Louisiana Medicaid
Asthma/COPD – Immunomodulators

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical authorization for the asthma immunomodulators.

Additional Point-of-Sale edits may apply.

By submitting the authorization request, the prescriber attests to the conditions available HERE.

Benralizumab (Fasenra® Pen/Syringe)

Approval Criteria for Initiation of Therapy

- ~~The recipient is 12 years of age or older; **AND**~~
- The recipient has a diagnosis of severe asthma with an eosinophilic phenotype (severe allergic asthma); **AND**
- The recipient is 6 years of age or older; **AND**
- For a non-preferred agent, there is no preferred alternative that is the exact same chemical entity, formulation, strength, etc.; **AND**
- For a non-preferred agent, previous use of a preferred product - **ONE** of the following is required:
    - The recipient has had *treatment failure* with at least one preferred product; **OR**
    - The recipient has had an *intolerable side effect* to at least one preferred product; **OR**
    - The recipient has *documented contraindication(s)* to all of the preferred products that are appropriate for the condition being treated; **OR**
    - There is *no preferred product that is appropriate* to use for the condition being treated; **AND**
- Benralizumab is **NOT** being used in combination with other monoclonal antibodies used to treat asthma; **AND**
- ~~Benralizumab~~The prescriber **states on the** request that benralizumab **IS** being used in combination with ~~an inhaled corticosteroid (ICS) plus either a long-acting beta agonist (LABA) **OR** another controller agent (e.g., leukotriene receptor antagonist [LTRA]));~~optimized pharmacotherapy for the treatment of asthma,; **AND**
- The recipient has a peripheral blood eosinophil count of ≥ 150 cells/µL within the previous 6 weeks (prior to treatment with benralizumab) [Date drawn and the results are **stated on the request**.]; **AND**
- The recipient has been compliant ~~with **ONE** of the following regimens~~ for at least 3 consecutive months with optimized pharmacotherapy for the treatment of asthma, which is **stated on the request**~~:~~; **AND**
    - ~~Medium to high dose ICS plus a LABA (this is the preferred regimen); **OR**~~

- ~~High dose ICS plus a LTRA (if the recipient is unable to take a LABA); **OR**~~
- ~~High dose ICS plus theophylline *(if the recipient is unable to take a LABA);* **OR**~~
- ~~Low to medium dose ICS plus tiotropium plus LTRA or theophylline *(if the recipient is unable to take LABA and high dose ICS);* **AND**~~

- Even with compliant use of ~~one of the above controller regimens~~optimized pharmacotherapy for at least 3 consecutive months, the recipient's asthma continues to be uncontrolled as defined by **ONE** of the following which is **stated on the request**:
  - The recipient has had two or more asthma exacerbations which required treatment with systemic corticosteroids in the previous 12 months; **OR**
  - The recipient has had one or more asthma exacerbations requiring hospitalization or an ED visit in the previous 12 months; **OR**
  - The recipient has an FEV1 < 80% predicted; **OR**
  - The recipient has an FEV1/FVC < 0.80; **OR**
  - The recipient's asthma worsens upon tapering of oral corticosteroid therapy; **AND**
- The dose is limited to 30 mg once every 4 weeks for the first 3 doses, followed by 30mg once every 8 weeks thereafter.

Approval Criteria for Continuation of Therapy

- The prescriber **states on the request** that the recipient is established on the medication with evidence of a positive response to therapy.

Duration of approval for initiation and continuation of therapy: 12 months

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Mepolizumab (Nucala®)

Approval Criteria for Initiation of Therapy

- ~~Mepolizumab is **NOT** being used in combination with other monoclonal antibodies used to treat asthma; **AND**~~
- For a non-preferred agent, there is no preferred alternative that is the exact same chemical entity, formulation, strength, etc.; **AND**
- For a non-preferred agent, previous use of a preferred product - **ONE** of the following is required:
  - The recipient has had *treatment failure* with at least one preferred product; **OR**
  - The recipient has had an *intolerable side effect* to at least one preferred product; **OR**
  - The recipient has *documented contraindication(s)* to all of the preferred products that are appropriate for the condition being treated; **OR**

- There is *no preferred product that is appropriate* to use for the condition being treated; **AND**

