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206-988-2000
206-988-2001
prnotification@kp.org

Kaiser Foundation Health Plan of Washington
Kaiser Foundation Health Plan of Washington Options, Inc.
CONTRACT MANAGER NAME
Provider Communications, RCB-C2W-02
PO Box 34262, Seattle WA 98124-1262

NOVEMBER 30, 2020

SITE OF CARE PRIOR AUTHORIZATION REQUIREMENT FOR NUCALA (MEPOLIZUMAB), NULOJIX (BELATACEPT), FASENRA (BENRALIZUMAB), XOLAIR (OMALIZUMAB)

Dear Provider,

Effective February 1, 2021, Site of Care prior authorization criteria will apply to the medication noted in the Drug Tables below. Site of Care is a prior authorization for the location at which an infused medication is administered under the medical benefit. When Site of Care is applied to a medication, the following site of care types are acceptable: an **outpatient standalone clinic, infusion center, provider's office, or home infusion**. Outpatient hospital-based infusion sites are not approved sites. This letter is notification that prior authorization approval is required before administering this medication under the medical benefit.

This only applies to Kaiser Foundation Health Plan of Washington Health Maintenance Organization (HMO) members and Kaiser Foundation Health Plan of Washington Options, Inc. Point of Service (POS) and Preferred Provider Organization (PPO) members who are ≥ 13 years old. **This change will NOT affect Medicare Advantage members.**

The following injectable drug will be added to the list of drugs requiring prior authorization for Site of Care:

NUCALA (MEPOLIZUMAB)

Drug Table 1. Additional Drugs Requiring Site of Care Prior Authorization

Therapy Class/Indication	Name	Generic Name	HCPCS
Asthma biologics	NUCALA	mepolizumab	J2182

Prior authorization clinical criteria were previously established for Nucala (mepolizumab) J2182. Members who are initiating treatment with Nucala (mepolizumab) will require a prior authorization review based upon the clinical criteria **and** the Site of Care.

Prior authorization clinical criteria for Nucala (mepolizumab):

For patients with severe eosinophilic asthma who meet the following criteria:

- Prescribed by an Allergist or Pulmonologist
- Patient is at least 6 years of age
- Failure, contraindication, or intolerance to benralizumab (applicable to patients 12 years old or greater)
- Documented severe persistent asthma
- Reversible airway obstruction as documented by the following:
  - Response to inhaled short-acting beta agonists (e.g., FEV_1 reversibility of >12% with at least a 200 mL increase in FEV1) within 30 minutes after administration of albuterol (90-180 mcg) OR
  - Positive exercise or methacholine challenge OR
  - Positive response (at least a 15% increase in FEV_1 with at least a 200 mL increase in FEV_1) after a course of treatment with inhaled or systemic corticosteroids

- Documentation of eosinophilic phenotype indicated by one of the following:
  - Non-oral corticosteroid (OCS) dependent: serum eosinophil count of ≥300 cells/mcL within the past 12 months
  - OCS dependent: serum eosinophil count of ≥ 150 cells/mcL within the previous 12 months.
- Patient has uncontrolled asthma (see **Table 1**) despite all the following:
  - Trigger avoidance measures
  - Comorbidities that can cause asthma exacerbations (e.g., gastroesophageal reflux disease [GERD], allergic rhinitis) and non-asthma diagnoses (e.g., laryngeal dysfunction, panic disorder) have been evaluated and treated
  - Aggressive drug therapy regimen for at least 6 months (see **Table 2**)

Exclusion criteria: If ONE or more of the following criteria is met, patient is NOT eligible:
- Current smoker who is not currently enrolled in a smoking cessation program (e.g., Quit for Life)
- Nonadherence to pre-requisite asthma drug therapies
  - Nonadherence is defined as less than 75% of proportion of days covered (calculated by day supply dispensed over the total number of days since treatment was initiated)
- Concomitant use with omalizumab, benralizumab, reslizumab, or dupilumab

