



Policy Type:PA/SP

Pharmacy Coverage Policy: EOCCO312

Description

Nemolizumab (Nemluvio) is an interleukin-31 (IL-31) receptor alpha antagonist.

Length of Authorization

- Initial: 12 months
- Renewal: 12 months

Quantity Limits

Product Name	Indication	Dosage Form	Quantity Limit	
nemolizumab (Nemluvio)	Prurigo Nodularis	30 mg prefilled pen	 First month: 2 (30mg) prefilled pens/28 days Maintenance: Under 90kg: 1 (30mg) prefilled pen/28 days 90kg or more: 2 (30mg) prefilled pens/28 days 	
	Atopic Dermatitis		First month: 2 (30mg) prefilled pens/28 days Maintenance: 1 (30mg) prefilled pen/28 days	

Initial Evaluation

- I. **Nemolizumab (Nemluvio)** may be considered medically necessary when the following criteria are met:
 - A. Medication is prescribed by, or in consultation with, a dermatologist; AND
 - B. Medication will not be used in combination with another biologic for the treatment of prurigo nodularis or atopic dermatitis [e.g., dupilumab (Dupixent), upadacitinib (Rinvoq)];
 AND
 - C. A diagnosis of prurigo nodularis (PN) when the following are met:
 - 1. Member is 18 years of age or older; AND
 - 2. Member has a confirmed diagnosis of moderate to severe prurigo nodularis based on all of the following:
 - i. Presence of nodules for at least 3 months; AND
 - Disease is moderate to severe in severity (e.g., Peak Pruritis Numeric Rating Scale (PP-NRS) score of at least 7; Investigator Global Assessment (IGA) score of 3 or 4; presence of at least 20 lesions on the body); AND





- Provider attests the underlying cause of prurigo nodularis (PN) is not considered to be drug-induced or caused by other medical conditions, such as dermatillomania; AND
- 3. Treatment with at least one medium to very high potency topical corticosteroid has been ineffective, not tolerated, or contraindicated; **AND**
- 4. Treatment with at least one of the following has been ineffective or not tolerated, unless <u>all</u> are contraindicated:
 - i. Topical calcineurin inhibitors (e.g., pimecrolimus cream, tacrolimus ointment)
 - ii. Topical vitamin D analogue (e.g., calcipotriene)
 - iii. Phototherapy (UVA or PUVB)
 - iv. Systemic immunosuppressants (e.g. methotrexate or cyclosporine); AND
- 5. Treatment with dupilumab (Dupixent) has been ineffective, contraindicated, or not tolerated; **OR**
- D. A diagnosis of **atopic dermatitis (AD)** when the following are met:
 - 1. Member is 12 years of age or older; AND
 - 2. Body surface area (BSA) involvement of at least 10%; OR
 - i. Involves areas of the face, ears, hands, feet, or genitalia; AND
 - 3. Treatment with at least <u>two</u> of the following groups has been ineffective or not tolerated, unless ALL are contraindicated:
 - i. Group 1: Topical corticosteroids of at least medium/moderate potency (e.g., clobetasol, betamethasone, halobetasol)
 - ii. Group 2: Topical calcineurin inhibitors (e.g. pimecrolimus cream, tacrolimus ointment)
 - iii. Group 3: Topical PDE-4 inhibitors (e.g. crisaborole [Eucrisa]); AND
 - 4. Treatment with dupilumab (Dupixent) has been ineffective, contraindicated, or not tolerated; **AND**
 - 5. Medication will be used in combination with topical corticosteroids and/or calcineurin inhibitors unless both are contraindicated
- II. Nemolizumab (Nemluvio) is considered <u>investigational</u> when used for all other conditions, including but <u>not limited to</u>:
 - A. Chronic Kidney Disease with associated moderate to severe pruritis
 - B. Systemic Sclerosis

Renewal Evaluation

I. Member has received a previous prior authorization approval for this agent through this health plan or has been established on therapy from a previous health plan; **AND**



