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
  - Second generation H1 antihistamine – 2 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), tralokinumab-ldrm (Adbry), nemolizumab-ilto (Nemluvio), or lebrikizumab-lbkz (Ebglyss)

- 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 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), tralokinumab-ldrm (Adbry), nemolizumab-ilto (Nemluvio), or lebrikizumab-lbkz (Ebglyss)
- 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
- Either steroid dependent asthma or eosinophilic asthma defined as:
  - Patient uses oral corticosteroids (OCS) daily to control asthma; **-OR-**
  - Patient has an eosinophilic asthma defined as a peripheral blood eosinophil count of at least 300 cells/microliter (0.3 x10^9/L) in the past 12 months.
- 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
- 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), tralokinumab-ldrm (Adbry), nemolizumab-ilto (Nemluvio), or lebrikizumab-lbkz (Ebglyss)

3. Prescriber is an otolaryngologist and patient has a diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP)

- Patient is at least 12 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), tralokinumab-ldrm (Adbry), nemolizumab-ilto (Nemluvio), or lebrikizumab-lbkz (Ebglyss)

4. Prescriber is a gastroenterologist and patient has a diagnosis of eosinophilic esophagitis

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- Patient is at least 1 year old and weighs at least 15 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***
- Patient is NOT currently taking mepolizumab (Nucala), reslizumab (Cinqair), benralizumab (Fasenra), tezepelumab-ekko (Tezspire), omalizumab (Xolair), tralokinumab-ldrm (Adbry), nemolizumab-ilto (Nemluvio), or lebrikizumab-lbkz (Ebglyss)

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), tralokinumab-ldrm (Adbry), nemolizumab-ilto (Nemluvio), or lebrikizumab-lbkz (Ebglyss)

6. Prescriber is a pulmonologist and patient has a diagnosis of chronic obstructive pulmonary disorder (COPD)

- Patient has an eosinophilic phenotype defined as an eosinophil count of at least 300 cells/microliter (0.3×10^9/L) in the past 12 months.
- Receiving maximal COPD drug therapy with either of the following for at least 3 months:
  - Triple inhaler therapy (inhaled corticosteroid [ICS] + long-acting beta-agonist [LABA] + long-acting muscarinic antagonist [LAMA])
  - Dual inhaler therapy (LABA + LAMA) if ICS use is not tolerated or contraindicated
- Patient has had two or more moderate, or one or more severe (requires hospitalization) exacerbations within the last year despite maximal COPD drug treatment.

- Patient does not smoke or vape (tobacco, cannabis) based on prescriber determination.
- Patient is NOT currently taking mepolizumab (Nucala), reslizumab (Cinqair), benralizumab (Fasenra), tezepelumab-ekko (Tezspire), omalizumab (Xolair), tralokinumab-ldrm (Adbry), nemolizumab-ilto (Nemluvio), or lebrikizumab-lbkz (Ebglyss)

7. Prescriber is an allergist and patient has a diagnosis of chronic spontaneous urticaria (CSU)

- Patient is at least 12 years of age
- Patient has tried and failed an adequate trial^ of, or patient has an allergy, intolerance, or contraindication to a second generation H1 antihistamine taken at a dose fourfold higher than the standard dose (e.g. fexofenadine, loratadine, cetirizine)
- Patient has had prior use of omalizumab (criteria based) for CSU
- Patient is NOT currently taking mepolizumab (Nucala), reslizumab (Cinqair), benralizumab (Fasenra), tezepelumab-ekko (Tezspire), omalizumab (Xolair), tralokinumab-ldrm (Adbry), nemolizumab-ilto (Nemluvio), or lebrikizumab-lbkz (Ebglyss)

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 OR documentation from dermatologist that these medications are not appropriate based on patient's disease severity
  - 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),

tralokinumab-ldrm (Adbry), nemolizumab-ilto (Nemluvio), or lebrikizumab-lbkz (Ebglyss)
- 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 OR documentation from dermatologist that these medications are not appropriate based on patient's disease severity
  - 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) OR documentation from dermatologist that these medications are not appropriate based on patient's disease severity
  - Azathioprine
  - Cyclosporine
  - Methotrexate
  - Mycophenolate
- Patient is NOT currently taking mepolizumab (Nucala), reslizumab (Cinqair), benralizumab (Fasenra), tezepelumab-ekko (Tezspire), omalizumab (Xolair), tralokinumab-ldrm (Adbry), nemolizumab-ilto (Nemluvio), or lebrikizumab-lbkz (Ebglyss)
- 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),

tralokinumab-ldrm (Adbry), nemolizumab-ilto (Nemluvio), or lebrikizumab-lbkz (Ebglyss)

3. Prescriber is an otolaryngologist and patient has a diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP)

- Patient is at least 12 years of age
- Patient has had a previous full endoscopic sinus surgery
- 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), tralokinumab-ldrm (Adbry), nemolizumab-ilto (Nemluvio), or lebrikizumab-lbkz (Ebglyss)