Evaluation for continuation of therapy:
- Evaluate response 6 months and then annually thereafter
- Clinical improvement must be demonstrated by at least one of the following:
  - Decreased use of rescue medications
  - Decreased frequency of exacerbations (defined as worsening of asthma that requires increase in ICS dose or treatment with systemic corticosteroids)
  - Improvement in lung function (e.g., FEV1) from pretreatment baseline
  - Objective improvement in quality of life: minimally important difference of 3 points on the Asthma Control Test
  - Improvement in asthma symptoms (such as asthmatic symptoms upon wakening, coughing, fatigue, shortness of breath, sleep disturbance, wheezing, or reduced missed days from work or school)
  - Decreased corticosteroid requirement if on OCS

Table 1: Evidence for severe refractory asthma and indicators of uncontrolled asthma

Evidence for severe refractory asthma
• Asthma meets criteria for moderate-to-severe asthma as defined by the NHLBI's EPR-3 and the patient has uncontrolled asthma which should be noted both subjectively and with objective evidence of asthma, despite the following: o Ruling out comorbid factors (e.g., allergy, sinusitis, GERD, anxiety disorder, panic disorder, vocal cord dysfunction) to determine if these measures can decrease the need to initiate biologic therapy o Address and manage all triggers from the home (e.g., animal dander if allergic, dust mites, foods, pollen, smoke exposure) o Aggressive trials of therapy (refer to Table 2)
Indicators of uncontrolled asthma
• Any one of the following criteria qualifies the patient as having uncontrolled asthma: o Two or more asthma exacerbations requiring systemic corticosteroids (≥3 days each) in the past 12 months o Serious exacerbations: at least one hospitalization, intensive care unit (ICU) stay or mechanical ventilation in the previous year o Asthma Control Test (ACT) is consistently <20

Table 2: Aggressive drug therapy regimens for asthma

Patients 12 years and older
A. Triple drug therapy with high-dose ICS plus LABA combination* plus tiotropium (Spiriva Respimat) (unless contraindications or intolerance) and on oral corticosteroid (OCS) for most days during the previous 6 months (e.g., ≥50% of

days)
OR

B. Triple drug therapy with high-dose ICS plus LABA combination* plus tiotropium (Spiriva Respimat) (unless contraindications or intolerance) who are not on daily OCS, but who otherwise meet other inclusion criteria and have had frequent severe exacerbations (≥2) in the past 12 months requiring systemic corticosteroids for ≥3 days and/or a history of a serious exacerbation requiring at least one hospitalization, ICU stay, or mechanical ventilation in the previous year
OR

C. Corticosteroid adverse effects: If a patient has been poorly controlled over at least one year and is experiencing corticosteroid adverse effects while on aggressive drug therapy (A or B), then treatment with a biologic drug may be considered.

**High-dose ICS plus LABA combinations include fluticasone/salmeterol 500/50 mcg, 1 inh twice daily or fluticasone salmeterol 230/21 mcg, 2 puffs twice daily*

Children 6 to 11 years of age

A. High-dose ICS** plus LABA combination plus montelukast
OR

B. Children on high-dose** ICS plus LABA combination who have had a prior trial of a leukotriene modifier may also be considered.

**High-dose ICS includes ciclesonide 160 mcg, 1 puff twice daily*

For patients with eosinophilic granulomatosis with polyangiitis (EGPA) who meet the following criteria:

- Prescribing by an Allergist, Pulmonologist, or Rheumatologist
- Patient is at least 18 years of age
- Documented severe disease (e.g., vasculitis with cerebral, cardiac, renal, or gastrointestinal involvement) or disease flares with tapering of corticosteroid therapy
- Documented trial and failure of, contraindication to, or clinical inappropriateness of treatment with at least one of the following immunosuppressants: azathioprine, cyclophosphamide, or methotrexate

Exclusion criteria**:** If ONE or more of the following criteria is met, patient is NOT eligible:

- Severe or clinically significant cardiovascular disease uncontrolled with standard treatment
- Patients with known evidence of lack of adherence to controller medications and/or ability to follow providers recommendations

Evaluation for Continuation of Therapy:

- Evaluate response after 6 months and then annually thereafter
- Consider discontinuation if there is not a significant decrease in utilization of systemic corticosteroids.