- II. Member is not continuing therapy based off being established on therapy through samples, manufacturer coupons, or otherwise. If they have, initial policy criteria must be met for the member to qualify for renewal evaluation through this health plan; **AND**
- III. Medication will not be used in combination with another biologic (e.g., dupilumab [Dupixent]) or Janus Kinase inhibitor (e.g., upadacitinib [Rinvoq]); AND
- IV. Member has exhibited improvement or stability of disease symptoms for the following:
 - For Prurigo Nodularis (PN): clearance of the skin as determined by Investigator Global Assessment (IGA) score of 0 or 1, reduced prurigo nodularis (PN) nodules, reduction in score on the Peak Pruritis Numeric Rating Scale (PP-NRS) scale
 - For Atopic Dermatitis (AD): clearance of the skin as determined by Investigator Global Assessment (IGA) score of 0 or 1, improvement in the Eczema Area and Severity Index-75

Supporting Evidence

- I. Nemolizumab (Nemluvio) is FDA approved for the treatment of prurigo nodularis in adult patients. It is pending FDA approval in December 2024 for atopic dermatitis. The safety and efficacy in other disease states is unknown.
- II. Due to the complexity of diagnosis and treatment, nemolizumab (Nemluvio) should be prescribed by, or in consultation with a dermatologist.

Prurigo Nodularis

- I. Prurigo nodularis (PN) is a distinct dermatological condition defined by the presence of chronic pruritis and multiple localized or generalized, elevated, firm, and nodular lesions. The exact underlying cause of PN is unknown, neural and immunologic processes both appear to play a role in its development. Prurigo nodularis (PN) is more common in women, older adults, and African Americans. The disease may arise without any other secondary dermatologic diagnosis, such as atopic dermatitis. Prurigo nodularis (PN) is associated with the severest itch of the various skin conditions as well as significant disease burden, including sleep disruption, anxiety, and depression. Prurigo nodularis (PN) is perpetuated by the sensitization induced by the scratch-itch cycle and treating any underlying cause alone may not provide sufficient relief.
- II. Although literature suggests up to 60% of patients with PN have a history of atopic conditions (atopic dermatitis, allergic rhinitis, asthma, etc.), both drugs induced PN (e.g., opioids, ACE inhibitors, etc.) or PN due to other medical conditions such as neuropathy or psychiatric disease (i.e. dermatillomania, obsessive compulsive disorder, etc.), should be considered and ruled out in the making of a diagnosis of PN. Additionally, short-term lesions, under three months, should also be ruled out for other dermatologic conditions, such as lichen planus. The American Academy of Dermatology (AAD) 2021 guidelines on the diagnosis of management of prurigo nodularis, outline traditional therapies used for PN before biologic therapy, such as dupilumab (Dupixent) or nemolizumab (Nemluvio), were approved. Treatment consists of moderate to very high potency topical steroids (TCS), including intralesional injections, topical calcineurin





inhibitors, capsaicin, narrowband ultraviolet (UVB) phototherapy, as well as systemic therapies. Systemic options include oral immunosuppressants, such as low dose methotrexate, cyclosporine, as well as neuromodulators (e.g., gabapentinoids, cannabinoids), antihistamines, and antidepressants (e.g., amitriptyline, doxepin).