- Mepolizumab is **NOT** being used in combination with other monoclonal antibodies used to treat asthma;

AND

- The recipient has a diagnosis of severe asthma with an eosinophilic phenotype (severe allergic asthma) and **ALL** of the following:
  - The recipient is 6 years of age or older on the date of the request; **AND**
  - ~~Mepolizumab~~The prescriber **states on the request** that mepolizumab **IS** being used in combination with ~~an inhaled corticosteroid (ICS) plus either a long-acting beta-agonist (LABA) **OR** another controller agent (e.g., leukotriene receptor antagonist [LTRA]);~~optimized pharmacotherapy for the treatment of asthma; **AND**
  - The recipient has:
    - A blood eosinophil count of ≥150 cells/µL within the previous 6 weeks (prior to treatment with mepolizumab) [Date drawn and results are **stated on the request**]; **OR**
    - A blood eosinophil count of ≥300 cells/µL at any time within the previous 12 months (prior to treatment with mepolizumab) [Date drawn and results are **stated on the request**]; **AND**
  - The recipient has been compliant ~~with **ONE** of the following regimens~~ for at least 3 consecutive months ~~prior to the date of the request (medications and dates of use are~~with optimized pharmacotherapy for the treatment of asthma, which is **stated on the request**~~):~~; **AND**
    - ~~Medium to high dose ICS plus an LABA *(this is the preferred regimen);* **OR**~~
    - ~~High dose ICS plus an LTRA *(if the recipient is unable to take an LABA);* **OR**~~
    - ~~High dose ICS plus theophylline *(if the recipient is unable to take an LABA);* **OR**~~
    - ~~Low to medium dose ICS plus tiotropium plus an LTRA or theophylline *(if the recipient is unable to take an LABA and high dose ICS);* **AND**~~
  - Even with compliant use of ~~one of the above controller regimens~~optimized pharmacotherapy for at least 3 consecutive months, the recipient's asthma continues to be uncontrolled as defined by **ONE** of the following which is **stated on the request**:
    - The recipient has had two or more asthma exacerbations which required treatment with systemic corticosteroids in the previous 12 months; **OR**

        - The recipient has had one or more asthma exacerbations requiring hospitalization or an ED visit in the previous 12 months; **OR**
        - The recipient has an FEV1 < 80% predicted; **OR**
        - The recipient has an FEV1/FVC < 0.80; **OR**
        - The recipient's asthma worsens upon tapering of oral corticosteroid therapy; **AND**
    - The following dosage limitations apply:
        - For severe asthma in recipients 6-11 years of age: 40mg once every 4 weeks; **OR**
        - For severe asthma in recipients 12 years of age or older: 100mg once every 4 weeks;

OR

- The recipient has a diagnosis of eosinophilic granulomatosis with polyangiitis (Churg-Strauss) and **ALL** of the following:
    - The recipient is 18 years of age or older on the date of the request; **AND**
    - The recipient has an absolute blood eosinophil count ≥150 cells/µL within the last 3 months [Date drawn and the results are **stated on the request**.]; **AND**
    - The recipient was compliant and has failed treatment with at least a 4-week trial of an oral corticosteroid (unless contraindicated or clinically significant adverse events are experienced **– date range of oral corticosteroid use and/or contraindications or clinically significant adverse events are stated on the request**); **AND**
    - The dose is limited to 300mg once every 4 weeks;

OR

- The recipient has a diagnosis of hypereosinophilic syndrome (HES) for at least 6 months without an identifiable non-hematologic secondary cause and **ALL** of the following (date of diagnosis must be **stated on the request**):
    - The recipient is 12 years of age or older on the date of the request; **AND**
    - The recipient has had an inadequate response with either oral corticosteroids (OCS), immunosuppressive therapy, or cytotoxic therapy (unless contraindicated or clinically significant adverse events are experienced **– list of previous medication used and/or contraindications or clinically significant adverse events are stated on the request**); **AND**
    - The dose is limited to 300mg once every 4 weeks;

OR

- The recipient has a diagnosis of chronic rhinosinusitis with nasal polyps and **ALL** of the following:
    - The recipient is 18 years of age or older on the date of the request; **AND**
    - The prescriber **states on the request** that the recipient is using mepolizumab as an add-on maintenance treatment in combination with other controller medications (e.g., intranasal corticosteroids); **AND**
    - The medication is prescribed by, or the request states that this medication is being prescribed in consultation with, an allergist or otolaryngologist; **AND**
    - The requested dose and dosing frequency are appropriate for the recipient's age, weight and diagnosis based on the prescribing information.

