

**NC Division of Medical Assistance
Outpatient Pharmacy
Prior Approval Criteria
Oral Inhaled Steroids**

**Medicaid and Health Choice
Effective Date: 9/15/2010
Revised Date: 01/19/2016**

Therapeutic Class Code: J5G, P5A

Therapeutic Class Description: Oral Inhaled Steroids

| Medication | Generic Code Number(s) | NDC Number(s) |
|----------------------------|----------------------------|--------------------------|
| Advair Diskus | 50584, 50594, 50604 | |
| Advair HFA | 97135, 97136, 97137 | |
| Alveseo | 24152, 24149 | |
| Asmanex | 18987, 24928, 24929, 99721 | |
| Breo Ellipta | 34647, 35808 | |
| Budesonide 0.25mg Respules | | 00093681545, 00093681573 |
| Budesonide 0.5mg Respules | | 00093681645, 00093681673 |
| Dulera | 28766, 28767 | |
| Flovent Diskus | 53633, 53634, 53635 | |
| Flovent HFA | 53636, 53638, 53639 | |
| Pulmicort Flexhaler | 98025, 27740, 98024 | |
| Pulmicort 1mg Respules | 62980 | |
| Symbicort | 98499, 98500 | |

Eligible Beneficiaries

NC Medicaid (Medicaid) beneficiaries shall be enrolled on the date of service and may have service restrictions due to their eligibility category that would make them ineligible for this service.

NC Health Choice (NHC) beneficiaries, ages 6 through 18 years of age, shall be enrolled on the date of service to be eligible, and must meet policy coverage criteria, unless otherwise specified.

EPSDT Special Provision: Exception to Policy Limitations for Beneficiaries under 21 Years of Age

42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiaries under 21 years of age **if the service is medically necessary health care** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination (includes any evaluation by a physician or other licensed clinician). This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his/her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems. Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the beneficiary's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the beneficiary's right to a free choice of providers.

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EPSDT does not require the state Medicaid agency to provide any service, product, or procedure

- a. ~~that is unsafe, ineffective, or experimental/investigational.~~
- b. ~~that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.~~

Service limitations on scope, amount, duration, frequency, location of service, and/or other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT and Prior Approval Requirements

- a. ~~If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does NOT eliminate the requirement for prior approval.~~
- b. ~~**IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *Basic Medicaid and NC Health Choice Billing Guide*, sections 2 and 6, and on the EPSDT provider page. The Web addresses are specified below.~~

~~***Basic Medicaid and NC Health Choice Billing Guide:***~~

~~<http://www.ncdhhs.gov/dma/basicmed/>~~

~~**EPSDT provider page:** <http://www.ncdhhs.gov/dma/epsdt/>~~

Health Choice Special Provision: Exceptions to Policy Limitations for Health Choice Beneficiaries ages 6 through 18 years of age

~~**EPSDT does not apply to NCHC beneficiaries.** If a NCHC beneficiary does not meet the clinical coverage criteria within the **Outpatient Pharmacy prior approval** clinical coverage criteria, the NCHC beneficiary shall be denied services. Only services included under the Health Choice State Plan and the DMA clinical coverage policies, service definitions, or billing codes shall be covered for NCHC beneficiaries.~~

Criteria:

Step therapy for Oral Inhaled Steroids:

- ~~QVAR (beclomethasone dipropionate) will not require prior authorization.~~
- ~~Patients must have a documented 30-day trial and failure of QVAR to receive other brand name oral inhaled steroids.~~

OR

- ~~Patients must have a documented 30-day trial and failure of any oral inhaled steroid product to receive long acting inhaled beta-agonist/steroid combination products.~~

• **Exemptions:**

1. ~~Patients with a documented contraindication, intolerable side effects, or allergy to QVAR (beclomethasone dipropionate) are exempt from the criteria.~~
2. ~~Patients who are currently stable on long acting inhaled beta-agonist/steroid combination products for symptom control are exempt from the criteria.~~

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3. Patients whose condition is severe enough to warrant combination therapy are exempt from the criteria.
4. Patients with COPD are exempt from the criteria.
5. Children 4 years old up to 5 years old may use Flovent (fluticasone) without prior authorization.

Procedures:

- Pharmacist may override the prior authorization edit at point of sale if the prescriber writes on the face of the prescription in his/her own handwriting: **"Meets PA Criteria"**. This information may also be entered in the comment block on e-prescriptions.
- May be approved for up to 24 months

References

1. The National Asthma Education and Prevention Program Expert Panel Report 3, Guidelines for the Diagnosis and Management of Asthma; U.S. Department of Health and Human Services- National Institutes of Health, National Heart, Lung, and Blood Institute. NIH Publication Number 08-5846. October 2007.
2. Respiratory Inhalant Products. Drug Facts and Comparisons, Wolters Kluwer Health. St. Louis (MO): updated monthly.
3. *Drug Class Review on inhaled Corticosteroids*, Final Report. Portland, OR: Oregon Evidence-based Practice Center, Oregon Health and Science University, January. 2006.
4. Manufacturer's Package Insert Breo Ellipta®, GlaxoSmithKline, Research Triangle Park, NC 27709, April 2014.