NULOJIX (BELATACEPT)

Drug Table 2. Additional Drugs Requiring Site of Care Prior Authorization

Therapy Class/Indication	Name	Generic Name	HCPCS
Prophylaxis of organ rejection; 5 exception doses; applies to kidney only	NULOJIX	belatacept	J0485

Prior authorization clinical criteria were previously established for Nulojix (belatacept) J0485. Members who are initiating treatment with Nulojix (belatacept) will require a prior authorization review based upon the clinical criteria **and** the Site of Care.

Prior authorization clinical criteria for Nulojix (belatacept):

Covered for patients who are post-renal transplant, Epstein-Barr Virus (EBV) seropositive

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FASENRA (BENRALIZUMAB)

Drug Table 3. Additional Drugs Requiring Site of Care Prior Authorization

Therapy Class/Indication	Name	Generic Name	HCPCS
Asthma biologics	FASENRA	benralizumab	J0517

Prior authorization clinical criteria were previously established for Fasenra (benralizumab) J0517. Members who are initiating treatment with Fasenra (benralizumab) will require a prior authorization review based upon the clinical criteria **and** the Site of Care.

Prior authorization clinical criteria for Fasenra (benralizumab):

Covered for patients with severe eosinophilic asthma who meet the following criteria:

- Prescribed by an Allergist or Pulmonologist
- Patient is at least 12 years of age
- Documented severe persistent asthma
- Reversible airway obstruction as documented by the following:
    - Response to inhaled short-acting beta agonists (e.g., FEV_1 reversibility of >12% with at least a 200 mL increase in FEV_1) within 30 minutes after administration of albuterol (90-180 mcg) OR
    - Positive exercise or methacholine challenge OR
    - Positive response (at least a 15% increase in FEV_1 with at least a 200 mL increase in FEV_1) after a course of treatment with inhaled or systemic corticosteroids
- Documentation of eosinophilic phenotype indicated by one of the following:
    - Non-oral corticosteroid (OCS) dependent: serum eosinophil count of ≥300 cells/mcL within the past 12 months
    - OCS dependent: serum eosinophil count of ≥ 150 cells/mcL within the previous 12 months
- Patient has uncontrolled asthma (see Table 1) despite all the following:
    - Trigger avoidance measures
    - Comorbidities that can cause asthma exacerbations (e.g., gastroesophageal reflux disease [GERD], allergic rhinitis) and non-asthma diagnoses (e.g., laryngeal dysfunction, panic disorder) have been evaluated and treated
    - Aggressive drug therapy regimen for at least 6 months (see Table 2)

Exclusion criteria: If ONE or more of the following criteria is met, patient is NOT eligible:

- Current smoker who is not currently enrolled in a smoking cessation program (e.g., Quit for Life)
- Nonadherence to pre-requisite asthma drug therapies
    - Nonadherence is defined as less than 75% of proportion of days covered (calculated by day supply dispensed over the total number of days since treatment was initiated)
- Concomitant use with omalizumab, mepolizumab, reslizumab, or dupilumab

Evaluation for Continuation of Therapy:

- Evaluate response after 6 months and then annually thereafter
- Clinical improvement must be demonstrated by at least one of the following:
    - Decreased use of rescue medications
    - Decreased frequency of exacerbations (defined as worsening of asthma that requires increase in ICS dose or treatment with systemic corticosteroids)
    - Improvement in lung function (e.g., FEV1) from pretreatment baseline
    - Objective improvement in quality of life: minimally important difference of 3 points on the Asthma Control Test
    - Improvement in asthma symptoms (such as asthmatic symptoms upon wakening, coughing, fatigue, shortness of breath, sleep disturbance, wheezing, or reduced missed days from work or school)
    - Decreased corticosteroid requirement if on OCS