Approval Criteria for Continuation of Therapy

- The prescriber **states on the request** that the recipient is established on the medication with evidence of a positive response to therapy.

Duration of approval for initiation and continuation of therapy: 12 months

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Omalizumab (Xolair®)

Approval Criteria for Initiation of Therapy

- For a non-preferred agent, there is no preferred alternative that is the exact same chemical entity, formulation, strength, etc.; **AND**
- For a non-preferred agent, previous use of a preferred product - **ONE** of the following is required:
    - The recipient has had *treatment failure* with at least one preferred product; **OR**
    - The recipient has had an *intolerable side effect* to at least one preferred product; **OR**
    - The recipient has *documented contraindication(s)* to all of the preferred products that are appropriate for the condition being treated; **OR**
    - There is *no preferred product that is appropriate* to use for the condition being treated;

AND

- The recipient has a diagnosis of moderate to severe persistent allergic asthma and **ALL** of the following**:**
    - The recipient is 6 years of age or older on the date of the request; **AND**
    - The date and results of the pre-treatment serum IgE level are **stated on the request**; **AND**

- The requested dose and dosing frequency are appropriate for the recipient's age, weight, and pre-treatment serum IgE level based on the dosing tables in the prescribing information; **AND**
- ~~The recipient has been adherent to medication therapy, using proper inhaler technique (if applicable) and had an inadequate response to medium to high dose inhaled corticosteroids **PLUS** inhaled long-acting beta-agonist **OR** leukotriene modifier. [Each medication and date range of treatment must be **stated on the request**. Adherence to drug therapy will be validated through claims data review];~~
- The recipient has been compliant for at least 3 consecutive months with optimized pharmacotherapy for the treatment of asthma, which is **stated on the request**; **AND**
- Even with compliant use of optimized pharmacotherapy for at least 3 consecutive months, the recipient's asthma continues to be uncontrolled as defined by **ONE** of the following which is **stated on the request**:
  - The recipient has had two or more asthma exacerbations which required treatment with systemic corticosteroids in the previous 12 months; **OR**
  - The recipient has had one or more asthma exacerbations requiring hospitalization or an ED visit in the previous 12 months; **OR**
  - The recipient has an FEV1 < 80% predicted; **OR**
  - The recipient has an FEV1/FVC < 0.80; **OR**
  - The recipient's asthma worsens upon tapering of oral corticosteroid therapy;

OR

- The recipient has a diagnosis of chronic spontaneous urticaria (previously referred to as chronic idiopathic urticaria) and **ALL** of the following**:**
  - The recipient is 12 years of age or older on the date of the request; **AND**
  - The recipient has been adherent to H1 antihistamine therapy for a minimum of 4 weeks but is still symptomatic. [Each medication and date range of treatment must be **stated on the request**. Adherence to drug therapy will be validated through claims data review];

OR

- The recipient has a diagnosis of nasal polyps with inadequate response to nasal corticosteroids and **ALL** of the following**:**
  - The recipient is 18 years of age or older on date of request; **AND**
  - The date and results of the pre-treatment serum IgE level are **stated on the request**; **AND**

- The requested dose and dosing frequency are appropriate for the recipient's age, weight, and pre-treatment serum IgE level based on the dosing tables in the prescribing information; **AND**
- The recipient has been adherent to nasal corticosteroid therapy for a minimum of 4 weeks but is still symptomatic. [Each medication and date range of treatment must be **stated on the request**. Adherence to drug therapy will be validated through claims data review]; **AND**
- ~~Omalizumab~~The prescriber **states on the request** that omalizumab **IS** being used in combination with a nasal corticosteroid [Medication must be **stated on the request**. Adherence to drug therapy will be validated through claims data review];

OR

- The recipient has a diagnosis of IgE-mediated food allergy and **ALL** of the following**:**
  - The recipient is 1 year of age or older on date of request; **AND**
  - The date and results of the pre-treatment serum IgE level are **stated on the request**; **AND**
  - The requested dose and dosing frequency are appropriate for the recipient's age, weight, and pre-treatment serum IgE level based on the dosing tables in the prescribing information~~;~~.

