NC Medicaid Outpatient Pharmacy Prior Approval Criteria Systemic Immunomodulators	Medicaid and Health Choice Effective Date: Amended Date:

DRAFT

Therapeutic Class Code: L1A
Therapeutic Class Description: Antipsoriatic Agents, Systemic

Medication
Spevigo

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.

EPSDT and Prior Approval Requirements
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.

IMPORTANT ADDITIONAL INFORMATION about EPSDT and prior approval is found in the NCTracks Provider Claims and Billing Assistance Guide, and on the EPSDT provider page. The Web addresses are specified

below.

***NCTracks Provider Claims and Billing Assistance Guide*:**
https://www.nctracks.nc.gov/content/public/providers/provider-manuals.html
EPSDT provider page: https://medicaid.ncdhhs.gov/medicaid/get-started/find-programs-and-services-right-you/medicaid-benefit-children-and-adolescents

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 NC Medicaid clinical coverage policies, service definitions, or billing codes shall be covered for NCHC beneficiaries.

Criteria for approval

- Beneficiary has a Diagnosis of generalized pustular psoriasis (GPP);
  AND
- Beneficiary is 18 years of age or older;
  AND
- Beneficiary does NOT have any of the following conditions: synovitis-acne-pustulosis-hyperostosis-osteitis (SAPHO) syndrome, primary erythrodermic psoriasis vulgaris, primary plaque psoriasis vulgaris without presence of pustules or with pustules that are restricted to psoriatic plaques, or drug-triggered acute generalized exanthematous pustulosis (AGEP);
  AND
- Beneficiary is experiencing an acute GPP flare of moderate to severe intensity defined by all of the following: Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) total score of ≥ 3 (moderate), presence of fresh pustules (new or worsening), a GPPGA pustulation sub score of ≥ 2 (mild), and ≥ 5% of body surface area with erythema and the presence of pustules;
  AND
- Beneficiary must NOT have history of hypersensitivity to any component of the product;
  AND
- Beneficiary has been evaluated and screened for the presence of latent tuberculosis (TB) prior to initiating treatment and will receive ongoing monitoring for presence of TB during treatment;
  AND
- Beneficiary does NOT have an active infection, including clinically important, localized infections;
  AND
- Beneficiary will NOT use concomitantly with any of the following: TNF-α inhibitor (e.g., adalimumab, infliximab), biologic response modifier (e.g., apremilsat, upadacitinib), or systemic immunosuppressant (e.g., retinoid, cyclosporine, methotrexate);
  AND
- Beneficiary has NOT received a live virus vaccine in the last 6 weeks and will NOT receive a live virus vaccine during therapy.

Procedures

- Approve for up to 30 days (Note: If GPP systems persist after initial dose, an additional 900 mg dose may be administered one week after initial dose; max of 2 doses per GPP flare)
- Coverage of one injectable immunomodulator at a time.

References

1. Spevigo [package insert]. Ridgefield, CT; Boehringer Ingelheim; September 2022.

Criteria Change Log

xx/xx/xxxx	Criteria effective date