

Print Clinical Attachments

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.

Quanam supports the ability to print a Clinical Attachment, which may assist in the completion of payer PA forms. Available clinical data that can be listed on the chart 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 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 LDL-C ≥ 70 mg/dL or ≥ 100 mg/dL, depending on insurance.

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](#)

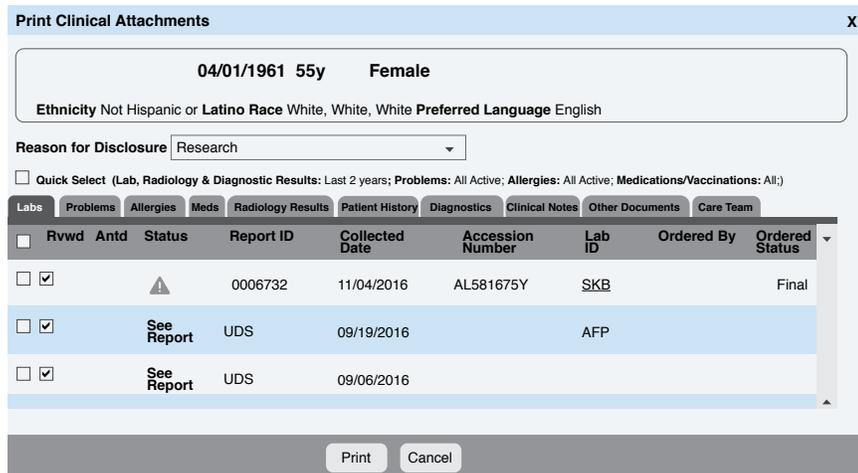
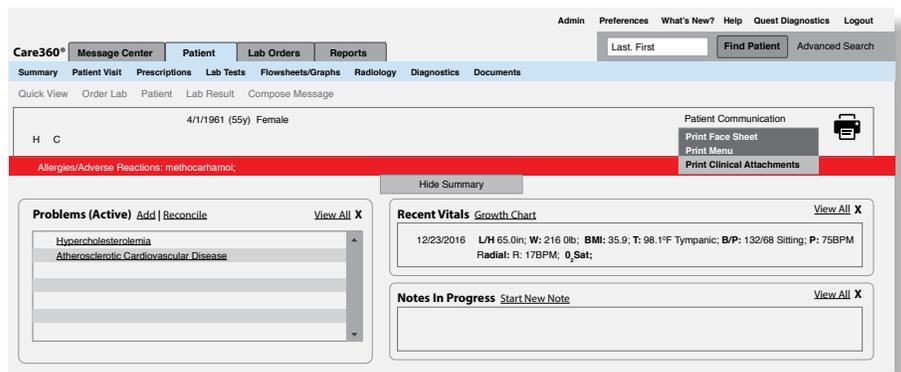


Praluent[®]
(alirocumab) Injection 75mg/mL
150mg/mL
Redefining Possible

To Create a Clinical Attachment:

After a patient has been identified by a prescriber as appropriate for treatment with PRALUENT, a Clinical Attachment may be printed to support PA requirements. The following steps illustrate how to create a Clinical Attachment containing clinical and patient demographic information necessary to complete a prior authorization form.

1. From the patient's chart, navigate to the **Patient Summary**
2. Select the **Printer icon** dropdown, and select **Print Clinical Attachments**



3. Choose Reason for Disclosure, then select appropriate content to include in the attachment such as **Problems, Meds, Patient History, Diagnosis**

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](#)

Prior Authorization Information

Quantum

4. Select the **Print** button to print the document

Clinical Attachment

Demographics

Home Phone:

Work Phone:

Mobile Phone:

Selected Problems

Description	Code	Onset Date	Resolution/ inactive Date	Status
Pure hypercholesterolemia	E78.0			Active
Myocardial Infarction	I21			Active

Selected Medication(s)

Medication Name	Sig	Date Issued	Status
Pravachol 80 mg oral tablet		12/23/2016	Active
Praluent 75 mg/mL injection		12/23/2017	Active

Past Medical History

Fracture L. Arm
Other, mixed, or unspecified drug abuse, unspecified use

Recent Tests

Test Names/Report	Lab ID	Collected Date	Out of Range	Requisition Number	Status
THYROID PANEL WITH TSH	SKB	11/04/2016		0006732	Final
LIPID PANEL	SKB	11/04/2017	Y	0006732	Final
COMPREHENSIVE METABOLIC PANEL	SKB	11/04/2016	See Report	0006732	Final

IMPORTANT SAFETY INFORMATION

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

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- The most commonly occurring adverse reactions in clinical trials in primary hyperlipidemia (including heterozygous familial hypercholesterolemia (HeFH)) ($\geq 5\%$ 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](#)



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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](#)



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