~~**AND**~~

- ~~For a non-preferred agent, there is no preferred alternative that is the exact same chemical entity, formulation, strength, etc.; **AND**~~
- ~~For a non-preferred agent, previous use of a preferred product - **ONE** of the following is required:~~
  - ~~The recipient has had *treatment failure* with at least one preferred product; **OR***~~
  - ~~The recipient has had an *intolerable side effect* to at least one preferred product; **OR***~~
  - ~~The recipient has *documented contraindication(s)* to all of the preferred products that are appropriate for the condition being treated; **OR***~~
    ~~There is *no preferred product that is appropriate* to use for the condition being treated~~.

Approval Criteria for Continuation of Therapy

- The prescriber **states on the request** that the recipient is established on the medication with evidence of a positive response to therapy.

Duration of approval for initiation and continuation of therapy: 12 months

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Reslizumab (Cinqair®)

Approval Criteria for Initiation of Therapy

- ~~The recipient is 18 years of age or older; **AND**~~
- The recipient has a diagnosis of severe asthma with an eosinophilic phenotype (severe allergic asthma); **AND**
- The recipient is 18 years of age or older; **AND**
- For a non-preferred agent, there is no preferred alternative that is the exact same chemical entity, formulation, strength, etc.; **AND**
- For a non-preferred agent, previous use of a preferred product - **ONE** of the following is required:
    - The recipient has had *treatment failure* with at least one preferred product; **OR**
    - The recipient has had an *intolerable side effect* to at least one preferred product; **OR**
    - The recipient has *documented contraindication(s)* to all of the preferred products that are appropriate for the condition being treated; **OR**
    - There is *no preferred product that is appropriate* to use for the condition being treated; **AND**
- Reslizumab is **NOT** being used in combination with other monoclonal antibodies used to treat asthma; **AND**
- ~~Reslizumab~~ The prescriber **states on the request** that reslizumab **IS** being used in combination with ~~an inhaled corticosteroid (ICS) plus either a long-acting beta agonist (LABA) **OR** another controller agent (e.g., leukotriene receptor antagonist [LTRA]);~~optimized pharmacotherapy for the treatment of asthma; **AND**
- The recipient has a baseline peripheral blood eosinophil count of ≥ 400 cells/µL within the previous 4 weeks (prior to treatment with reslizumab) [Date drawn and the results are **stated on the request**]; **AND**
- The recipient has been compliant ~~with **ONE** of the following regimens~~ for at least 3 consecutive months~~:~~ with optimized pharmacotherapy for the treatment of asthma, which is **stated on the request**; **AND**
    - ~~Medium to high dose ICS plus a LABA *(this is the preferred regimen);* **OR**~~
    - ~~High dose ICS plus a LTRA *(if the recipient is unable to take a LABA);* **OR**~~
    - ~~High dose ICS plus theophylline *(if the recipient is unable to take a LABA);* **OR**~~
    - ~~Low to medium dose ICS plus tiotropium plus a LTRA or theophylline *(if the recipient is unable to take LABA and high dose ICS);* **AND**~~
- Even with compliant use of ~~one of the above controller regimens~~optimized pharmacotherapy for at least 3 consecutive months, the recipient's asthma continues to be uncontrolled as defined by **ONE** of the following which is **stated on the request**:

    - The recipient has had two or more asthma exacerbations which required treatment with systemic corticosteroids in the previous 12 months; **OR**
    - The recipient has had one or more asthma exacerbations requiring hospitalization or an ED visit in the previous 12 months; **OR**
    - The recipient has an FEV1 < 80% predicted; **OR**
    - The recipient has an FEV1/FVC < 0.80; **OR**
    - The recipient's asthma worsens upon tapering of oral corticosteroid therapy; **AND**
- The dose is limited to 3mg/kg once every 4 weeks.

Approval Criteria for Continuation of Therapy

- The prescriber **states on the request** that the recipient is established on the medication with evidence of a positive response to therapy.

