

Continuity of Care Document

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.

Athena supports the ability to print a Continuity of Care Document (CCD), which may assist in the completion of payer PA forms. Available clinical data that can be listed on the CCD 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 ≥ 70 mg/dL or ≥ 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](#)



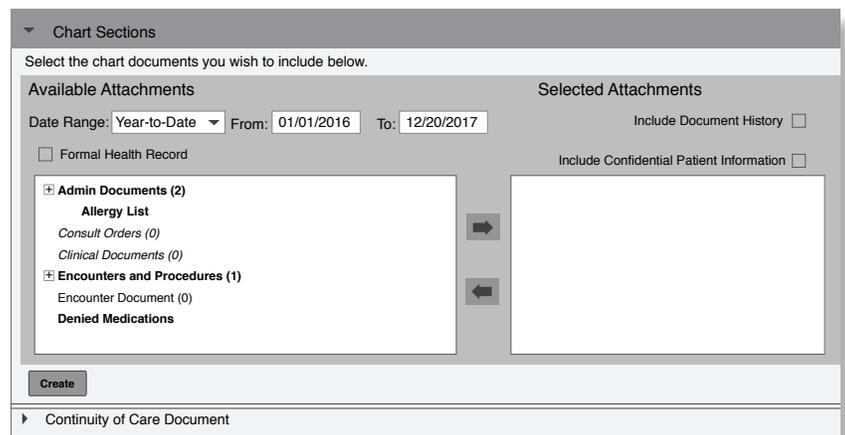
After a patient has been identified by a prescriber as appropriate for treatment with PRALUENT, a CCD may be printed to support PA requirements. The following steps illustrate how to create a CCD containing clinical and patient demographic information necessary to complete a prior authorization form.

To Create a CCD:

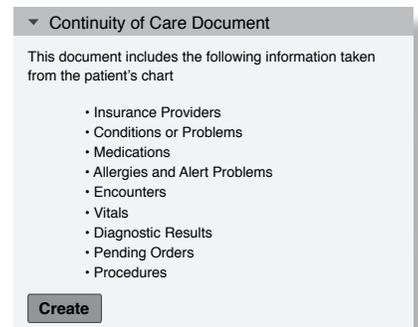
1. From the patient's **Facesheet**, select **Chart Export**



2. Select **Date Range** and **sections** of the CCD to include



3. Confirm the sections and select **Create**



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

AthenaHealth

4. Determine disposition method

Submit By electronic file Action note

Close Pin to Top?

Delete

Leave in REVIEW to

Save Cancel

5. Annotate disposition method

Submission Completed By electronic file Action note

Error Identified Send back to Review Pin to Top?

Leave in REVIEW to

Save Cancel

Test, AMY (id #274732, dob: 03/25/1963) Created On: December 20, 2016

CCD Export Record

MRN:
Sex:
Next of Kin:

Patient:
Birthdate:
Guardian:

Table of Contents

- Insurance Providers
- Conditions or Problems
- Medications
- Allergies and Alert Problems
- Encounters
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- Procedures

Insurance Providers

Insurance Package	Reporting Category	Relationship to Insured	ID#
HUMANA (PPO)	Humana	Self	12314546

Conditions or Problems

Problem Name	SNOMED Code
Hypercholesterolemia	
Atherosclerosis	

MEDICATIONS

FDB Name	Sig	Start Date	Stop Date	RxNorm Name	RxNorm Code	Note

A CCD Export Record is created.

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](#)


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

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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