

Utilization Management Policy Name: Nucala® & Fasenra® subcutaneous injection

Restricted Product(s):

- Nucala (mepolizumab)
- Fasenra (benralizumab)

FDA Approved Use:

Nucala:

- Add-on maintenance treatment of patients with severe asthma aged 12 years and older with an eosinophilic phenotype.
- The treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA).
- Limitations of use: Not for relief of acute bronchospasm or status asthmaticus

Fasnera:

- Add-on maintenance treatment of patients with severe asthma in adults and children 12 years or older with an eosinophilic phenotype.
- Limitations of use: Not for relief of acute bronchospasm or status asthmaticus

Criteria for Approval of Restricted Product(s):

Initial Criteria for Approval:

For patients that are new to the plan and currently taking the medication, the criteria pertain to when the patient started the medication.

1. The patient has a diagnosis of eosinophilic asthma; **AND**
 - a. The patient is 12 years of age or older; **AND**
 - b. The patient has one of the following:
 - i. Eosinophil counts greater than or equal to 150 cells/microliter at initiation of therapy; **OR**
 - ii. Eosinophil counts greater than or equal to 300 cells/microliter in the past 12 months; **AND**
 - c. The patient does **NOT** have a hyper-eosinophilic syndrome, neoplastic disease, or known/suspected parasitic infection; **AND**
 - d. The patient has had two or more exacerbations in the past year despite therapy with:
 - i. 12 months of high-dose inhaled corticosteroid (ICS) given in combination with a minimum of 3 months of controller medication (either a long-acting beta2-agonist [LABA], or leukotriene receptor antagonist [LTRA], or theophylline), unless the individual is intolerant of, or has a medical contraindication to these agents; **OR**

- ii. 6 months of ICS with daily oral glucocorticoids given in combination with a minimum of 3 months of controller medication (either a LABA, or LTRA, or theophylline), unless the individual is intolerant of, or has a medical contraindication to these agents; **OR**
- 2. The patient has a diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA/Churg-Strauss Syndrome); **AND**
 - a. The request is for Nucala; **AND**
 - b. The patient is 18 years of age or older; **AND**
 - c. The patient has been diagnosed for six months or greater; **AND**
 - d. They patient is stable on oral corticosteroids; **AND**
- 3. For formularies that exclude (non-formulary) the requested medication, Non-formulary Exception Criteria applies (outlined below) *

Duration of Approval: 365 days

Continuation Criteria for Approval:

- 1. The patient was approved through Blue Cross NC initial criteria for approval; **OR**
- 2. The patient would have met criteria for approval at the time they started therapy; **AND**
- 3. For patients using Nucala or Fasenera for eosinophilic asthma they demonstrated one or more of the following while taking the medication:
 - a. Decreased utilization of rescue medications;
 - b. Decreased frequency of exacerbations (defined as worsening of asthma that requires an increase in ICS dose or treatment with systemic corticosteroids);
 - c. Increase in predicted FEV1 from pretreatment baseline;
 - d. Reduction in reported asthma-related symptoms, such as, asthmatic symptoms upon awakening, coughing, fatigue, shortness of breath, sleep disturbance, or wheezing.
- 4. For patients using Nucala for eosinophilic granulomatosis;
 - a. The member is stable on oral corticosteroid therapy.

Duration of Approval: 365 days

Quantity Limitations: quantity limitations apply to brand and associated generic products.

Nucala (mepolizumab) syringe/ autoinjector	Quantity per Day (unless specified)
Eosinophilic Asthma	1 syringe/ autoinjector per 28 days
Eosinophilic Granulomatosis with Polyangiitis	3 syringes/ autoinjectors per 28 days

BLUE CROSS®, BLUE SHIELD® and the Cross and Shield Symbols are registered marks of the Blue Cross and Blue Shield Association, an association of independent Blue Cross and Blue Shield Plans. Blue Cross NC is an independent licensee of the Blue Cross and Blue Shield Association. All other marks are the property of their respective owners.

Fasenra Pen (benralizumab) autoinjector	Quantity per Day (unless specified)
Eosinophilic Asthma	1 pen per 56 days

Quantity Limit Exception Criteria:

1. The quantity (dose) requested is for documented titration purposes at the initiation of therapy (authorization for a 90 day titration period); **AND**
2. The prescribed dose cannot be achieved using a lesser quantity of a higher strength; **AND**
3. The quantity (dose) requested does not exceed the maximum FDA labeled dose, when specified, or to the safest studied dose per the manufacturer’s product insert; **OR**
4. If the quantity (dose) requested exceeds the maximum FDA labeled dose, when specified, or to the safest studied dose per the manufacturer’s product insert, then the prescriber must submit documentation in support of therapy with a higher dose for the intended diagnosis (submitted documentation may include medical records OR fax form which reflects medical record documentation that shows the length of time the requested dose has been used, and what other medications and doses have been tried and failed).

***Non-formulary Exception Criteria**

Non-Formulary Exception criteria applies on formularies which exclude requested product(s). Satisfactory completion of criteria points (above) may satisfy some, or all, portions of the Non-Formulary Exception Criteria. This criteria is summarized as:

- a) Request must be for an FDA approved indication; **AND**
- b) Patient must have a trial and failure of up to **TWO** formulary medications or a clinical contraindication/intolerance to those medications not tried.

References: all information referenced is from FDA package insert unless otherwise noted below.

