~~APPROVED~~ DRAFT PA Criteria

Initial Approval Date: July 10, 2019
Revised Dates: April 20, 2022; January 19, 2022;
July 21, 2021; July 8, 2020;
October 9, 2019

CRITERIA FOR PRIOR AUTHORIZATION

Atopic Dermatitis (AD) Agents

BILLING CODE TYPE For drug coverage and provider type information, see the KMAP Reference Codes webpage.

MANUAL GUIDELINES Prior authorization will be required for all current and future dose forms available. All medication-specific criteria, including drug-specific indication, age, and dose for each agent is defined in Tables 1 and 2 below.

Abrocitinib (Cibinqo™)
Crisaborole (Eucrisa®)
Dupilumab (Dupixent®)
Pimecrolimus (Elidel®)
Ruxolitinib (Opzelura™)
Tacrolimus (Protopic®)
Tralokinumab-ldrm (Adbry™)
Upadacitinib (Rinvoq®)

GENERAL CRITERIA FOR INITIAL PRIOR AUTHORIZATION: (must meet all of the following)

- Must be approved for the indication, age, and not exceed dosing limits listed in Tables 1 and 2.
- For all agents listed, the preferred PDL drug, if applicable, which treats the PA indication, is required unless the patient meets the non-preferred PDL PA criteria.
- For crisaborole, pimecrolimus and tacrolimus one of the following must be met:[1,2,7,8,9]
  - Patient must have had an adequate trial (at least 3 weeks)[1,3] of at least one prescription-strength topical corticosteroid or a contraindication to all agents listed in ~~Table 2~~Table 3.
  - Patient has atopic dermatitis on the face, neck, genitalia, skin folds, and/or axillae.[1-3,5]
- For ruxolitinib, all of the following must be met[1-2,9,10]:
  - Patient must have had an adequate trial (at least 3 weeks)[1,3] of one (or contraindication to all) of the following listed in ~~Table 3~~Table 1: a topical calcineurin inhibitor or a phosphodiesterase-4 inhibitor.
  - Patient must not concurrently use with other immunosuppressive agents such as topical calcineurin inhibitors listed in ~~Table 3~~Table 1 or any agents listed in Table 4 or Table 5.
- ~~For dupilumab and tralokinumab all of the following must be met:~~For all agents in Table 2, all of the following must be met:
  - Must be prescribed by or in consultation with a dermatologist, allergist, or immunologist.[2,3]
  - Patient must have had an adequate trial (at least 8 weeks) of one or contraindication (including pediatric age) to all systemic conventional agents listed in Table 4.[4]
  - Prescriber must provide the baseline of the following criteria:[2,6,11]
    - Eczema Area and Severity Index (EASI) score of ≥ 16.[6,10-13]
- For abrocitinib and upadacitinib all of the following must be met:
  - Patient must have had an adequate trial (at least 8 weeks) of one or contraindication (including pediatric age) to all biologic agents listed in Table 2.[12-13]
- For all requested immunomodulating biologics or janus kinase (JAK) inhibitors, patient must not concurrently be on another immunomodulating biologic or JAK inhibitor listed in Table 5. After discontinuing the current immunomodulating biologic or JAK inhibitor, the soonest that a new immunomodulating biologic or JAK inhibitor will be authorized is at the next scheduled dose.

~~APPROVED~~ ~~DRAFT~~ PA Criteria

Table 1. FDA-approved age and dosing limits for topical Atopic Dermatitis (AD) Agents.[6-9~~11~~]

Medication	Indication(s)	Age	Dosing Limits
Calcineurin Inhibitors			
Pimecrolimus (Elidel®)	Mild to moderate AD	≥ 2 years	Thin layer applied twice daily
Tacrolimus (Protopic®)	Moderate to severe AD	≥ 2 years	Ages 16 years and older: 0.03% or 0.1% thin layer applied twice daily Ages 2 to 15 years: 0.03% thin layer applied twice daily
Phosphodiesterase-4 Enzyme Inhibitors			
Crisaborole (Eucrisa®)	Mild to moderate AD	≥ 3 months	Thin layer applied twice daily
Janus Kinase Inhibitors			
Ruxolitinib (Opzelura™)	Mild to moderate AD	≥ 12 years	Thin layer applied twice daily to affected areas of up to 20% body surface area – do not use more than 60 grams per week

Table 2. FDA-approved age and dosing limits for systemic Atopic Dermatitis (AD) Agents.[10-13]

