DRUG DETERMINATION POLICY

Title: DDP-22 Atopic Dermatitis Agents

Effective Date: 03/01/2022

Physicians Health Plan
PHP Insurance Company
PHP Service Company

Important Information - Please Read Before Using This Policy

The following policy applies to health benefit plans administered by PHP and may not be covered by all PHP plans. Please refer to the member's benefit document for specific coverage information. If there is a difference between this general information and the member's benefit document, the member's benefit document will be used to determine coverage. For example, a member's benefit document may contain a specific exclusion related to a topic addressed in a coverage policy.

Benefit determinations for individual requests require consideration of:

1. The terms of the applicable benefit document in effect on the date of service.
2. Any applicable laws and regulations.
3. Any relevant collateral source materials including coverage policies.
4. The specific facts of the particular situation.

Contact PHP Customer Service to discuss plan benefits more specifically.

1.0 Policy:

This policy describes the determination process for coverage of specific drugs that require prior approval.

This policy does not guarantee or approve benefits. Coverage depends on the specific benefit plan. Drug Determination Policies are not recommendations for treatment and should not be used as treatment guidelines.

2.0 Background or Purpose:

Dupixent and Eucrisa are specialty drugs indicated for a number of diagnoses and are associated with some adverse effects. These criteria were developed and implemented to ensure appropriate use for the intended diagnoses and mitigation of adverse effects, if possible.

3.0 Clinical Determination Guidelines:

Document the following with chart notes:

I. Phosphodiesterace-4 Enzyme Inhibitor: Eucrisa topical (crisaborole) [must meet all listed below]:

   A. Age: at least three months.

   B. Diagnosis and severity: mild to moderate atopic dermatitis.

   C. Other therapies: contraindicated, inadequate response for two months of each agent or significant adverse effects to one therapy from topical steroids and one calcineurin inhibitor.

      1. Topical mid-strength to super-potent corticosteroid: unless the face, neck and/or intertriginous areas are affected.

      2. Topical calcineurin Inhibitor: tacrolimus, pimecrolimus.

   D. Dosage regimen:

      1. Eucrisa topical (crisaborole): apply a thin film to affected area(s) two times daily.

   E. Approval:

1. Initial: six months.

2. Re-approval: one year (reduced percentage of body surface area [BSA] affected and/or reduced pruritic severity).

II. Interleukine-4 Receptor Antagonist: Dupixent subcutaneous (dupilumab SQ) [must meet all listed below]:

A. Age: at least six years.

B. Prescriber: dermatologist or allergist.

C. Diagnosis and severity: moderate to severe atopic dermatitis not controlled with topical prescription therapies or if the therapies are not advisable [must meet all listed below]:

1. Exacerbating factors that could contribute to the member's atopic dermatitis have been evaluated and addressed (e.g., non-compliance, environmental triggers, allergy patch testing etc.).

2. Body surface area (BSA): at least 10 percent.

3. Severity [must meet both below]:

a. Documentation of current pruritus and other symptoms severity (e.g., erythema, edema, xerosis, erosions. excoriations, oozing/crusting and/or lichenification).

b. Interfering with routine daily activities (e.g., skin infections, sleep disturbances).

D. Other therapies: contraindicated, inadequate response after two months or significant adverse effects to topical and systemic therapies listed below.

1. Topical: one mid-strength to super-potent corticosteroid trials and one calcineurin inhibitor trial [must meet both listed below].

a. Mid-strength to super-potent corticosteroid: unless the face, neck and/or intertriginous areas are affected.

b. Topical calcineurin Inhibitor: tacrolimus, pimecrolimus.

2. Systemic chronic disease-modifying anti-rheumatic drug (DMARD).

a. Chronic traditional DMARD's: cyclosporine, azathioprine, methotrexate or mycophenolate.

E. Dosage regimen:

AGE	LOADING DOSE	MAINTENANCE DOSE
Adult	600mg	300mg every two weeks
Pediatric		
15 to <30Kg	600mg	300mg every four weeks
30 to <60Kg	400mg	300mg every two weeks
≥60Kg	600mg	300mg every two weeks

F. Approval.

1. Initial: six months.

2. Re-approval: one year (must demonstrate reduced percentage body surface area affected, reduced pruritus/symptom severity and/or improve ability to perform routine daily activities).

