Drug Use Research & Management Program
Oregon State University, 500 Summer Street NE, E35
Salem, Oregon 97301-1079
Phone 503-947-5220 | **Fax** 503-947-2596

Drug Class Literature Scan: Atopic Dermatitis and Topical Antipsoriatics

Date of Review: October 2020

Date of Last Review: July 2019
Literature Search: 04/17/2019 – 5/20/2020

Current Status of PDL Class:
See **Appendix 1**.

Conclusions:

- Since the last atopic dermatitis (AD) and topical antipsoriatic class update, 1 high-quality systematic review[1] and 1 high-quality guideline update have been published.[2]
- A 2020 Cochrane review evaluated the safety and efficacy of biologics for chronic rhinosinusitis in adults.[1] Most of the patients were enrolled in trials that evaluated dupilumab, the only biologic Food and Drug Administration (FDA)-approved for management of chronic rhinosinusitis with nasal polyps.[3] The primary outcomes were health-related quality of life (HRQL) and serious adverse events.[1] Health-related quality of life was measured with the Sino-Nasal Outcome Test-22 (SNOT-22; score range 0 to 110; minimal clinically important difference [MCID] 8.9 points). At 24 weeks, the SNOT-22 score was 19.61 points lower in participants receiving dupilumab (95% confidence interval [CI] -22.54 to -16.69).[1] The sample sizes were insufficient and the length of follow-up too short (16 to 52 weeks) to adequately assess the risks of serious side effects.[1]
- The Canadian Agency for Drugs and Technologies in Health (CADTH) published updated recommendations for the use of dupilumab in atopic dermatitis April 2020.[2] The following recommendations are included in the guideline. Dupilumab should be initiated if the following criteria are met:
    - Patient is 12 years and older with moderate-to-severe AD whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.[2]
    - Patients must have had an adequate trial or be ineligible for each of the following therapies: phototherapy (where available), methotrexate, and cyclosporine.[2]
    - The physician must provide the Eczema Area and Severity Index (EASI) and Physician Global Assessment (PGA) score at the time of the initial request.[2]
    - For continued renewal, the physician must provide proof of beneficial clinical effect, defined as 75% or greater improvement from baseline in EASI score (EASI-75) six months after treatment initiation.[2]
- In March 2020, the FDA expanded the indication for crisaborole in children aged 3 months and older for management of mild-to-moderate AD.[4]
- In May 2020, the FDA expanded the indication for dupilumab in children aged 6 years and older for management of moderate-to-severe AD.[3]

Author: Deanna Moretz, PharmD, BCPS

Recommendations:

- Revise Prior Authorization (PA) criteria for AD and topical antipsoriatics to reflect expanded indication for crisaborole in children aged 3 months and older with moderate AD.
- Revise PA criteria for dupilumab to reflect expanded indication for management of moderate-to-severe AD not well controlled by topical prescription medications in children older than 6 years of age.
- Review costs in executive session.

Summary of Prior Reviews and Current Policy

According to the Health Evidence Review Commission (HERC), severe AD and severe psoriasis are funded conditions.[5] Mild AD and mild psoriasis continue to be an unfunded conditions.[5] The HERC Guideline Note 21 provides guidance for coverage and management of inflammatory skin diseases.[5] At the May 2018 meeting, the Pharmacy and Therapeutics (P and T) committee approved revising the PA criteria for topical antipsoriatic drugs to include agents used to manage AD. In addition, the committee approved a recommendation to make dupilumab a non-preferred medication on the Practitioner-Managed Prescription Drug Plan (PMPDP) with PA criteria. After reviewing comparative costs in executive session, tacrolimus 0.03% ointment, tacrolimus 0.1% ointment, and pimecrolimus 1% cream were designated as preferred agents and crisaborole was maintained as a non-preferred agent.

At the July 2019 P and T meeting, a new PA document was approved for dupilumab utilization in moderate-to-severe AD, chronic rhinosinusitis with nasal polyps, and moderate-to-severe asthma. Utilization of AD medications and topical antipsoriatics is very low (3 patients in the first quarter of 2020) in the fee-for-service (FFS) population. Claims were processed for 2 drugs: dupilumab injection and tacrolimus ointment in the first quarter of 2020. The PDL status for topical antipsoriatics and AD medications is presented in **Appendix 1**. The PA criteria for dupilumab and topical agents used to manage psoriasis and AD are included in **Appendix 4**.

