UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 1165-9
Program	Prior Authorization/Notification
Medication	Repatha® (evolocumab)
P&T Approval Date	9/2015, 9/2016, 9/2017, 2/2018, 5/2019, 5/2020, 6/2021, 6/2022, 6/2023
Effective Date	9/1/2023; Oxford: N/A

1. Background:

Repatha® (evolocumab) is a PCSK9 (Proprotein Convertase Subtilisin Kexin Type 9) inhibitor antibody indicated:

- To reduce the risk of myocardial infarction, stroke, and coronary revascularization in adults with established cardiovascular disease[1]
- As an adjunct to diet, alone or in combination with other low-density lipoprotein cholesterol (LDL-C)-lowering therapies (e.g., statins, ezetimibe), for the treatment of adults with primary hyperlipidemia (including heterozygous familial hypercholesterolemia) to reduce LDL-C
- As an adjunct to other LDL-C-lowering therapies (e.g., statins, ezetimibe, LDL apheresis) in adults and pediatric patients aged 10 years and older with homozygous familial hypercholesterolemia (HoFH) to reduce LDL-C[1]
- As an adjunct to diet and other LDL-C-lowering therapies in pediatric patients aged 10 years and older with heterozygous familial hypercholesterolemia (HeFH) to reduce LDL-C

2. Coverage Criteria[a]:

A. **Hyperlipidemia**

1. **Initial Authorization**

a. **Repatha** will be approved based on **all** of the following criteria:

(1) **One** of the following diagnoses:

(a) Primary hyperlipidemia

-OR-

(b) Atherosclerotic cardiovascular disease (ASCVD) (e.g., acute coronary syndromes, history of myocardial infarction, stable or unstable angina, coronary or other arterial revascularization, stroke, transient ischemic attack, or peripheral arterial disease presumed to be of atherosclerotic origin)

-AND-

(2) Patient has received comprehensive counseling regarding appropriate diet

-AND-

(3) Not used in combination with another proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor [e.g., Praluent (alirocumab)]

-AND-

(4) Not used in combination with Leqvio (inclisiran)

Authorization will be issued for 12 months

2. **Reauthorization**

a. **Repatha** will be approved based on **all** of the following criteria:

(1) Documentation of positive clinical response to Repatha therapy

-AND-

(2) Patient continues to receive comprehensive counseling regarding appropriate diet

-AND-

(3) Not used in combination with another proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor [e.g., Praluent (alirocumab)]

-AND-

(4) Not used in combination with Leqvio (inclisiran)

Authorization will be issued for 12 months

B. Heterozygous Familial Hypercholesterolemia

1. **Initial Authorization**

a. **Repatha** will be approved based on **all** of the following criteria:

(1) Diagnosis of heterozygous familial hypercholesterolemia (HeFH)

-AND-

(2) Patient has received comprehensive counseling regarding appropriate diet

-AND-

(3) Not used in combination with another proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor [e.g., Praluent (alirocumab)]

-AND-

(4) Not used in combination with Leqvio (inclisiran)

-AND-

(5) **One** of the following:

(a) Patient is equal to or greater than 18 years old

-OR-

(b) **Both** of the following:

i. Patient is less than 18 years old

-AND-

ii. Patient is receiving other lipid-lowering therapy (e.g., statin, ezetimibe, LDL apheresis)

Authorization will be issued for 12 months

2. **Reauthorization**

a. **Repatha** will be approved based on **all** of the following criteria:

(1) Documentation of positive clinical response to Repatha therapy

-AND-

(2) Patient continues to receive comprehensive counseling regarding appropriate diet

-AND-

(3) Not used in combination with another proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor

-AND-

(4) Not used in combination with Leqvio (inclisiran)

-AND-

(5) **One** of the following:

(a) Patient is equal to or greater than 18 years old

-OR-

(b) **Both** of the following:

i. Patient is less than 18 years old

-AND-

ii. Patient is receiving other lipid-lowering therapy (e.g., statin, ezetimibe, LDL apheresis)

Authorization will be issued for 12 months

C. **Homozygous Familial Hypercholesterolemia**

1. **Initial Authorization**

a. **Repatha** will be approved based on **all** of the following criteria:

(1) Diagnosis of homozygous familial hypercholesterolemia

-AND-

(2) Patient is receiving other lipid-lowering therapy (e.g., statin, ezetimibe, LDL apheresis)

-AND-

(3) Patient has received comprehensive counseling regarding appropriate diet

-AND-

(4) Not used in combination with another proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor [e.g., Praluent (alirocumab)]

-AND-

(5) Not used in combination with Juxtapid (lomitapide)

Authorization will be issued for 12 months

2. **Reauthorization**

a. **Repatha** will be approved based on **all** of the following criteria:

(1) Documentation of positive clinical response to Repatha therapy

-AND-

(2) Patient is receiving other lipid-lowering therapy (e.g., statin, ezetimibe, LDL apheresis)

-AND-

(3) Patient continues to receive comprehensive counseling regarding appropriate diet

-AND-

(4) Not used in combination with another proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor

-AND-

(5) Not used in combination with Juxtapid (lomitapide)

Authorization will be issued for 12 months

[a]State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Medical Necessity, Supply Limits and Step Therapy may be in place.

4. References:

1. Repatha [package insert]. Thousand Oaks, CA: Amgen Inc.; September 2021.

Program	Prior Authorization/Notification – Repatha® (evolocumab)
Change Control	
9/2015	New program.
9/2016	Annual Review. Updated reference.
9/2017	Annual review with no changes to coverage criteria.
2/2018	Updated background and coverage criteria to include new indication for patients with primary hyperlipidemia alone or in combination with other lipid lowering therapies. Updated reference.
5/2019	Annual review. Removed Kynamro from homozygous familial

	hypercholesterolemia criteria as no longer on market. Updated reference.
5/2020	Annual review with no changes to coverage criteria.
6/2021	Annual review. Updated initial authorization duration to 12 months. Added Praluent as an example to concomitant use criteria to align PCSK9 program formatting. No changes to coverage criteria. Updated reference.
6/2022	Annual review. Updated background and coverage criteria to include new indications per package insert for pediatric patients with heterozygous familial hypercholesterolemia and homozygous familial hypercholesterolemia. Updated reference.
6/2023	Annual review. Updated background. Added criteria that Repatha is not to be used in combination with Leqvio.