

Criteria-Based Consultation Prescribing Program

CRITERIA FOR DRUG COVERAGE

Dupilumab (Dupixent)

Notes:

- Quantity Limits: Yes
- ^ Adequate trial is defined as the following:
 - Topical corticosteroids – 8 weeks
 - Topical calcineurin inhibitors – 6 weeks
 - Phototherapy – 8 weeks
 - Systemic medications for dermatology indications – 6 weeks
- Intolerance excludes adverse drug reactions that are expected, mild in nature, resolve with continued treatment, and do not require medication discontinuation
- *Topical calcineurin inhibitors include tacrolimus (Protopic) 0.03% and 0.1% ointment and pimecrolimus (Elidel) 1% cream. Tacrolimus is the formulary preferred topical calcineurin inhibitor.
 - FDA approved ages:
 - Tacrolimus 0.03% and pimecrolimus 1%: 2 years of age and older. Evidence from clinical trials supports the safe and effective use (off-label) of these products in children younger than 2, including in infants.
 - Tacrolimus 0.1%: 16 years of age and older.
- **If patient experienced an intolerance to one proton pump inhibitor (PPI), trial of a different PPI is recommended
- ***If patient experienced an intolerance to one swallowed inhaled corticosteroid, trial of a different swallowed inhaled corticosteroid is recommended

Initiation (new start) criteria: Non-formulary **dupilumab (Dupixent)** will be covered on the prescription drug benefit for 12 months when the following criteria are met:

1. Prescriber is a dermatologist or allergist and patient has a diagnosis of moderate to severe atopic dermatitis

If patient is 6 months of age to 5 years of age (if 6 years of age or older, see separate criteria):

- Patient has tried and failed an adequate trial[^] of, or patient has an allergy or intolerance to the following medications
 - At least 2 medium (Class 5) to super-potent/ultrahigh potency (Class 1) topical corticosteroids
 - At least 1 topical calcineurin inhibitor*
- Patient is NOT currently taking mepolizumab (Nucala), reslizumab (Cinqair), benralizumab (Fasenra), tezepelumab-ekko (Tezspire), omalizumab (Xolair), or tralokinumab (Adbry)
- Patient is NOT currently on a Janus kinase inhibitor (oral or topical) for atopic dermatitis

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If patient is 6 years of age or older:

- Patient has tried and failed an adequate trial[^] of, or patient has an allergy or intolerance to the following medications
 - At least 1 medium (Class 5) to super-potent/ultrahigh potency (Class 1) topical corticosteroid
 - At least 1 topical calcineurin inhibitor*
 - Patient has tried and failed an adequate trial[^] of narrowband ultraviolet B (NB-UVB) phototherapy (unless documented by prescriber phototherapy not appropriate)
 - Patient has tried and failed an adequate trial[^] of, or patient has an allergy or intolerance to at least 1 of the following systemic medications (or contraindication to all)
 - Azathioprine
 - Cyclosporine
 - Methotrexate
 - Mycophenolate
 - Patient is NOT currently taking mepolizumab (Nucala), reslizumab (Cinqair), benralizumab (Fasenra), tezepelumab-ekko (Tezspire), omalizumab (Xolair), or tralokinumab (Adbry)
 - Patient is NOT currently on a Janus kinase inhibitor (oral or topical) for atopic dermatitis
2. Prescriber is an allergist or pulmonologist and patient has a diagnosis of moderate-to-severe asthma
- Patient is at least 6 years of age
 - Patient has an eosinophilic phenotype related to asthma with a serum eosinophil count in the past 12 months of either:
 - 300 cells/mcL or greater if NOT taking daily oral corticosteroids (OCS) or
 - 150 cells/mcL or greater if taking daily OCS
 - Patient has uncontrolled asthma defined as any of the following:
 - Two or more exacerbations in the past 12 months requiring OCS bursts for more than 3 days
 - One serious exacerbation requiring hospitalization or ER visit within the past 12 months
 - Asthma Control Test (ACT) is consistently less than 20 over the past 12 months
 - Dependence on daily OCS for asthma control

