Louisiana Medicaid
Heart Disease – Hyperlipidemia – Lipotropics (Other)

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request:

- Prior authorization for non-preferred lipotropic (other) agents; **OR**
- Clinical authorization for alirocumab (Praluent®), evolocumab (Repatha®), evinacumab-dgnb (Evkeeza™), inclisiran (Leqvio®) and lomitapide (Juxtapid®)

Additional Point-of-Sale edits may apply.

*These agents may have a **Black Box Warning(s)** and may be subject to **Risk Evaluation and Mitigation Strategy (REMS)** under FDA safety regulations. Please refer to individual prescribing information for details.*

Approval Criteria for Non-Preferred Lipotropics (Other) Agents (Other than Evkeeza™, Juxtapid®, Leqvio®, Praluent®, and Repatha®)

- There is no preferred alternative that is the exact same chemical entity, formulation, strength, etc.; **AND**
- Previous use of a preferred product – **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 all of 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**
- 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 concomitant drug therapies or disease states that limit the use of the requested medication and will not receive the requested medication in

combination with any medication that is contraindicated or not recommended per FDA labeling**.**

Duration of initial and reauthorization approval: 12 months

Alirocumab (Praluent®)

Approval Criteria

- The recipient has **ONE** of the following diagnoses:
  - atherosclerotic cardiovascular disease; **OR**
  - primary hyperlipidemia (including heterozygous familial hypercholesterolemia [HeFH]); **OR**
  - homozygous familial hypercholesterolemia (HoFH); **AND**
- The recipient is 18 years of old or older on the date of the request; **AND**
- The requested medication is prescribed by, or the request states that this medication is being prescribed in consultation with, either a cardiologist or specialist in the treatment of lipid disorders; **AND**
- The recipient has received the maximally-tolerated FDA-approved dose of a statin agent for at least ~~12~~ 8 consecutive weeks without adequate response, **OR** has a documented intolerance to, or contraindication to statin agents [the name of the statin agent and date range of treatment are **stated on the request]**; **AND**
- For a non-preferred product, there is no preferred alternative that is the exact same chemical entity, formulation, strength, etc.; **AND**
- For a non-preferred product – **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 all of 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; **AND**
- By submitting the authorization request, the prescriber attests to the following:
  - The requested medication will not be used with other PCSK9 inhibitors; **AND**
  - Other treatment options (e.g., niacin or bile acid sequestrants) will be prescribed concomitantly if the recipient is intolerant to statins; **AND**
  - 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 concomitant drug therapies or disease states that limit the use of the requested medication and will not receive the requested medication in combination with any medication that is contraindicated or not recommended per FDA labeling.

Duration of initial approval: 6 months

Reauthorization Criteria

- The recipient continues to meet initial approval criteria; **AND**
- The prescriber **states on the request** that the recipient is established on the medication with evidence of a positive response to therapy.

Duration of reauthorization approval: 12 months

Evinacumab-dgnb (Evkeeza™)

Approval Criteria

- The recipient is 12 years of age or older on the date of the request; **AND**
- The recipient has a diagnosis of homozygous familial hypercholesterolemia (HoFH); **AND**
- The recipient is currently receiving at least **ONE** low-density lipoprotein-cholesterol (LDL-C) lowering agent, the name of which is **stated on the request**; **AND**
- Evkeeza™ is prescribed by, or the request states that this medication is being prescribed in consultation with, either a cardiologist or specialist in the treatment of lipid disorders; **AND**
- The recipient has a documented failure of, or intolerance to, or contraindication to an adequate trial (~~3 months~~8 weeks) of a statin agent [the name of the statin agent and date range of treatment are **stated on the request]**; **AND**
- For a non-preferred product, there is no preferred alternative that is the exact same chemical entity, formulation, strength, etc.; **AND**
- For a non-preferred product – **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 all of 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; **AND**
- By submitting the authorization request, the prescriber attests to the following:
    - The recipient does not have other causes of hypercholesterolemia, including those with heterozygous familial hypercholesterolemia (HeFH); **AND**
    - 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 concomitant drug therapies or disease states that limit the use of the requested medication and will not receive the requested medication in combination with any medication that is contraindicated or not recommended per FDA labeling.

Duration of initial approval: 6 months

Reauthorization Criteria

- The recipient continues to meet initial approval criteria; **AND**
- The recipient is currently receiving at least **ONE** low-density lipoprotein-cholesterol (LDL-C) lowering agent, the name of which is **stated on the request**; **AND**
- The prescriber **states on the request** that the recipient is established on the medication with evidence of a positive response to therapy.

Duration of reauthorization approval: 12 months

Evolocumab Subcutaneous SureClick; Pushtronex; Syringe (Repatha®)

