

AvMed

PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request. All other information may be filled in by office staff; **fax to 1-305-671-0200**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process can be delayed.**

Drug Requested: Juxtapid[®] (lomitapide)

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member AvMed #: _____ Date of Birth: _____

Prescriber Name: _____

Prescriber Signature: _____ Date: _____

Office Contact Name: _____

Phone Number: _____ Fax Number: _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

Dosing Schedule: _____ Length of Therapy: _____

Diagnosis: _____ ICD Code, if applicable: _____

Weight (if applicable): _____ Date weight obtained: _____

Requested Medication is **ONE** of the following:

- ☐ New Start
- ☐ Continuation of therapy – provide therapy start date: _____

Recommended Dosage:

- **Adults** – Oral: Initial: 5 mg once daily; after ≥ 2 weeks of therapy, may increase to 10 mg once daily, as tolerated; then at ≥ 4 -week intervals, may increase to 20 mg once daily, then to 40 mg once daily, and finally to a maximum dose of 60 mg/day as tolerated.
- **Children ≥ 2 years and Adolescents < 18 years** – Oral: Initial dose and titration schedule varies based on age; titrate dose as needed based on patient tolerability, desired low-density lipoprotein cholesterol (LDL-C) levels, and adverse effects. Adjust dose as needed when patient crosses into next age group.

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Age Groups	Weeks 0 to 4	Weeks 5 to 8	Weeks 9 to 12	Weeks 13 to 16	Weeks 17 and beyond
2 to < 11 years	2 mg once daily	Continue 2 mg once daily	Increase to 5 mg once daily	Increase to 10 mg once daily	Increase to 20 mg once daily. Max daily dose: 20 mg/day
11 to < 16 years	2 mg once daily	Increase to 5 mg once daily	Increase to 10 mg once daily	Increase to 20 mg once daily	Increase to 40 mg once daily. Max daily dose: 40 mg/day
16 to < 18 years	5 mg once daily	Increase to 10 mg once daily	Increase to 20 mg once daily	Increase to 40 mg once daily	Continue 40 mg once daily. Max daily dose: 40 mg/day

Quantity Limits:

- 2, 5 & 10 mg capsules – 1 capsule per day
- 20 & 30 mg capsules – 2 capsules per day

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Initial Authorization: 6 months

- ☐ Member must be 2 years of age or older
- ☐ Requested medication is prescribed by or in consultation with a specialist in cardiology, lipidology, or endocrinology
- ☐ Baseline low-density lipoprotein cholesterol (LDL-C), total cholesterol (TC), apolipoprotein B (apo B), and non-high density lipoprotein cholesterol (non-HDL-C) labs must be obtained prior to initiating treatment (**please submit labs from the past 30 days with request**)
- ☐ Member does **NOT** have heterozygous familial hypercholesterolemia (HeFH)
- ☐ Member has a diagnosis of Homozygous Familial Hypercholesterolemia (HoFH) confirmed by at least **ONE** of the following:
 - ☐ Documented DNA test for functional mutation(s) in LDL receptor alleles or alleles known to affect LDL receptor functionality (**submit test results with request**)
 - ☐ Untreated LDL-C > 500 mg/dL **OR** treated LDL-C ≥ 300 mg/dL along with **ONE** of the following
 - ☐ Cutaneous or tendon xanthoma before 10 years of age
 - ☐ Untreated LDL cholesterol levels consistent with heterozygous FH in both parents (> 190 mg/dL)
- ☐ Member has been receiving stable background lipid lowering therapy for at least 4 weeks (**verified by pharmacy paid claims**)