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- Patient has uncontrolled asthma despite good adherence (at least 75% over the past 3 months) to a regimen containing: a high dose inhaled corticosteroid (ICS), AND at least one additional asthma controller medication, such as a long-acting beta2 agonist (LABA), leukotriene receptor antagonist (LRTI [e.g., montelukast]), long-acting muscarinic antagonist (LAMA), or daily OCS
 - Patient is NOT currently taking mepolizumab (Nucala), reslizumab (Cinqair), benralizumab (Fasenra), tezepelumab-ekko (Tezspire), omalizumab (Xolair), or tralokinumab (Adbry)
3. Prescriber is an otolaryngologist and patient has a diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP)
- Patient is at least 18 years of age
 - Patient has persistent rhinosinusitis (*swelling of the sinuses and nasal cavity*) with severe nasal blockage that includes at least 2 of the following symptoms for at least 12 weeks:
 - Rhinorrhea (*runny nose*)
 - Facial pain, pressure, or fullness
 - Nasal blockage, obstruction, or congestion
 - Partial or complete loss of smell
 - Patient has bilateral nasal polyps; with polyps filling the middle meatuses and obstructing the sinus ostia
 - Patient has had a previous full endoscopic sinus surgery and failure of normalization of the sinus mucosa with post-operative drug therapies
 - Patient has received prior treatment with 2 or more courses of OCS for the treatment of nasal polyps in the past 12 months (unless unable to use OCS)
 - Patient will continue to take a nasal corticosteroid concomitantly with dupilumab; unless contraindicated or intolerance to nasal corticosteroids
 - Patient is NOT currently taking mepolizumab (Nucala), reslizumab (Cinqair), benralizumab (Fasenra), tezepelumab-ekko (Tezspire), omalizumab (Xolair), or tralokinumab (Adbry)
4. Prescriber is a gastroenterologist and patient has a diagnosis of eosinophilic esophagitis
- Patient is at least 12 years old and weighs at least 40 kilograms
 - Patient had an inadequate response after an 8-week trial of at least 1 PPI**
 - Patient had an inadequate response after an 8-week trial of at least 1 swallowed inhaled corticosteroid***

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- Patient is NOT currently taking mepolizumab (Nucala), reslizumab (Cinqair), benralizumab (Fasenra), tezepelumab-ekko (Tezspire), omalizumab (Xolair), or tralokinumab (Adbry)
- 5. Prescriber is a dermatologist and patient has a diagnosis of prurigo nodularis
- Patient is at least 18 years old
- Patient has tried and failed an adequate trial[^] of, or patient has an allergy or intolerance to the following medications
 - At least 1 high potency (Class 2) or super-potent/ultrahigh potency (Class 1) topical corticosteroid
 - At least 1 of the following: Methotrexate, cyclosporine, or azathioprine
 - At least 1 gabapentinoid (gabapentin or pregabalin)
 - At least 1 antidepressant
- Patient has tried and failed an adequate trial[^] of phototherapy (unless documented by prescriber phototherapy not appropriate)
- Patient is NOT currently taking mepolizumab (Nucala), reslizumab (Cinqair), benralizumab (Fasenra), tezepelumab-ekko (Tezspire), omalizumab (Xolair), or tralokinumab (Adbry)

Criteria for new members entering Kaiser Permanente already taking the medication who have not been reviewed previously: Non-formulary dupilumab (Dupixent) will be covered on the prescription drug benefit for 12 months when the following criteria are met:

1. Prescriber is a dermatologist or allergist and patient has a diagnosis of moderate to severe atopic dermatitis

If patient is 6 months of age to 5 years of age (if 6 years of age or older, see separate criteria):

- Patient has tried and failed an adequate trial[^] of, or patient has an allergy or intolerance to the following medications
 - At least 2 medium (Class 5) to super-potent/ultrahigh potency (Class 1) topical corticosteroids
 - At least 1 topical calcineurin inhibitor*
- Patient is NOT currently taking mepolizumab (Nucala), reslizumab (Cinqair), benralizumab (Fasenra), tezepelumab-ekko (Tezspire), omalizumab (Xolair), or tralokinumab (Adbry)

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- Patient is NOT currently on a Janus kinase inhibitor (oral or topical) for atopic dermatitis

If patient is 6 years of age or older:

- Patient has tried and failed, or patient has an allergy or intolerance, to the following medications
 - At least 1 medium (Class 5) to super-potent/ultrahigh potency topical corticosteroid (Class 1)
 - At least 1 topical calcineurin inhibitor*
 - Patient has tried and failed narrowband ultraviolet B (NB-UVB) phototherapy (unless documented by prescriber phototherapy not appropriate)
 - Patient has tried and failed, or patient has an allergy or intolerance, to at least 1 of the following systemic medications (or contraindication to all)
 - Azathioprine
 - Cyclosporine
 - Methotrexate
 - Mycophenolate
 - Patient is NOT currently taking mepolizumab (Nucala), reslizumab (Cinqair), benralizumab (Fasenra), tezepelumab-ekko (Tezspire), omalizumab (Xolair), or tralokinumab (Adbry)
 - Patient is NOT currently on a Janus kinase inhibitor (oral or topical) for atopic dermatitis
2. Prescriber is an allergist or pulmonologist and patient has a diagnosis of moderate to severe asthma
- Patient is at least 6 years of age
 - Dupilumab is used in combination with a high-dose (or maximally tolerated) ICS and at least one additional asthma controller medication, such as a LABA, LRTI, LAMA, or daily OCS
 - Patient is NOT currently taking mepolizumab (Nucala), reslizumab (Cinqair), benralizumab (Fasenra), tezepelumab-ekko (Tezspire), omalizumab (Xolair), or tralokinumab (Adbry)
3. Prescriber is an otolaryngologist and patient has a diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP)
- Patient is at least 18 years of age
 - Patient has had a previous full endoscopic sinus surgery

