BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINE

ZORYVE™ (roflumilast) cream
ZORYVE™ (roflumilast) foam
Generic Equivalent (if available)

This Pharmacy Coverage Guideline (PCG):
- Provides information about the reasons, basis, and information sources we use for coverage decisions
- Is not an opinion that a drug (collectively "Service") is clinically appropriate or inappropriate for a patient
- Is not a substitute for a provider's judgment (Provider and patient are responsible for all decisions about appropriateness of care)
- Is subject to all provisions e.g. (benefit coverage, limits, and exclusions) in the member's benefit plan; and
- Is subject to change as new information becomes available.

Scope
- This PCG applies to Commercial and Marketplace plans
- This PCG does not apply to the Federal Employee Program, Medicare Advantage, Medicaid or members of out-of-state Blue Cross and/or Blue Shield Plans

Instructions & Guidance
- To determine whether a member is eligible for the Service, read the entire PCG.
- This PCG is used for FDA approved indications including, but not limited to, a diagnosis and/or treatment with dosing, frequency, and duration.
- Use of a drug outside the FDA approved guidelines, refer to the appropriate Off-Label Use policy.
- The "Criteria" section outlines the factors and information we use to decide if the Service is medically necessary as defined in the Member's benefit plan.
- The "Description" section describes the Service.
- The "Definition" section defines certain words, terms or items within the policy and may include tables and charts.
- The "Resources" section lists the information and materials we considered in developing this PCG
- **We do not accept patient use of samples as evidence of an initial course of treatment, justification for continuation of therapy, or evidence of adequate trial and failure.**
- Information about medications that require prior authorization is available at www.azblue.com/pharmacy. You must fully complete the request form and provide chart notes, lab workup and any other supporting documentation. The prescribing provider must sign the form. Fax the form to BCBSAZ Pharmacy Management at (602) 864-3126 or email it to Pharmacyprecert@azblue.com.

Criteria:

ZORYVE (roflumilast) cream

➢ **Criteria for initial therapy:** Zoryve (roflumilast) **cream** and/or generic equivalent (if available) is considered ***medically necessary*** and will be approved when **ALL** the following criteria are met:

1. Prescriber is a physician specializing in the patient's diagnosis or is in consultation with a Dermatologist

2. **ONE** of the following:
   a. **For Zoryve 0.05% and age of 2 to 5 years of age or older**: Mild to moderate atopic dermatitis
   b. **For Zoryve 0.15% and age of 6 years of age or older** : Mild to moderate atopic dermatitis

c. **For Zoryve 0.3% and age of 6 years of age or older** : Plaque psoriasis

3. Body surface area involved is of the following:
   a. **For mild to moderate atopic dermatitis:** at least 3%
   b. **For plaque psoriasis:** 2% to 20%

4. **For plaque psoriasis or atopic dermatitis BOTH** of the following: (see Definitions section)
   a. Investigator's Global Assessment (IGA) score is at least 2
   b. Worst Itch-Numeric Rating Scale (WI-NRS) score of 4 or higher

5. **ONE** of the following**:**
   a. **Zoryve 0.05% & 0.15% cream for mild to moderate atopic dermatitis**: Individual has documented failure (used for ≥ 2 consecutive months), contraindication per FDA label, intolerance, or is not a candidate for a trial of **ONE** of the following topical therapies: (see Definitions section)
      i. For eyelids, face, neck intertriginous and genital areas **BOTH** of the following:
         1. **ONE** topical calcineurin inhibitor, such as pimecrolimus (generic or brand Elidel) or tacrolimus (generic or brand Protopic)
         2. Eucrisa (crisaborole)
      ii. For all other body areas **ONE** of the following:
         1. **For mild disease:** Failure, contraindication per FDA label, intolerance, or is not a candidate for **TWO** low potency corticosteroids (such as desonide 0.05%, fluocinolone acetonide 0.01%, and others)
         2. **For moderate disease:** Failure, contraindication per FDA label, intolerance, or is not a candidate for **TWO** medium to high potency corticosteroids (such as triamcinolone acetonide 0.1%, mometasone furoate 0.1%, betamethasone dipropionate 0.05%, desoximetasone 0.05%, and others)
   b. **Zoryve 0.3% cream for plaque psoriasis**: Depending on age, severity, and location of disease, individual has documented failure (used for ≥ 2 consecutive months), contraindication per FDA label, intolerance, or is not a candidate for a trial of **ALL** of the following categories:
      i. A trial of a least **TWO** topical therapies for plaque psoriasis (e.g., anthralin, calcipotriene, coal tar, corticosteroid, tazarotene, pimecrolimus, tacrolimus) (see Definitions section)
      ii. A trial of **ONE** immunosuppressive treatment (e.g., cyclosporine, methotrexate)
      iii. A trial of Ultraviolet Light therapy (e.g., Photochemotherapy (i.e., psoralen plus ultraviolet A therapy), Phototherapy (i.e., ultraviolet light therapy), or Excimer laser) unless the area(s) of involved skin are too extensive or involve sensitive areas or the individual cannot travel to a care center or there is no care center