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- ☐ Requested therapy will be used in conjunction with a low-fat or heart-healthy diet and other LDL-lowering therapies (e.g., statins, ezetimibe, PCSK9 inhibitors, LDL apheresis)
- ☐ Member has had an unsuccessful 3-month trial of **ALL** the following, unless not FDA-approved for use in the member's age (**verified by pharmacy and medical paid claims and/or submitted genetic test results**):
 - ☐ Highest available (or maximally tolerated) dose of atorvastatin **OR** rosuvastatin
 - ☐ ezetimibe (Zetia[®])
 - ☐ PCSK9 inhibitor indicated for HoFH (e.g., Repatha), unless contraindicated or if pathogenic/likely pathogenic null-null variant (e.g. LDLR, APOB, PCSK9, or LDLRAP1) is confirmed by genetic testing
 - ☐ Evkeeza[®] (evinacumab)
- ☐ Despite pharmacological treatment with Evkeeza, a PCSK9 inhibitor, maximally tolerated statin therapy, and ezetimibe, the member's LDL cholesterol remains ≥ 100 mg/dL (or ≥ 70 mg/dL for members with clinical atherosclerotic cardiovascular disease [ASCVD]) while on therapy (**submit pre- and post-treatment cholesterol labs**)
- ☐ If there has been **no response** to a PCSK9 inhibitor (e.g. after an adherent trial, labs show LDL-C has remained the same or increased), PCSK9 inhibitor therapy will be discontinued (**NOTE**: PCSK9 inhibitor therapy may be continued with Juxtapid if LDL-C lowering has been demonstrated while on a PCSK9 inhibitor)

***Provider please note: If the member is not able to use the maximum dose of atorvastatin or rosuvastatin due to muscle symptoms, documentation of a causal relationship must be established between statin use and muscle symptoms**

- ☐ Member must meet **ONE** of the following:
 - ☐ Clinical documentation must demonstrate that the member experienced pain, tenderness, stiffness, cramping, weakness, and/or fatigue in addition to **ALL** the following:
 - ☐ Muscle symptoms resolve after discontinuation of statin
 - ☐ Muscle symptoms occurred when re-challenged at a lower dose of the same statin
 - ☐ Muscle symptoms occurred after switching to an alternative statin
 - ☐ Documentation ruling out non-statin causes of muscle symptoms (e.g., hypothyroidism, reduced renal function, reduced hepatic function, rheumatologic disorders, such as polymyalgia rheumatica, steroid myopathy, vitamin D deficiency, or primary muscle disease)
 - ☐ Member has been diagnosed with rhabdomyolysis associated with statin use and the diagnosis is supported by acute neuromuscular illness or dark urine **AND** an acute elevation in creatine kinase (usually $> 5,000$ IU/L or 5 times the upper limit of normal [ULN])
- ☐ Prescriber and member are enrolled in the Juxtapid REMS program, and provider will monitor the member's liver function during treatment with Juxtapid
- ☐ Member has no contraindications to therapy with Juxtapid (e.g., pregnancy, coadministration with moderate or strong CYP3A4 inhibitors, moderate to severe hepatic impairment, or active liver disease)

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- ☐ Prescriber attests member has been counseled to reduce risk of fat-soluble nutrient deficiency by taking daily supplements that contain amounts of vitamin E, alpha-linolenic acid, eicosapentaenoic acid (EHA), and docosahexaenoic acid (DHA) as recommended in the Juxtapid prescribing information
- ☐ The member's dose will **NOT** exceed the age-specific maximum recommended dose

Reauthorization: 12 months. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ☐ Requested therapy continues to be used in conjunction with a low-fat or heart-healthy diet and other LDL-lowering therapies (e.g., statins, ezetimibe, PCSK9 inhibitors, LDL apheresis)
- ☐ Member has experienced a reduction in LDL-C when compared to the initial baseline labs (**submit labs collected within the last 3 months**)
- ☐ Member has **NOT** experienced any unacceptable toxicity from therapy (e.g., elevated transaminases, hepatic steatosis, hepatotoxicity, or intolerable gastrointestinal side effects)
- ☐ Prescriber will continue to monitor the member's liver function during treatment with Juxtapid
- ☐ Member has no contraindications to therapy with Juxtapid (e.g., pregnancy, coadministration with moderate or strong CYP3A4 inhibitors, moderate to severe hepatic impairment, or active liver disease)
- ☐ Prescriber attests member has been counseled to reduce risk of fat-soluble nutrient deficiency by taking daily supplements that contain amounts of vitamin E, alpha-linolenic acid, eicosapentaenoic acid (EHA), and docosahexaenoic acid (DHA) as recommended in the Juxtapid prescribing information
- ☐ The member's dose will **NOT** exceed the age-specific maximum recommended dose

Medication being provided by Specialty Pharmacy – Proprium Rx

Not all drugs may be covered under every Plan

If a drug is non-formulary on a Plan, documentation of medical necessity will be required.

*****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.*****

****Previous therapies will be verified through pharmacy paid claims or submitted chart notes.****