Methods:

A Medline literature search for new systematic reviews and randomized controlled trials (RCTs) assessing clinically relevant outcomes to active controls, or placebo if needed, was conducted. The Medline search strategy used for this literature scan is available in **Appendix 3**, which includes dates, search terms and limits used. The OHSU Drug Effectiveness Review Project, Agency for Healthcare Research and Quality (AHRQ), National Institute for Health and Clinical Excellence (NICE), Department of Veterans Affairs, and CADTH resources were manually searched for high quality and relevant systematic reviews. When necessary, systematic reviews are critically appraised for quality using the AMSTAR tool and clinical practice guidelines using the AGREE tool. The FDA website was searched for new drug approvals, indications, and pertinent safety alerts.

The primary focus of the evidence is on high quality systematic reviews and evidence-based guidelines. Randomized controlled trials will be emphasized if evidence is lacking or insufficient from those preferred sources.

New Systematic Reviews:

<u>Cochrane: Biologics for Chronic Rhinosinusitis</u>

A 2020 Cochrane review evaluated the safety and efficacy of biologics for chronic rhinosinusitis in adults.[1] Literature was searched through September 2019 with a focus on identifying RCTs with at least three months follow-up comparing biologics against placebo/no treatment in patients with chronic rhinosinusitis.[1] Eight RCTs met inclusion criteria. Of 986 adult participants, 984 had severe chronic rhinosinusitis with nasal polyps; 43% to 100% of participants also had asthma.[1]

Three biologics, with different targets, were evaluated: dupilumab, mepolizumab and omalizumab. Only dupilumab is FDA-approved for management of chronic rhinosinusitis. Overall the risk of bias was low or unclear for most domains in the included trials.[1] All the studies were sponsored or supported by industry.

Three studies (784 participants) evaluated dupilumab versus placebo/no treatment.[1] Health-related quality of life was measured with the SNOT-22 (score 0 to 110; MCID 8.9 points).[1] At 24 weeks, the SNOT-22 score was 19.61 points lower (better) in participants receiving dupilumab (MD -19.61, 95% CI -22.54 to -16.69; 3 studies; 784 participants; high-quality evidence).[1] Symptom severity measured on a 0- to 10-point visual analogue scale (VAS) was 3.00 lower in those receiving dupilumab (95% CI -3.47 to -2.53; 3 studies; moderate-quality evidence).[1] The sample sizes were insufficient and the length of follow-up too short (16 to 52 weeks) to adequately assess the risks of serious side effects.[1]

After review, 6 systematic reviews were excluded due to poor quality, wrong study design of included trials (e.g., observational), comparator (e.g., no control or placebo-controlled), or outcome studied (e.g., non-clinical).[6-11]

New Guidelines:

High Quality Guidelines:

Canadian Agency for Drugs and Technologies in Health

In April 2020, CADTH published updated recommendations for the use of dupilumab in atopic dermatitis.[2] Dupilumab should be initiated if the following criteria are met:

- Patient is 12 years and older with moderate-to-severe AD whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.[2]
- Patients must have had an adequate trial or be ineligible for each of the following therapies: phototherapy (where available), methotrexate, and cyclosporine.[2]
- The physician must provide the EASI and PGA score at the time of the initial request.[2]
- The maximum duration of authorization is 6 months.[2]
- The patient must be under the care of a dermatologist.[2]
- Dupilumab is not to be used in combination with phototherapy or immunosuppressant drugs, such as methotrexate or cyclosporine.[2]

Renewal Criteria:

- The physician must provide proof of beneficial clinical effect, defined as 75% or greater improvement from baseline in EASI score (EASI-75) six months after treatment initiation.[2]

Additional Guidelines for Clinical Context:

