NC Division of Medical Assistance
Outpatient Pharmacy
Prior Approval Criteria
Topical Antihistamines

Medicaid and Health Choice
Effective Date: Feb. 25, 2019

Therapeutic Class Code: L3P

Therapeutic Class Description: Dermatological Antipruritics-Antihistamines Topical

Medication	Generic Code Number(s)
Prudoxin 5% cream	21210
Zonalon 5% cream	21210
doxepin 5% cream	21210

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 does not apply to NCHC beneficiaries**.

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.

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EPSDT and Prior Approval Requirements
EPSDT DOES NOT ELIMINATE THE REQUIREMENT FOR PRIOR APPROVAL IF PRIOR APPROVAL IS REQUIRED. Additional information on EPSDT guidelines may be accessed at https://medicaid.ncdhhs.gov/medicaid/get-started/find-programs-and-services-right-you/medicaids-benefit-children-and-adolescents.

Indications: Indicated for the short-term management of moderate pruritus in adults with Atopic Dermatitis or Lichen Simplex Chronicus

Initial Criteria for Coverage:

1. Atopic Dermatitis:
    - Beneficiary must have had previous treatment with at least one other topical antihistamine **AND** at least two topical steroid creams
    - Length of therapy may be approved for up to 10 days.
    - Quantity limit of 45 grams per 90 days

2. Lichen Simplex Chronicus:
    - Beneficiary must have had previous treatment with at least two topical steroid creams
    - Length of therapy may be approved for up to 10 days.
    - Quantity limit of 45 grams per 90 days

Continuation of Coverage (renewal request) Criteria:

1. **Initial** criteria above must be met and documentation provided that indicates the beneficiary has benefited from therapy but remains at high risk
2. Minimum of 3 months have passed between prior uses
3. Length of therapy may be approved for up to 10 days
4. Quantity limit of 45 grams per 90 days

References

1. Prudoxin package insert, Prestium Pharma, Newtown, PA. updated June 2015
2. Zonalon package insert, Bioglan Pharma, Inc., Malvern, PA. updated March 2015

Criteria Change Log

02/25/2019	Criteria effective date