4. Prescriber is a gastroenterologist and patient has a diagnosis of eosinophilic esophagitis

- Patient is at least 1 year old and weights at least 15 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), tralokinumab-ldrm (Adbry), nemolizumab-ilto (Nemluvio), or lebrikizumab-lbkz (Ebglyss)

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)

Dupilumab (Dupixent)

- Patient is NOT currently taking mepolizumab (Nucala), reslizumab (Cinqair), benralizumab (Fasenra), tezepelumab-ekko (Tezspire), omalizumab (Xolair), tralokinumab-ldrm (Adbry), nemolizumab-ilto (Nemluvio), or lebrikizumab-lbkz (Ebglyss)

6. Prescriber is a pulmonologist and patient has a diagnosis of chronic obstructive pulmonary disorder (COPD)

- Receiving COPD drug therapy with either of the following:
  - Triple inhaler therapy (inhaled corticosteroid [ICS] + long-acting beta-agonist [LABA] + long-acting muscarinic antagonist [LAMA])
  - Dual inhaler therapy (LABA + LAMA) if ICS use is not tolerated contraindicated
- Patient has had two or more moderate, or one or more severe (requires hospitalization) exacerbations within the last year despite maximal COPD drug treatment.
- Patient reports they do not smoke or vape (tobacco, cannabis).
- Patient is NOT currently taking mepolizumab (Nucala), reslizumab (Cinqair), benralizumab (Fasenra), tezepelumab-ekko (Tezspire), omalizumab (Xolair), tralokinumab-ldrm (Adbry), nemolizumab-ilto (Nemluvio), or lebrikizumab-lbkz (Ebglyss)

7. Prescriber is an allergist and patient has a diagnosis of chronic spontaneous urticaria (CSU)

- Patient is at least 12 years of age
- Patient has tried and failed an adequate trial^ of, or patient has an allergy, intolerance, or contraindication to a second generation H1 antihistamine taken at a dose fourfold higher than the standard dose (e.g. fexofenadine, loratadine, cetirizine)
- Patient has had prior use of omalizumab (criteria based) for CSU
- Patient is NOT currently taking mepolizumab (Nucala), reslizumab (Cinqair), benralizumab (Fasenra), tezepelumab-ekko (Tezspire), omalizumab (Xolair), tralokinumab-ldrm (Adbry), nemolizumab-ilto (Nemluvio), or lebrikizumab-lbkz (Ebglyss)

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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CRITERIA FOR DRUG COVERAGE
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), tralokinumab-ldrm (Adbry), nemolizumab-ilto (Nemluvio), or lebrikizumab-lbkz (Ebglyss)

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), tralokinumab-ldrm (Adbry), nemolizumab-ilto (Nemluvio), or lebrikizumab-lbkz (Ebglyss)

3. Prescriber is an otolaryngologist and patient has a diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP)
- 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), tralokinumab-ldrm (Adbry), nemolizumab-ilto (Nemluvio), or lebrikizumab-lbkz (Ebglyss)

4. Prescriber is a gastroenterologist and patient has a diagnosis of eosinophilic esophagitis
- 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), tralokinumab-ldrm (Adbry), nemolizumab-ilto (Nemluvio), or lebrikizumab-lbkz (Ebglyss)

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), tralokinumab-ldrm (Adbry), nemolizumab-ilto (Nemluvio), or lebrikizumab-lbkz (Ebglyss)

6. Prescriber is a pulmonologist and patient has a diagnosis of chronic obstructive pulmonary disorder (COPD)
- The patient has shown a clinical response to dupilumab as evidenced by at least 1 of the following:
  - Reduction in COPD exacerbations from baseline
  - patient has a reduction in severity or frequency of COPD-related symptoms (e.g., wheezing, shortness of breath, coughing, sputum production, etc.)
  - Patient has an increase in FEV1 from baseline.
- Patient is NOT currently using mepolizumab (Nucala), reslizumab (Cinqair), benralizumab (Fasenra), tezepelumab-ekko (Tezspire), omalizumab (Xolair), tralokinumab-ldrm (Adbry), nemolizumab-ilto (Nemluvio), or lebrikizumab-lbkz (Ebglyss)

7. Prescriber is an allergist and patient has a diagnosis of chronic spontaneous urticaria (CSU)
- Patient has responded to dupilumab treatment as determined by prescriber (e.g. decreased severity of itching, decreased number and/or size of hives)
- Patient is NOT currently using mepolizumab (Nucala), reslizumab (Cinqair), benralizumab (Fasenra), tezepelumab-ekko (Tezspire), omalizumab (Xolair), tralokinumab-ldrm (Adbry), nemolizumab-ilto (Nemluvio), or lebrikizumab-lbkz (Ebglyss)