Prior Authorization Information

Centricity

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.

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 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

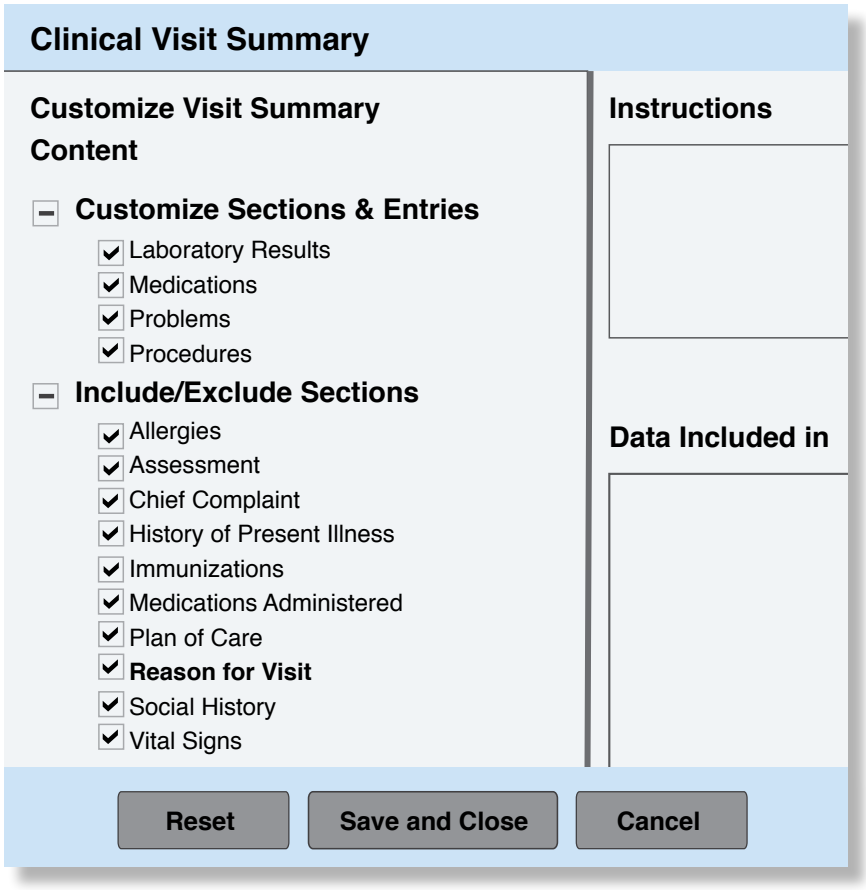
Prior Authorization Information

Centricity

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**



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

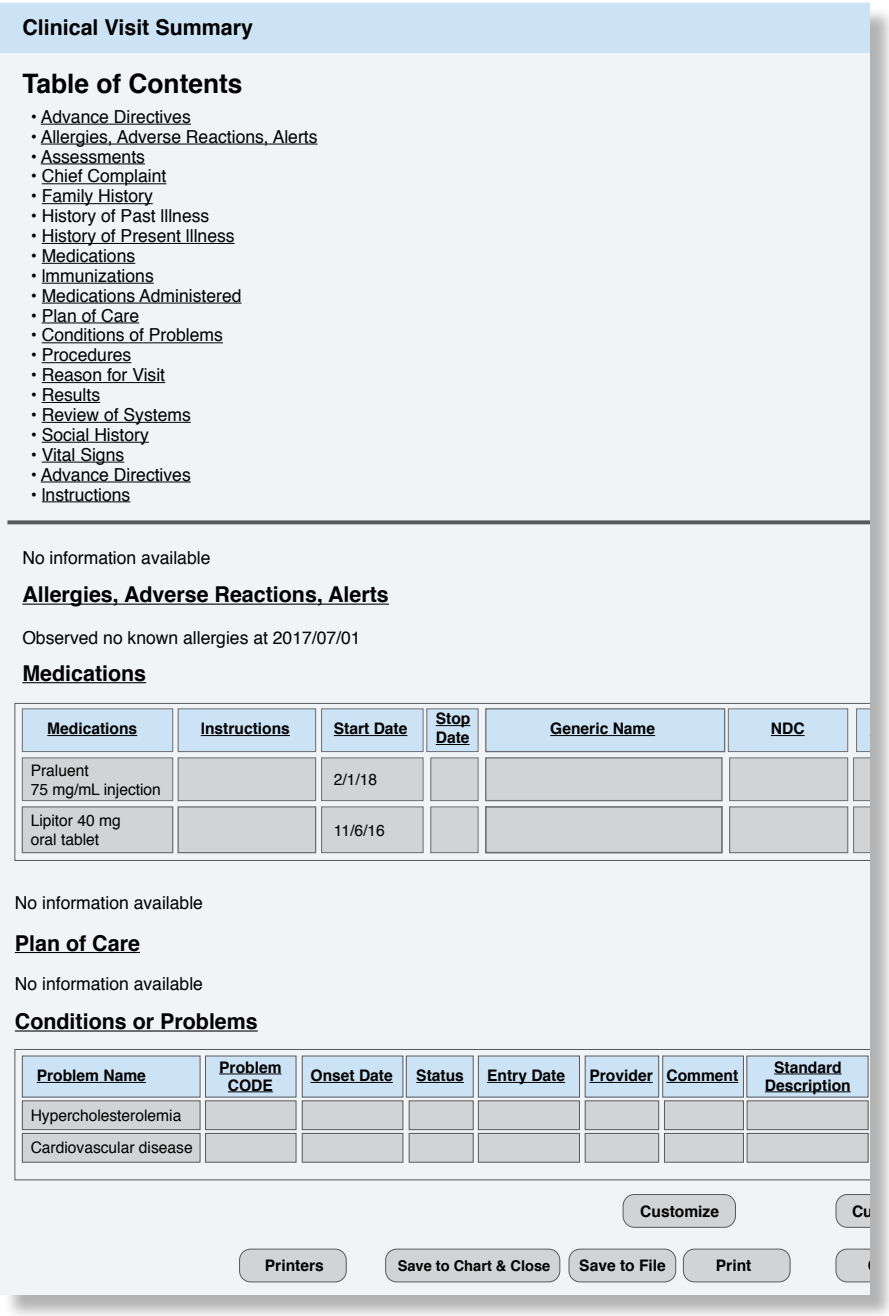
Please see accompanying full Prescribing Information

Praluent® (alirocumab) Injection 75mg/mL 150mg/mL

Redefining Possible

Prior Authorization Information

Centricity



Clinical Visit Summary

Table of Contents

- Advance Directives
- Allergies, Adverse Reactions, Alerts
- Assessments
- Chief Complaint
- Family History
- History of Past Illness
- History of Present Illness
- Medications
- Immunizations
- Medications Administered
- Plan of Care
- Conditions of Problems
- Procedures
- Reason for Visit
- Results
- Review of Systems
- Social History
- Vital Signs
- Advance Directives
- Instructions

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							
Cardiovascular disease							

Customize

Printers | Save to Chart & Close | Save to File | Print

4. **Print** the Clinical Visit Summary

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

Please see accompanying full Prescribing Information

Praluent® (alirocumab) Injection 75mg/mL 150mg/mL

Redefining Possible

Prior Authorization Information

Centricity

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
- 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

Praluent® (alirocumab) Injection 75mg/mL 150mg/mL

Redefining Possible

Please see accompanying full Prescribing Information

Prior Authorization Information

Centricity

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

Praluent® (alirocumab) Injection 75mg/mL 150mg/mL

Redefining Possible

SANOFI REGENERON