

### Clinical Visit Summary

Comprehensive EHR documentation of patient medical histories can help support efforts to avoid failed prior authorization (PA) requests. Once a prescriber has determined the appropriate patient for PRALUENT, EHR medical history reports can help support a prior authorization request. Knowledge of payer utilization management criteria and patient medical history reports can help to reduce submission of patients who are not PA criteria eligible.

GE Centricity supports the ability to print a Clinical Visit Summary, which may assist in the completion of payer PA forms. Available clinical data that can be listed on the Clinical Visit Summary include diagnosis, current and prior medications, lab values, and other clinical or patient demographic information. For PRALUENT, PA criteria may require a diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD), maximally tolerated statin therapy (eg, atorvastatin 40 mg/day), and LDL-C  $\geq 70$  mg/dL or  $\geq 100$  mg/dL, depending on insurance.

### 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](#)



## To Create a Clinical Visit Summary from a Signed Document:

After a patient has been identified by a prescriber as appropriate for treatment with PRALUENT, a Clinical Visit Summary may be printed to support PA requirements.

1. From the patient's charts, select the document in the documents list, right-click and choose **Create Clinical Visit Summary**
2. From the display of the Clinical Visit Summary, select **Customize**
3. Uncheck sections to exclude extraneous information, select **Save and Close**

The screenshot shows a dialog box titled "Clinical Visit Summary" with a light blue header. The main content area is divided into two columns. The left column is titled "Customize Visit Summary Content" and contains two sections: "Customize Sections & Entries" and "Include/Exclude Sections". Each section has a list of items with checkboxes. In the "Customize Sections & Entries" section, all items (Laboratory Results, Medications, Problems, Procedures) are checked. In the "Include/Exclude Sections" section, all items (Allergies, Assessment, Chief Complaint, History of Present Illness, Immunizations, Medications Administered, Plan of Care, Reason for Visit, Social History, Vital Signs) are checked. The right column is titled "Instructions" and "Data Included in" and contains two empty rectangular boxes. At the bottom of the dialog box, there are three buttons: "Reset", "Save and Close", and "Cancel".

## 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**<sup>®</sup>  
(alirocumab) Injection 75mg/mL  
150mg/mL  
Redefining Possible

#### 4. **Print** the Clinical Visit Summary

**Clinical Visit Summary**

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No information available

**Allergies, Adverse Reactions, Alerts**

Observed no known allergies at 2017/07/01

**Medications**

Medications	Instructions	Start Date	Stop Date	Generic Name	NDC
Praluent 75 mg/mL injection		2/1/18			
Lipitor 40 mg oral tablet		11/6/16			

No information available

**Plan of Care**

No information available

**Conditions or Problems**

Problem Name	Problem CODE	Onset Date	Status	Entry Date	Provider	Comment	Standard Description
Hypercholesterolemia							
Atherosclerosis							

Customize

Printers
Save to Chart & Close
Save to File
Print

## 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

Please see accompanying full [Prescribing Information](#)



## INDICATIONS AND USAGE

- PRALUENT® (alirocumab) 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
- 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 ( $\geq 5\%$  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) 300 mg 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

Please see accompanying full [Prescribing Information](#)



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