Louisiana Medicaid
Asthma/COPD – Immunomodulators~~, Asthma~~

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.

*T~~Some of t~~hese agents may have **Black Box Warnings** and/or may be subject to **Risk Evaluation and Mitigation Strategy (REMS)** under FDA safety regulations. Please refer to individual prescribing information for details.*

Benralizumab (Fasenra® Pen/Syringe)

Approval Criteria

- ~~Recipient~~ The recipient is 12 years of age or older; **AND**
- ~~Recipient~~ The recipient has a diagnosis of severe asthma with an eosinophilic phenotype (severe allergic 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; **OR**
    - The recipient is established on the medication with positive clinical outcomes; **AND**
- Benralizumab is **NOT** being used in combination with other monoclonal antibodies used to treat asthma; **AND**
- 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]); **AND**
- ~~Recipient~~ 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~~documented~~** **on the request**.]; **AND**

- ~~Recipient~~ The recipient has been compliant with **ONE** of the following regimens for at least 3 consecutive months which is **stated on the request**:
    - 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, the recipient's asthma continues to be uncontrolled as defined by **ONE** of the following which is ~~noted~~ **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**
- ~~Dose~~ The dose is limited to 30 mg once every 4 weeks for the first 3 doses, followed by 30mg once every 8 weeks thereafter; **AND**
- By submitting the authorization request, the prescriber attests to the following:
    - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
    - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
    - The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not receive the requested medication in combination with any medication that is contraindicated or not recommended per FDA labeling.
    - ~~The recipient has no inappropriate concomitant drug therapies or disease states.~~

Reauthorization Criteria

- The recipient continues to meet initial approval criteria; **AND**
- ~~Benralizumab is **NOT** being used in combination with other monoclonal antibodies used to treat asthma; **AND**~~The prescriber **states on the request** that the recipient is established

on the medication with evidence of a ~~is documentation of clinically significant~~ positive response to ~~benralizumab~~ therapy.

- ~~Benralizumab is **NOT** being used in combination with other monoclonal antibodies used to treat asthma; **AND**~~
- ~~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]); **AND**~~
- ~~Recipient remains compliant with **ONE** of the following regimens:~~
  - ~~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**~~
- ~~Dose is limited to 30 mg every 4 weeks for the first 3 doses, followed by once every 8 weeks thereafter; **AND**~~

- ~~There is documentation of clinically significant positive response to benralizumab therapy.~~

Duration of initial and reauthorization approval: 12 months

Mepolizumab (Nucala®)

Approval Criteria

- 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; **OR**
- The recipient is established on the medication with positive clinical outcomes;

AND

- The recipient has a diagnosis of severe asthma with an eosinophilic phenotype (severe allergic asthma)~~,~~ and~~**AND**~~ **ALL** of the following:
  - The recipient is 6 years of age or older on the date of the request; **AND**
  - 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]); **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**~~**documented**~~ **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**~~**documented**~~ **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 **stated**~~**documented**~~ **on the request**):
    - 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, the recipient's asthma continues to be uncontrolled as defined by **ONE** of the following which is **stated**~~**documented**~~ **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** ~~**documented**~~ **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); **AND**
    - The dose is limited to 300mg once every 4 weeks;

OR ~~**AND**~~

- 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); **AND**
    - The dose is limited to 300mg once every 4 weeks;

AND ~~.~~

- By submitting the authorization request, the prescriber attests to the following:
    - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
    - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**

- The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not receive the requested medication in combination with any medication that is contraindicated or not recommended per FDA labeling.
- ~~The recipient has no inappropriate concomitant drug therapies or disease states.~~

Reauthorization Criteria

- The recipient continues to meet~~s ALL of the~~ initial approval criteria (except pre-treatment parameters); **AND**
- The prescriber **states on the request** that the recipient is established on the medication with evidence of a ~~ is documentation of clinically significant~~ positive response to ~~benralizumab~~ therapy.~~There is documentation of **clinically significant positive response to mepolizumab therapy** in the recipient's medical record, and this is **documented on the request**.~~
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Duration of initial and reauthorization approval: 12 months

Omalizumab (Xolair®)

Approval Criteria

- The recipient has a diagnosis of moderate to severe persistent allergic asthma and~~; **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**~~**documented**~~ **on the request**; **AND**
  - The requested dose and dosing frequency are appropriate for the recipient's age, ~~weight~~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**~~**listed**~~ **on the request**. Adherence to drug therapy will be validated through claims data review];

~~OR~~
OR
~~AND~~

- The recipient has a diagnosis of 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~~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 **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];

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; **OR**

- The recipient is established on the medication with positive clinical outcomes; **AND**

- By submitting the authorization request, the prescriber attests to the following:
  - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
  - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
  - The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not receive the requested medication in combination with any medication that is contraindicated or not recommended per FDA labeling.