- III. Safety and efficacy of nemolizumab (Nemluvio) was studied in two similarly designed Phase 3, double-blind, multicenter, placebo-controlled trials (OLYMPIA 1 and 2). Five hundred and sixty total adult patients, mainly white and diagnosed with prurigo nodularis for at least six months, were randomized 2:1 to receive either nemolizumab (Nemluvio) at 30 mg or 60 mg monthly versus matching placebo. Patients had prior use of topical therapies in 78% in the nemolizumab (Nemluvio) arm and 72% in placebo, with prior systemic therapies of 57% and 62% respectively. Most patients at baseline were on topical steroids (78%) with either antihistamine use (39%), another topical agent (22%), or immunosuppressants (19%); though use was not allowed during the trial period. At baseline, 65% of patients had 20-100 nodules over their body, an average Peak Pruritis Numeric Rating Scale (PP-NRS) of 8.5, 58% had Investigator's Global Assessment (IGA) score of 3 (moderate PN), and 42% had IGA score of 4 (severe PN). The co-primary endpoints assessed improvement in skin lesions and pruritis from baseline to Week 16 using PP-NRS and IGA scales.
- IV. Investigator global assessment (IGA) score is a five-point scale rating from 0 (clear, no nodules) to 4 (severe, ≥100 nodules) done by providers to assess disease severity. The peak pruritis numeric rating scale (PP-NRS) is an 11-point scale from 0 (no itch) to 10 (worst itch imaginable) that asks the patient to rate itch at the worst moment during the previous 24 hours, it is interchangeable with the worst itch numeric rating scale. The PP-NRS score is a validated endpoint with a clinical meaningful change seen by improvement of four points. Patients in OLYMPIA 1 and 2 all had an IGA score of 3 or 4 (moderate to severe skin involvement) and a PP-NRS score of ≥7 (severe itch).
- V. Both primary endpoints in OLYMPIA 1 and 2 were met:
 - OLYMPIA 1: A significantly greater improvement in itch intensity and skin lesions with nemolizumab (Nemluvio) treatment was observed at week 16 compared to placebo. There were 58.4% of subjects treated with nemolizumab (Nemluvio) who had a ≥ 4-point improvement in weekly average PP-NRS score from baseline compared to 16.7% in placebo group (P < 0.0001). There were 26.3% of nemolizumab (Nemluvio)-treated subjects achieving IGA success, as defined by an IGA response of 0 (clear) or 1 (almost clear) and a ≥ 2-point reduction from baseline, compared to 7.3% in placebo group (P = 0.0025).</p>
 - OLYMPIA 2: A greater proportion of patients achieving an improvement in PP-NRS by four or more points and obtaining an IGA score of 0 or 1 on nemolizumab (Nemluvio) (n=183) versus placebo (n=91). PP-NRS: 103 versus 19 patients, treatment difference of 37.4 (26.3-48.5, P<0.001) and IGA: 69 versus 10 patients, treatment difference of 28.5 (18.8-38.2 P<0.001).





VI. Key secondary endpoints such as the number of patients reaching the PP-NRS reduction by week four and improvement in the sleep disturbance numerical rating scale also reached statistically significant differences in both clinical trials with an average 30% more patients achieving improvement in both clinical trial endpoints.

Atopic Dermatitis

- I. Atopic dermatitis (AD) is a common, chronic, flaring inflammatory skin disease affecting millions of people worldwide. In the US, 31.6 million adults have moderate-to-severe AD, with symptoms of eczematous lesions, pruritis, and sleep disturbances Treatments for mild-to-moderate atopic dermatitis include topical corticosteroids (TCS), topical calcineurin inhibitors (TCI), phototherapy, and/or crisaborole (Eucrisa) a PDE4 inhibitor. Symptomatic treatments include oral and topical antihistamines and sleep aids for nighttime pruritus. Treatment choice between these products is dependent on severity, location, and other patient specific factors (e.g., allergies, age). According to the 2024 AAD guidelines, TCIs may be preferable to TCS in patients with recalcitrance to steroids, sensitive areas involved, steroid-induced atrophy, and long-term uninterrupted topical steroid use.
- II. Treatment for moderate to severe disease includes the same topical classes noted above and, for those not amenable to topical, systemic immunosuppressants (e.g., corticosteroids, cyclosporine, methotrexate, azathioprine, mycophenolate mofetil), JAK inhibitors (e.g., abrocitinib, upadacitinib), and interleukin-13 antagonists (e.g., dupilumab, lebrikizumab, tralokinumab) can be used. Currently, there are no head-to-head trials evaluating safety and/or efficacy differences or superiority between biologic therapies in atopic dermatitis. Dupilumab (Dupixent) has an established safety and efficacy profile for the treatment of atopic dermatitis and is approved down to six months of age. Upadacitinib (Rinvoq), lebrikizumab (Ebglyss), tralokinumab (Adbry) have been evaluated and FDA approved in patients down to 12 years of age. Abrocitinib (Cibinqo) is FDA approved in adult patients only.
- III. There may be patient specific scenarios in which the use of additional topical agents following failure of one class of topical agents would be impractical. Insight from dermatology specialists indicate that patients who have at least 15% body surface area (BSA) involvement, or involvement in sensitive areas (e.g., eyelids, axilla, genitals, gluteal cleft), and have severe disease are potential candidates for systemic biologic therapy. Severe disease, as defined by NICE guidelines, includes widespread areas of dry skin, incessant itching, redness (with or without excoriation, extensive skin thickening, bleeding, oozing, cracking, and alteration of pigmentation), severe limitation of everyday activities and psychosocial functioning, and nightly loss of sleep; severe disease can also be classified as physician's global assessment (PGA) score of 4.0. Additionally, administration of topical agents may become impractical for patients with high disease burden (BSA ≥ 20%), considering twice daily administration is necessary for non-steroid topical agents for optimal efficacy.
- IV. Nemolizumab (Nemluvio) was studied in two identical, Phase 3, multicenter, randomized, placebo-controlled trials (ARCADIA 1 and 2). A total of 1,728 patients aged 12 years and older, with moderate to severe AD, not controlled by topical therapies alone, were randomized 2:1 to receive nemolizumab (Nemluvio) 30 mg monthly or matching placebo. Patients remained on





