



Praluent® (alirocumab) – New orphan indication

- On April 1, 2021, the FDA approved Regeneron's **Praluent (alirocumab)**, as an adjunct to other low density lipoprotein cholesterol (LDL-C)-lowering therapies in adult patients with homozygous familial hypercholesterolemia (HoFH) to reduce LDL-C.
- Praluent is also approved:
 - To reduce the risk of myocardial infarction, stroke, and unstable angina requiring hospitalization in adults with established cardiovascular disease.
 - As an adjunct to diet, alone or in combination with other LDL-C-lowering therapies, in adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH), to reduce LDL-C.
- The approval of Praluent for the new indication was based on ODYSSEY HoFH, a double-blind, placebo-controlled study in 45 adult patients with HoFH. Patients were taking maximally tolerated doses of statins with or without other lipid-lowering therapy and required additional LDL-C reduction. Patients were randomized to Praluent or placebo.
 - At week 12, the treatment difference between Praluent and placebo in mean LDL-C percent change from baseline was -36% (95% CI: -51, -20; $p < 0.0001$).
- The recommended dose of Praluent for the treatment of HoFH is 150 mg once every 2 weeks administered subcutaneously.
 - LDL-C should be assessed when clinically appropriate. The LDL-lowering effect of Praluent may be measured as early as 4 weeks after initiation.
 - Refer to the Praluent drug label for dosing for its other indications



OptumRx® specializes in the delivery, clinical management and affordability of prescription medications and consumer health products. We are an Optum® company — a leading provider of integrated health services. Learn more at [optum.com](https://www.optum.com).

All Optum® trademarks and logos are owned by Optum, Inc. All other brand or product names are trademarks or registered marks of their respective owners.

This document contains information that is considered proprietary to OptumRx and should not be reproduced without the express written consent of OptumRx.

RxNews® is published by the OptumRx Clinical Services Department.

©2021 Optum, Inc. All rights reserved.