6. **If available**: Individual has failure after adequate trial, contraindication per FDA label, intolerance, or is not a candidate for a **generic equivalent** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] (see Definitions section)

7. Individual does not have moderate to severe liver impairment (Child-Pugh B or C)

8. Will **NOT** be used concurrently with Eucrisa (crisaborole), Otezla (apremilast) or Daliresp (roflumilast) due to similar mechanism of action and is not receiving concurrently Enbrel (etanercept), Cimzia

(certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Stelara (ustekinumab), Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Siliq (brodalumab), Ilumya (tildrakizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Dupixent (dupilumab), tralokinumab), Rinvoq/Rinvoq LQ (upadactinib), Xeljanz/Xeljanz XR (tofacitinib), Opzelura (ruxolitinib), Cibinqo (abrocitinib), Vtama (tapinarof)

Initial approval duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Zoryve (roflumilast) cream and/or generic equivalent (if available) is considered ***medically necessary*** and will be approved when **ALL** the following criteria are met **(samples are not considered for continuation of therapy)**:

1. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with a Dermatologist

2. Individual has documentation of positive clinical response to therapy defined as **TWO** of the following:
   a. Achievement of an IGA score of 'clear (0)'
   b. Achievement of an IGA score of 'almost clear (1)' **PLUS** a 2-grade improvement from baseline
   c. Achievement of a ≥4-point improvement from baseline WI-NRS score
   d. No evidence individual has developed any significant unacceptable adverse drug reactions that may exclude continued use

3. Individual has been adherent with the medication

4. **If available**: Individual has failure after adequate trial, contraindication per FDA label, intolerance, or is not a candidate for a **generic equivalent** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] (see Definitions section)

5. Individual does not have moderate to severe liver impairment (Child-Pugh B or C)

6. Will **NOT** be used concurrently with Eucrisa (crisaborole), Otezla (apremilast) or Daliresp (roflumilast) due to similar mechanism of action and is not receiving concurrently Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Stelara (ustekinumab), Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Siliq (brodalumab), Ilumya (tildrakizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Dupixent (dupilumab), tralokinumab), Rinvoq/Rinvoq LQ (upadactinib), Xeljanz/Xeljanz XR (tofacitinib), Opzelura (ruxolitinib), Cibinqo (abrocitinib), Vtama (tapinarof)

Renewal duration: 12 months

- Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

1. **Off-Label Use of Non-Cancer Medications**

2. **Off-Label Use of Cancer Medications**

ZORYVE (roflumilast) foam

➢ **Criteria for initial therapy:** Zoryve (roflumilast) **foam** and/or generic equivalent (if available) is considered ***medically necessary*** and will be approved when **ALL** the following criteria are met:

1. Prescriber is a physician specializing in the patient's diagnosis or is in consultation with a Dermatologist

2. Individual is **ONE** of the following:
   a. **For plaque psoriasis of scalp and body**: 12 years of age or older
   b. **For seborrheic dermatitis**: 9 years of age or older

3. Individual has a confirmed diagnosis of **ONE** of the following:
   a. Plaque psoriasis of scalp and body
   b. Seborrheic dermatitis

4. **Additional criteria for plaque psoriasis:**
   a. Total overall involvement of plaque psoriasis affects up to 25% of the scalp and body, at least 10% of the scalp, and up to 20% of non-scalp areas
   b. Investigator's Global Assessment (IGA) score is at least 2

5. **Additional criteria for seborrheic dermatitis:**
   a. Involves up to 20% BSA involvement that may include scalp and/or face and/or trunk and/or intertriginous areas
   b. Investigator's Global Assessment (IGA) score is at least 3 (see Definitions section)
   c. Erythema and Overall Assessment of Scaling scores of at least 2 (see Definitions section)