background topical steroids (TCS) and topical calcineurin inhibitors (TCI), if applicable. At baseline, 71% of patients had an IGA score of 3 with an average eczema area and severity index score (EASI-75) of 27.3 affecting on average 19% of their body surface area (BSA). The change from baseline to week 16 in the IGA score and a 75% improvement in the EASI-75 were coprimary endpoints.

- V. Both co-primary endpoints were met in each trial:
 - Thirty-six percent and 38% of nemolizumab-treated patients in ARCADIA 1 and 2 achieved clear skin, defined by an investigator's global assessment score of clear (0) or almost-clear (1), when compared to the placebo group (25% and 26%, respectively; p<0.001).
 - Forty-four percent and 42% of nemolizumab-treated patients in ARCADIA 1 and 2 achieved at least a 75% improvement in the eczema area and severity index score, when compared to the placebo group (29% and 30%, respectively; p<0.001).
- VI. Key secondary endpoints, such as the number of patients reaching the PP-NRS reduction by week four and improvement in the sleep disturbance numerical rating scale, also reached statistically significant differences in both ARCADIA 1 and 2.

Evidence Summary

- I. Overall, the quality of evidence for nemolizumab (Nemluvio) is considered moderate. Well-designed Phase 3 trials in both PN and AD showed statistical significance in the co-primary endpoints as well as key secondary endpoints. For atopic dermatitis, these endpoints reflect skin improvement and less disease burden overall. For prurigo nodularis, these endpoints reflect marked clinically meaningful changes in reduction of itch as well as clearing PN nodules from the body. There was an underrepresented population in the African American enrollment for PN, which leads to uncertainty in the applicability in this population.
- II. The most common individual adverse events of both OLYMPIA trials (occurring in ≥5% of the patients) that emerged during the treatment period in the nemolizumab (Nemluvio) group and were reported with higher frequency than in the placebo group were atopic dermatitis (5.5% versus zero) and headache (6.6 versus 4.4%). Overall, more adverse events occurred in the nemolizumab (Nemluvio) arms than the placebo arms in both OLYMPIA trials (66.5 versus 59.1%) and ARCADIA trials (45.5 versus 44.5%). The pooled adverse events of special interest that occurred more frequently in the nemolizumab (Nemluvio) groups than in the placebo groups were peripheral or facial edema and asthma; whereas infections were more common in the placebo groups than in the nemolizumab groups. The ARCADIA trial also had herpes zoster infections specifically associated with nemolizumab use. All peripheral or facial edema events were nonserious and were considered to be mild or moderate in severity.
- III. The use of nemolizumab (Nemluvio) over 30 mg monthly for AD has not been studied in the U.S. or approved by the FDA and requests for quantities over 30 mg monthly would be considered experimental. While nemolizumab (Nemluvio) has been studied as 60 mg monthly dose for the treatment of prurigo nodularis (PN), as well as approved in Japan as a 60 mg monthly dose for the use in AD, the up dosing remains experimental in this PN and is not supported by the FDA. When higher than the FDA approved dosing is requested, the use of other biologic therapies should be considered.





IV. Nemolizumab (Nemluvio) for AD is approved for add-on to topical corticosteroids and/or calcineurin inhibitors and should be initiated on top of conventional therapies. Once the disease, has improved, topical therapies should be discontinued.