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- Patient continues to take a nasal corticosteroid concomitantly with dupilumab; unless contraindicated or intolerance to nasal corticosteroids
 - Patient is NOT currently taking mepolizumab (Nucala), reslizumab (Cinqair), benralizumab (Fasenra), tezepelumab-ekko (Tezspire), omalizumab (Xolair), or tralokinumab (Adbry)
4. Prescriber is a gastroenterologist and patient has a diagnosis of eosinophilic esophagitis
- Patient is at least 12 years old and weights at least 40 kilograms
 - Patient had an inadequate response after an 8-week trial of at least one PPI
 - Patient had an inadequate response after an 8-week trial of at least one swallowed inhaled corticosteroid
 - Patient is NOT currently taking mepolizumab (Nucala), reslizumab (Cinqair), benralizumab (Fasenra), tezepelumab-ekko (Tezspire), omalizumab (Xolair), or tralokinumab (Adbry)
5. Prescriber is a dermatologist and patient has a diagnosis of prurigo nodularis
- Patient is at least 18 years old
 - Patient has tried and failed an adequate trial[^] of, or patient has an allergy or intolerance to the following medications
 - At least 1 high potency (Class 2) or super-potent/ultra-high potency (Class 1) topical corticosteroid
 - At least 1 of the following: Methotrexate, cyclosporine, or azathioprine
 - At least 1 gabapentinoid (gabapentin or pregabalin)
 - At least 1 antidepressant
 - Patient has tried and failed an adequate trial[^] of phototherapy (unless documented by prescriber phototherapy not appropriate)
 - Patient is NOT currently taking mepolizumab (Nucala), reslizumab (Cinqair), benralizumab (Fasenra), tezepelumab-ekko (Tezspire), omalizumab (Xolair), or tralokinumab (Adbry)

Continued use criteria for patients previously approved per the above criteria who are currently stable on the medication: Non-formulary **dupilumab (Dupixent)** will continue to be covered on the prescription drug benefit for 12 months when the following criteria are met:

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Dupilumab (Dupixent)

1. Prescriber is a dermatologist or allergist and patient has a diagnosis of moderate to severe atopic dermatitis
 - Patient has responded to dupilumab treatment as determined by prescriber
 - Patient is NOT currently taking mepolizumab (Nucala), reslizumab (Cinqair), benralizumab (Fasenra), tezepelumab-ekko (Tezspire), omalizumab (Xolair), or tralokinumab (Adbry)
2. Prescriber is an allergist or pulmonologist and patient has a diagnosis of moderate to severe asthma
 - The patient has shown a clinical response to dupilumab as evidenced by 1 of the following:
 - Reduction in asthma exacerbation from baseline
 - Decreased utilization of rescue medications
 - Increase in percent predicted FEV1 from pretreatment baseline
 - Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing, etc.)
 - Patient is currently using dupilumab with an at least 1 additional asthma controller medication, such as an: inhaled corticosteroid (ICS), or long-acting beta2 agonist (LABA); or leukotriene receptor antagonist (LRTI [e.g., montelukast]); or long-acting muscarinic antagonist (e.g., tiotropium); or daily OCS.
 - Patient is NOT currently taking mepolizumab (Nucala), reslizumab (Cinqair), benralizumab (Fasenra), tezepelumab-ekko (Tezspire), omalizumab (Xolair), or tralokinumab (Adbry)
3. Prescriber is an otolaryngologist and patient has a diagnosis of chronic rhinosinusitis with nasal polyposis (CRS_{NP})
 - The patient has responded to dupilumab treatment as determined by prescriber (e.g., improvement in nasal congestion, improvement in sense of smell, reduction in size of polyps)
 - Patient is currently using dupilumab with a nasal corticosteroid; unless history of contraindication or intolerance to nasal corticosteroids.
 - Patient is NOT currently taking mepolizumab (Nucala), reslizumab (Cinqair), benralizumab (Fasenra), tezepelumab-ekko (Tezspire), omalizumab (Xolair), or tralokinumab (Adbry)
4. Prescriber is a gastroenterologist and patient has a diagnosis of eosinophilic esophagitis

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Dupilumab (Dupixent)

- Patient has responded to dupilumab treatment as determined by prescriber
 - Patient is NOT currently taking mepolizumab (Nucala), reslizumab (Cinqair), benralizumab (Fasenra), tezepelumab-ekko (Tezspire), omalizumab (Xolair), or tralokinumab (Adbry)
5. Prescriber is a dermatologist and patient has a diagnosis of prurigo nodularis
- Patient has responded to dupilumab treatment as determined by prescriber
 - Patient is NOT currently taking mepolizumab (Nucala), reslizumab (Cinqair), benralizumab (Fasenra), tezepelumab-ekko (Tezspire), omalizumab (Xolair), or tralokinumab (Adbry)

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