G. Exclusions: use in conjunction with other biologicals (e.g., Xolair, infliximab, Enbrel, Nucala, etc.).

III. Janus Kinase Inhibitors: Rinvoq oral (upadacitinib po)

A. Age: at least twelve (at least 88 pounds)

B. Prescriber: dermatologist or allergist.

C. Diagnosis and severity: moderate to severe atopic dermatitis not controlled with topical prescription therapies or if the therapies are not advisable [must meet all listed below]:

1. Exacerbating factors that could contribute to the member's atopic dermatitis have been evaluated and addressed (e.g., non-compliance, environmental triggers, allergy patch testing etc.).

2. Body surface area (BSA): at least 10 percent.

3. Severity [must meet both below]:

a. Documentation of current pruritus and other symptoms severity (e.g., erythema, edema, xerosis, erosions. excoriations, oozing/crusting and/or lichenification).

b. Interfering with routine daily activities (e.g., skin infections, sleep disturbances).

D. Other therapies: contraindicated, inadequate response after two months or significant adverse effects to topical and systemic therapies listed below.

1. Topical: one mid-strength to super-potent corticosteroid trials and one calcineurin inhibitor trial [must meet both listed below].

a. Mid-strength to super-potent corticosteroid: unless the face, neck and/or intertriginous areas are affected.

b. Topical calcineurin Inhibitor: tacrolimus, pimecrolimus.

2. Systemic chronic disease-modifying anti-rheumatic drug (DMARD).

a. Chronic traditional DMARD's: cyclosporine, azathioprine, methotrexate or mycophenolate.

IV. Appropriate medication use [must meet one listed below]:

A. FDA approval status [must meet one listed below]:

1. FDA approved: product, indication, and/or dosage regimen.

2. Non-FDA approved: Compendium support (Lexicomp™) for use of a drug for a non-FDA approved indication or dosage regimen

B. Place in therapy: sequence of therapy supported by national or international accepted guidelines and/or studies (e.g., oncologic, infectious conditions).

4.0 Coding:
None.

5.0 References, Citations & Resources:

1. Lexicomp Online®, Lexi-Drugs®, Hudson, Ohio: Lexi-Comp, Inc; Dupixent accessed June 2021.
2. Lexicomp Online®, Lexi-Drugs®, Hudson, Ohio: Lexi-Comp, Inc.; Eucrisa accessed June 2021.
3. Lexicomp Online®, Lexi-Drugs®, Hudson, Ohio: Lexi-Comp, Inc.; Rinvoq accessed February 22
4. Evolving Concepts in Atopic Dermatitis. Curr Allergy Asthma Rep. 2017;17;42.
5. https://www.psoriasis.org/about-psoriasis/treatments/topicals/steroids/potency-chart accessed October 2017.

6.0 Appendices:

See pages 4-6.

7.0 Revision History:

Original Effective Date: 10/25/2017

Next Review Date: 07/28/20222

Revision Date	Reason for Revision
7/19	New format, replaced abbreviations, clarified other therapies.
6/20	Annual review: replaced abbreviations; clarified instruction language; revised Eucrisa age; and revised Dupixent age, steroid trial and dosage approved by P&T Committee 8/26/20.
6/21	Annual review; changed trial of steroid to one agent, clarified criteria instructions, Reformatting, added appropriate use
02/07/2022	Ad Hoc review; added drug class names and Skyrizi to the policy with patient safety and monitoring information; clarified criteira instructions, added Rinvoq

Appendix I: Patient Safety and Monitoring

Drug	Adverse Reactions	Monitoring	REMS
Eucrisa crisaborole topical	• Dermatology: application site pain (4%) • Pregnancy: adverse effects not shown in animal studies	• Hypersensitivity medications and symptoms	None needed
Dupixent dupilumab subcutaneous	• Dermatology: injection. site reaction (10%) • Ophthalmic conjunctivitis (10%) • Pregnancy: monoclonal antibodies known to cross the placenta	• Hypersensitivity medications and symptoms • Ophthalmic: ocular adverse effects	None needed
Rinvoq oral upadacitinib po	• Respiratory: upper respiratory tract infection (14%)	• Labs: lymphocytes; neutrophil, Hgb and liver function tests (baselines and periodically; lipids (3 months after treatment starts and periodically) • Cardiovascular: signs and symptoms of thrombosis · • Dermatology: skin examinations · • Infections: viral hepatitis (pretreatment and periodically), tuberculosis, signs and symptoms of infection	The FDA has concluded there is an increased risk of serious cardiovascular-related events (eg, heart attack, stroke), cancer (eg, lymphoma, lung cancer), thrombosis, and death with the use of Janus kinase (JAK) inhibitors.

