Sample Letter of Medical Necessity for JUXTAPID® (lomitapide) capsules

This sample letter is intended as a general guide for submitting information to payers to substantiate medical necessity of JUXTAPID. It is prescriber's responsibility to verify and ensure the accuracy of the content included in the letter. All information provided to payers must be truthful and accurate. ***Use of the information in this letter does not guarantee that the payer will provide coverage for JUXTAPID and is not intended to be a substitute for, or an influence on, the independent medical judgment of the prescriber.***

For additional information, please contact Compass at 1-85-JUXTAPID (1-855-898-2743) Monday through Friday from 8AM - 7PM ET. Visit JUXTAPID.com to download a copy. Please see full Prescribing Information available at JUXTAPIDpro.com and https://protect-us.mimecast.com/s/cZ9RC4xWr0tEjgQlODbdi?domain=juxtapidpro.com.

[Date]
ATTN: Medical Review
[Contact name]
[Insurance company]
[Insurance street address]
[Insurance city, state, ZIP]

Re:
[Patient name]
[Date of birth]
[Policy #]
[Group #]

Dear [Contact name]:

I am writing on behalf of [patient name] to document the medical necessity for JUXTAPID® (lomitapide) capsules for the treatment of homozygous familial hypercholesterolemia (HoFH). This letter provides the clinical history, treatment rationale, and other documents that support the use of JUXTAPID for this adult patient with HoFH.

Clinical History
[Patient name] is a [age]-year-old [female/male]. The patient was initially diagnosed with HoFH by [name of referring physician], and has been in my care since [date]. The diagnosis of HoFH for this patient is based upon [provide details regarding the patient's diagnostic workup and history. Payers often request the patient's clinical history, including but not limited to: response to statins and other lipid lowering therapy, LDL-C levels, history of CVD, family history on both sides of elevated cholesterol and/or CVD, any physical findings such as xanthomas.] Currently, the patient [discuss the patient's current condition (e.g., signs, symptoms, functioning)].

Prior Therapies
[Include other therapies used for the same diagnosis, dosages, duration of treatment and reason for discontinuation.]

Product Description
JUXTAPID is a microsomal triglyceride transfer protein inhibitor indicated as an adjunct to a low-fat diet and other lipid-lowering treatments, including LDL apheresis where available, to reduce low-density lipoprotein cholesterol (LDL-C), total cholesterol (TC), apolipoprotein B (apo B), and non-high-density lipoprotein cholesterol (non-HDL-C) in patients with homozygous familial hypercholesterolemia (HoFH).

The safety and effectiveness of JUXTAPID have not been established in patients with hypercholesterolemia who do not have HoFH, including those with heterozygous familial hypercholesterolemia (HeFH). The effect of JUXTAPID on cardiovascular morbidity and mortality has not been determined.

Because of the risk of hepatotoxicity, JUXTAPID is available only through a restricted program called the JUXTAPID REMS Program. **JUXTAPID should only be prescribed to patients with a clinical or laboratory diagnosis consistent with HoFH.**

I have completed the necessary training for the appropriate selection and monitoring of patients for the safe use of JUXTAPID per the conditions of the REMS program. I am certified to prescribe JUXTAPID under the conditions of the JUXTAPID REMS Program, and have completed the FDA required patient counseling with [INSERT PATIENT NAME] on the JUXTAPID REMS Program requirements and the JUXTAPID REMS Program Prescription Authorization Form.

Rationale for Initiating JUXTAPID
[Highlight factors that led you to recommend the use of JUXTAPID for this adult patient with HoFH, which may include pretreatment LDL level and current LDL level.]

In closing, I ask that you approve JUXTAPID coverage for [Patient name] and that you update your formulary to include coverage for this medication for adult HoFH patients. Please contact me at [prescriber's telephone number] or [prescriber's email] if additional information is required for approval of this request. I look forward to receiving your response as soon as possible.

Enclosed is the full Prescribing Information including Box Warning for JUXTAPID

Sincerely,

[Prescriber name]

Enclosures
JUXTAPID full Prescribing Information including Box Warning
{Excerpts of medical records}