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

Criteria-Based Consultation Prescribing Program
CRITERIA FOR DRUG COVERAGE
Dupilumab (Dupixent)

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

Criteria-Based Consultation Prescribing Program
CRITERIA FOR DRUG COVERAGE
Dupilumab (Dupixent)

- 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 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), 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)

Criteria-Based Consultation Prescribing Program
CRITERIA FOR DRUG COVERAGE
Dupilumab (Dupixent)

- 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

- 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 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), 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)

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:

Criteria-Based Consultation Prescribing Program
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), 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 (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), or tralokinumab (Adbry)

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

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)