)
Kineret (anakinra)
Leqselvi (deuruxolitinib)
Litfulo (ritlecitinib)
Nemludio (nemolizumab-ilto)
Nucala (mepolizumab)
Olumiant (baricitinib)
Omlyclo (omalizumab-igec)
Omvoh (mirikizumab-mrkz)
Opzelura (ruxolitinib)
Orencia (abatacept)
Otezla (apremilast)
Otezla XR (apremilast extended-release)
Otulfi (ustekinumab-aauz)
Pyzchiva (ustekinumab-ttwe)
Remicade (infliximab)
Renflexis (infliximab-abda)
Rhapsido (remibrutinib)
Riabni (rituximab-arrx)
Rinvoq (upadacitinib)
Rituxan (rituximab)
Rituxan Hycela (rituximab/hyaluronidase human)
Ruxience (rituximab-pvvr)
Saphnelo (anifrolumab-fnia)
Selarsdi (ustekinumab-aekn)
Siliq (brodalumab)
Simlandi (adalimumab-ryvk)
Simponi (golimumab)
Simponi ARIA (golimumab)
Skyrizi (risankizumab-rzaa)
Sotyktu (deucravacitinib)
Spevigo (spesolimab-sbzo) subcutaneous injection
Starjemza (ustekinumab-hmny)
Stelara (ustekinumab)
Steqeyma (ustekinumab-stba)
Taltz (ixekizumab)
Tezspire (tezepelumab-ekko)
Tofidence (tocilizumab-bavi)
Tremfya (guselkumab)
Truxima (rituximab-abbs)
Tyenne (tocilizumab-aazg)
Tyruko (natalizumab-sztn)
Tysabri (natalizumab)
Ustekinumab
Velsipity (etrasimod)
Wezlana (ustekinumab-auub)
Xeljanz (tofacitinib)
Xeljanz XR (tofacitinib extended release)
Xolair (omalizumab)
Yesintek (ustekinumab-kfce)
Yuflyma (adalimumab-aaty)
Yusimry (adalimumab-aqvh)
Zeposia (ozanimod)
Zymfentra (infliximab-dyyb)