~~The recipient has no inappropriate concomitant drug therapies or disease states.~~

~~**OR**~~

- ~~The recipient has a diagnosis of chronic idiopathic urticaria; **AND**~~
  - ~~The recipient is 12 years of age or older on the date of the request; **AND**~~
  - ~~The recipient has been adherent to H_1 antihistamine therapy for a minimum of 4 weeks, but is still symptomatic. [Each medication and date range of treatment must be listed on the request. Adherence to drug therapy will be validated through claims data review]; **AND**~~
- ~~For a non-preferred, 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; **OR**~~
  - ~~The recipient is established on the medication with positive clinical outcomes; **AND**~~
- ~~By submitting the authorization request, the prescriber attests to the following:~~
  - ~~The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation~~

Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**

- All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
- The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not receive the requested medication in combination with any medication that is contraindicated or not recommended per FDA labeling.

OR

- The recipient has a diagnosis of nasal polyps with inadequate response to nasal corticosteroids; **AND**
  - 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 documented 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 listed on the request. Adherence to drug therapy will be validated through claims data review]; AND
  - Omalizumab **IS** being used in combination with a nasal corticosteroid [Medication must be listed on the request. Adherence to drug therapy will be validated through claims data review]; **AND**
- For a non-preferred, 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; **OR**
  - The recipient is established on the medication with positive clinical outcomes; **AND**
- By submitting the authorization request, the prescriber attests to the following:

- ~~The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**~~
- ~~All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**~~
- ~~The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not receive the requested medication in combination with any medication that is contraindicated or not recommended per FDA labeling.~~

~~o The recipient has no inappropriate concomitant drug therapies or disease states.~~

Reauthorization Criteria

- ~~Recipient~~ The recipient continues to meet initial approval criteria; **AND**
- ~~Prescriber states on the request that there is evidence of a positive response to therapy as indicated by improvement in signs, symptoms, and/or lab results compared to baseline.~~The prescriber **states on the request** that the recipient is established on the medication with evidence of a ~~ is documentation of clinically significant~~ positive response to ~~benralizumab~~ therapy.

Duration of initial and reauthorization approval: 12 months

Reslizumab (Cinqair®)

Approval Criteria

- ~~Recipient~~ The recipient is 18 years of age or older; **AND**
- ~~Recipient~~ The recipient has a diagnosis of severe asthma with an eosinophilic phenotype (severe allergic 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; **OR**
    - The recipient is established on the medication with positive clinical outcomes; **AND**
- Reslizumab is **NOT** being used in combination with other monoclonal antibodies used to treat asthma; **AND**
- 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]); **AND**
- ~~Recipient~~ 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**~~**documented**~~ **on the request**]; **AND**
- ~~Recipient~~ The recipient has been compliant with **ONE** of the following regimens for at least 3 consecutive months:
    - 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, the recipient's asthma continues to be uncontrolled as defined by **ONE** of the following which is ~~noted~~ **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**
- ~~Dose~~ The dose is limited to 3mg/kg once every 4 weeks; **AND**
- By submitting the authorization request, the prescriber attests to the following:
    - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**

- All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
- The recipient has no concomitant drug therapies or disease states that limit the use of the requested medication and will not receive the requested medication in combination with any medication that is contraindicated or not recommended per FDA labeling.
- ~~The recipient has no inappropriate concomitant drug therapies or disease states.~~

Reauthorization Criteria

- The recipient continues to meet initial approval criteria; **AND**
- The prescriber **states on the request** that the recipient is established on the medication with evidence of a positive response to therapy.~~Reslizumab is **NOT** being used in combination with other monoclonal antibodies used to treat asthma; **AND**~~
- ~~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]); **AND**~~
- ~~Recipient remains compliant with ONE of the following regimens:~~
  - ~~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**~~
- ~~Dose is limited to 3mg/kg once every 4 weeks; **AND**~~
- ~~There is documentation of clinically significant positive response to reslizumab therapy.~~

Duration of initial and reauthorization approval: 12 months

References

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Wechsler ME, Akuthota P, Jayne D. Mepolizumab or placebo for eosinophilic granulomatosis with polyangiitis. N Engl J Med. 2017;376(20):1921-1932.

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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	~~October 2020~~January 2021
Updated diagnosis to include hypereosinophilic syndrome, formatting changes, updated references / December 2020	April 2021~~December 2020~~
Updated diagnosis of Xolair® to include nasal polyps, formatting changes, updated references / January 2021	~~January 2021~~July 2021