NC Division of Medical Assistance Outpatient Pharmacy Prior Approval Criteria Lupus Medications	Medicaid and Health Choice Effective Date: 04/05/2018

Therapeutic Class Code: Z2Y
Therapeutic Class Description: Immunosuppresive Agents; Miscellaneous; Immunomodulator, B-Lymphocyte Stim (BLYS)-Specific Inhibitor

Medication	Generic Code Number(s)	NDC Number(s)
Benlysta®	43658, 43661, 29633, 29634	49401008835, 49401008801, 49401008842, 49401008847, 49401010101, 49401010201

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 (NCHC) 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.
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 for Initial Coverage:

- Beneficiary has a diagnosis of active systemic lupus erythematosus (SLE)
- Benlysta is prescribed by or in consultation with a rheumatologist
- Beneficiary must be auto-antibody positive
- Beneficiary must be utilizing Benlysta in combination with standard treatment regimens (NSAIDs, corticosteroids, anti-malarials, and immunosuppressive drugs) or standard treatment regimens were not tolerated or not beneficial.
- Beneficiary must not have a diagnosis of severe active lupus nephritis or severe active central nervous system lupus, or concurrently use other biologics and/or IV cyclophosphamide.
- Maximal length of approval: 12 months

Criteria for Renewal Coverage:

- There is documented improvement in functional impairment such as 1) fewer flares that required steroid treatment; 2) lower average daily oral prednisone dose; 3) improved daily function either as measured through a validated functional scale or through improved daily performance documented at clinic visits; 4) sustained improvement in laboratory measures of lupus activity.
- Maximum length of approval: 12 months

Subsequent authorizations will be granted based on current progress notes from the physician documenting disease status and clinical response.

References:

Benlysta full prescribing information. Rockville, MD: Human Genome Sciences, Inc.

Criteria Change Log

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