Approval Criteria

- The recipient has **ONE** of the following diagnoses [age requirements apply]:
  - atherosclerotic cardiovascular disease [18 years of age or older]; **OR**
  - primary hyperlipidemia (including heterozygous familial hypercholesterolemia [HeFH]) [18 years of age or older]; **OR**
  - heterozygous familial hypercholesterolemia (HeFH) [10 years to less than 18 years of age] **AND** the recipient is currently receiving at least **ONE** low-density lipoprotein-cholesterol (LDL-C) lowering agent, the name of which is **stated on the request**; **OR**
  - homozygous familial hypercholesterolemia (HoFH) [10 years of age or older] **AND** the recipient is currently receiving at least **ONE** low-density lipoprotein-cholesterol (LDL-C) lowering agent, the name of which is **stated on the request**; **AND**
- The requested medication is prescribed by, or the request states that this medication is being prescribed in consultation with, either a cardiologist or specialist in the treatment of lipid disorders; **AND**
- The recipient has received the maximally-tolerated FDA-approved dose of a statin agent for at least ~~12~~ 8 consecutive weeks without adequate response, **OR** has a documented intolerance to, or contraindication to statin agents [the name of the statin agent and date range of treatment are **stated on the request]**; **AND**
- For a non-preferred product, there is no preferred alternative that is the exact same chemical entity, formulation, strength, etc.; **AND**
- For a non-preferred product – **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 all of 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; **AND**
- By submitting the authorization request, the prescriber attests to the following:
  - The requested medication will not be used with other PCSK9 inhibitors; **AND**
  - Other treatment options (e.g., niacin or bile acid sequestrants) will be prescribed concomitantly if the recipient is intolerant to statins; **AND**

- 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 concomitant drug therapies or disease states that limit the use of the requested medication and will not receive the requested medication in combination with any medication that is contraindicated or not recommended per FDA labeling.

Duration of initial approval: 6 months

Reauthorization Criteria

- The recipient continues to meet initial approval criteria; **AND**
- Where applicable according to initial approval criteria, the recipient is currently receiving at least **ONE** low-density lipoprotein-cholesterol (LDL-C) lowering agent, the name of which is **stated on the request**; **AND**
- The prescriber **states on the request** that the recipient is established on the medication with evidence of a positive response to therapy.

Duration of reauthorization approval: 12 months

Inclisiran (Leqvio®)

Approval Criteria

- The recipient is 18 years of old or older on the date of the request; **AND**
- The recipient has a diagnosis of:
  - Heterozygous familial hypercholesterolemia (HeFH); **OR**
  - Clinical atherosclerotic cardiovascular disease (ASCVD); **AND**
- The recipient has received the maximally-tolerated FDA-approved dose of a statin agent for at least ~~12~~ 8 consecutive weeks and requires additional lowering of LDL-C [the name of the statin agent and date range of treatment are **stated on the request**]; **AND**
- The recipient will continue to receive the maximally-tolerated FDA-approved dose of a statin agent [the name of the statin agent is **stated on the request**]; **AND**
- The requested medication is prescribed by, or the request states that this medication is being prescribed in consultation with, either a cardiologist or specialist in the treatment of lipid disorders; **AND**
- For a non-preferred product, there is no preferred alternative that is the exact same chemical entity, formulation, strength, etc.; **AND**
- For a non-preferred product – **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 all of 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; **AND**
- By submitting the authorization request, the prescriber attests to the following:
    - The requested medication will not be used in combination with PCSK9 therapy; **AND**
    - 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 concomitant drug therapies or disease states that limit the use of the requested medication and will not receive the requested medication in combination with any medication that is contraindicated or not recommended per FDA labeling.

Duration of initial approval: 6 months

Reauthorization Criteria

- The recipient continues to meet initial approval criteria; **AND**
- The recipient will continue to receive the maximally-tolerated FDA-approved dose of a statin agent [the name of the statin agent is **stated on the request**]; **AND**
- The prescriber **states on the request** that the recipient is established on the medication with evidence of a positive response to therapy.

Duration of reauthorization approval: 12 months

Lomitapide (Juxtapid®)

Approval Criteria

- The recipient is 18 years of age or older; **AND**
- The recipient has a diagnosis of homozygous familial hypercholesterolemia (HoFH); **AND**
- The recipient is currently receiving at least **ONE** lipid lowering treatment, the name of which is **stated on the request**; **AND**
- Juxtapid® is prescribed by, or the request states that this medication is being prescribed in consultation with, either a cardiologist or specialist in the treatment of lipid disorders; **AND**
- The recipient has a documented failure of, or intolerance to, or contraindication to an adequate trial (~~3~~ 8 weeks~~months~~) of a statin agent [the name of the statin agent and date range of treatment are **stated on the request]**; **AND**
- For a non-preferred product, there is no preferred alternative that is the exact same chemical entity, formulation, strength, etc.; **AND**
- For a non-preferred product – **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 all of 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; **AND**
- 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 concomitant drug therapies or disease states that limit the use of the requested medication and will not receive the requested medication in combination with any medication that is contraindicated or not recommended per FDA labeling.

Duration of initial approval: 6 months

Reauthorization Criteria

- The recipient continues to meet initial approval criteria; **AND**
- The recipient is currently receiving at least **ONE** lipid lowering treatment, the name of which is **stated on the request**; **AND**
- The prescriber **states on the request** that the recipient is established on the medication with evidence of a positive response to therapy.

Duration of reauthorization approval: 12 months

References

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Revision / Date	**Implementation Date**
Single PDL Implementation	May 2019
Updated diagnosis for Praluent®, added Evkeeza™, updated references, removed defining parameters for diagnosis, formatting changes / May 2021	October 2021
Formatting changes, removed quantity limits for Praluent®, Repatha®, and Juxtapid® / August 2021	January 2022
Updated age indication for Repatha® / October 2021	April 2022
Clarified concurrent use requirements for Juxtapid® / December 2021	April 2022
Added Leqvio®, formatting changes, updated references / February 2022	July 2022
Modified statin previous use requirement for Evkeeza™, Juxtapid®, Leqvio®, Praluent®, and Repatha® / May 2023	July 2023