Opzelura (ruxolitinib) Prior Authorization with Quantity Limit Program Summary

This program applies to Medicaid.

For Medicaid, the Non-Preferred Drug Supplement applies.

The BCBS MN Step Therapy Supplement applies to this program for Medicaid

POLICY REVIEW CYCLE

Effective Date	Date of Origin
04-01-2024	03-01-2022

FDA APPROVED INDICATIONS AND DOSAGE

Agent(s)	FDA Indication(s)	Notes	Ref#
Opzelura™ (ruxolitinib) Cream	Topical short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in non-immunocompromised patients 12 years of age and older whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable Topical treatment of nonsegmental vitiligo in adult and pediatric patients 12 years of age and older Limitation of Use: Use of Opzelura in combination with therapeutic biologics, other Janus kinase (JAK) inhibitors, or potent immunosuppressants such as azathioprine or cyclosporine is not recommended		1

See package insert for FDA prescribing information: https://dailymed.nlm.nih.gov/dailymed/index.cfm

CLINICAL RATIONALE

Atopic Dermatitis	Atopic dermatitis (AD), also known as atopic eczema, is a chronic, pruritic inflammatory dermatosis affecting up to 25% of children and 1-5% of adults. AD follows a relapsing course and is associated with elevated serum immunoglobulin (IgE) levels and a personal or family history of type I allergies, allergic rhinitis, and/or asthma. Onset is most common between 3 and 6 months of age, with approximately 60% of patients developing the eruption in the first year of life and 90% by age 5. While the majority of affected individuals have resolution of disease by adulthood, 10 to 30% do not, and a smaller percentage first develop symptoms as adults. AD has a complex pathogenesis involving genetic, immunologic, and environmental factors, which lead to a dysfunctional skin barrier and dysregulation of the immune system. Clinical findings include erythema, edema, xerosis, erosions/excoriations, oozing and crusting, and lichenification. These clinical findings vary by patient age and chronicity of lesions. Pruritus is a hallmark of the condition that is responsible for much of the disease burden borne by patients and their families. Typical patterns include facial, neck and extensor involvement in infants and children; flexure involvement in any age group, with sparing of groin and axillary regions.(2) Goals of treatment are to reduce symptoms (pruritus and dermatitis), prevent exacerbations, and minimize therapeutics risks.(3) Despite its relapsing and remitting nature, the majority of patients with AD can achieve clinical improvement and disease control with nonpharmacological interventions (e.g., emollient use), conventional topical therapies (including corticosteroids and calcineurin inhibitors) and

	environmental and occupational modifications, when necessary.(3-5) The American Academy of Dermatology (AAD) guidelines suggest application of moisturizers should be an integral part of the treatment of patients with AD as there is strong evidence that their use reduces disease severity and need for pharmacologic intervention. They are an important component of maintenance treatment and prevention of flares.(4) The AAD recommends topical corticosteroids (TCS) for patients who fail to respond to good skin care and regular use of emollients alone. Proactive, intermittent use of TCS as maintenance therapy (1-2 times weekly) on areas that commonly flare is recommended to help prevent relapses and is more effective than use of emollients alone. Monitoring by physical exam for cutaneous side effects during long-term, potent steroid use is suggested. Proactive, once to twice weekly application of mid-potency TCS for up to 40 weeks has not demonstrated adverse events (e.g., purpura, telangiectasia, striae, focal hypertrichosis, acneiform/rosacea-like eruptions, skin atrophy) in clinical trials.(4) It is recommended that patients with acute flares use super high or high potency TCS for one to two weeks, and then replace these with lower potency preparations until the lesions resolve.(6) AAD notes that mid- to higher potency TCS are appropriate for short courses to gain rapid control of symptoms, but long-term management should use the least-potent corticosteroid that is effective.(4)
	