6. Has Itch-Numeric Rating Scale (WI-NRS) score of 4 or higher

7. **For Zoryve 0.3% foam for seborrheic dermatitis** Individual has documented failure (used for ≥ 3 consecutive months), contraindication per FDA label, intolerance, or is not a candidate for a trial of the following categories depending on location of disease:
   a. **Scalp seborrheic dermatitis,** depending on severity **ONE** of the following:
      i. Antifungal shampoo (e.g., ketoconazole 2%, ciclopirox 1%)
      ii. Antifungal shampoo (e.g., ketoconazole 2% shampoo) in combination with a high-potency topical corticosteroid
   b. **Facial and intertriginous area seborrheic dermatitis,** depending on severity and location **BOTH** of the following:
      i. Low-potency topical corticosteroid
      ii. Topical antifungal agent
   c. **Trunk seborrheic dermatitis, BOTH** of the following:
      i. Low-potency topical corticosteroid
      ii. Topical antifungal agent
   d. **Chest or the upper back seborrheic dermatitis**

i. Medium-potency topical corticosteroid until symptoms subside then switch to topical antifungal

8. **For Zoryve 0.3% foam for plaque psoriasis**: Depending on age, severity, and location of disease, individual has documented failure (used for > 2 consecutive months), contraindication per FDA label, intolerance, or is not a candidate for a trial of **ALL** of the following categories:
    a. A trial of a least **TWO** topical therapies for plaque psoriasis (e.g., anthralin, calcipotriene, coal tar, corticosteroid, tazarotene, pimecrolimus, tacrolimus) (see Definitions section)
    b. A trial of **ONE** immunosuppressive treatment (e.g., cyclosporine, methotrexate)
    c. A trial of Ultraviolet Light therapy (e.g., Photochemotherapy (i.e., psoralen plus ultraviolet A therapy), Phototherapy (i.e., ultraviolet light therapy), or Excimer laser) unless the area(s) of involved skin are too extensive or involve sensitive areas or the individual cannot travel to a care center or there is no care

9. **If available**: Individual has failure after adequate trial, contraindication per FDA label, intolerance, or is not a candidate for a **generic equivalent** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] (see Definitions section)

10. Individual does not have moderate to severe liver impairment (Child-Pugh B or C)

11. Will **NOT** be used concurrently with Eucrisa (crisaborole), Otezla (apremilast) or Daliresp (roflumilast) due to similar mechanism of action and is not receiving concurrently Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Stelara (ustekinumab), Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Siliq (brodalumab), Ilumya (tildrakizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Dupixent (dupilumab), tralokinumab), Rinvoq/Rinvoq LQ (upadactinib), Xeljanz/Xeljanz XR (tofacitinib), Opzelura (ruxolitinib), Cibinqo (abrocitinib), Vtama (tapinarof)

Initial approval duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Zoryve (roflumilast) foam and/or generic equivalent (if available) is considered ***medically necessary*** and will be approved when **ALL** the following criteria are met **(samples are not considered for continuation of therapy)**:

1. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with a Dermatologist

2. Individual has documentation of positive clinical response to therapy defined as **THREE** of the following:
    a. Achievement of an IGA score of 0 ('clear)' or 1 ('almost clear') **PLUS** a 2-grade improvement from baseline
    b. Achievement of an Overall Assessment of Erythema score of 0 or 1 plus a ≥2 grade improvement from Baseline
    c. Achievement of an Overall Assessment of Scaling score of 0 or 1, plus a ≥2 grade improvement from Baseline
    d. Achievement of a ≥4-point improvement from baseline WI-NRS score

e. No evidence individual has developed any significant unacceptable adverse drug reactions that may exclude continued use

3. Individual has been adherent with the medication

4. **If available**: Individual has failure after adequate trial, contraindication per FDA label, intolerance, or is not a candidate for a **generic equivalent** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] (see Definitions section)

5. Individual does not have moderate to severe liver impairment (Child-Pugh B or C)

6. Will **NOT** be used concurrently with Eucrisa (crisaborole), Otezla (apremilast) or Daliresp (roflumilast) due to similar mechanism of action and is not receiving concurrently Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Stelara (ustekinumab), Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Siliq (brodalumab), Ilumya (tildrakizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Dupixent (dupilumab), tralokinumab), Rinvoq/Rinvoq LQ (upadactinib), Xeljanz/Xeljanz XR (tofacitinib), Opzelura (ruxolitinib), Cibinqo (abrocitinib), Vtama (tapinarof)