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Evidence for severe refractory asthma
• Asthma meets criteria for moderate-to-severe asthma as defined by the NHLBI's EPR-3 and the patient has uncontrolled asthma which should be noted both subjectively and with objective evidence of asthma, despite the following: o Ruling out comorbid factors (e.g., allergy, sinusitis, GERD, anxiety disorder, panic disorder, vocal cord dysfunction) to determine if these measures can decrease the need to initiate biologic therapy o Address and manage all triggers from the home (e.g., animal dander if allergic, dust mites, foods, pollen, smoke exposure). o Aggressive trials of therapy (refer to Table 2)
Indicators of uncontrolled asthma
• Any one of the following criteria qualifies the patient as having uncontrolled asthma: o Two or more asthma exacerbations requiring systemic corticosteroids (≥3 days each) in the past 12 months o Serious exacerbations: at least one hospitalization, intensive care unit (ICU) stay or mechanical ventilation in the previous year o Asthma Control Test (ACT) is consistently <20

Table 2: Aggressive drug therapy regimens for asthma

A. Triple drug therapy with high-dose ICS plus LABA combination* plus tiotropium (Spiriva Respimat) (unless contraindications or intolerance) and on oral corticosteroid (OCS) for most days during the previous 6 months (e.g., ≥50% of days)

OR

B. Triple drug therapy with high-dose ICS plus LABA combination* plus tiotropium (Spiriva Respimat) (unless contraindications or intolerance) who are not on daily OCS, but who otherwise meet other inclusion criteria and have had frequent severe exacerbations (≥2) in the past 12 months requiring systemic corticosteroids for ≥3 days and/or a history of a serious exacerbation requiring at least one hospitalization, ICU stay, or mechanical ventilation in the previous year

OR

C. Corticosteroid adverse effects: If a patient has been poorly controlled over at least one year and is experiencing corticosteroid adverse effects while on aggressive drug therapy (A or B) then treatment with a biologic drug may be considered.

**High-dose ICS plus LABA combinations include fluticasone/salmeterol 500/50 mcg, 1 inh twice daily or fluticasone salmeterol 230/21 mcg, 2 puffs twice daily*

XOLAIR (OMALIZUMAB)

Drug Table 4. Additional Drugs Requiring Site of Care Prior Authorization

Therapy Class/Indication	Name	Generic Name	HCPCS
Asthma biologics	XOLAIR	omalizumab	J2357

Prior authorization clinical criteria were previously established for Xolair (omalizumab) J2357. Members who are initiating treatment with Xolair (omalizumab) will require a prior authorization review based upon the clinical criteria **and** the Site of Care.

Prior authorization clinical criteria for Xolair (omalizumab):

Covered for patients with moderate-to-severe persistent allergic asthma who meet the following criteria:

- Prescribing physician is an Allergist or Pulmonologist
- Patient age 6 years or older
- Documented moderate-to-severe persistent asthma
- Documented atopic asthma by the following methods
  - Specific IgE by skin PRICK test OR CAP “RAST” AND
  - Determination of atopic status by an Allergist
- Documented baseline total IgE serum level between 30 and 700 international units/mL for patients ≥ 12 years OR between 30 and 1300 international units/mL for children 6 to 11 years AND total serum IgE and weight are within dosage range
- Reversible airway obstruction as documented by the following
  - Response to inhaled short-acting beta agonists (e.g., FEV_1 reversibility of >12% with at least a 200 mL increase in FEV_1) within 30 minutes after administration of albuterol (90-180 mcg) OR
  - Positive exercise or methacholine challenge OR
  - Positive response (at least a 15% increase in FEV_1 with at least a 200 mL increase in FEV_1) after a course of treatment with inhaled or systemic corticosteroids
- Patient has uncontrolled asthma (see Table 1 below) despite all the following:
  - Trigger avoidance measures