	Topical calcineurin inhibitors (TCIs) (e.g., pimecrolimus, tacrolimus) are recommended by the AAD as second-line therapy and are effective for acute and chronic treatment. They are particularly useful in selected clinical situations such as recalcitrance to steroids; for sensitive areas (face, anogenital, skin folds); for steroid-induced atrophy; and when there is long-term uninterrupted topical steroid use. TCIs are recommended for use on actively affected areas as a steroid-sparing agent. Proactive, intermittent use of TCIs as maintenance therapy (2-3 times per week) on areas that commonly flare is recommended to help prevent relapses while reducing need for TCS and is more effective than use of emollients alone.(4) Prescribing information for Elidel® (pimecrolimus) cream and Protopic® (tacrolimus) ointment indicate evaluation after 6 weeks if symptoms of AD do not improve for adults and pediatrics.(7,8)
	
	Phototherapy is recommended as a treatment for both acute and chronic AD in children and adults, after failure of the mentioned above. Systemic immunomodulator agents are indicated and recommended for the subset of adult and pediatric patients in whom optimized topical regimens using emollients, topical anti-inflammatory therapies, adjunctive methods, and/or phototherapy do not adequately control the signs and symptoms of disease. Phototherapy and systemic immunomodulating agents may also be used in patients whose medical, physical, and/or psychological states are greatly affected by their skin disease. Oral cyclosporine, azathioprine, methotrexate, and mycophenolate mofetil are the most commonly used systemic immunomodulators and most efficacious for treating AD. The AAD recommends that systemic corticosteroids should be avoided if possible and should exclusively be reserved for acute, severe exacerbations and as a short-term bridge to other systemic, steroid sparing therapies.(5)
	
	The American Academy of Family Physicians recommend the following for the treatment of AD:(9)
	
	• Maintenance treatment should consist of twice daily application of an emollient and once daily bathing using a soap-free cleanser
	• Mild flare:
	  ○ Continue maintenance treatment with twice daily topical steroid (low to medium potency)
	  ○ If there is clinical improvement, continue maintenance therapy
	  ○ If no clinical improvement or inadequate improvement, start treatment options for moderate AD
	• Moderate flare:
	  ○ Continue maintenance treatment with twice daily topical steroid (medium to high potency) AND twice daily TCI

	○ Additional therapies to add on include Eucrisa, twice weekly bleach baths, wet wrap therapy ○ If there is clinical improvement, switch to mild treatment options ○ If no clinical improvement or inadequate improvement, start treatment options for severe AD • Severe flare: ○ Continue maintenance treatment with twice daily topical steroid (high potency) AND twice daily topical calcineurin inhibitor ○ Additional therapies to add on include twice weekly bleach baths, wet wrap therapy ○ Referral to a specialist
Vitiligo	Vitiligo is an acquired skin pigmentation disorder characterized by well defined, depigmented areas of the skin. The depigmentation is due to a loss of epidermal melanocytes. Vitiligo can present in a localized or generalized distribution, with the lesions coalescing into larger depigmented areas. The underlying cause of vitiligo is yet unknown.(10) Vitiligo is commonly classified into two different forms, segmental and non-segmental. Non-segmental vitiligo (NSV) tends to evolve over time in both distribution and extension patterns. NSV is an umbrella term for a number of different subtypes of vitiligo. These include acrofacial, generalized, mucosal (multifocal), and universal. NSV is characterized by depigmented lesions that vary in size and often involve both sides of the body. Involvement of the scalp and other hair-bearing areas may manifest with patches of gray or white hairs, while body hair is generally spared. Segmental vitiligo (SV) tends to have an earlier age of onset, that rapidly progresses but has a limited course. Depigmentation spreads within a segment within 6-24 months and then stops. Hair follicles are more frequently involved early in the disease course with SV, with up to 50% of patients exhibiting poliosis, a localized cluster of white hair shafts, in affected areas.(11) The diagnosis of vitiligo is based off of clinical presentation and with a Woods lamp, which is a handheld ultraviolet device. The Woods lamp is also used to track progression of lesions over time. There are a number of other indications that can mimic vitiligo and it is important to rule those out with a close examination of the skin. Vitiligo does not cause scaling or textural changes in the skin.(10) The British Association of Dermatology guidelines recommend first-line therapy with potent or very potent topical corticosteroids once daily avoiding the periocular area. Topical calcineurin inhibitors may be considered in patients with facial vitiligo or used in an intermittent regimen in combination with potent corticosteroids for patients with lesions in areas of thinner skin. Topical therapies should be evaluated every 3 to 6 months to check for improvement. Phototherapy is also recommended as a second-line option in patients that have had an inadequate response to topical therapies.(12)
Efficacy	*Atopic Dermatitis*(1) Two double-blind, randomized, vehicle-controlled trials of identical design (TRuE-AD1 and TRuE-AD2, NCT03745638 and NCT03745651, respectively) enrolled a total of 1249 adult and pediatric subjects aged 12 and older. Subjects had affected body surface area (BSA) of 3 to 20%, and an Investigator's Global Assessment (IGA) score of 2 (mild) to 3 (moderate) on a severity scale of 0 to 4. The baseline Itch Numerical Rating Scale (Itch NRS), defined as the 7-day average of the worst level of itch intensity in the last 24 hours, was 5 on a scale of 0 to 10. In both trials, subjects were randomized 2:2:1 to treatment with Opzelura, ruxolitinib cream, 0.75%, or vehicle cream twice daily (BID) for 8 weeks. The primary efficacy endpoint was the proportion of subjects at week 8 achieving IGA treatment success (IGA-TS) defined as a score of 0 (clear) or 1 (almost clear) with greater than or equal to 2 grade improvement from baseline. Efficacy was also assessed using a greater than or equal to 4-point improvement in Itch NRS. Opzelura was 38.9% and 44.1% more effective than placebo for IGA-TS and 36.7% and 35.8% more effective than placebo for Itch NRS in trials 1 and trial 2 respectively.