Investigational or Not Medically Necessary Uses

- I. Nemolizumab (Nemluvio) has not been FDA-approved, or sufficiently studied for safety and efficacy for the conditions or settings listed below:
 - A. Chronic Kidney Disease with associated moderate to severe pruritis
 - i. Clinical trial NCT05075408, NemoCKDaP, was a Phase II multicenter, double-blind, randomized, placebo-controlled trial over 12 weeks evaluating the efficacy and safety of nemolizumab versus placebo to reduce the intensity of pruritic in adult hemodialysis participants with moderate to severe prutitis. A total of 258 adult patients with end-stage kidney disease (ESKD) on hemodialysis three times per week for at least three months before the trial, prutitis for at least three months with a worse-itch numeric rating scale (WI-NRS) of five or better were enrolled and randomized. Patients were randomized to nemluvio (30 or 60mg monthly) versus placebo. The primary endpoint was the number of responders with an improvement in the WI-NRS by at least four points at the end of week 12. Results have not been published as of October 2024. All requests for this indication are considered experimental and investigational.
 - B. Systemic Sclerosis
 - i. Clinical trial NCT05214794, is an open-label, single-arm, Phase II study to assess efficacy and safety in patients with systemic sclerosis in Japan. Patients aged 20-70 years old, with diagnosis of systemic sclerosis (SSc) by the American college of Rheumatology (ACR) and European League Against Rheumatism (EULAR) 2013 criteria. All patients had moderate to severe skin sclerosis involvement and received nemolizumab. The change in baseline in the modified Rodnan Skin Score (mRSS) at week 24 was the primary endpoint at week 24. The modified Rodnan skin score (mRSS) is a measure of skin thickness and is used as a primary or secondary outcome measure in clinical trials of systemic sclerosis (scleroderma). It is a validated endpoint used as a surrogate for disease activity, severity and mortality in patients with dcSSc (diffuse SSc). In early dcSSc, an increase in skin thickening is generally associated with new or worsening internal organ involvement and increased mortality. Worsening mRSS is associated with higher mortality, and both negative renal and cardiac outcomes. Results have not been published as of October 2024. All requests for this indication are considered experimental and investigational.





Appendix

I. Table 1: Topical Corticosteroid Potency Chart

Potency Group	Corticosteroid	Vehicle type/form	Brand names	Available strength(s), percent (except as noted)
	Betamethasone	Gel, lotion, ointment	Diprolene	0.05
	dipropionate, augmented	(optimized)		
		Cream, gel, ointment, solution (scalp)	Temovate	0.05
Super-high		Cream, emollient base	Temovate E	0.05
potency	Clobetasol propionate	Lotion, shampoo, spray aerosol	Clobex	0.05
(Group 1)		Foam aerosol	Olux-E, Tovet	0.05
		Solution (scalp)	Cormax	0.05
	Fluocinonide	Cream	Vanos	0.1
	Flurandrenolide	Tape (roll)	Cordran	4 mcg/cm2
	Halobetasol propionate	Cream, lotion, ointment	Ultravate	0.05
	Amcinonide	Ointment	Cyclocort¶, Amcort¶	0.1
	Betamethasone	Ointment	Diprosone¶	0.05
	dipropionate	Cream, augmented formulation (AF)	Diprolene AF	0.05
	Clobetasol propionate	Cream	Impoyz	0.025
High	Desoximetasone	Cream, ointment, spray	Topicort	0.25
potency	Desoximetasone	Gel	Topicort	0.05
(Group 2)	Diflorasone diacetate	Ointment	ApexiCon¶, Florone¶	0.05
(0:000 2)		Cream, emollient	ApexiCon E	0.05
	Fluocinonide	Cream, gel, ointment, solution	Lidex¶	0.05
	Halcinonide	Cream, ointment, solution	Halog	0.1
	Halobetasol propionate	Lotion	Bryhali	0.01
	Amcinonide	Cream	Cyclocort¶, Amcort¶	0.1
		Lotion	Amcort¶	0.1
	Betamethasone dipropionate	Cream, hydrophilic emollient	Diprosone¶	0.05
	Betamethasone valerate	Ointment	Valisone¶	0.1
High potency (Group 3)		Foam	Luxiq	0.12
	Desoximetasone	Cream	Topicort LP¶	0.05
	Diflorasone diacetate	Cream	Florone¶	0.05
	Diflucortolone valerate (not available in United States)	Cream, oily cream, ointment	Nerisone (Canada, United Kingdom, others)	0.1
	Fluocinonide	Cream aqueous emollient	Lidex-E¶	0.05
	Fluticasone propionate	Ointment	Cutivate	0.005
	Mometasone furoate	Ointment	Elocon	0.1



