

ABOUT THIS GUIDE

This Guide provides a high-level overview of Patient Summary Reports in Care360 and how they can be used to help identify clinically appropriate and approvable patients who may be candidates for PRALUENT® (alirocumab) therapy based on the approved Indication. The overview is meant to provide guidance for you, your practice electronic health record (EHR) champion, or IT staff.

Experienced users are the main focus of this Guide; not every step is included in the instructions, and this is not a replacement for training from Care360. There are several ways to approach each workflow in Care360. This Guide highlights one workflow; however, you may be familiar with an alternative approach. Please note that this Guide was created based upon Care360 version 2016.2. Screens and features may change as new software versions are released.

INDICATIONS AND USAGE

- PRALUENT is a PCSK9 (Proprotein Convertase Subtilisin/Kexin Type 9) inhibitor antibody indicated as adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or clinical atherosclerotic cardiovascular disease, who require additional lowering of LDL-C
- The effect of PRALUENT on cardiovascular morbidity and mortality has not been determined

IMPORTANT SAFETY INFORMATION

- PRALUENT is contraindicated in patients with a history of a serious hypersensitivity reaction to PRALUENT. Reactions have included hypersensitivity vasculitis and hypersensitivity reactions requiring hospitalization

Please see accompanying full [Prescribing Information](#)



Using Patient Summary Reports

The Patient Summary Report can be helpful to identify Atherosclerotic Cardiovascular Disease (ASCVD) or Heterozygous Familial Hypercholesterolemia (HeFH) patients meeting certain criteria, including diagnosis, current and prior medications, LDL-C values, and other clinical or patient demographic information. When used effectively, this report provides an opportunity to identify patients with uncontrolled LDL-C who are clinically appropriate and approvable for PRALUENT therapy based upon clinician decision to treat.

A Patient Summary Report can be used to streamline the PRALUENT payer approval process by:

- Determining clinically appropriate and approvable patients based on payer utilization management criteria
- Reducing burden and frustration of submitting patients who are not prior authorization (PA) criteria-eligible based on the payer coverage
- Identifying gaps-in-care to contact patients who may be considered for treatment modification

IMPORTANT SAFETY INFORMATION

- Hypersensitivity reactions (e.g., pruritus, rash, urticaria), including some serious events (e.g., hypersensitivity vasculitis and hypersensitivity reactions requiring hospitalization), have been reported with PRALUENT treatment. If signs or symptoms of serious allergic reactions occur, discontinue treatment with PRALUENT, treat according to the standard of care, and monitor until signs and symptoms resolve

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Patient Summary Report Criteria

Patient Summary Reports can be created from multiple criteria such as lab values, medications, and patient diagnoses. For example, EHR criteria could include patients with clinical ASCVD, being on maximally tolerated statin therapy atorvastatin 40 mg/day and having elevated LDL-C ≥ 70 mg/dL or ≥ 100 mg/dL, depending on insurance.

Factors That May Impact Patient Summary Reports

The number of patients appearing on a Patient Summary Report may be impacted by the clinical data available in the EHR; for example, if lab results are saved in the EHR as a PDF file and not available for use as 'data' to be queried. Additionally, in those cases where lab results are received from multiple laboratories, it may be necessary to select each lab's order codes to enable all appropriate patients to appear on the Patient Summary Report.

The query criteria should consider active patients only (not deceased or inactive, as determined by the practice). Also, medications prescribed before the EHR was implemented might not be included in a patient's medications list. These information gaps can reduce the number of patients on a Patient Summary Report.



Praluent[®]
(alirocumab) Injection 75mg/mL
150mg/mL
Redefining Possible

Reporting: Creating a Patient Summary Report

A patient list, called a Patient Summary Report in Care360, is an EHR system report that identifies all patients meeting certain criteria. Available criteria include diagnosis, current and prior medications, lab values, and other clinical or patient demographic information.

A Patient Summary Report may be created to identify patients with heterozygous familial hypercholesterolemia or atherosclerotic cardiovascular disease who are not at their LDL-C goal who are currently on maximally tolerated statin therapy.

The following steps illustrate how to run a Patient Summary Report to help identify examples of appropriate patients for PRALUENT, based on the approved indication, who may be candidates for treatment intensification in Care360.