	Nonsegmental Vitiligo(1) Two double-blind, randomized, vehicle-controlled trials of identical design (TRuE-V1 and TRuE-V2, NCT04052425 and NCT04057573, respectively) enrolled a total of 674 adult and pediatric subjects aged 12 years and older. Subjects had depigmented areas affecting greater than or equal to 0.5% facial body surface area (F-BSA), greater than or equal to 3% non-facial BSA, and total body vitiligo area (facial and non-facial, including hands, feet, upper and lower extremities, and trunk body areas) of up to 10% BSA. In both trials, subjects were randomized 2:1 to treatment with Opzelura or vehicle cream twice daily (BID) for 24 weeks followed by an additional 28 weeks of treatment with Opzelura twice daily for all subjects. Lesions on the face were assessed with the facial Vitiligo Area Scoring Index (F-VASI) and lesions on the total body (including the face) were assessed with the total body Vitiligo Area Scoring Index (T-VASI). The primary efficacy endpoint was the proportion of subjects achieving at least 75% improvement in F-VASI (F-VASI75) at week 24 and the proportion of participants achieving at least 90% improvement in F-VASI (F-VASI90). Opzelura was 22.5% and 16.9% more effective than placebo for F-VASI75 and 13.3% and 13.5% more effective than placebo for F-VASI90 in trials 1 and trial 2 respectively.

Safety	Opzelura carries the following boxed warnings:(1)
	
