Registry Reports

eClinicalWorks

ABOUT THIS GUIDE

This Guide provides a high-level overview of Registry Reports in eClinicalWorks 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 eClinicalWorks. There are several ways to approach each workflow in eClinicalWorks. This Guide highlights one workflow; however, you may be familiar with an alternative approach. Please note that this Guide was created based upon eClinicalWorks version 10. Screens and features may change as new software versions are released.

INDICATIONS AND USAGE

PRALUENT (alirocumab) is indicated:

- 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 lipid-lowering therapies (e.g., statins, ezetimibe), for the treatment of adults with primary hyperlipidemia (including heterozygous familial hypercholesterolemia) to reduce low-density lipoprotein cholesterol (LDL-C)

IMPORTANT SAFETY INFORMATION

- PRALUENT is contraindicated in patients with a history of a serious hypersensitivity reaction to PRALUENT, including hypersensitivity vasculitis and hypersensitivity reactions requiring hospitalization

Please see accompanying full Prescribing Information

Praluent®
(alirocumab) Injection 75mg/mL 150mg/mL
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Using Registry Reports

The Registry Report can be helpful to identify established Cardiovascular Disease (eg, myocardial infarction, stroke or unstable angina requiring hospitalization) 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 Registry 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

Report Criteria

Registry Reports can be created from multiple criteria such as lab values, medications, and patient diagnoses. For example, EHR criteria could include patients with a diagnosis of established cardiovascular disease (eg, myocardial infarction, stroke or unstable angina requiring hospitalization) with or without concomitant use of maximally tolerated statin therapy (eg, atorvastatin 40 mg/day) and having elevated LDL-C ≥70 mg/dL or ≥100 mg/dL, depending on insurance.

Factors That May Impact Registry Reports

The number of patients appearing on a Registry 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 Registry 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 Registry Report.

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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Reporting: Creating a Registry Report

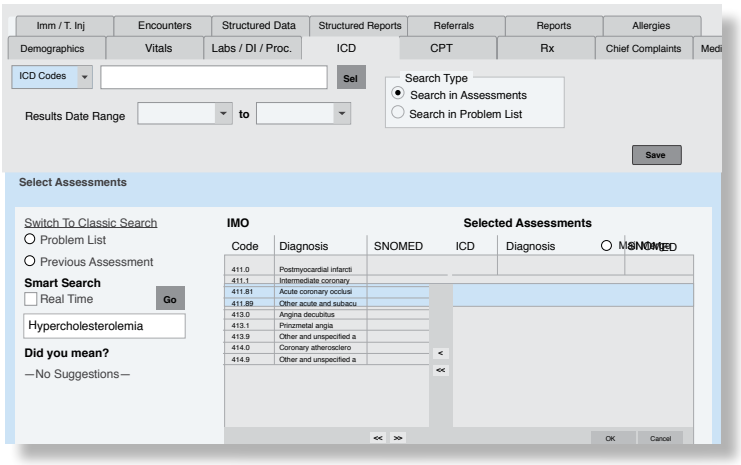
A patient list, called Registry Reports in eClinicalWorks, is an EHR system report that identifies all patients meeting certain criteria. Available criteria include diagnosis, current and prior medications, lab values, and other clinical or patient demographic information.

A report may be created to identify patients with heterozygous familial hypercholesterolemia or established cardiovascular disease (eg, myocardial infarction, stroke or unstable angina requiring hospitalization) who are not at their LDL-C goal who may also be currently on maximally tolerated statin therapy.

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

REPORTING: CREATING A REGISTRY REPORT

1. Navigate to **Reports, Registry.**
2. Select the **ICD** tab, click **Sel** to search for appropriate diagnosis codes (Cardiovascular Disease [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). Click **OK** when done.