REPORTING: CREATING A PATIENT SUMMARY REPORT

1. Navigate to Reports, and select Patient > Patient Summary.
2. Navigate to **Informatics Query**.
3. Select appropriate criteria; Test Names/Codes for Lab (LDL-C \geq 70 mg/dL or \geq 100 mg/dL, depending on insurance), Medications (eg, atorvastatin, rosuvastatin), Diagnoses (Clinical ASCVD [eg, stroke, transient ischemic attack, acute coronary syndromes, history of myocardial infarction, stable or unstable angina, coronary or other arterial revascularization, peripheral arterial disease] plus hypercholesterolemia OR HeFH).
4. After all criteria have been added, click **Run Query**.

The screenshot shows the 'Informatics Query Criteria' interface. It is organized into four main sections:

- Test Names/Codes:** Includes checkboxes for 'Include All Tests' and 'Show Analytes', a 'Date Collected or Reported' dropdown set to 'Last (x) Days' with a value of '30 Days', a 'Search Labs By' dropdown set to 'Collected Date', and input fields for 'Status', 'Lab ID', and 'Account Number' with a 'Find Tests' button.
- Analyte Names/Codes:** Includes a checkbox for 'Show Out of Range Results Only' and a 'Status' dropdown with a 'Find Analytes' button.
- Medications:** Includes checkboxes for 'Include All Medications' and 'Show Active Only', a 'Date Medication Issued' dropdown set to 'Last (x) Days' with a value of '30 Days', and an 'Include Unknown Date' checkbox. It also has input fields for 'Medication Name' (with a 'Starts With' dropdown and an 'X' character), 'Prescribed to Pharmacy' (with a 'Starts With' dropdown), and buttons for 'Add a Medication' and 'Add a Pharmacy'.
- Diagnoses:** Includes input fields for 'ICD Code' (with a 'Starts With' dropdown), 'Diagnosis Description' (with a 'Starts With' dropdown), and a 'Diagnosis Date' dropdown, along with an 'Add a Diagnosis' button.

IMPORTANT SAFETY INFORMATION

- The most commonly occurring adverse reactions (\geq 5% of patients treated with PRALUENT and occurring more frequently than with placebo) are nasopharyngitis, injection site reactions, and influenza

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- The most commonly occurring adverse reactions ($\geq 5\%$ of patients treated with PRALUENT and occurring more frequently than with placebo) are nasopharyngitis, injection site reactions, and influenza
- Local injection site reactions including erythema/redness, itching, swelling, and pain/tenderness were reported more frequently in patients treated with PRALUENT 75 mg and/or 150 mg every 2 weeks (7.2% versus 5.1% for PRALUENT and placebo, respectively). Few patients discontinued treatment because of these reactions (0.2% versus 0.4% for PRALUENT and placebo, respectively), but patients receiving PRALUENT had a greater number of injection site reactions, had more reports of associated symptoms, and had reactions of longer average duration than patients receiving placebo
- The once-monthly (Q4W) 300mg dosing regimen had a higher rate of local injection site reactions as compared to PRALUENT 75 mg Q2W or placebo (16.6%, 9.6%, and 7.9%, respectively) in a trial in which all patients received an injection of drug or placebo every 2 weeks to maintain the blind. The discontinuation rate due to injection site reactions was 0.7% in the 300 mg Q4W arm and 0% in the other 2 arms
- Neurocognitive events were reported in 0.8% of patients treated with PRALUENT and 0.7% of patients treated with placebo. Confusion or memory impairment were reported more frequently by those treated with PRALUENT (0.2% for each) than in those treated with placebo ($<0.1\%$ for each)
- Liver-related disorders (primarily related to abnormalities in liver enzymes) were reported in 2.5% of patients treated with PRALUENT and 1.8% of patients treated with placebo, leading to treatment discontinuation in 0.4% and 0.2% of patients, respectively. Increases in serum transaminases to greater than 3 times the upper limit of normal occurred in 1.7% of patients treated with PRALUENT and 1.4% of patients treated with placebo
- The most common adverse reactions leading to treatment discontinuation in patients treated with PRALUENT were allergic reactions (0.6% versus 0.2% for PRALUENT and placebo, respectively) and elevated liver enzymes (0.3% versus $<0.1\%$)
- PRALUENT is a human monoclonal antibody. As with all therapeutic proteins, there is a potential for immunogenicity with PRALUENT

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Praluent[®]
(alirocumab) Injection 75mg/mL
150mg/mL
Redefining Possible

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