Louisiana ~~Fee-for-Service~~ Medicaid
Mepolizumab (Nucala®)

~~Mepolizumab (Nucala®) requires clinical authorization.~~ The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request prior authorization for mepolizumab (Nucala®).

~~Requests will be considered for approval if all of the following~~Approval ~~c~~Criteria ~~are met:~~

- Mepolizumab is **NOT** being used in combination with other monoclonal antibodies used to treat asthma; **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 inappropriate concomitant drug therapies or disease states; **AND**~~
- ~~Recipient~~ The recipient has a diagnosis of severe asthma with an eosinophilic phenotype (severe allergic asthma), **AND ALL** of the following:
  - ~~Recipient~~ The recipient is ~~12~~ 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**
  - ~~Recipient~~ The recipient has:
    - A ~~peripheral~~ blood eosinophil count of ≥150 cells/µL within the previous 6 weeks (prior to treatment with mepolizumab) [Date drawn and results are **documented on the request**]; **OR**
    - A ~~peripheral~~ 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 **documented on the request**]; **AND**
  - ~~Recipient~~ 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 **documented on the request**):
    - Medium to high dose ICS plus an LABA *(this is the preferred regimen);* **OR**

Formatted: Font: Bold

Formatted: Font: Bold

        - 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 ~~noted~~ **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**
        - ~~o~~ For severe asthma in recipients 12 years of age or older: 100mg once every 4 weeks; ~~Dose is limited to 100mg once every 4 weeks;~~ **OR**
- ~~Recipient~~ The recipient has a diagnosis of eosinophilic granulomatosis with polyangiitis (Churg-Strauss) and **ALL** of the following:
    - ~~Recipient~~ The recipient is 18 years of age or older on the date of the request; **AND**
    - ~~Recipient~~ The recipient has an absolute blood eosinophil count ≥150 cells/µL within the last 3 months [Date drawn and the results are documented on the request.]; **AND**
    - ~~Recipient~~ 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**
    - ~~Dose~~ The dose is limited to 300mg once every 4 weeks.
- 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**

Formatted: Font: Bold

Formatted

- 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 ~~inappropriate~~ concomitant drug therapies or disease states that are contraindicated or not recommended with mepolizumab (Nucala®).~~;~~ ~~**AND**~~
-

Re~~quests to continue treatment with mepolizumab will be considered for approval if all of the following~~ authorization ~~criteria~~ Criteria ~~are met:~~

- The recipient meets ~~,~~ALL of the initial approval criteria (except pre-treatment parameters)~~Mepolizumab is **NOT** being used in combination with other monoclonal antibodies used to treat asthma~~; **AND**

~~- By submitting the authorization request, the prescriber attests to the following:~~
  ~~a. 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**~~
  ~~b. 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**~~
  ~~c. The recipient has no inappropriate concomitant drug therapies or disease states; **AND**~~
~~- Recipients with a diagnosis of severe asthma with an eosinophilic phenotype (severe allergic asthma) continue to meet **ALL** of the following criteria:~~
  ~~o Mepolizumab **IS** being used in combination with an ICS plus either a LABA **OR** another controller agent (e.g., LTRA]); **AND**~~
  ~~o 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**~~
  ~~o Dose is limited to 100mg once every 4 weeks; **AND**~~
  ~~o There is documentation of clinically significant positive response to mepolizumab therapy; **OR**~~

Formatted: Font: (Default) Times New Roman, 12 pt

Formatted: Indent: Left: 0.75", Hanging: 0.31", Space Before: 12 pt, Bulleted + Level: 1 + Aligned at: 0.5" + Indent at: 0.75"

Formatted: Font: Not Bold

- ~~Recipients with a diagnosis of eosinophilic granulomatosis with polyangiitis (Churg-Strauss) continue to meet all of the following criteria:~~
  - ~~Dose is limited to 300mg once every 4 weeks; **AND**~~
- There is documentation of **clinically significant positive response to mepolizumab therapy** in the recipient's medical record, and this is **documented on the request**.

Duration of initial and reauthorization approval~~, both initial and reauthorization~~: 12 months

References

National Asthma Education and Prevention Program, Third Expert Panel on the Diagnosis and Management of Asthma. Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma. Bethesda (MD): National Heart, Lung, and Blood Institute (US); 2007

Nucala® (mepolizumab) [package insert]. Philadelphia, PA: GlaxoSmithKline LLC; ~~2017~~2019. ~~Retrieved from~~ https://www.gsksource.com/pharma/content/dam/GlaxoSmithKline/US/en/Prescribing_Information/Nucala/pdf/NUCALA-PI-PIL.PDF

Spiriva® (tiotropium) [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc; 2018. ~~Retrieved from~~ https://docs.boehringer-ingelheim.com/Prescribing%20Information/PIs/Spiriva/Spiriva.pdf

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

Revision	Date
Single PDL Implementation	May 2019
Removed FFS from title, modified minimum age for eosinophilic asthma to 6 years of age, added reauthorization criteria, removed footer, added revision table	April 2020

Formatted

Formatted: Font: Bold

Field Code Changed

Field Code Changed