Renewal duration: 12 months

- Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

1. **Off-Label Use of Non-Cancer Medications**

2. **Off-Label Use of Cancer Medications**

Description:

Zoryve (roflumilast) cream 0.3% is a phosphodiesterase 4 (PDE4) inhibitor indicated for topical treatment of plaque psoriasis, including intertriginous areas, in an individual 6 years of age or older. Zoryve (roflumilast) cream 0.15% is indicated for topical treatment of mild to moderate atopic dermatitis, in an individual 6 years of age or older. Zoryve (roflumilast) cream 0.05% is indicated for topical treatment of mild to moderate atopic dermatitis, in an individual 2 to 5 years of age. Zoryve (roflumilast) foam 0.3% is indicated for topical treatment of seborrheic dermatitis, in an individual 9 years of age or older and is indicated for topical treatment of plaque psoriasis of the scalp and body in an individual 12 years of age or older.

Roflumilast and its active metabolite (roflumilast N-oxide) are inhibitors of PDE4. Inhibition of PDE4 (a major cyclic 3',5'-adenosine monophosphate (cyclic AMP) metabolizing enzyme) leads to accumulation of intracellular cyclic AMP. The specific mechanism(s) by which roflumilast exerts its therapeutic action is not well defined.

PHARMACY COVERAGE GUIDELINE

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Generic Equivalent (if available)

Definitions:

U.S. Food and Drug Administration (FDA) MedWatch Forms for FDA Safety Reporting
MedWatch Forms for FDA Safety Reporting | FDA

Available topical therapies for ATOPIC DERMATITIS in adults (Note: For information purposes only. List may be incomplete and does not imply preference or formulary status)	
Name	**Formulations**
Corticosteroids	Numerous products and numerous potencies that are appropriate for age and distribution of disease
Calcineurin inhibitors in areas at high risk of atrophy (e.g., face, skin folds)	Pimecrolimus cream (ex., Elidel, & generics) Tacrolimus ointment (ex., Nuju; Protopic, & generics)
Janus kinase (JAK) inhibitor in areas at high risk of atrophy (e.g., face, skin folds)	Ruxolitinib cream (ex., Opzelura)
Phosphodiesterase 4 inhibitors	Crisaborole ointment (ex., Eucrisa) Roflumilast 0.15% cream (ex., Zoryve)
Available systemic therapies for ATOPIC DERMATITIS in adults (Note: For information purposes only. List may be incomplete and does not imply preference or formulary status)	
Name	**Formulations**
Biologic immunomodulatory agent	Dupilumab (ex., Dupixent) Lebrikizumab (ex., Ebglyss) Tralokinumab (ex., Adbry)
Janus kinase (JAK) inhibitor	Abrocitinib (ex., Cibinqo) Upadacitinib (ex., Rinvoq)

Available topical therapies for CHRONIC PLAQUE PSORIASIS in adults (Note: For information purposes only. List may be incomplete and does not imply preference or formulary status)	
Name	**Formulations**
Corticosteroids	Numerous products and numerous potencies that are appropriate for age and distribution of disease (e.g., triamcinolone acetonide, fluocinonide, clobetasol propionate, halobetasol propionate)
Calcineurin inhibitors - generally reserved for intertriginous, genital, or facial plaques as primary therapy or as corticosteroid-sparing therapy	Pimecrolimus cream (ex., Elidel, & generics) Tacrolimus ointment (ex., Nuju; Protopic, & generics)
Phosphodiesterase 4 inhibitors	Roflumilast 0.3% cream/foam (ex., Zoryve)
Retinoid	Tazarotene cream, gel
Vitamin D analogs	Calcipotriene cream, foam, ointment, solution Calcitriol ointment
Aryl hydrocarbon receptor agonist	Tapinarof cream (ex., Vtama)
Combination products	Several types: corticosteroid/retinoid or corticosteroid/vitamin D analog

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Available systemic therapies for CHRONIC PLAQUE PSORIASIS in adults (Note: For information purposes only. List may be incomplete and does not imply preference or formulary status)	
Biologic IL-23 inhibitors	**Small molecule phosphodiesterase 4 inhibitor**
Guselkumab (ex., Tremfya)	Apremilast (ex., Otezla)
Risankizumab (ex., Skyrizi)	**Small molecule tyrosine kinase 2 inhibitor**
Tildrakizumab (ex., Ilumya)	Deucravacitinib (ex., Sotyktu)
Biologic IL-17 inhibitors	**Other therapies**
Bimekizumab (ex., Bimzelx)	Acitretin
Brodalumab (ex., Siliq)	Cyclosporine (modified)
Ixekizumab (ex., Taltz)	Methotrexate
Secukinumab (ex., Cosentyx)	
Biologic IL-12/23 inhibitor	
Ustekinumab (ex., Stelara)	
Biologic TNF-alpha inhibitors	
Adalimumab (ex., Humira, & biosimilars)	
Certolizumab pegol (ex., Cimzia)	
Etanercept (ex., Enbrel)	
Infliximab (ex., Remicade & biosimilars)	