Medication	Indication(s)	Age	Dosing Limits
Interleukin-4 Receptor Antagonists			
Dupilumab (Dupixent®)*	Moderate to severe AD	≥ 6 years	Adults: 600 mg (given as two 300 mg injections) initially SC followed by 300 mg every other week Ages 6 to 17 years: 15 to < 30 kg: 600 mg (given as two 300 mg injections) initially SC followed by 300 mg every 4 weeks 30 to < 60 kg: 400 mg (given as two 200 mg injections) initially SC followed by 200 mg every other week ≥ 60 kg: 600 mg (given as two 300 mg injections) initially SC followed by 300 mg every other week
Interleukin-13 Receptor Antagonists			
Tralokinumab-ldrm (Adbry™)*	Moderate to severe AD	≥ 18 years	600 mg (given as four 150 mg injections) initially SC followed by 300 mg every other week
Janus Kinase Inhibitors			
Abrocitinib (Cibinqo™)	Refractory, moderate to severe atopic dermatitis	≥ 18 years	100 mg orally once daily; may be increased to 200 mg orally once daily in patients not responding to 100 mg daily.
Upadacitinib (Rinvoq®)	Refractory, moderate to severe atopic dermatitis	≥ 12 years	Ages 12 to < 65 years, weighing at least 40 kg: 15 mg orally once daily; may be increased to 30 mg once daily in patients not responding to 15 mg daily. Ages 65 years and older: 15 mg orally once daily.

SC: subcutaneous. * Biologic agent.

~~APPROVED~~ DRAFT PA Criteria

CRITERIA FOR RENEWAL PRIOR AUTHORIZATION: (must meet all of the following)

- Must not exceed dosing limits listed in Tables 1 and 2.
- For crisaborole, pimecrolimus, ruxolitinib and tacrolimus: Prescriber must attest that the patient has received clinical benefit from continued treatment with the requested medication.
- For abrocitinib, dupilumab, ~~and~~ tralokinumab and upadacitinib:
  - Prescriber must provide at least one of the following measurements:
    - EASI improvement ≥ 75% compared to baseline.[6,11-13]
- For all requested biologics or janus kinase (JAK) inhibitors, patient must not concurrently be on another biologic or JAK inhibitor listed in Table 5. After discontinuing the current biologic or JAK inhibitor, the soonest that a new biologic or JAK inhibitor will be authorized is at the next scheduled dose.

LENGTH OF APPROVAL (INITIAL AND RENEWAL): 12 months

FOR DRUGS THAT HAVE A CURRENT PA REQUIREMENT, BUT NOT FOR THE NEWLY APPROVED INDICATIONS, FOR OTHER FDA-APPROVED INDICATIONS, AND FOR CHANGES TO AGE REQUIREMENTS NOT LISTED WITHIN THE PA CRITERIA:

- **THE PA REQUEST WILL BE REVIEWED BASED UPON THE FOLLOWING PACKAGE INSERT INFORMATION: INDICATION, AGE, DOSE, AND ANY PRE-REQUISITE TREATMENT REQUIREMENTS FOR THAT INDICATION.**

LENGTH OF APPROVAL (INITIAL AND RENEWAL): 12 MONTHS

Table 3~~2~~. List of topical corticosteroids in the treatment of atopic dermatitis.[1]

Topical Corticosteroid Agents
Alclometasone (Aclovate)
Amcinonide (Cyclocort)
Betamethasone (AlphaTrex, Diprolene, Diprolene AF)
Clobetasol (Clobex, Clobex Spray, Clodan, Cormax Scalp Application, Impoyz, Olux, Olux-E, Temovate, Temovate E)
Clocortolone (Cloderm)
Desonide (Desonate, DesOwen, LoKara, Tridesilon, Verdeso)
Desoximetasone (Topicort)
Flurandrenolide (Cordran, Nolix)
Fluticasone (Beser, Cutivate)
Halcinonide (Halog)
Halobetasol (Halac, Ultravate)
Hydrocortisone (Cortizone, Westcort)
Mometasone (Elocon)
Prednicarbate (Dermatop)
Triamcinolone (Kenalog, Trianex, Triderm)

~~Table 3. List of topical conventional therapy in the treatment of atopic dermatitis.[1,6]~~

~~Topical Conventional Agents~~	
~~Calcineurin Inhibitors~~	~~Phosphodiesterase-4 Inhibitors~~
~~Protopic® (tacrolimus 1% & 0.03%)~~	~~Eucrisa® (crisaborole)~~
~~Elidel® (pimecrolimus 1%)~~	

Table 4. List of systemic conventional therapy in the treatment of atopic dermatitis.[1,6]

Systemic Conventional Agents
Gengraf®, Neoral® (cyclosporine)
Azasan®, Imuran® (azathioprine)
Trexall®, Rheumatrex®, Otrexup®, Rasuvo® (methotrexate)
CellCept®, Myfortic® (mycophenolate mofetil)

Table 5. List of immunomodulating biologic agents/janus kinase inhibitors (agents not to be used concurrently).