- Comorbidities that can cause asthma exacerbations (e.g., gastroesophageal reflux disease [GERD], allergic rhinitis) and non-asthma diagnoses (e.g., laryngeal dysfunction, panic disorder) have been evaluated and treated
- Aggressive drug therapy regimen for at least 6 months (see Table 2)

Exclusion criteria: If ONE or more of the following criteria is met, patient is NOT eligible:

- Current smoker who is not currently enrolled in a smoking cessation program (e.g., Quit for Life)
- Nonadherence to pre-requisite asthma drug therapies
  - Nonadherence is defined as less than 75% of proportion of days covered (calculated by day supply dispensed over the total number of days since treatment was initiated)
- Concomitant use with mepolizumab, benralizumab, reslizumab, or dupilumab

Evaluation for Continuation of Therapy:

- Evaluate response after 6 months and then annually thereafter.
- Clinical improvement must be demonstrated by at least one of the following:
  - Decreased use of rescue medications
  - Decreased frequency of exacerbations (defined as worsening of asthma that requires increase in ICS dose or treatment with systemic corticosteroids)
  - Improvement in lung function (e.g., FEV1) from pretreatment baseline
  - Objective improvement in quality of life: minimally important difference of 3 points on the Asthma Control Test
  - Improvement in asthma symptoms (such as asthmatic symptoms upon wakening, coughing, fatigue, shortness of breath, sleep disturbance, wheezing, or reduced missed days from work or school)
  - Decreased corticosteroid requirement if on OCS

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Evidence for severe refractory asthma
• Asthma meets criteria for moderate-to-severe asthma as defined by the NHLBI's EPR-3 and the patient has uncontrolled asthma which should be noted both subjectively and with objective evidence of asthma, despite the following: o Ruling out comorbid factors (e.g., allergy, sinusitis, GERD, anxiety disorder, panic disorder, vocal cord dysfunction) to determine if these measures can decrease the need to initiate biologic therapy o Address and manage all triggers from the home (e.g., animal dander if allergic, dust mites, foods, pollen, smoke exposure) o Aggressive trials of therapy (refer to Table 2)
Indicators of uncontrolled asthma
• Any one of the following criteria qualifies the patient as having uncontrolled asthma: o Two or more asthma exacerbations requiring systemic corticosteroids (≥3 days each) in the past 12 months o Serious exacerbations: at least one hospitalization, intensive care unit (ICU) stay or mechanical ventilation in the previous year

- Asthma Control Test (ACT) is consistently <20

Table 2: Aggressive drug therapy regimens for asthma

Patients 12 years and older
D. Triple drug therapy with high-dose ICS plus LABA combination* plus tiotropium (Spiriva Respimat) (unless contraindications or intolerance) and on oral corticosteroid (OCS) for most days during the previous 6 months (e.g., ≥50% of days) **OR** **E.** Triple drug therapy with high-dose ICS plus LABA combination* plus tiotropium (Spiriva Respimat) (unless contraindications or intolerance) who are not on daily OCS, but who otherwise meet other inclusion criteria and have had frequent severe exacerbations (≥2) in the past 12 months requiring systemic corticosteroids for ≥3 days and/or a history of a serious exacerbation requiring at least one hospitalization, ICU stay, or mechanical ventilation in the previous year **OR** **F.** Corticosteroid adverse effects: If a patient has been poorly controlled over at least one year and is experiencing corticosteroid adverse effects while on aggressive drug therapy (A or B) then treatment with a biologic drug may be considered. **High-dose ICS plus LABA combinations include fluticasone/salmeterol 500/50 mcg, 1 inh twice daily or fluticasone salmeterol 230/21 mcg, 2 puffs twice daily*
Children 6 to 11 years of age
C. High-dose ICS** plus LABA combination plus montelukast **OR** **D.** Children on high-dose** ICS plus LABA combination who have had a prior trial of a leukotriene modifier may also be considered **High-dose ICS includes ciclesonide 160 mcg, 1 puff twice daily*