Policy Implementation/Update Information:

- November 2019: Criteria change: Corrected age requirement of Nucala to 12 years of age.
- October 2019: Criteria update: Added new to market Fasentra pen injection to criteria.
- September 2019: Criteria update: Updated age criteria for eosinophilic asthma from 12 years of age to 6 years of age.
- August 2019: Original utilization management criteria issued.

Non-Discrimination and Accessibility Notice

BLUE CROSS®, BLUE SHIELD® and the Cross and Shield Symbols are registered marks of the Blue Cross and Blue Shield Association, an association of independent Blue Cross and Blue Shield Plans. Blue Cross NC is an independent licensee of the Blue Cross and Blue Shield Association. All other marks are the property of their respective owners.

Discrimination is Against the Law

- Blue Cross and Blue Shield of North Carolina (“Blue Cross NC”) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex.
- Blue Cross NC does not exclude people or treat them differently because of race, color, national origin, age, disability, or sex.

Blue Cross NC:

- Provides free aids and services to people with disabilities to communicate effectively with us, such as:
 - Qualified interpreters
 - Written information in other formats (large print, audio, accessible electronic formats, other formats)
- Provides free language services to people whose primary language is not English, such as:
 - Qualified interpreters
 - Information written in other languages
- If you need these services, contact Customer Service **1-888-206-4697**, TTY and TDD, call **1-800-442-7028**.
- If you believe that Blue Cross NC has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:
 - Blue Cross NC, PO Box 2291, Durham, NC 27702, Attention: Civil Rights Coordinator- Privacy, Ethics & Corporate Policy Office, Telephone **919-765-1663**, Fax **919-287-5613**, TTY **1-888-291-1783** civilrightscoordinator@bcbsnc.com
- You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, Civil Rights Coordinator - Privacy, Ethics & Corporate Policy Office is available to help you.
- You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at: U.S. Department of Health and Human Services 200 Independence Avenue, SW Room 509F, HHH Building Washington, D.C. 20201 **1-800-368-1019, 800-537-7697** (TDD). Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>.

BLUE CROSS®, BLUE SHIELD® and the Cross and Shield Symbols are registered marks of the Blue Cross and Blue Shield Association, an association of independent Blue Cross and Blue Shield Plans. Blue Cross NC is an independent licensee of the Blue Cross and Blue Shield Association. All other marks are the property of their respective owners.

- This Notice and/or attachments may have important information about your application or coverage through Blue Cross NC. Look for key dates. You may need to take action by certain deadlines to keep your health coverage or help with costs. You have the right to get this information and help in your language at no cost. Call Customer Service **1-888-206-4697**.

ATTENTION: If you speak another language, language assistance services, free of charge, are available to you. Call 1-888-206-4697 (TTY: 1-800-442-7028).

ATENCIÓN: Si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1-888-206-4697 (TTY: 1-800-442-7028).

注意: 如果您講廣東話或普通話, 您可以免費獲得語言援助服務。請致電 1-888-206-4697 (TTY : 1-800-442-7028) 。

CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1-888-206-4697 (TTY: 1-800-442-7028).

주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 1-888-206-4697 (TTY: 1- 800-442-7028)번으로 전화해 주십시오.

ATTENTION : Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 1-888-206-4697 (ATS : 1-800-442-7028).

ملحوظة: إذا كنت تتحدث اللغة العربية، فإن خدمات المساعدة اللغوية تتوافر لك بالمجان. اتصل برقم 1-888-206-4697. المبرقة الكاتبة: 1-800-442-7028.

LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1-888-206-4697 (TTY: 1-800-442-7028).

ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 1-888-206-4697 (телетайп: 1-800-442-7028).

PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nang walang bayad. Tumawag sa 1-888-206-4697 (TTY: 1-800-442-7028).

સુચના: જો તમે ગુજરાતી બોલતા હો, તો નિ:સુલ્ક ભાષા સહાય સેવાઓ તમારા માટે ઉપલબ્ધ છે. ફોન કરો 1-888-206-4697 (TTY: 1-800-442-7028).

BLUE CROSS®, BLUE SHIELD® and the Cross and Shield Symbols are registered marks of the Blue Cross and Blue Shield Association, an association of independent Blue Cross and Blue Shield Plans. Blue Cross NC is an independent licensee of the Blue Cross and Blue Shield Association. All other marks are the property of their respective owners.

ចំណាំ៖ ប្រសិនបើលោកអ្នកនិយាយជាភាសាខ្មែរ សេវាកម្មជំនួយផ្នែកភាសាមានផ្តល់ជូនសម្រាប់លោកអ្នកដោយមិនគិតថ្លៃ។ សូមទំនាក់ទំនងតាមរយៈលេខ៖ 1-888-206-4697 (TTY: 1-800-442-7028)។

ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 1-888-206-4697 (TTY: 1-800-442-7028).

ध्यान दें: यदि आप हिन्दी बोलते हैं तो आपके लिए मुफ्त में भाषा सहायता सेवाएं उपलब्ध हैं। 1-888-206-4697 (TTY: 1-800-442-7028) पर कॉल करें।

ໂປດຊາບ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ, ໂດຍບໍ່ເສັຽຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທ 1-888-206-4697 (TTY: 1-800-442-7028).

注意事項: 日本語を話される場合、無料の言語支援をご利用いただけます。1-888-206-4697 (TTY: 1-800-442-7028) まで、お電話にてご連絡ください。