Joint American Academy of Dermatology–National Psoriasis Foundation

Guidelines of care for the management and treatment of psoriasis in pediatric patients younger than 18 years old were published by the American Academy of Dermatology (AAD) in conjunction with the National Psoriasis Foundation (NPF) in 2020.[12] This guideline addresses the management of psoriasis and its extracutaneous manifestations in children and adolescents, with attention to topical and systemic treatment options, phototherapy, and comorbidities, including psychosocial wellness and quality of life (QOL).[12] Evidence was obtained by using a search of the PubMed and MEDLINE databases from January 2011 through December 31, 2017, for clinical questions addressed in the previous version of this guideline published in 2008.[12] A multidisciplinary workgroup (WG) of recognized psoriasis experts consisting of dermatologists, a rheumatologist, a cardiologist, and representatives from a patient advocacy organization were

convened to identify important clinical questions with regard to pediatric psoriasis.[12]Significant efforts were taken to minimize the potential for conflicts of interest to influence guideline content. Funding of guideline production by medical or pharmaceutical entities was prohibited, full disclosure was obtained and evaluated for all guideline contributors throughout the guideline development process, and recusal was used to manage identified relationships.[12]

The only recommendation that addressed the use of medications in the topical atopic dermatitis/psoriasis class was the use of tacrolimus 0.1% ointment for off-label use as monotherapy for pediatric psoriasis of the face and genital region.[12] (Strength of Recommendation: C - Recommendation based on consensus, opinion, case studies, or disease-oriented evidence.)[12]

National Institute for Health and Care Excellence : A recommendation for crisaborole for treating mild to moderate atopic dermatitis in people aged 2 years and older is under development. No publication date has been announced.

After review, 2 guidelines were excluded due to poor quality.[13,14]

New Formulations/Indications

Crisaborole

In March 2020, crisaborole (Eucrisa™) received expanded FDA approval for use in pediatric patients 3 months of age and older with mild-to-moderate atopic dermatitis.[4] Previously, crisaborole was indicated for mild-to-moderate atopic dermatitis in patients 2 years and older. Use of crisaborole in pediatric patients aged 2 years and older is supported by data from two 28-day adequate, vehicle-controlled safety and efficacy trials which included 1,313 pediatric subjects ages 2 years to 17 years of whom 874 received crisaborole.[4] Additionally, use of crisaborole in pediatric patients ages 3 months to less than 2 years was supported by data from a 28-day open-label, safety and pharmacokinetics (PK) trial in 137 subjects.[4] No new safety signals were identified in subjects 3 months to less than 2 years of age.[4] The most commonly reported adverse reaction in subjects 2 years and older was application site pain.[4]

Dupilumab

In May 2020, the FDA expanded approval of dupilumab (Dupixent®) for use in children aged 6 years and older for treatment of moderate-to-severe AD not well controlled with topical prescription medications.[3] Previously, dupilumab was approved for use in children 12 years and older with AD. Safety and efficacy of dupilumab in adolescents with inadequately controlled AD was evaluated in a phase 3, placebo-controlled RCT that recruited 251 patients.[15] Patients were randomized (1:1:1) to 16-week treatment with dupilumab 200 mg every 2 weeks (n = 43; baseline weight <60 kg), dupilumab 300 mg (n = 39; baseline weight ≥60 kg) every 2 weeks; dupilumab 300 mg every 4 weeks (n = 84), or placebo (n = 85).[15] The primary outcome was the proportion of patients with 75% or more improvement from baseline in EASI-75 and Investigator's Global Assessment (IGA) score of 0 or 1 on a 5-point scale (scores range from 0 to 4, with higher scores indicating greater severity) at week 16.[15]

The proportion of patients with EASI-75 improvement from baseline increased in patients treated with dupilumab (every 2 weeks (41.5%) and dupilumab every 4 weeks (38.1%) compared to placebo (8.2%). Absolute differences compared to placebo were 33.2% (95% CI, 21.1%-45.4%) and 29.9% (95% CI, 17.9%-41.8%) for 2 week and 4 week dosing regimens, respectively.[15] Efficacy of the 2 week dosing regimen was generally superior to the 4 week dosing regimen.[15] Patients in the dupilumab arms had higher percentage values of conjunctivitis (9.8% and 10.8% with 2 and 4 week dosing vs. 4.7% with placebo) and injection site reactions (8.5% and 6.0% with 2 and 4 week dosing vs. 3.5% with placebo), and lower risk of nonherpetic skin infections (9.8% and 9.6% with 2 and 4 week dosing vs. 18.8% with placebo).[15]

New FDA Safety Alerts: No new safety alerts have been published since the last class update.