Duration of approval for initiation and continuation of therapy: 12 months

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Tezepelumab-ekko (Tezspire™)

Approval Criteria for Initiation of Therapy

- ~~The recipient is 12 years of age or older; **AND**~~
- The recipient has a diagnosis of severe asthma; **AND**
- The recipient is 12 years of age or older; **AND**
- For a non-preferred agent, there is no preferred alternative that is the exact same chemical entity, formulation, strength, etc.; **AND**
- For a non-preferred agent - **ONE** of the following is required:
    - The recipient has had *treatment failure* with at least one preferred product; **OR**
    - The recipient has had an *intolerable side effect* to at least one preferred product; **OR**
    - The recipient has *documented contraindication(s)* to all of the preferred products that are appropriate for the condition being treated; **OR**
    - There is *no preferred product that is appropriate* to use for the condition being treated; **AND**
- Tezepelumab medication is **NOT** being used in combination with other monoclonal antibodies used to treat asthma; **AND**
- The prescriber **states on the request** that tezepelumab **IS** being used in combination with optimized pharmacotherapy for the treatment of asthma; **AND**
- The recipient has been compliant ~~with an inhaled corticosteroid (ICS) plus either a long-acting beta agonist (LABA) **OR** another controller agent (e.g., leukotriene receptor antagonist [LTRA]) for~~ for at least 3 consecutive months ~~prior to the date of the request~~

[Nameswith optimized pharmacotherapy for the treatment of medications must beasthma, which is **stated on the request**];; **AND**

- Even with compliant use of a controller regimenoptimized pharmacotherapy for at least 3 consecutive months, the recipient's asthma continues to be uncontrolled as defined by **ONE** of the following which is **stated on the request**:
    - The recipient has had two or more asthma exacerbations which required treatment with systemic corticosteroids in the previous 12 months; **OR**
    - The recipient has had at least one or more asthma exacerbationexacerbations requiring hospitalization or an ED visit in the previous 12 months; **OR**
    - The recipient has an FEV1 < 80% predicted; **ANDOR**
    - This medication is **NOT** being used in combination with other monoclonal antibodies used to treatThe recipient has an FEV1/FVC < 0.80; **OR**
- The recipient's asthma; **AND**
    - This medication **IS** being used in combination with an inhaled worsens upon tapering of oral corticosteroid (ICS) plus either a long-acting beta agonist (LABA) **OR** another controller agent (e.g., leukotriene receptor antagonist [LTRA]) [Names of medications must be **stated on the request**].therapy.

Approval Criteria for Continuation of Therapy

- This medication **IS** being used in combination with an inhaled corticosteroid (ICS) plus either a long-acting beta agonist (LABA) **OR** another controller agent (e.g., leukotriene receptor antagonist [LTRA]) [Names of medications must be **stated on the request**]; **AND**
- The prescriber **states on the request** that the recipient is established on the medication with evidence of a positive response to therapy.

Duration of approval for initiation and continuation of therapy: 12 months

References

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Revision / Date	**Implementation Date**
Single PDL Implementation / May 2019	May 2019
For Nucala®, removed FFS from title, modified minimum age for eosinophilic asthma to 6 years of age, added reauthorization criteria, removed footer, added revision table / November 2019	March 2020
Combined clinical criteria of Cinqair®, Fasenra®, Nucala® and Xolair® on one document; added non-preferred criteria wording; formatting changes and updated references / October 2020	January 2021
Updated diagnosis to include hypereosinophilic syndrome, formatting changes, updated references / December 2020	April 2021
Updated diagnosis of Xolair® to include nasal polyps, formatting changes, updated references / January 2021	July 2021
Updated diagnosis of Nucala® to include nasal polyps and updated references / August 2021	January 2022
Combined Tezspire™ criteria with Asthma, Immunomodulators / November 2022	January 2023
Updated wording for Xolair® diagnosis of chronic spontaneous urticaria, updated references / August 2023	October 2023
Added diagnosis of IgE-mediated food allergy to Xolair®, formatting changes, updated references / February 2024	July 2024

Modified minimum age for Fasenra® to 6 years of age, modified wording in asthma related criteria to ‘optimized pharmacotherapy for the treatment of asthma’, formatting changes, updated references / May 2024	October 2024