	• Serious infections leading to hospitalization or death, including tuberculosis and bacterial, invasive fungal, viral, and other opportunistic infections, have occurred in patients receiving Janus kinase (JAK) inhibitors for inflammatory conditions
	  ○ Reported infections include:
	  ▪ Active tuberculosis, which may present with pulmonary or extrapulmonary disease
	  ▪ Invasive fungal infections, including candidiasis and pneumocystosis
	  ▪ Bacterial, viral, and other infections due to opportunistic pathogens
	  ○ Avoid use of Opzelura in patients with an active, serious infection, including localized infections. If a serious infection develops, interrupt Opzelura until the infection is controlled. The risks and benefits of treatment with Opzelura should be carefully considered prior to initiating therapy in patients with chronic or recurrent infection. Patients should be closely monitored for the development of signs and symptoms of infection during and after treatment with Opzelura.
	• Higher rate of all cause mortality, including sudden cardiovascular death have been observed in patients treated with JAK inhibitors for inflammatory conditions
	• Lymphoma and other malignancies have been observed in patients treated with JAK inhibitors for inflammatory conditions
	• Higher rate of major adverse cardiac events (MACE), including cardiovascular death, myocardial infarction, and stroke has been observed in patients treated with JAK inhibitors for inflammatory conditions
	• Thrombosis, including deep venous thrombosis, pulmonary embolism, and arterial thrombosis, some fatal, have occurred in patients treated with JAK inhibitors for inflammatory conditions compared to placebo. Many of these adverse reactions were serious and some resulted in death. Patients with symptoms of thrombosis should be promptly evaluated
	
	Opzelura has no FDA labeled contraindications for use.

REFERENCES

Number	Reference
1	Opzelura prescribing information. Incyte Corp. January 2023.

Number	Reference
2	Eichenfield LF, Tom WL, Chamlin SL, Feldman SR, Hanifin JM, Simpson EL, et al. Guidelines of Care for the Management of Atopic Dermatitis: Section 1. Diagnosis and Assessment of Atopic Dermatitis. *J Am Acad Dermatol*. 2014 Feb;70(2):338-51.
3	Sidbury R, Tom WL, Bergman JN, Cooper KD, Silverman RA, Berger TG, et al. Guidelines of care for the management of atopic dermatitis: Section 4. Prevention of disease flares and use of adjunctive therapies and approaches. J Am Acad Dermatol. 2014 Dec;71(6):1218-33.
4	Eichenfield L, Tom W, Berger T, et al. Guidelines of care for the management of atopic dermatitis. Section 2. Management and treatment of atopic dermatitis with topical therapies. J Am Acad Dermatol 2014;71(1):116-32.
5	Sidbury, Robert, MD., et al. Guidelines of Care for the Management of Atopic Dermatitis. Section 3. Management and Treatment with Phototherapy and Systemic Agents. J Am Acad Dermatol 2014; 71 (2): 327-349.
6	Schneider L, Tilles S, Lio P, et al. Atopic dermatitis: a practice parameter update 2012. J Allergy Clin Immunol 2013; 131:295.
7	Elidel prescribing information. Valeant Pharmaceuticals. September 2020.
8	Protopic prescribing information. Astellas Pharma US Inc. February 2019.
9	Frazier W, Bhardwaj N. Atopic Dermatitis: Diagnosis and Treatment. Am Fam Physician. 2020 May 15;101(10):590-598. PMID: 32412211.
10	Alikhan A, Felsten LM, Daly M, Petronic-Rosic V. Vitiligo: a comprehensive overview Part I. Introduction, epidemiology, quality of life, diagnosis, differential diagnosis, associations, histopathology, etiology, and work-up. J Am Acad Dermatol 2011; 65:473.
11	Ezzedine K, Lim HW, Suzuki T, et al. Revised classification/nomenclature of vitiligo and related issues: the Vitiligo Global Issues Consensus Conference. Pigment Cell Melanoma Res 2012; 25:E1.
12	Eleftheriadou, V., Atkar, R., Batchelor, J., McDonald, B., Novakovic, L., Patel, J., Ravenscroft, J., Rush, E., Shah, D., Shah, R., Shaw, L., Thompson, A., Hashme, M., Exton, L., Mohd Mustapa, M., Manounah, L. and (2022), British Association of Dermatologists guidelines for the management of people with vitiligo 2021*. Br J Dermatol, 186: 18-29. https://doi.org/10.1111/bjd.20596.

