ABOUT THIS GUIDE

This Guide provides a high-level overview of Patient Lists in Epic 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 Epic. There are several ways to approach each workflow in Epic. This Guide highlights one workflow; however, you may be familiar with an alternative approach. Please note that this Guide was created based upon Epic version 2015. 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

Using Patient Lists

The Patient List 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 Patient List 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

Patient List Criteria

Patient Lists 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 Patient Lists

The number of patients appearing on a Patient List 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 List.

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 List.

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

Please see accompanying full Prescribing Information

Praluent®
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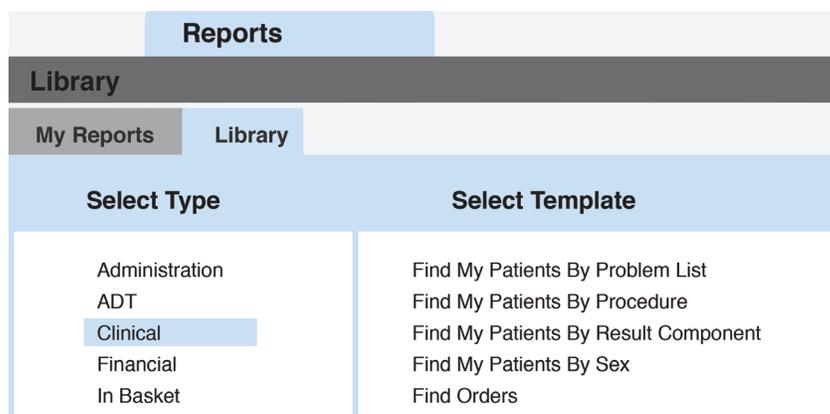
Reporting: Creating a Patient List

A Patient List 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 on maximally tolerated statin therapy.

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

REPORTING: CREATING A PATIENT LIST

1. Navigate to Reports, My Reports, Library, and select **clinical**.

2. Choose the appropriate Clinical Report for modification, such as Find Patients, General Criteria. Select **Edit.**

3. From the Criteria tab, click **Criteria**.

Reports		
Library		
My Reports	**Library**	
Select Type		**Select Template**
Administration		Find My Patients By Problem List
ADT		Find My Patients By Procedure
Clinical		Find My Patients By Result Component
Financial		Find My Patients By Sex
In Basket		Find Orders

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 Patient List

4. Set appropriate search criteria, for example:

   - Patient Base

   - Last Result Value (ie, LDL-C ≥ 70 mg/dL or ≥ 100 mg/dL, depending on insurance)

   - Medication(s) (eg, atorvastatin, rosuvastatin)

   - Problem List (diagnosis 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)

   - Logic Type

   - Date Range

Criteria	Display	Appearance	Summary	Print Layout	Toolbar	General

Search Patients   Change Criteria…

This is a copy of the Find Patients _ Generic Criteria. It hides criteria and uses the simple UL

Patient Base
My patients

Patient Base	⦿ One of		Relationship	Value
	○ All of	1		
Last Result Value (by Common Name)	⦿ One of	2		
	○ All of			

			Relationship	Value
Patient Status	⦿ One of	1		
	○ All of	2		

			Relationship	Value
Problem List by Grouper	⦿ One of	1		
	○ All of	2		

Choose Logic   **Specify Date Range**

⦿ All of the above   From date: ▦
○ Any of the above
○ Custom   To date: ▦
                Edit

Run   Save As   Restore   Close

5. Click **Run.** The patient list is displayed and can be filtered and arranged as desired.

Chronic Conditions: My Patients with Hypercholesterolemia (5442) as of Fri 2/19/2010 9:304 AM   (?) Resize ⇕ Close

| Filters | Options ▾ | Chart | Orders | Encounter | Refill | Telephone | Letter | General Letters | Multi-patient | Message | HM Modifiers | More |

| Detail | Summary |

Results loaded: 55 of 55   Results shown: 5 of 5   Select All   Show All

Patient	Age	Sex	PCP	Last BP(S)	Last BP(D)	Last BMI	Pt. Portal Status	Phone
Jones, John	52 y.o.	Male	Smith, Mary	148	92	24	Activated	HM: 555-555-1111 WK: 555-555-2222
Doe, Jane	73 y.o.	Male	Smith, Mary	133	86	21	Not Used	HM: 555-555-3333
Lopez, Juan	62 y.o.	Male	Smith, Mary	142	83	24		HM: 555-555-4444 WK: 555-555-5555

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

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- 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

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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

Please see accompanying full Prescribing Information

SANOFI **REGENERON**

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