Appendix II – Topical Steroid Potency Chart

Brand name	Generic name
CLASS 1—Superpotent	
Clobex Lotion/Spray/Shampoo, 0.05%	Clobetasol propionate
Cordran Tape, 0.05%	Flurandrenolide
Cormax Cream/Solution, 0.05%	Clobetasol propionate
Diprolene Ointment, 0.05%	Betamethasone dipropionate
Olux E Foam, 0.05%	Clobetasol propionate
Olux Foam, 0.05%	Clobetasol propionate
Psorcon Ointment, 0.05%	Diflorasone diacetate
Psorcon E Ointment, 0.05%	Diflorasone diacetate
Temovate Cream/Ointment/Solution, 0.05%	Clobetasol propionate
Topicort Topical Spray, 0.25%	Desoximetasone
Ultravate Cream/Ointment, 0.05%	Halobetasol propionate
Ultravate Lotion, 0.05%	Halobetasol propionate
Vanos Cream, 0.1%	Fluocinonide
CLASS 2—Potent	
Diprolene Cream AF, 0.05%	Betamethasone dipropionate
Elocon Ointment, 0.1%	Mometasone furoate
Florone Ointment, 0.05%	Diflorasone diacetate
Halog Ointment/Cream, 0.1%	Halcinonide
Lidex Cream/Gel/Ointment, 0.05%	Fluocinonide
Psorcon Cream, 0.05%	Diflorasone diacetate
Topicort Cream/Ointment, 0.25%	Desoximetasone
Topicort Gel, 0.05%	Desoximetasone
CLASS 3—Upper Mid-Strength	
Cutivate Ointment, 0.005%	Fluticasone propionate
Lidex-E Cream, 0.05%	Fluocinonide
Luxiq Foam, 0.12%	Betamethasone valerate
CLASS 4—Mid-Strength	
Cordran Ointment, 0.05%	Flurandrenolide
Elocon Cream, 0.1%	Mometasone furoate
Kenalog Cream/Spray, 0.1%	Triamcinolone acetonide
Synalar Ointment, 0.03%	Fluocinolone acetonide
Topicort LP Cream, 0.05%	Desoximetasone
Topicort LP Ointment, 0.05%	Desoximetasone
Westcort Ointment, 0.2%	Hydrocortisone valerate
CLASS 5—Lower Mid-Strength	
Capex Shampoo, 0.01%	Fluocinolone acetonide
Cordran Cream/Lotion/Tape, 0.05%	Flurandrenolide
Cutivate Cream/Lotion, 0.05%	Fluticasone propionate
DermAtop Cream, 0.1%	Prednicarbate
DesOwen Lotion, 0.05%	Desonide
Locoid Cream/Lotion/Ointment/Solution, 0.1%	Hydrocortisone
Pandel Cream, 0.1%	Hydrocortisone
Synalar Cream, 0.03%/0.01%	Fluocinolone acetonide
Westcort Cream, 0.2%	Hydrocortisone valerate
CLASS 6—Mild	
Aclovate Cream/Ointment, 0.05%	Alclometasone dipropionate
Derma-Smoothe/FS Oil, 0.01%	Fluocinolone acetonide
Desonate Gel, 0.05%	Desonide
Synalar Cream/Solution, 0.01%	Fluocinolone acetonide

Verdeso Foam, 0.05%	Desonide
CLASS 7—Least Potent	
Cetacort Lotion, 0.5%/1%	Hydrocortisone
Cortaid Cream/Spray/Ointment	Hydrocortisone
Hytone Cream/Lotion, 1%/2.5%	Hydrocortisone
Micort-HC Cream, 2%/2.5%	Hydrocortisone
Nutracort Lotion, 1%/2.5%	Hydrocortisone
Synacort Cream, 1%/2.5%	Hydrocortisone