IMPORTANT SAFETY INFORMATION

- The most commonly occurring adverse reactions in clinical trials in primary hyperlipidemia (including heterozygous familial hypercholesterolemia (HeFH)) (≥5% of patients treated with PRALUENT and occurring more frequently than with placebo) are nasopharyngitis, injection site reactions, and influenza

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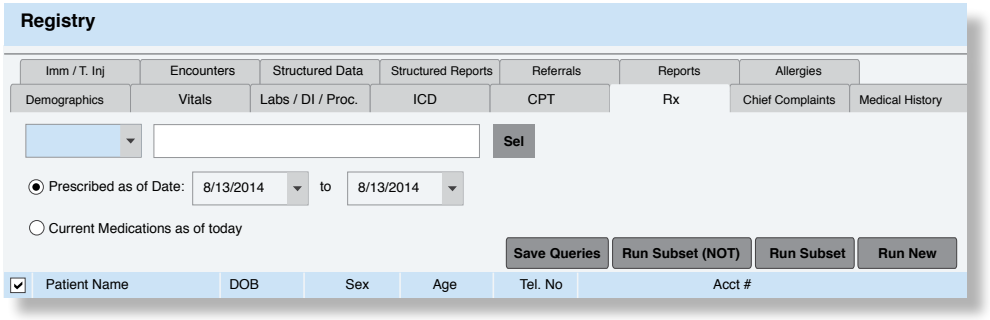
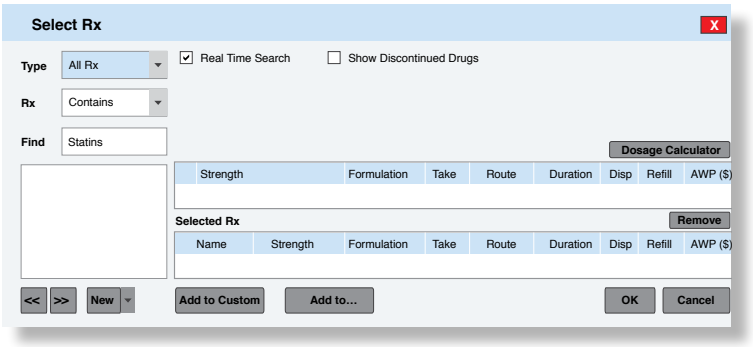
Reporting: Creating a Registry Report

3. Click **Run New.**
4. Select the **Rx** tab. Select **Drug Class,** then click the Sel button to find a specific class of medications.



5. From RX dropdown, select **Contains** and enter drug class; ie, **Statin.**
6. Highlight the desired medication(s) (eg, atorvastatin, rosuvastatin), and click **OK.** Then click **Run Subset.**
7. Select **Lab/DI/Proc** tab, select appropriate lab test and result values (ie, LDL-C ≥ 70 mg/dL or ≥ 100 mg/dL, depending on insurance). Click **OK** and click **Run Subset.**



8. Save Registry Reports for future use by clicking **Save Queries.**

IMPORTANT SAFETY INFORMATION

- The most commonly occurring adverse reactions in the cardiovascular outcomes trial (>5% of patients treated with PRALUENT and occurring more frequently than placebo) were non-cardiac chest pain, nasopharyngitis, and myalgia

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IMPORTANT SAFETY INFORMATION

- PRALUENT is contraindicated in patients with a history of a serious hypersensitivity reaction to PRALUENT, including hypersensitivity vasculitis and hypersensitivity reactions requiring hospitalization
- 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
- The most commonly occurring adverse reactions in clinical trials in primary hyperlipidemia (including heterozygous familial hypercholesterolemia (HeFH)) (≥5% of patients treated with PRALUENT and occurring more frequently than with placebo) are nasopharyngitis, injection site reactions, and influenza
- The most commonly occurring adverse reactions in the cardiovascular outcomes trial (>5% of patients treated with PRALUENT and occurring more frequently than placebo) were non-cardiac chest pain, nasopharyngitis, and myalgia
- In the primary hyperlipidemia (including HeFH) clinical trials, 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 75mg 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

Please see accompanying full Prescribing Information

IMPORTANT SAFETY INFORMATION *(cont.)*

- In a cardiovascular outcomes trial, local injection site reactions were reported in 3.8% of patients treated with PRALUENT versus 2.1% patients treated with placebo, and led to permanent discontinuation in 0.3% of patients versus <0.1% of patients, respectively
- In the primary hyperlipidemia trials, 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
- In the primary hyperlipidemia trials, 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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