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	Triamcinolone acetonide	Cream, ointment	Aristocort HP¶, Kenalog¶, Triderm	0.5
	Betamethasone dipropionate	Spray	Sernivo	0.05
	Clocortolone pivalate	Cream	Cloderm	0.1
	Fluocinolone acetonide	Ointment	Synalar¶	0.025
	Flurandrenolide	Ointment	Cordran	0.05
	Hydrocortisone valerate	Ointment	Westcort	0.2
Medium potency	Mometasone furoate	Cream, lotion, ointment, solution	Elocon¶	0.1
(Group 4)		Cream	Kenalog¶, Triderm	0.1
		Ointment	Kenalog¶	0.1
	Triamcinalana acatonida	Ointment	Trianex	0.05
	Triamcinolone acetonide	Aerosol spray	Kenalog	0.2 mg per 2 second spray
		Dental paste	Oralone	0.1
	Betamethasone dipropionate	Lotion	Diprosone¶	0.05
	Betamethasone valerate	Cream	Beta-Val, Valisone¶	0.1
	Decenide	Ointment	DesOwen, Tridesilon¶	0.05
	Desonide	Gel	Desonate	0.05
	Fluocinolone acetonide	Cream	Synalar¶	0.025
	Flurandrenolide	Cream, lotion	Cordran	0.05
Lower-mid	Fluticasone propionate	Cream, lotion	Cutivate	0.05
potency (Group 5)	Hydrocortisone butyrate	Cream, lotion, ointment, solution	Locoid, Locoid Lipocream	0.1
	Hydrocortisone probutate	Cream	Pandel	0.1
	Hydrocortisone valerate	Cream	Westcort¶	0.2
	Prednicarbate	Cream (emollient), ointment	Dermatop	0.1
	Totono ta chen de la Ch	Lotion	Kenalog¶	0.1
	Triamcinolone acetonide	Ointment	Kenalog¶	0.025
	Alclometasone dipropionate	Cream, ointment	Aclovate	0.05
	Betamethasone valerate	Lotion	Beta-Val¶, Valisone¶	0.1
	Desonide	Cream	DesOwen, Tridesilon¶	0.05
Low		Lotion	DesOwen, LoKara	0.05
potency		Foam	Verdeso	0.05
(Group 6)	Fluocinolone acetonide	Cream, solution	Synalar¶	0.01
		Shampoo	Сарех	0.01
		Oil (48% refined peanut oil)	Derma-Smoothe/FS Body, Derma-Smoothe/FS Scalp	0.01
	Triamcinolone acetonide	Cream, lotion	Kenalog¶, Aristocort¶	0.025
	Hydrocortisone (base, ≥2%)	Cream, ointment	Hytone, Nutracort¶	2.5
Looot waters t		Lotion	Hytone, Ala Scalp, Scalacort	2
Least potent		Solution	Texacort	2.5
(Group 7)	Hydrocortisone (base, <2%)	Ointment	Cortaid, Cortizone 10, Hytone, Nutracort	1



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		Cream	Cortaid¶, Cortizone 10, Hytone, Synacort	1
		Gel	Cortizone 10	1
		Lotion	Aquanil HC, Sarnol-HC, Cortizone 10	1
		Spray	Cortaid	1
		Solution	Cortaid, Noble, Scalp Relief	1
		Cream, ointment	Cortaid	0.5
Hydrocortisone acetate	Ludrocorticono ocototo	Cream	MiCort-HC	2.5
	Lotion	Nucort	2	

¶ Inactive United States brand name for specific product; brand may be available outside United States

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Related Policies

Policies listed below may be related to the current policy. Related policies are identified based on similar indications, similar mechanisms of action, and/or if a drug in this policy is also referenced in the related policy.

Policy Name	Disease state
dupilumab (Dupixent)	Prurigo Nodularis
dupilumab (Dupixent)	
Lebrikizumab (Ebglyss)	
tralokinumab (Adbry)	
Systemic Janus Associated Kinase (JAK)	Atopic Dermatitis
Inhibitors in Chronic Inflammatory	
Disease	
ruxolitinib (Jakafi, Opzelura)	

Policy Implementation/Update:

Action and Summary of Changes	Date
Update to the criteria for AD to include in combination on initial review only, following label.	2/2025
Policy created	11/2024