

**NC Medicaid
Outpatient Pharmacy Prior Approval Criteria
Hormonal Products for Beneficiaries under 18**

Effective Date: August 1, 2023

Therapeutic Class Code: V10, P1P, P1M

Therapeutic Class Description: LHRH(GNRH) AGONIST ANALOG PITUITARY SUPPRESSANTS

Medication
Zoladex (gosrelin)
Supprelin (histrelin)
leuprolide
Triptodur (triptorelin)

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.

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

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1. 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.
2. **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>

- Prior approval is required for beneficiaries under 18 years of age
- Coverage will **not** be provided for beneficiaries under 18 years of age as a puberty blocker for gender affirming care **unless** the medication for gender affirming care was initiated **PRIOR** to August 1, 2023.
- Coverage will be provided for beneficiaries under 18 for the indications below.
 - a. Zoladex (goserelin)
 - i. Carcinoma of prostate (management and palliative)
 - ii. Endometriosis
 - iii. Endometrial-thinning prior to endometrial ablation for dysfunctional uterine bleeding
 - iv. Palliative treatment of advanced breast cancer
 - v. Breast cancer treatment
 - vi. Ovarian preservation during chemotherapy treatment
 - b. Supprelin (histrelin)
 - i. Central precocious puberty
 - ii. Prostate cancer
 - c. leuprolide
 - i. Prostate cancer
 - ii. Central precocious puberty
 - iii. Endometriosis
 - iv. Anemia caused by uterine fibroids
 - v. Breast cancer (ovarian suppression)
 - d. Triptodur (triptorelin)
 - i. Central precocious puberty
 - ii. Prostate cancer
 - iii. Breast cancer-ovarian suppression

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References

1. North Carolina Session Law 2023-111 (formerly HB 808), makes it unlawful for a medical professional to perform a surgical gender transition procedure on a minor or to prescribe, provide, or dispense puberty-blocking drugs or cross-sex hormones to a minor except as permitted under G.S. 90-21.152. However, medical professionals may continue or complete a course of treatment for a minor that includes a surgical gender transition procedure or the administration of puberty-blocking drugs or cross-sex hormones if the course of treatment commenced prior to August 1, 2023, if: 1) treatment was active as of that date; 2) in the reasonable medical judgement of the medical professional it is in the best interest of the minor to continue or complete the treatment; and 3) the minors parents or guardians consent to the continuation or completion of the treatment. This exception to the general prohibition on treatment is known as the grandfather clause.
2. Zoladex [package insert]. Deerfield, IL,; TerSera Therapeutics LLC; December 20220.
3. Suprellin [package insert]. Malvern, PA; Endo Pharmaceuticals LLC; April 2022.
4. Leuprolide www.accessdata.fda.gov: initial approval 1989.
5. Triptodur [package insert]. Woburn, MA; Azurity Pharmaceuticals; November 2023.

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Criteria Change Log

08/01/2023	Criteria effective date