Available topical therapies for SEBORRHEIC DERMATITIS in adults (Note: For information purposes only. List may be incomplete and does not imply preference or formulary status)	
Area involved	**Formulations**
Scalp	• Mild (dandruff): Antifungal shampoos (ketoconazole 2%, ciclopirox 1%) Alternative antifungal shampoos available OTC (zinc pyrithione 1% and selenium sulfide 2.5%) • Moderate to severe: Antifungal shampoos (e.g., ketoconazole 2% shampoo) in combination with a high-potency topical corticosteroid in a formulation (lotion, spray, foam)
Face	• Low-potency topical corticosteroids, topical antifungal agents, or a combination of the two • Alternatives to topical corticosteroids: Zoryve (roflumilast) 0.3% foam • Seborrheic dermatitis of face with mustache & beard, ketoconazole 2% shampooing of facial hair. Low-potency corticosteroid can be added to the initial treatment to control inflammation and itching
Trunk	• Low-potency topical corticosteroid, topical antifungal agents, or a combination of the two • Seborrheic dermatitis of chest or upper back, medium-potency topical corticosteroids can be used until symptoms subside then switch to topical antifungal

Intertriginous	• Low-potency topical corticosteroid, topical antifungal agents, or a combination of the two
Prevention	• Ketoconazole 2% shampoo or ciclopirox 1% shampoo once per week for seborrheic dermatitis of the scalp • Ketoconazole 2% shampoo (as facial or body wash) or ketoconazole 2% cream once per week for face, trunk, and intertriginous areas • Other topical azoles or ciclopirox can be used as alternatives to topical ketoconazole

Physician/Investigator Global Assessment (PGA/IGA) score:
PGA/IGA is a tool for assessing the current state/severity of an individual's psoriasis at a given timepoint. It is a static 5-point assessment of overall disease severity, as determined by the provider, using the clinical characteristics of erythema, scaling, and plaque thickness/elevation as guidelines. Higher scores represent more severe disease.

0	Clear	No signs of psoriasis, but post-inflammatory discoloration may be present
1	Almost clear	Only minimal plaque elevation, scaling, and erythema
2	Mild	Slight plaque elevation, scaling, and erythema
3	Moderate	Moderate plaque elevation, scaling, and erythema
4	Severe	Very marked plaque elevation, scaling, and erythema

Psoriasis Area and Severity Index (PASI):

	Head	Upper Extremities	Trunk	Lower extremities
1. Redness[1]				
2. Thickness[1]				
3. Scale[1]				
4. Sum of rows 1,2 and 3				
5. Area score[2]				
6. Score of row 4 x row 5 x the area multiplier	row 4 x row 5 x 0.1	row 4 x row 5 x 0.2	Row 4 x row 5 x 0.3	Row 4 x row 5 x 0.4
7. Sum row 6 for each column for PASI score				

Steps in generating PASI score:
(a) Divide body into four areas: head, arms, trunk to groin, and legs to top of buttocks.
(b) Generate an average score for the erythema, thickness, and scale for each of the 4 areas (0 = clear; 1–4 = increasing severity)[1].
(c) Sum scores of erythema, thickness, and scale for each area.
(d) Generate a percentage for skin covered with psoriasis for each area and convert that to a 0–6 scale (0 = 0%; 1 = <10%; 2 = 10–<30%; 3 = 30–<50%; 4 = 50–<70%; 5 = 70–<90%; 6 = 90–100%).
(e) Multiply score of item (c) above times item (d) above for each area and multiply that by 0.1, 0.2, 0.3, and 0.4 for head, arms, trunk, and legs, respectively.
(f) Add these scores to get the PASI score.

[1] Erythema, induration and scale are measured on a 0–4 scale (none, slight, mild, moderate, severe)
[2] Area scoring criteria (score: % involvement)
0: 0 (clear)
1: <10%
2: 10–<30%
3: 30–<50%

4: 50–<70% 5: 70–<90% 6: 90–<100%
Feldman, SR and Krueger, GG. Psoriasis assessment tools in clinical trials. Ann Rheum Dis 2005; 64 (Suppl III): ii65-ii68.