References:

1. Chong LY, Piromchai P, Sharp S, et al. Biologics for chronic rhinosinusitis. *Cochrane Database Syst Rev.* 2020;2(2):Cd013513.
2. Canadian Agency for Drugs and Technologies in Health (CADTH) Canadian Drug Expert Committee Recommendation. Dupliumab. https://www.cadth.ca/dupilumab-0. April 2020. Accessed June 2, 2020.
3. Dupixent® (dupilumab) Product Information. Tarrytown, NY: Regeneron Pharmaceuticals, Inc. May 2020.
4. Eucrisa (crisaborole) topical ointment Prescribing Information. New York, NY; Pfizer Labs. March 2020.
5. Health Evidence Review Commission. Searchable Prioritized List, Guideline Notes, Multisector Interventions and Services Recommended for Non-Coverage. Accessed May 12, 2020.
6. Hanna S, Zip C, Shear NH. What Is the Risk of Harm Associated With Topical Calcineurin Inhibitors? *J Cutan Med Surg.* 2019;23(4_suppl):19S-26S.
7. Wernham AGH, Veitch D, Grindlay DJC, Rogers NK, Harman KE. What's new in atopic eczema? An analysis of systematic reviews published in 2017. Part 1: treatment and prevention. *Clin Exp Dermatol.* 2019;44(8):861-867.
8. Solman L, Lloyd-Lavery A, Grindlay DJC, Rogers NK, Thomas KS, Harman KE. What's new in atopic eczema? An analysis of systematic reviews published in 2016. Part 1: treatment and prevention. *Clin Exp Dermatol.* 2019;44(4):363-369.
9. Hong CH, Gooderham M, Bissonnette R. Evidence Review of Topical Calcineurin Inhibitors for the Treatment of Adult Atopic Dermatitis. *J Cutan Med Surg.* 2019;23(4_suppl):5S-10S.
10. Seger EW, Wechter T, Strowd L, Feldman SR. Relative efficacy of systemic treatments for atopic dermatitis. *J Am Acad Dermatol.* 2019;80(2):411-416.e414.
11. Lee GR, Maarouf M, Hendricks AK, Lee DE, Shi VY. Current and emerging therapies for hand eczema. *Dermatologic Therapy.* 2019;32(3):e12840.
12. Menter A, Cordoro KM, Davis DMR, et al. Joint American Academy of Dermatology/National Psoriasis Foundation guidelines of care for the management and treatment of psoriasis in pediatric patients. *J Am Acad Dermatol.* 2020;82(1):161-201.
13. Aoki V, Lorenzini D, Orfali RL, et al. Consensus on the therapeutic management of atopic dermatitis - Brazilian Society of Dermatology. *An Bras Dermatol.* 2019;94(2 Suppl 1):67-75.
14. Reda AM, Elgendi A, Ebraheem AI, et al. A practical algorithm for topical treatment of atopic dermatitis in the Middle East emphasizing the importance of sensitive skin areas. *Journal of Dermatological Treatment.* 2019;30(4):366-373.
15. Simpson EL, Paller AS, Siegfried EC, et al. Efficacy and Safety of Dupilumab in Adolescents With Uncontrolled Moderate to Severe Atopic Dermatitis: A Phase 3 Randomized Clinical Trial. *JAMA dermatology.* 2019;156(1):44-56.

Appendix 1: Current Preferred Drug List

Generic	Brand	Route	Form	PDL
pimecrolimus	ELIDEL	TOPICAL	CREAM (G)	Y
pimecrolimus	PIMECROLIMUS	TOPICAL	CREAM (G)	Y
tacrolimus	PROTOPIC	TOPICAL	OINT. (G)	Y
tacrolimus	TACROLIMUS	TOPICAL	OINT. (G)	Y
dupilumab	DUPIXENT	SUB-Q	SYRINGE	N
crisaborole	EUCRISA	TOPICAL	OINT. (G)	N

Appendix 2: New Comparative Clinical Trials

A total of 15 citations were manually reviewed from the initial literature search. After further review, all citations were excluded because of wrong study design (e.g., observational), comparator (e.g., no control or placebo-controlled), or outcome studied (e.g., non-clinical).