Biologic Agents/Janus Kinase Inhibitors		
Actemra® (tocilizumab)	Ilumya™ (tildrakizumab-asmn)	Siliq® (brodalumab)
Adbry™ (tralokinumab)	Kevzara® (sarilumab)	Simponi® (golimumab)
Benlysta® (belimumab)	Kineret® (anakinra)	Simponi Aria (golimumab)
Cibinqo™ (abrocitinib)	Nucala® (mepolizumab)	Skyrizi™ (risankizumab-rzaa)
Cimzia® (certolizumab)	Olumiant® (baricitinib)	Stelara® (ustekinumab)
Cinqair® (reslizumab)	Opzelura™ (ruxolitinib)	Taltz® (ixekizumab)
Cosentyx® (secukinumab)	Orencia® (abatacept)	Tezspire™ (tezepelumab-ekko)
Dupixent® (dupilumab)	Remicade® (infliximab) & biosimilars (Avsola™, Inflectra®, Ixifi™, Renflexis®)	Tremfya® (guselkumab)
Enbrel® (etanercept) & biosimilars (Erelzi™, Eticovo®)	Rinvoq™ (upadacitinib)	Tysabri® (natalizumab)
Entyvio® (vedolizumab)	Rituxan® (rituximab) & biosimilars (Riabni™, Ruxience™, Truxima®)	Xeljanz® (tofacitinib)
Fasenra™ (benralizumab)	Rituxan Hycela™ (rituximab/hyaluronidase)	Xeljanz XR® (tofacitinib)
Humira® (adalimumab) & biosimilars (Abrilada™, Amjevita™, Cyltezo™, Hulio™, Hyrimoz™, Yusimry™)	Saphnelo™ (anifrolumab)	Xolair® (omalizumab)
Ilaris® (canakinumab)		

References

1. Guidelines of care for the management of atopic dermatitis. J Am Acad Dermatol. 2014; 70:116-32, 327-49. Available at https://www.aad.org/practicecenter/quality/clinical-guidelines. Accessed 6/2/20.
2. Boguniewicz M, Fonacier L, Guttman-Yassky E, et al. Atopic dermatitis yardstick: practical recommendations for an evolving therapeutic landscape. Ann Allergy Asthma Immunol. 2018;120:10–22.e2. Available at https://www.annallergy.org/article/S1081-1206(17)31260-7/fulltext. Accessed 6/2/20.
3. Wollenberg A, Barbarot S, Bieber T, et al. Consensus-based European guidelines for treatment of atopic eczema (atopic dermatitis) in adults and children: part I. J Eur Acad Dermatol Venereol. 2018;32:657–682. Available at https://www.eadv.org/clinical-guidelines. Accessed 6/2/20.
4. Wollenberg A, Barbarot S, Bieber T, et al. Consensus-based European guidelines for treatment of atopic eczema (atopic dermatitis) in adults and children: part II. J Eur Acad Dermatol Venereol. 2018;32:850-878. Available at https://www.eadv.org/clinical-guidelines. Accessed 6/2/20.
5. Current guidelines for the evaluation and management of atopic dermatitis: A comparison of the Joint Task Force Practice Parameter and American Academy of Dermatology guidelines. J Allergy Clin Immunol 2017;139(4)S49-S57. Available at https://www.sciencedirect.com/science/article/pii/S0091674917301495. Accessed on 6/2/20.
6. Eucrisa Ointment 2% (crisaborole) [package insert]. New York, NY: Pfizer Labs; April 2020.
7. Elidel (pimecrolimus) [package insert]. Bridgewater, NJ: Valeant Pharmaceuticals; December 2017.
8. Protopic (tacrolimus) [package insert]. Madison, NJ: LEO Pharma Inc; February 2019.
9. Opzelura (ruxolitinib) [package insert]. Wilmington, DE: Incyte Corporation; September 2021.
10. Dupixent (dupilumab) [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc., Sanofi Genzyme; ~~October~~ December 2021.
11. Adbry (tralokinumab-ldrm) [package insert]. Madison, NJ: LEO Pharma A/S; ~~December 2021~~January 2022.
12. Cibinqo (abrocitinib) [package insert]. New York, NY: Pfizer Labs; January 2022.
~~11.~~13. Rinvoq (upadacitinib) [package insert]. North Chicago, IL: AbbVie Inc.; January 2022.