Initial Approval Date: July 10, 2019

CRITERIA FOR PRIOR AUTHORIZATION

Asthma 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 table 1 below.

Benralizumab (Fasenra™)
Dupilumab (Dupixent®)
Mepolizumab (Nucala®)
Omalizumab (Xolair®)
Reslizumab (Cinqair®)

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 Table 1.
- Must be prescribed by or in consultation with a pulmonologist, allergist, or immunologist.[1,2]
- For all agents listed, the preferred PDL drug, which treats the PA indication, is required unless the patient meets the non-preferred PDL PA criteria.
- Must have experienced ≥ 2 exacerbations within the last 12 months despite meeting all of the following:
  - Exacerbation is defined as requiring the use of any of the following:
    - Oral/systemic corticosteroids.
    - Urgent care or hospital admission.
    - Intubation.
  - Patient must be taking two long-term controller medications, including a high-dose inhaled corticosteroid (ICS) and a long-acting beta$_2$-agonist (LABA) listed in Table 2.[1,2]
    - Combination ICS/LABA products are considered as two controller medications. Patient must be 80% adherent on all long-term controller medications.
  - Patient must have had an adequate trial (at least 90 consecutive days within the past 120 days) of or contraindication to a leukotriene modifier as a third long-term controller medication listed in Table 2.
- Prescriber has submitted the patient's baseline FEV_1 value.
- For benralizumab, mepolizumab, and reslizumab: patient must have a confirmed eosinophilic phenotype, defined by blood eosinophils of greater than or equal to 150 cells/mcL at baseline.[3,4,5]
- For omalizumab, the patient must have a positive skin test or in vitro reactivity to a perennial aeroallergen.[7]
- For dupilumab: patient must have one of the following:
  - A confirmed eosinophilic phenotype, defined as blood eosinophils of greater than or equal to 150 cells/mcL at baseline.[6]
  - Corticosteroid dependent asthma, defined as daily oral corticosteroid (at least 5 mg per day of prednisone/prednisolone or equivalent).[6,8,9]
- For all requested biologics or janus kinase (JAK) inhibitors, patient must not concurrently be on another biologic or JAK inhibitor listed in Table 3. 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.

Table 1. FDA-approved age and dosing limits for Asthma agents

Medication	Indication(s)	Age	Dosing Limits
Interleukin-4 Receptor Antagonists			
Dupilumab (Dupixent®)	Moderate to severe asthma - eosinophilic phenotype Moderate to severe asthma - corticosteroid dependent Moderate to severe asthma with comorbid atopic dermatitis	≥ 12 years	600mg SC initially, then 300mg every other week.
Interleukin-5 Antagonists			
Benralizumab (Fasenra™)	Severe Asthma	≥ 12 years	30 mg SC every 4 weeks for the first 3 doses, and then every 8 weeks.
Mepolizumab (Nucala®)	Severe Asthma	≥ 12 years	100 mg SC every 4 weeks.
Reslizumab (Cinqair®)	Severe Asthma	≥ 18 years	3 mg/kg IV once every 4 weeks.
IgG monoclonal antibodies (IgE Inhibitors)			
Omalizumab (Xolair®)	Moderate to Severe Asthma	≥ 6 years	375mg SC every 2 weeks (dosing is based on weight and pretreatment IgE level).

SC: subcutaneous. IV: intravenous.

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

- Patient demonstrates at least one of the following:
  - A decrease in frequency of exacerbations from baseline (defined as a reduction of oral/systemic corticosteroids of at least 50% and/or asthma-related hospitalization and/or asthma-related emergency department visits).
  - Improved lung function, defined as an FEV_1 increase of at least 100mL over baseline.
- Must not exceed dosing limits listed in Table 1.
- For all requested biologics or janus kinase (JAK) inhibitors, patient must not concurrently be on another biologic or JAK inhibitor listed in Table 3. 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): 6 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 2. List of conventional therapy in the treatment of asthma

Inhaled Corticosteroids (ICS)	Long-Acting Beta-Agonists (LABA)	ICS/LABA Combination	Leukotriene Modifiers
Beclomethasone (Qvar)	Salmeterol (Serevent)	Fluticasone/Salmeterol (Advair, AirDuo)	Singulair® (montelukast)
Budesonide (Pulmicort)	Formoterol (Perforomist)	Budesonide/Formoterol (Symbicort)	Accolate® (zafirlukast)
Ciclesonide (Alvesco)		Mometasone/Formoterol (Dulera)	Zyflo® (zileuton)
Flunisolide (Aerospan)		Fluticasone/Vilanterol (Breo Ellipta)	
Fluticasone (Flovent, Armonair, Arnuity)			
Mometasone (Asmanex)			

Table 3. List of biologic agents/janus kinase inhibitors (agents not to be used concurrently)

Biologic Agents/Janus Kinase Inhibitors		
Actemra® (tocilizumab)	Humira® (adalimumab)	Rituxan® (rituximab)
Amevive® (alefacept)	Hyrimoz™ (adalimumab-adaz)	Siliq® (brodalumab)
Amjevita™ (adalimumab-atto)	Ilaris® (canakinumab)	Simponi® (golimumab)
Cimzia® (certolizumab)	Ilumya™ (tildrakizumab-asmn)	Simponi Aria (golimumab)
Cinqair® (reslizumab)	Inflectra® (infliximab-dyyb)	Skyrizi™ (Risankizumab)
Cosentyx® (secukinumab)	Ixifi™ (infliximab-qbtx)	Stelara® (ustekinumab)
Cyltezo™ (adalimumab-adbm)	Kevzara® (sarilumab)	Taltz® (ixekizumab)
Dupixent® (benralizumab)	Kineret® (anakinra)	Tremfya® (guselkumab)
Enbrel® (etanercept)	Nucala® (mepolizumab)	Tysabri® (natalizumab)
Entyvio® (vedolizumab)	Olumiant® (baricitinib)	Xeljanz® (tofacitinib)
Erelzi™ (etanercept-szzs)	Orencia® (abatacept)	Xeljanz XR® (tofacitinib)
Eticovo® (etanercept-ykro)	Remicade® (infliximab)	Xolair® (omalizumab)
Fasenra™ (benralizumab)	Renflexis® (infliximab-abda)	

References

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2. Global Initiative for Asthma. Pocket Guide for Asthma Management and Prevention (for Adults and Children Older than 5 Years). A Pocket Guide for Health Professionals 2019. Fontana, WI, USA. Available from www.ginasthma.org, accessed 5/22/19.
3. NUCALA (mepolizumab) [package insert]. Philadelphia, PA: GlaxoSmithKline, LLC; Dec 2017.
4. CINQAIR (reslizumab) [package insert]. Frazer, PA: Teva Respiratory, LLC; Jan 2019.
5. Fasenra (benralizumab) [package insert]. Sodertalje, Sweden: AstraZeneca AB; Nov 2017.
6. Dupixent (dupilumab) [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc., Sanofi-Aventis US, LLC; Mar 2019.

7. Xolair (omalizumab) [package insert]. South San Francisco, CA: Genentech, Inc.; May 2019.
8. Efficacy and Safety of Dupilumab in Glucocorticoid-Dependent Severe Asthma. N Engl J Med. 2018 Jun 28;378(26):2475-2485. doi: 10.1056/NEJMoa1804093. Epub 2018 May 21.
9. ClinicalTrials.gov [Internet]. Identifier: NCT02528214, Evaluation of Dupilumab in Patients with Severe Steroid Dependent Asthma (VENTURE). https://clinicaltrials.gov/ct2/show/NCT02528214. Accessed July 2019.

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