Appendix 3: Medline Search Strategy

Ovid MEDLINE(R) without Revisions 1996 to May Week 3 2020, Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations 1946 to May 20, 2020

1. Dermatitis, Atopic/	13907
2. Eczema/	3811
3. Psoriasis	35149
3. Calcineurin Inhibitors/	3733
4. Pimecrolimus.mp.	902
5. Tacrolimus/	13668
6. Crisaborole.mp.	97
7. Dupilumab.mp.	552
8. 1 or 2 or 3	36342
9. 4 or 5 or 6 or 7 or 8	16808
10. 8 and 9	1210
11. limit 10 to (english language and humans and yr="2019 -Current" and (clinical trial, all or clinical trial, phase i or clinical trial, phase ii or clinical trial, phase iii or clinical trial, phase iv or clinical trial or comparative study or controlled clinical trial or meta-analysis or multicenter study or practice guideline or pragmatic clinical trial or randomized controlled trial or "systematic review"))	15

Atopic Dermatitis and Topical Antipsoriatics

Goal(s):

- Restrict dermatological drugs only for funded OHP diagnoses. Severe psoriasis and Severe atopic dermatitis treatments are funded on the OHP. Treatments for mild psoriasis, seborrheic dermatitis, keratoderma and other hypertrophic and atrophic conditions of skin are not funded.

Length of Authorization:

- From 6 to 12 months

Requires PA:

- Non-preferred antipsoriatics
- All atopic dermatitis drugs
- STC = 92 and HIC = L1A, L5F, L9D, T0A
- This PA does not apply to biologics for psoriasis, or dupilumab which are subject to separate clinical PA criteria.

Covered Alternatives:

- Preferred alternatives listed at www.orpdl.org/drugs/

Table 1. FDA-approved ages for atopic dermatitis drugs

Drug	Minimum Age
Crisaborole	3 months
Pimecrolimus	2 years
Tacrolimus 0.03%	2 years
Tacrolimus 0.1%	16 years

Approval Criteria		
1. What diagnosis is being treated?	Record ICD 10 code.	
2. Is the diagnosis for seborrheic dermatitis, keratoderma or other hypertrophic and atrophic conditions of skin?	**Yes:** Pass to RPh; deny, not funded by the OHP.	**No:** Go to #3

Approval Criteria		
3. Is the request for treatment of severe inflammatory skin disease? Severe disease is defined as:[1] • Having functional impairment as indicated by Dermatology Life Quality Index (DLQI) ≥ 11 or Children's Dermatology Life Quality Index (CDLQI) ≥ 13 (or severe score on other validated tool) AND one or more of the following: 1. At least 10% body surface area involved 2. Hand, foot or mucous membrane involvement	**Yes:** Go to #4	**No:** Pass to RPh; deny, not funded by the OHP
4. Is the diagnosis psoriasis?	**Yes:** Go to #8	**No:** Go to #5
5. Is the diagnosis atopic dermatitis?	**Yes:** Go to #6	**No:** Go to #10
6. Does the patient meet the age requirements per the FDA label (Table 1)?	**Yes:** Go to #7	**No:** Pass to RPh. Deny; medical appropriateness
7. Does the patient have a documented contraindication, intolerance or failed trials of at least 2 first line agents indicated for the treatment of severe AD (topical corticosteroids)?* *Note pimecrolimus and crisaborole are FDA approved to manage mild to moderate AD, while tacrolimus is FDA approved to manage moderate to severe AD.	**Yes:** Document drug and dates trialed, and intolerances or contraindications (if applicable): 1._____(dates) 2._____(dates) Approve for length of treatment; maximum 6 months.	**No:** Pass to RPh. Deny; medical appropriateness
8. Is the requested product preferred?	**Yes:** Approve for length of treatment; maximum 1 year.	**No:** Go to #9

Approval Criteria		
9. Will the prescriber consider a change to a preferred product? **Message:** Preferred products are evidence-based reviewed for comparative effectiveness & safety by the Pharmacy and Therapeutics (P&T) Committee.	**Yes:** Inform provider of preferred alternatives. Approve for length of treatment; maximum 1 year.	**No**: Approve for length of treatment; maximum 1 year.
10. RPH only: All other indications need to be evaluated as to whether they are funded by the OHP.*	**If funded, or clinic provides supporting literature:** Approve for 1 year.	**If not funded:** Deny, not funded by the OHP.

