

**NC Division of Medical Assistance
 Outpatient Pharmacy
 Prior Approval Criteria
 Juxtapid® (lomitapide) and Kynamro® (mipomersen)**

**Medicaid and Health Choice
 Effective Date: August 15, 2014
 Amended Date:**

Therapeutic Class Code: M4Q, M4R

Therapeutic Class Description: Antihyperlipidemic-MTP Inhibitor and Antihyperlipidemic – Apolipoprotein B-100 Synthesis Inhibitor

Medication	Generic Code Number(s)
Juxtapid 5, 10, 20mg capsules	33909, 33912, 33913, 38571, 38573, 38574
Kynamro 200mg/ml injection	34226

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:

- Recipient has been diagnosed with homozygous familial hypercholesterolemia (HoFH).
and
- Enrolled in Juxtapid REMS program (for Juxtapid) ~~or Kynamro REMS program (Kynamro)~~
and
- At least 18 years old or older.
and
- Beneficiary is receiving concurrent lipid lowering therapy or is unable to use concurrent lipid lowering therapy
and
- Obtain a negative pregnancy test in females of reproductive potential.
and
- Measure ALT, AST, alkaline phosphatase, and total bilirubin before initiating treatment
and
- During the first year, measure liver-related tests (ALT and AST, at a minimum) prior to each increase in dose or monthly, whichever occurs first. After the first year, do these tests at least every 3 months and before any increase in dose.

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Procedures:

Approval may be for up to 1 year for up to 60mg once a day (Juxtapid) ~~or up to 200mg per week (Kynamro).~~

References

1. Prescribing Information-Juxtapid® (lomitapide) Aegerion Pharmaceuticals, Inc., Cambridge, Massachusetts 02142. December 2012.
2. ~~Prescribing Information—Kynamro® (mipomersen) Genzyme Corporation, Cambridge Massachusetts 02142. January 2013.~~

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Criteria Change Log

08/15/2014	Criteria effective date (Juxtapid only)
01/20/2016	Added criteria for Kynamro
Xx/xx/xxxx	Remove GCNs, Remove Kynamro (off market)