Clinical Alerts

Greenway PrimeSUITE

About This Guide

This Guide provides a high-level overview of Clinical Alerts in Greenway PrimeSUITE. 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 Greenway PrimeSUITE. There are several ways to approach each workflow in Greenway PrimeSUITE. This Guide highlights one workflow; however, you may be familiar with an alternative approach. Please note that this Guide was created based upon Greenway PrimeSUITE version 17.40. 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



Using Clinical Alerts

Clinical decision support (CDS) tools such as Clinical Alerts provide clinicians and staff with patient-specific information, intelligently filtered and presented at appropriate times to help improve the delivery of care. Clinical Alerts can assist with identifying gaps-in-care and may enhance patient outcomes and improve care consistency—a benefit to both providers and patients.

Clinical Alerts can be created to alert health care professionals (HCPs) to consider PRALUENT therapy for appropriate patients during the visit.

Factors That May Impact Clinical Alerts

The display of Clinical Alerts 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 map proprietary lab test codes to LOINC to enable all appropriate patients to display alerts.

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 limit the number of patients where Clinical Alerts are displayed.

Clinical Alerts can help identify whether the patient is a candidate for PRALUENT treatment based on clinical appropriateness and payer utilization management criteria via:

- Reminders during the patient exam workflow, such as ordering lab tests or other diagnostics, adjusting or adding medications to a patient's treatment plan, or providing patient education on LDL-C goals
- Identification of patients who, for example, have a diagnosis of established cardiovascular disease (eg, myocardial infarction, stroke or unstable angina requiring hospitalization) and may also be on maximally tolerated statin therapy (eg, atorvastatin 40 mg/day), and having elevated LDL-C ≥70 mg/dL or ≥100 mg/dL, depending on insurance

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



Reminders: Using Clinical Alerts

Greenway PrimeSUITE enables the setup of reminders, called Clinical Alerts, based on criteria. Available criteria include diagnosis, current and prior medications, lab values, and other clinical or patient demographic information. Clinical Alerts are displayed when the data in the patient chart meet the criteria.

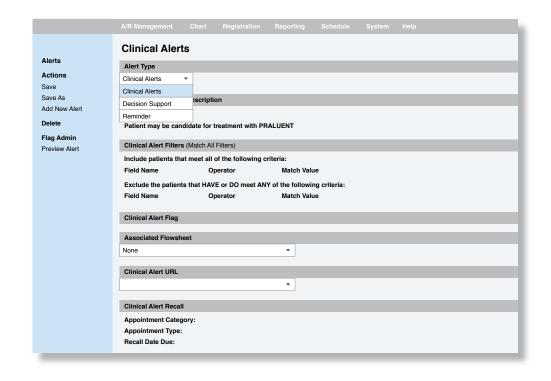
For example, a Clinical Alert may be created to alert the HCP of patients with uncontrolled LDL-C who are clinically appropriate and approvable for PRALUENT therapy based upon the approved Indication.

The following steps illustrate how to create Clinical Alerts to identify patients who may be candidates for treatment with PRALUENT based on having established cardiovascular disease (eg, myocardial infarction, stroke or unstable angina requiring hospitalization), being on atorvastatin 40 mg/day, and having LDL-C ≥70 mg/dL.

To Create and Activate a Clinical Alert:

Use the EHR tip sheet to identify patients that may be appropriate for PRALUENT. For each patient on the resulting list, complete these steps:

- Navigate to Chart, Clinical Alerts
- From the Alert Type dropdown, select Clinical Alerts. Add a description of the alert



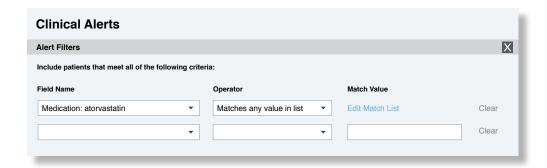
IMPORTANT SAFETY INFORMATION

 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

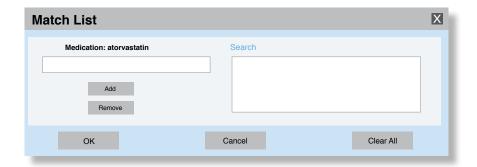


Reminders: Using Clinical Alerts

- 3. Click on Clinical Alert Filters:
 - From the Field Name dropdown, select Medication: (eg, atorvastatin)
 - From the Operator dropdown, select
 Matches Any Value in List



- Click on Edit Match List, and search for, or enter, the medication name(s) (Ex: atorvastatin) as appropriate
- 5. To complete the list, click **OK**



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



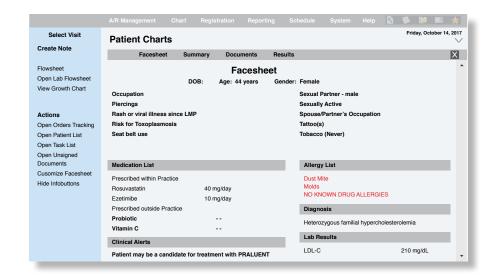
Reminders: Using Clinical Alerts

- 6. Add additional Alert Filters for diagnosis of established cardiovascular disease (eg, myocardial infarction, stroke or unstable angina requiring hospitalization), lab result value (eg LDL-C ≥70), etc, as appropriate
- 7. Click **OK** to close Alert Filters
- 8. Select Clinical Alert Flag. Choose a flag to display with the alert. Click OK
- 9. Click Save from the Actions menu

Viewing Clinical Alerts

Clinical Alerts are displayed on the Facesheet in Patient Charts.

Alerts can also be configured to display as Patient Flag Alerts that pop up during specific functions.





(alirocumab) Injection 75mg/ml. 150mg/ml

Redefining Possible

IMPORTANT SAFETY INFORMATION

· 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 Pralue

of longer average duration than patients receiving placebo

reactions, had more reports of associated symptoms, and had reactions

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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 <u>Prescribing Information</u>



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