NC Medicaid **Effective Date: August 15, 2014**
Outpatient Pharmacy
Prior Approval Criteria
Juxtapid® (lomitapide) **Amended Date: January 05, 2026**

Therapeutic Class Code: M4Q
Therapeutic Class Description: Antihyperlipidimic-MTP Inhibitor and Antihyperlipidemic – Apolipoprotein B-100 Synthesis Inhibitor

Medication
Juxtapid

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

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 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

Criteria for Coverage:

- Recipient has been diagnosed with homozygous familial hypercholesterolemia (HoFH).
  and
- Enrolled in Juxtapid REMS program (for Juxtapid)
  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.

Procedures:
Approval may be for up to 1 year for up to 60mg once a day

References

1. Prescribing Information-Juxtapid® (lomitapide) Aegerion Pharmaceuticals, Inc., Cambridge, Massachusetts 02142. December 2012. Updated January 2024.

Criteria Change Log

08/15/2014	Criteria effective date (Juxtapid only)
01/20/2016	Added criteria for Kynamro
04/14/2021	Remove GCNs, Remove Kynamro (off market)
01/05/2026	Criteria reviewed. No changes.