

**NC Division of Medical Assistance  
 Outpatient Pharmacy  
 Prior Approval Criteria  
 Crinone 8% Gel (progesterone)**

**Medicaid and Health Choice  
 Effective Date: 11/01/2014**

**DRAFT**

**Therapeutic Class Code:** G2A

**Therapeutic Class Description:** Progestational Agents

Medication	Generic Code Number(s)	NDC Number(s)
Crinone 8% Gel (progesterone)	63011	

**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**

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:**

- Documented ultrasound of transvaginal cervical length (TVCL)  $\leq$  25mm between weeks 17 and 24 of gestation **OR**
- **Diagnosis of secondary amenorrhea in patients who have failed Crinone 4% gel**
- Crinone 8% is not being used for infertility

**Procedures:**

- Approve for 2 boxes (15 single use applicators per box) per 30 days
- Approve until the end of pregnancy.
- **For secondary amenorrhea: approve for 12 months**

**References**

1. Romero R, Niolaides K, Conde-Agudelo A, et al. Vaginal progesterone in women with an asymptomatic sonographic short cervix in the mid trimester decreases preterm delivery and neonatal morbidity: a systematic review and metaanalysis of individual patient data. Am J Obstet Gynecol 2012;206:124.e1-19
2. Campbell S. Universal Cervical length screening and vaginal progesterone prevents early preterm births, reduces neonatal morbidity and is cost saving: doing nothing is no longer an option. Ultrasound Obstet Gynecol. 38 (1), 1-9 (2011)

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3. Fonseca, EB. Progesterone and the risk of preterm birth among women with a short cervix. *N Engl J Med* 2007 Aug, 2:357(5): 462-9
4. DeFranco, E.A., et al. Vaginal progesterone is associated with a decrease in risk for early preterm birth and improved neonatal outcome in women with a short cervix: a secondary analysis from a randomized, double-blind, placebo-controlled trial. *Ultrasound Obstet Gynecol* 2007; 30: 697–705
5. O’Brien, J.M, et al. Effect of progesterone on cervical shortening in women at risk for preterm birth: secondary analysis from a multinational, randomized, double-blind, placebo-controlled trial. *Ultrasound Obstet Gynecol* 2009; 34: 653-659
6. Crinone (package insert). Irvine, CA; Allergan. June 2017.

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**Criteria Change Log**

11/01/2014	Criteria effective date
xx/xx/xxxx	Removed GSN's Added diagnosis of secondary amenorrhea for coverage