Pruritus Numerical Rating Scale (NRS):
Numerical Rating Scale - Pruritus Resources (pruritussymposium.de) [Accessed October 09, 2021]

The NRS is comprised of one item and is represented by numbers 0 (“no itch”) to 10 (“worst imaginable itch”). Patients are asked to rate the intensity of their itch using this scale. It features high reliability and concurrent validity and is a popular choice for all patients due to its simple format. Time needed for completion: 1 minute. It has been validated in several languages.

- It can be interpreted as follows:
  - NRS 0 - no pruritus
  - NRS < 3 - mild pruritus
  - NRS ≥ 3 < 7 - moderate pruritus
  - NRS ≥ 7 < 9 - severe pruritus
  - NRS ≥ 9 - very severe pruritus

On a scale from 0 (no itch) to 10 (worst imaginable itch), how would you rate your itch overall (on average) during the past 24-hour? (Select number)										
0	1	2	3	4	5	6	7	8	9	10

Overall Assessment of Erythema		
Symptom	**Score**	**Description**
Erythema	0	None: No evidence of erythema
	1	Mild: Barely perceptible erythema which is faint or patchy
	2	Moderate: Distinct erythema
	3	Severe: Intensely (fiery red) erythema

Overall Assessment of Scaling		
Symptom	**Score**	**Description**
Scaling	0	None: No scaling evident of lesions
	1	Mild: Barely detectable, scattered, small flaking scales
	2	Moderate: Scales clearly visible and prominent
	3	Severe: Coarse, thick scales, with flaking into clothes or skin

Eczema Area and Severity Index (EASI) score (A-E):
An EASI score is a tool used to measure the extent (area) and severity of atopic eczema. EASI score does not include a grade for dryness or scaling. Include only inflamed areas.

A. Body regions:
There are four body regions:

- Head and neck
  - Face occupies 33% (17% each side), neck 33% (17% front and back) and scalp 33% of the head and neck region
- Trunk (including genital area)
  - Front occupies 55% and back 45% of the trunk
- Upper limbs
  - Each arm occupies 50% of the upper limbs region (front or back of one arm is 25%)
- Lower limbs (including buttocks)
  - Each leg occupies 45% (front or back of one leg is 22.5%) and buttocks 10% of the lower limbs region

B. Area score:
Area score is recorded for each of the four regions of the body. The area score is the percentage of skin affected by eczema for each body region.

Area score	Percentage of skin affected by eczema in each region
0	No active eczema in this region
1	1-9
2	10-29
3	30-49
4	50-69
5	70-89
6	90-100: the entire region is affected by eczema

C. Severity score:
Severity score is recorded for each of the four regions of the body. The severity score is the sum of the intensity scores for four signs. The four signs are:

1. Redness (erythema, inflammation)
2. Thickness (induration, papulation, swelling—acute eczema)
3. Scratching (excoriation)
4. Lichenification (lined skin, furrowing, prurigo nodules—chronic eczema).

The *average* intensity of each sign in each body region is assessed as: none (0), mild (1), moderate (2) and severe (3). Half scores are allowed. It may be difficult to assess redness in dark skin. If in doubt, increase the average redness score by one level.

Score	Intensity of redness, thickness/swelling, scratching. lichenification
0	None, absent
1	Mild (just perceptible)
2	Moderate (obvious)
3	Severe

D. Calculations:

For each region, record the intensity for each of four signs and calculate the severity score.

- Severity score = redness intensity + thickness intensity + scratching intensity + lichenification intensity

For each region, multiple the severity score by the area score and by a multiplier. The multiplier is different for each body site.

- Head and neck: severity score x area score x 0.1 (in children 0–7 years, x 0.2)
- Trunk: severity score x area score x 0.3
- Upper limbs: severity score x area score x 0.2
- Lower limbs: severity score x area score x 0.4 (in children 0–7 years, x 0.3)

Add up the total scores for each region to determine the final EASI score. The minimum EASI score is 0 and the maximum EASI score is 72.

E. Interpretation:

The suggested severity levels for the EASI are as follows:

0	Clear
0.1-1.0	Almost clear
1.1-7.0	Mild
7.1-21.0	Moderate
21.1-50.0	Severe
50.1-72.0	Very severe

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