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Opzelura	ruxolitinib phosphate cream	1.5 %	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
Opzelura	Ruxolitinib Phosphate Cream	1.5 %	1	Tube	30	DAYS			

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Opzelura	ruxolitinib phosphate cream	1.5 %	Medicaid

CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Opzelura	Ruxolitinib Phosphate Cream	1.5 %	Medicaid

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval

Indication	PDL Preferred Agents
Atopic Dermatitis	Dupixent

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

1. ONE of the following:
   A. The patient has a diagnosis of mild to moderate atopic dermatitis AND ALL of the following:
      1. The patient's affected body surface area (BSA) is less than or equal to 20% **AND**
      2. The patient is NOT immunocompromised **AND**
      3. ONE of the following:
         A. The patient's medication history includes at least a low-potency topical corticosteroid AND ONE of the following:
            1. The patient has had an inadequate response to least a low-potency a topical corticosteroid **OR**
            2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over ALL topical corticosteroids **OR**
         B. The patient has an intolerance or hypersensitivity to therapy with a topical corticosteroid **OR**
         C. The patient has an FDA labeled contraindication to ALL topical corticosteroids **OR**
         D. The patient is currently being treated with the requested agent as indicated by ALL of the following:
            1. A statement by the prescriber that the patient is currently taking the requested agent **AND**
            2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
            3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**
         E. The prescriber has provided documentation that ALL topical corticosteroids cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**
      4. ONE of the following:
         A. The patient's medication history includes a topical calcineurin inhibitor AND ONE of the following:
            1. The patient has had an inadequate response to a topical calcineurin inhibitor **OR**
            2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over ALL topical calcineurin inhibitors **OR**
         B. The patient has an intolerance or hypersensitivity to therapy with a topical calcineurin inhibitor **OR**

Module	Clinical Criteria for Approval
	C. The patient has an FDA labeled contraindication to ALL topical calcineurin inhibitors **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL topical calcineurin inhibitors cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 5. The patient will be using standard maintenance therapy (e.g., topical emollients, good skin care practices) in combination with the requested agent **OR** B. The patient has a diagnosis of nonsegmental vitiligo AND ALL of the following: 1. Vitiligo is NOT restricted from coverage under the patient's benefit **AND** 2. The patient's affected body surface area (BSA) is less than or equal to 10% **AND** 3. ONE of the following: A. The patient has vitiligo impacting areas other than the face, neck, or groin AND ONE of the following: 1. The patient's medication history includes a potent topical corticosteroid AND ONE of the following: A. The patient has had an inadequate response to a potent topical corticosteroid **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over ALL potent topical corticosteroids **OR** 2. The patient has an intolerance or hypersensitivity to therapy with a potent topical corticosteroid **OR** 3. The patient has an FDA labeled contraindication to ALL potent topical corticosteroids **OR** 4. The prescriber has provided information indicating why the patient cannot use at least a potent topical corticosteroid for the treatment of vitiligo **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL potent topical corticosteroids cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** B. The patient has vitiligo on the face, neck, or groin AND ONE of the following:

Module	Clinical Criteria for Approval
	1. The patient's medication history includes a potent topical corticosteroid OR a topical calcineurin inhibitor AND ONE of the following: A. The patient has had an inadequate response to a potent topical corticosteroid OR a topical calcineurin inhibitor **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over ALL potent topical corticosteroids AND topical calcineurin inhibitors **OR** 2. The patient has an intolerance or hypersensitivity to therapy with a potent topical corticosteroid OR a topical calcineurin inhibitor **OR** 3. The patient has an FDA labeled contraindication to ALL potent topical corticosteroids AND topical calcineurin inhibitors **OR** 4. The prescriber has provided information indicating why the patient cannot use at least a potent topical corticosteroid OR a topical calcineurin inhibitor for the treatment of vitiligo **OR** 5. The patient is currently being treated with the requested agent as indicated by ALL of the following: A. A statement by the prescriber that the patient is currently taking the requested agent **AND** B. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** C. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** 6. The prescriber has provided documentation that ALL potent topical corticosteroids AND topical calcineurin inhibitors cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** C. The patient has another FDA approved indication for the requested agent **AND** 2. If the patient has an FDA approved indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 3. ONE of the following: A. The requested agent is a preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) **OR** B. The request is for a non-preferred agent in the Minnesota Medicaid Preferred Drug List (PDL) and ONE of the following: 1. The patient is currently being treated with the requested agent and is experiencing a positive therapeutic outcome AND the prescriber provides documentation that switching the member to a preferred drug is expected to cause harm to the member or that the preferred drug would be ineffective **OR** 2. The patient has tried and had an inadequate response to two preferred chemically unique agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) as indicated by BOTH of the following: A. ONE of the following: 1. Evidence of a paid claim(s) within the past 999 days **OR** 2. The prescriber has stated that the patient has tried the required prerequisite/preferred agent(s) in the past 999 days **AND**

