NC Medicaid	**Medicaid and Health Choice**
Outpatient Pharmacy	**Effective Date: September 27, 2020**
Prior Approval Criteria	**Amended Date:**
Relistor	

Therapeutic Class Code: H3Y
Therapeutic Class Description: Mu-Opioid Receptor Antagonists, Peripherally-Acting

Medication
Relistor syringe
Relistor tablet
Relistor vial

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

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.

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

Criteria for Coverage of Relistor tablets:

a. Beneficiary has a diagnosis of opioid-induced constipation with chronic non-cancer pain (including patients with chronic pain related to prior cancer or its treatment who do not require frequent opioid dosage escalation);
b. Beneficiary is age 18 or older;
c. Beneficiary does not have known or suspected mechanical gastrointestinal obstruction;
d. Beneficiary has received opioids for at least 4 weeks duration;
e. Beneficiary has tried and failed or has contraindication, or intolerance to Amitiza AND Movantik; and
f. Initial approval shall be for up to 4 months.

Criteria for Coverage of Relistor vial/syringe:

a. Beneficiary has a diagnosis of opioid-induced constipation with one of the following:
    1. Chronic non-cancer pain (including patients with chronic pain related to prior cancer or its treatment who do not require frequent opioid dosage escalation)
    2. Advanced illness or pain caused by active cancer who require opioid dosage escalation for palliative care; and
b. Beneficiary is age 18 or older
c. Beneficiary does not have known or suspected mechanical gastrointestinal obstruction

d. Beneficiary has received opioids for at least 4 weeks duration
e. Beneficiary has tried and failed or has contraindication, or intolerance to Amitiza AND Movantik
f. Initial approval shall be for up to 4 months.

Criteria for Continuation of Coverage of Relistor:

a. All of the above criteria for initial coverage of Relistor are met.
b. Documentation is submitted that indicates the beneficiary has had an improvement in their symptoms from baseline.
c. Reauthorization shall be for up to 12 months.

References

1. Prescriber Information- Relistor. Salix Pharmaceuticals. Bridgewater, NJ. Revised 11/2018.

Criteria Change Log	
09/27/2020	Criteria effective date