P&T/DUR Review: *10/20 (DM); 7/19 (DM); 5/19 (DM) 3/18 (DM); 9/17; 7/15; 1/15; 09/10; 9/09; 3/09; 5/07; 2/06*
Implementation: *11/1/20, 8/19/19; 4/16/18; 10/15; 8/15; 9/13; 6/12; 9/10; 1/10; 7/09; 6/07; 9/06*

**The Health Evidence Review Commission has stipulated via Guideline Note 21 that mild, uncomplicated inflammatory skin conditions including psoriasis, atopic dermatitis, lichen planus, Darier disease, pityriasis rubra pilaris, and discoid lupus are not funded. Uncomplicated is defined as no functional impairment; and/or involving less than 10% of body surface area and no involvement of the hand, foot, or mucous membranes.*

References:

1. *Oregon Health Evidence Review Commission. Coverage Guidance and Reports. http://www.oregon.gov/oha/hpa/csi-herc/pages/index.aspx Accessed June 2, 2020.*

Dupilumab

Goal(s):

- Promote use that is consistent with national clinical practice guidelines and medical evidence.

Length of Authorization:

- 6 months

Requires PA:

- Dupilumab (Dupixent®) pharmacy and physician administered claims

Covered Alternatives:

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

Table 1. Maximum Adult Doses for Inhaled Corticosteroids.

High Dose Corticosteroids:	**Maximum Dose**
Qvar (beclomethasone)	320 mcg BID
Pulmicort Flexhaler (budesonide)	720 mcg BID
Alvesco (ciclesonide)	320 mcg BID
Aerospan (flunisolide)	320 mcg BID
Arnuity Ellipta (fluticasone furoate)	200 mcg daily
Flovent HFA (fluticasone propionate)	880 mcg BID
Flovent Diskus (fluticasone propionate)	1000 mcg BID
Asmanex Twisthaler (mometasone)	440 mcg BID
Asmanex HFA (mometasone)	400 mcg BID
High Dose Corticosteroid / Long-acting Beta-agonists	**Maximum Dose**
Symbicort (budesonide/formoterol)	320/9 mcg BID
Advair Diskus (fluticasone/salmeterol)	500/50 mcg BID
Advair HFA (fluticasone/salmeterol)	460/42 mcg BID
Breo Ellipta (fluticasone/vilanterol)	200/25 mcg daily
Dulera (mometasone/formoterol)	400/10 mcg BID

Table 2. FDA-approved ages for dupilumab.

Condition	**Minimum Age**
Asthma	12 years
Atopic dermatitis	6 years
Chronic rhinosinusitis with nasal polyposis	18 years

Approval Criteria	
1. What diagnosis is being treated?	Record ICD 10 code.

Approval Criteria		
2. Is the diagnosis an OHP funded diagnosis?	**Yes:** Go to #3	**No:** Pass to RPh. Deny, not funded by the OHP.
3. Is this a request for continuation of therapy?	**Yes:** Go to **Renewal Criteria**	**No:** Go to #4
4. Is the medication being prescribed by or in consultation with a dermatologist, otolaryngologist, or allergist who specializes in management of severe asthma?	**Yes:** Go to # 5	**No:** Pass to RPh. Deny; medical appropriateness
5. Is the patient within FDA-approved age limits for the requested indication (Table 2)?	**Yes:** Go to #6	**No:** Pass to RPh. Deny; medical appropriateness.
6. Is the diagnosis Severe Atopic Dermatitis (AD)? Severe disease is defined as:[1] • Having functional impairment as indicated by Dermatology Life Quality Index (DLQI) ≥ 11 or Children's Dermatology Life Quality Index (CDLQI) ≥ 13 (or severe score on other validated tool) AND one or more of the following: 1. At least 10% body surface area involved 2. Hand, foot or mucous membrane involvement	**Yes:** Go to #7	**No:** Go to #8

