About This Guide

This Guide provides a high-level overview of Alerts in Cerner. 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 Cerner. There are several ways to approach each workflow in Cerner. This Guide highlights one workflow; however, you may be familiar with an alternative approach. Please note that this Guide was created based upon Cerner version 2012.01.28. 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
Redefining Possible

Alerts

Cerner

Using Alerts

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

Factors That May Impact Alerts

The display of 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 select each lab's order codes to enable all appropriate patients to appear on the patient list.

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 alerts are displayed.

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

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Reminders: Using CDS and Alerts

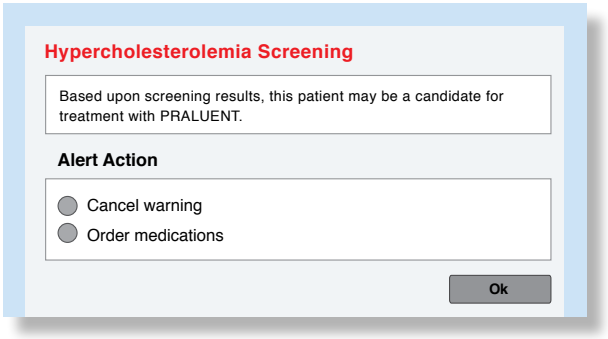
Cerner enables the setup of Alerts which are based on a set of criteria-based clinical decision support (CDS) or with Discern Developer rules. Available criteria include diagnosis, current and prior medications, lab values, and other clinical or patient demographic information. Alerts are displayed when the data in the patient chart meet the criteria.

For example, an 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. Setup of CDS rules and Alerts are typically handled by IT Staff, Cerner IT Analysts, or onsite Clinical Informaticists, not by end-user staff.

Examples of Information to Include When Requesting a Discern Developer Rule and Alert:

NOTE: To see a list of patients for whom this reminder will display, use the EHR patient identification tip sheet to create a patient list. The list will identify patients who may be appropriate for PRALUENT using specific criteria (eg, diagnosis of established cardiovascular disease, option to include: [eg, myocardial infarction, stroke or unstable angina requiring hospitalization] atorvastatin 40 mg/day, LDL-C ≥70 mg/dL).

1. **Evoke:** what data triggers the Discern Developer rule to run, for example:
   - A patient with established cardiovascular disease, with or without concomitant use of a maximally tolerated statin therapy (eg, atorvastatin 40 mg/day) and having elevated LDL-C (eg, ≥70 mg/dL or ≥100 mg/dL), depending on insurance
2. **Logic:** when to display the alert, for example:
   - When specific medications exist in the patient chart, and a lab result value outside the normal range
3. **Action:** what should the end user see, for example:
   - A message displayed to certain users, with a priority setting, or required response



To View an Alert

When a medication order meets the criteria entered, the mCDS window displays.

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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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

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