Louisiana Fee-for-Service Medicaid
Lipotropics (Other)

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request authorization for non-preferred agents in this therapeutic category**.**

Approval criteria for non-preferred agents (ALL criteria must met)

- By submitting the authorization request, the prescriber attests to the following:
  - The prescribing information for the requested medication has been thoroughly reviewed, including any Black Box Warning, Risk Evaluation and Mitigation Strategy (REMS), contraindications, minimum age requirements, recommended dosing, and prior treatment requirements; **AND**
  - All laboratory testing and clinical monitoring recommended in the prescribing information have been completed as of the date of the request and will be repeated as recommended; **AND**
  - The recipient has no inappropriate concomitant drug therapies or disease states; **AND**
- There is no preferred alternative that is the exact same chemical entity, formulation, strength, etc.; **AND**
- **ONE** of the following is required:
  - The recipient has had a *treatment failure* with at least one preferred product; **OR**
  - The recipient has had an *intolerable side effect* to at least one preferred product; **OR**
  - The recipient has *documented contraindication(s)* to the preferred products that are appropriate to use for the condition being treated; **OR**
  - There is *no preferred product that is appropriate* to use for the condition being treated; **OR**
  - The prescriber states that the recipient is currently using the requested medication **AND ONE** of the following applies:
    - There is evidence in pharmacy claims of at least 60 days of the requested medication within the previous 90-day period; **OR**
    - There is evidence in pharmacy claims of less than 60 days of the requested medication **AND** the prescriber states the recipient has been treated with the requested medication in an inpatient facility; **OR**
    - There is evidence in pharmacy claims of less than 60 days of the requested medication **AND** the prescriber has verified that the pharmacy has dispensed at least 60 days of medication (billed to other insurance, and therefore not viewable in pharmacy claims).; **AND**
- Additional approval criteria must also be met if request is for the following non-preferred agents: lomitapide, mipomersen, aliocumab, or evolocumab. [See below for further information.]

Additional Criteria for Selected Non-Preferred Agents

Lomitapide (Juxtapid®)*
Mipomersen (Kynamro®)*

- Recipient is 18 years of age or older; **AND**
- Recipient must have a confirmed diagnosis of homozygous familial hypercholesterolemia (HoFH) as defined by at least **ONE** of the following clinical criteria:

    - history of genetic testing confirming genetic mutations indicating HoFH; **OR**
    - treatment history for LDL-C > 300mg/dl or non-HDL-C > 330mg/dl; **OR**
    - documented history of untreated LDL-C > 500 mg/dL and at least one of the following:
        - tendinous and/or cutaneous xanthoma prior to age 10 years; **OR**
        - elevated LDL-C > 190 mg/dL prior to lipid-lowering treatment consistent with heterozygous familial hypercholesterolemia [HeFH] in both parents; **AND**
- Prescriber has consulted with either a cardiologist or specialist in the treatment of lipid disorders; **AND**
- Recipient has a documented failure of, or intolerance to, or contraindication to an adequate trial (3 months) of a statin agent; **AND**
- Recipient does not have moderate or severe hepatic impairment (based on Child-Pugh category B or C) or active liver disease; **AND**
- The following quantity limits apply:
    - Juxtapid® #30 capsules per 30 days;
    - Kynamro® #4 injections per 28 days; **AND**
- Submission of a request for one of these agents serves as attestation to the following:
    - A low-fat diet will be initiated as part of therapeutic lifestyle changes for this recipient; **AND**
    - Laboratory measurement of the most current lipid levels (within the last 3 months) was obtained prior to initiation of treatment and will be repeated at least every 3 months for the first year of treatment; **AND**
    - Laboratory measurement of ALT, AST, alkaline phosphatase, and total bilirubin was obtained prior to initiation of treatment, and will be repeated according to manufacturer recommendations as follows:
        - Kynamro®: monthly during the first year of treatment, and every 3 months at a minimum thereafter; **OR**
        - Juxtapid®: monthly or prior to each dose escalation (whichever comes first) during the first year of treatment, and every 3 months and before any increase in dose thereafter; **AND**
    - Treatment will be discontinued for clinically significant liver toxicity described as elevated liver enzymes presenting with clinical symptoms of liver injury (such as nausea, vomiting, abdominal pain, fever, jaundice, lethargy, flu-like symptoms), increases in bilirubin ≥2x the upper limit of normal (ULN), or active liver disease; **AND**
    - For use of Juxtapid® in females of reproductive age (18-55 years of age):
        - The prescriber has obtained a negative pregnancy test prior to initiation of treatment; **AND**
        - The recipient is not breast-feeding.

***Kynamro® and Juxtapid® have Black Box Warnings and is subject to Risk Evaluation and Mitigation Strategy (REMS) under FDA safety Regulations; refer to individual prescribing information for details.**

Aliocumab (Praluent®)
Evolocumab Subcutaneous SureClick; Pushtronex; Syringe (Repatha®)

- For Praluent® **OR** Repatha®, recipient is 18 years of age or older **AND** has **ONE** of the following diagnoses:
    - atherosclerotic cardiovascular disease; **OR**
    - primary hyperlipidemia (heterozygous familial hypercholesterolemia [HeFH]); **OR**

- For Repatha® only, recipient is 13 years of age or older and has a diagnosis of homozygous familial hypercholesterolemia (HoFH) confirmed by the presence of at least **ONE** of the following clinical or laboratory criteria:
    - history of genetic testing confirming genetic mutations indicating HoFH; **OR**
    - treatment history for LDL-C > 300mg/dl or non-HDL-C > 330mg/dl; **OR**
    - documented history of untreated LDL-C > 500 mg/dL and at least one of the following:
        - tendinous and/or cutaneous xanthoma prior to age 10 years; **OR**
        - elevated LDL-C > 190 mg/dL prior to lipid-lowering treatment consistent with HeFH in both parents; **AND**
- Prescriber has consulted with either a cardiologist or specialist in the treatment of lipid disorders; **AND**
- Recipient has received the maximum FDA-approved dose of a statin agent for at least 12 consecutive weeks without adequate response, **OR** has a documented intolerance to, or contraindication to statin agents; **AND**
- The following quantity limits apply:
    - Repatha®:
        - for HeFH # 2 syringes (140mg) per 28 days or # 1 syringe (420mg) per 28 days
        - for HoFH # 1 syringe (420mg) per 28 days
    - Praluent®:
        - #2 injections per 28 days; **AND**
- Submission of a request for one of these agents serves as attestation to the following:
    - The recipient is at a high or very high risk of cardiovascular events based on the recipient's most recent LDL cholesterol level and a calculated atherosclerotic cardiovascular disease risk score of > 7.5% ; **AND**
    - Non-pharmacologic therapies/specific lifestyle modifications such as diet, alcohol use, smoking, and exercise have been addressed with recipient; **AND**
    - A maximally-tolerated preferred statin will be prescribed concomitantly unless all statins are contraindicated or not tolerated; **AND**
    - Other treatment options (e.g., niacin or bile acid sequestrants) will be prescribed concomitantly if the recipient is intolerant to statins.

Authorization renewal for all agents based upon the following criteria (ALL conditions must be met):

- Recipient continues to meet initial approval criteria; **AND**
- Recipient is tolerating and is adherent to current treatment; **AND**
- Recipient has had a positive response to treatment as indicated by improvement in signs, symptoms, and lab results (lipid profile) compared to baseline; **AND**
- For Juxtapid® and Kynamro® **ONLY**, liver function tests are being monitored according to manufacturers' recommendations as noted in the above criteria.

Duration of authorization approval

Initial Approval: 6 months
Reauthorization Approval: 12 months

References

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