Covered for patients with chronic idiopathic urticaria who are:

- 12 years of age or older, and
- with urticaria (hives) on most days of the week for ≥6 weeks, and
- in which no external allergic cause or contributing disease can be identified, and
- when prescribed by or in consultation with an allergist, and
- Have failed, are intolerant to, or have a contraindication to an adequate duration of all of the following:
  - Histamine-1 receptor antagonist at four times the FDA-approved dose, and
  - Leukotriene receptor antagonist (4 weeks minimum)
- Limited to 1 injection (150 mg or 300 mg) every 4 weeks. Initial authorization period: 6 months. Afterwards, annual re-authorization is required.
- Reauthorization requires documentation of continued patient benefit on therapy.

You can request prior authorization using one of the following methods:

- Use the Kaiser Permanente provider website. You can send your request for authorization using our Referral Request tool. Using this method is easy and is the quickest way to obtain your authorization, sometimes immediately if your request is auto approved.
- Fax your request to the Review Services department at 1-888-282-2685.

- Contact Review Services at 1-800-289-1363, Monday – Friday from 8 a.m. to 5 p.m. After business hours, please leave a voice message with your contact information. Messages received after normal business hours are returned on the next business day.

A complete list of office-administered injectable drugs requiring prior authorization can be found on Kaiser Permanente provider website at **https://wa-provider.kaiserpermanente.org** under the header "Authorization & Clinical Review." Site of Care reviews are intended to ensure consistent benefit adjudication as well as appropriate utilization in accordance with the Medical Policy Committee's criteria for coverage.

Site of Care Prior Authorization Criteria Exceptions:

A hospital outpatient setting may be used for infusion of drugs on the site of care optimization list only if **one** of the following is met:

1. Member is medically unstable based upon submitted clinical history. Examples, including, but not limited to, cardiopulmonary conditions that may increase risk of adverse reactions, inability to safely tolerate intravenous volume loads, unstable vascular access requiring ultrasound guidance; or
2. Previous experience of a severe adverse event following infusion. Examples, including, but not limited to, anaphylaxis, seizure, thromboembolism, myocardial infarction, renal failure; or
3. Continuing experience of adverse events that cannot be mitigated (e.g. not mitigated by pre-medications or by reducing the rate of infusion); or
4. Physically and/or cognitively impaired AND no home caregiver available; or
5. The member's home is not eligible for home infusion services (such as home is not within the service area determined by the home infusion provider or is deemed unsuitable for care by the home infusion provider). Clinical notes supporting an exception must be included (e.g., dates of prior anaphylactic experience, specific details of adverse reactions and attempts to mitigate).

Note: For new start members, alternative Site of Care criteria will be waived for payment of the administration of the first dose for all drugs, to allow for adequate transition time to arrange for a non-hospital outpatient setting for the infusion. Further dose exceptions may be applicable depending on the drug (see Table 1) and/or to ensure continuity of care.

Additional Information

Coverage determinations, once completed, will be available online using the Referral Status Inquiry application and will be mailed to the member.

Failure to obtain a prior authorization for the above medications will result in a denial of payment.

Please refer to the provisions of your agreement with Kaiser Permanente, including obtaining the member's prior written agreement to be financially responsible for the specific non-covered service, to determine when providers may bill a member for non-covered services.
If you have any questions about these changes, please contact the Provider Assistance Unit toll-free at 509-241-7206 or toll-free at 1-888-767-4670, Monday – Friday from 8 a.m. to 5 p.m.

Sincerely,

Bruce Wilson, MD, Chair
Pharmacy & Therapeutics Committee