

Juxtapid[®], Kynamro[®] – Prior Authorization Request

Send completed form to: Case Review Unit CVS/caremark Specialty Programs Fax: 866-249-6155

CVS/caremark administers the prescription benefit plan for the patient identified. This patient's benefit plan requires prior authorization for certain medications in order for the drug to be covered. To make an appropriate determination, providing the most accurate diagnosis for the use of the prescribed medication is necessary. **Please respond below and fax this form to CVS/caremark toll-free at 866-249-6155.** If you have questions regarding the prior authorization, please contact CVS/caremark at **866-814-5506**. For inquiries or questions related to the patient's eligibility, drug copay or medication delivery, please contact the Specialty Customer Care Team: CaremarkConnect[®] 800-237-2767.

| | |
|------------------------------------|---------------------------------|
| Patient Name: | Date: |
| Patient's ID: | Patient's Date of Birth: |
| Physician's Name: | |
| Specialty: | NPI#: |
| Physician Office Telephone: | Physician Office Fax: |

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

1. What drug is being prescribed?
 Juxtapid[®] Kynamro[®] Other _____
2. What is the prescribed dose and frequency? _____ mg per day/week (circle one)
3. What is the diagnosis?
 Homozygous familial hypercholesterolemia (HoFH)
 Other _____
4. What is the ICD code? _____
5. Would the prescriber like to request an override of the step therapy requirement? Yes No If no, skip to #8
6. Has the member received the medication through a pharmacy or medical benefit within the past 180 days? Yes No
ACTION REQUIRED: Please provide documentation to substantiate the member had a prescription paid for within the past 180 days (i.e., PBM medication history, pharmacy receipt, EOB etc.)
7. Is the medication effective in treating the member's condition? Yes No
 Continue to #8 and complete this form in its entirety.
8. What is the patient's age? _____ years
9. What is the prescriber's specialty?
 Lipid specialist, skip to #11 Cardiometabolic specialist, skip to #11
 Cardiology Endocrinology
 Other _____
10. Does the patient live in an area where access to lipid specialists and cardiometabolic specialists is limited (e.g., rural or island)? Yes No
11. Is the patient receiving the prescribed drug? Yes No **If Yes, document PA / reference #** _____
12. Does the patient have documented skin fibroblast LDLR activity less than 20% normal OR mutations in both alleles at LDLR, APO-B, PCSK9, OR ARH adapter protein gene locus?
Attention Required: If Yes, attach documentation of test results
 Yes – skin fibroblast LDLR activity less than 20% normal
 Yes – mutations in both alleles at LDLR
 Yes – mutations in both alleles at APO-B

- Yes – mutations in both alleles at PCSK9
- Yes – mutations in both alleles at ARH adapter protein gene locus
- No, skip to #17

13. Is the documentation of the test result attached? Yes No

14. What is the patient's **untreated** low-density lipoprotein cholesterol (LDL-C) level? _____ mg/dL Unknown
Action Required: Attach untreated LDL-C level. If Unknown, skip to #16.

15. Is the untreated LDL-C level attached? Yes No

16. What is the patient's triglyceride level (TG)? _____ mg/dL Unknown
Action Required: Attach triglyceride level. If Unknown, skip to #16.

17. Is the current triglyceride level attached? Yes No

18. Do both of the patient's parents have a history of LDL-C levels greater than 190mg/dL? Yes No Unknown
Action Required: If yes, attach documentation of LDL-C levels. If no/unknown, skip to #20.

19. Is the documentation of both parents' LDL-C levels attached? Yes No Skip to #22

20. Did/does patient have tendon or cutaneous xanthomas at age 10 or younger? Yes No
Action Required: If yes, attach documentation (e.g., chart notes with age or date(s))

21. Is documentation (e.g., chart notes with age or date(s)) attached? Yes No

22. Prior to initiation of treatment with Juxtapid or Kynamro, is/was the patient experiencing an inadequate response to at least a 3-month trial of a combination lipid-lowering therapy regimen? Yes No

23. Please specify the treatment option the patient is/was receiving as part of the combination treatment.
Action Required: If yes, indicate below and attach documentation of previous and current treatment regimen(s).

List medications tried, daily dose and duration. Please include brand-name if applicable (e.g., combination products and fenofibrate products)

| | | |
|-------------|-------------------------|-----------------------|
| Drug: _____ | Total daily dose: _____ | Total duration: _____ |
| Drug: _____ | Total daily dose: _____ | Total duration: _____ |
| Drug: _____ | Total daily dose: _____ | Total duration: _____ |
| Drug: _____ | Total daily dose: _____ | Total duration: _____ |
| Drug: _____ | Total daily dose: _____ | Total duration: _____ |

24. Is the documentation of previous and current treatment regimen(s) (e.g., LDL-apheresis, name of medications, total daily doses) attached? Yes No

25. What is the patient's **treated** low-density lipoprotein cholesterol (LDL-C) level? _____ mg/dL Unknown
If greater than or equal to 300mg/dL, skip to #28.

26. Does the patient have a documented coronary heart disease? Yes No
 CHD is defined as having at least one of the following (Indicate below or mark "None of the above."):

- A prior myocardial infarction (MI)
- A prior coronary artery bypass graft surgery (CABG)
- Coronary arteriogram demonstrating significant coronary artery disease (CAD) or a prior percutaneous transluminal coronary angioplasty (PTCA) with or without arterectomy or coronary stent placement
- Significant angina pectoris with a positive thallium or other heart scanning stress test
- None of the above

Action Required: If yes, attach documentation.

27. Is the documentation of coronary heart disease with date(s) of event attached? Yes No

28. Does the patient have moderate or severe hepatic impairment (e.g., Child-Pugh B or C)? Yes No

Complete the following section if the patient is currently on the prescribed drug.

29. Has therapy with the prescribed agent demonstrated efficacy by (maintenance of) LDL-C reduction greater than 20% from levels immediately prior to initiation of treatment with the prescribed agent? Yes No

Action Required: Attach documentation of reduction.

30. Are the current LDL-C level and documentation of the LDL-C reduction (or maintenance of LDL-C reduction) attached?

Yes No

31. What are the current ALT and AST levels? **Attach documentation of liver function tests.**

- ALT and AST less than 3 times upper limit of normal
- ALT or AST 3-5 times upper limit of normal
- ALT or AST greater than or equal to 5 times upper limit of normal

32. Are the liver function test results attached? Yes No

33. If the ALT or AST less than 3 times upper limit of normal, does the patient have clinical symptoms of liver injury or toxicity, increases in bilirubin greater than or equal to 2 times upper limit of normal (ULN), or active liver disease?

Yes No Not applicable

I attest that this information is accurate and true, and that documentation supporting this information is available for review if requested by CVS/caremark or the benefit plan sponsor.

X _____

Prescriber or Authorized Signature

Date: (mm/dd/yy)

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