Approval Criteria		
7. Does the patient have a documented contraindication or failed trial of the following treatments: • Moderate to high potency topical corticosteroid (e.g., clobetasol, desoximetasone, desonide, mometasone, betamethasone, halobetasol, fluticasone, or fluocinonide) AND • Topical calcineurin inhibitor (tacrolimus, pimecrolimus) or topical phosphodiesterase (PDE)-4 inhibitor (crisaborole) AND • Oral immunomodulator therapy (cyclosporine, methotrexate, azathioprine, mycophenolate mofetil, or oral corticosteroids)?	**Yes**: Document drug and dates trialed and intolerances (if applicable): 1._____(dates) 2._____(dates) 3._____(dates) Approve for length of treatment; maximum 6 months.	**No**: Pass to RPh. Deny; medical appropriateness
8. Is the claim for moderate-to-severe asthma with an eosinophilic phenotype or with oral corticosteroid dependent asthma?	**Yes:** Go to # 9	**No:** Go to # 12
9. Is the patient currently receiving another monoclonal antibody for asthma (e.g., omalizumab, mepolizumab, benralizumab or reslizumab)?	**Yes:** Pass to RPh. Deny; medical appropriateness.	**No:** Go to #10
10. Has the patient required at least 1 hospitalization or ≥ 2 ED visits in the past 12 months while receiving a maximally-dosed inhaled corticosteroid (Table 1) AND 2 additional controller drugs (i.e., long-acting inhaled beta-agonist, montelukast, zafirlukast, or tiotropium)?	**Yes:** Go to #11 Document number of hospitalizations or ED visits in past 12 months: _____. This is the baseline value to compare to in renewal criteria.	**No:** Pass to RPh. Deny; medical appropriateness.

Approval Criteria		
11. Has the patient been adherent to current asthma therapy in the past 12 months?	**Yes:** Approve for 6 months	**No:** Pass to RPh. Deny; medical appropriateness.
12. Does the patient have chronic rhinosinusitis with nasal polyposis?	**Yes:** Go to # 13	**No:** Pass to RPh. Deny; medical appropriateness.
13. Has the patient failed medical therapy with intranasal corticosteroids (2 or more courses administered for 12 to 26 weeks[1])?	**Yes:** Approve for 6 months	**No:** Pass to RPh. Deny; medical appropriateness

Renewal Criteria		
1. Is the request to renew dupilumab for atopic dermatitis?	**Yes:** Go to #2	**No:** Go to #3
2. Have the patient's symptoms improved with dupilumab therapy? • at least a 50% reduction in the Eczema Area and Severity Index score (EASI 50) from when treatment started OR • at least a 4-point reduction in the Dermatology Life Quality Index (DLQI) from when treatment started OR • at least a 2 point improvement on the Investigators Global Assessment (IGA) score?	**Yes:** Approve for 12 months	**No:** Pass to RPh. Deny; medical appropriateness.
3. Is the request to renew dupilumab for moderate to severe asthma?	**Yes:** Go to # 4	**No:** Go to # 6

Renewal Criteria		
4. Is the patient currently taking an inhaled corticosteroid and 2 additional controller drugs (i.e., long-acting inhaled beta-agonist, montelukast, zafirlukast, or tiotropium)?	**Yes:** Go to #5	**No:** Pass to RPh. Deny; medical appropriateness.
5. Has the patient reduced their systemic corticosteroid dose by ≥50% compared to baseline?	**Yes:** Approve for up to 12 months.	**No:** Pass to RPh. Deny; medical appropriateness.
6. Have the patient's symptoms of chronic rhinosinusitis with polyposis improved?	**Yes:** Approve for up to 12 months	**No:** Pass to RPh. Deny; medical appropriateness.

1. Chong LY, Head K, Hopkins C, Philpott C, Burton MJ, Schilder AG. Different types of intranasal steroids for chronic rhinosinusitis. *Cochrane Database Syst Rev.* 2016; 4:Cd011993.

P&T/DUR Review: 10/20 (DM), 11/19 (DM); 9/19; 7/19
Implementation: 11/1/20; 1/1/2020; 8/19/19

1. *Oregon Health Evidence Review Commission. Coverage Guidance and Reports. http://www.oregon.gov/oha/hpa/csi-herc/pages/index.aspx Accessed June 2, 2020*