Module	Clinical Criteria for Approval
	B. ONE of the following: 1. The required prerequisite/preferred agent(s) was discontinued due to lack of effectiveness or an adverse event **OR** 2. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over the prerequisite/preferred agent(s) **OR** C. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to the preferred agents within the same drug class in the Minnesota Medicaid Preferred Drug List (PDL) that is not expected to occur with the requested agent **OR** D. The prescriber has provided documentation that the required prerequisite/preferred agent(s) cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **OR** E. The prescriber has submitted documentation supporting the use of the non-preferred agent over the preferred agent(s) **AND** 4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., dermatologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 5. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table): 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: 1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND** 2. The prescriber has provided information in support of combination therapy (submitted copy required, e.g., clinical trials, phase III studies, guidelines required) **AND** 6. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 3 months for atopic dermatitis and 6 months for nonsegmental vitiligo NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria.

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. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** 3. ALL of the following: A. The requested quantity (dose) exceeds the program quantity limit **AND** B. The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication **AND** C. The prescriber has provided information in support of therapy with a higher dose for the requested indication **Length of Approval**: 3 months for atopic dermatitis and 6 months for nonsegmental vitiligo

CONTRAINDICATION AGENTS

Contraindicated as Concomitant Therapy
Agents NOT to be used Concomitantly
Abrilada (adalimumab-afzb)
Actemra (tocilizumab)
Adalimumab
Adbry (tralokinumab-ldrm)
Amjevita (adalimumab-atto)
Arcalyst (rilonacept)
Avsola (infliximab-axxq)
Benlysta (belimumab)
Bimzelx (bimekizumab-bkzx)
Cibinqo (abrocitinib)
Cimzia (certolizumab)
Cinqair (reslizumab)
Cosentyx (secukinumab)
Cyltezo (adalimumab-adbm)
Dupixent (dupilumab)
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)

Contraindicated as Concomitant Therapy
Inflectra (infliximab-dyyb)
Infliximab
Kevzara (sarilumab)
Kineret (anakinra)
Litfulo (ritlecitinib)
Nucala (mepolizumab)
Olumiant (baricitinib)
Omvoh (mirikizumab-mrkz)
Opzelura (ruxolitinib)
Orencia (abatacept)
Otezla (apremilast)
Remicade (infliximab)
Renflexis (infliximab-abda)
Riabni (rituximab-arrx)
Rinvoq (upadacitinib)
Rituxan (rituximab)
Rituxan Hycela (rituximab/hyaluronidase human)
Ruxience (rituximab-pvvr)
Siliq (brodalumab)
Simponi (golimumab)
Simponi ARIA (golimumab)
Skyrizi (risankizumab-rzaa)
Sotyktu (deucravacitinib)
Stelara (ustekinumab)
Taltz (ixekizumab)
Tezspire (tezepelumab-ekko)
Tremfya (guselkumab)

Contraindicated as Concomitant Therapy
Truxima (rituximab-abbs)
Tysabri (natalizumab)
Velsipity (etrasimod)
Wezlana (ustekinumab-auub)
Xeljanz (tofacitinib)
Xeljanz XR (tofacitinib extended release)
Xolair (omalizumab)
Yuflyma (adalimumab-aaty)
Yusimry (adalimumab-aqvh)
Zeposia (ozanimod)
Zymfentra (infliximab-dyyb)