Prior Authorization Information

Allscripts Professional

Document Templates

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.

Allscripts Professional supports the ability to print a patient summary from a Document Template, which may assist in the completion of payer PA forms. Available clinical data that can be listed on the patient 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

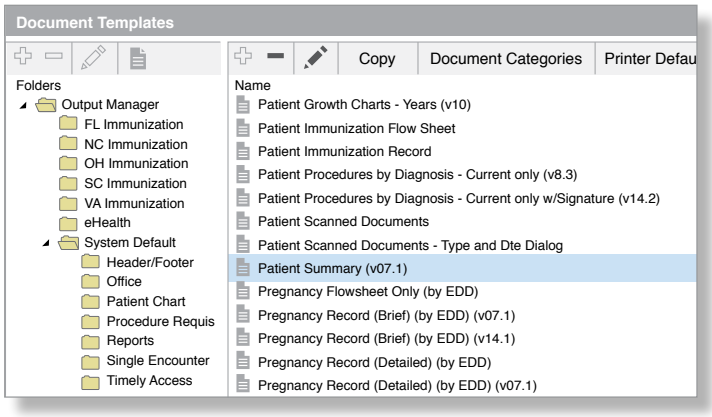
Prior Authorization Information

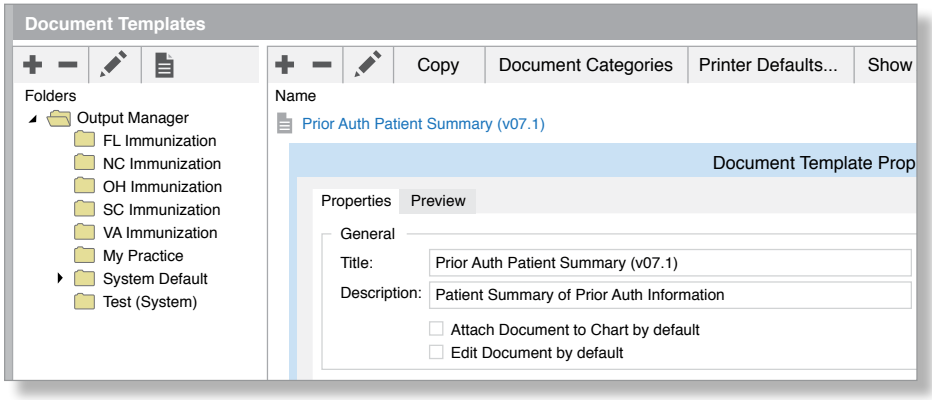
Allscripts Professional

After a patient has been identified by a prescriber as appropriate for treatment with PRALUENT, a Patient Summary based on an Output Template may be printed to support PA requirements. The following steps illustrate how to create a Patient Summary Document Template (based on a system-delivered output template) containing clinical and patient demographic information necessary to complete a prior authorization form.

To Create a Prior Authorization Patient Summary Document Template

1. Navigate to **Output Manager,** select **Document Templates.**
2. From the **System Defaults** folder, locate **Patient Summary** and choose **Copy.** Save in an appropriate folder.
3. From the folder, highlight the copy and choose **Edit** (pencil icon).
4. In the **Document Template Properties** dialog box, enter a **Title,** such as "Prior Authorization Patient Summary" and **Description** as desired.





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

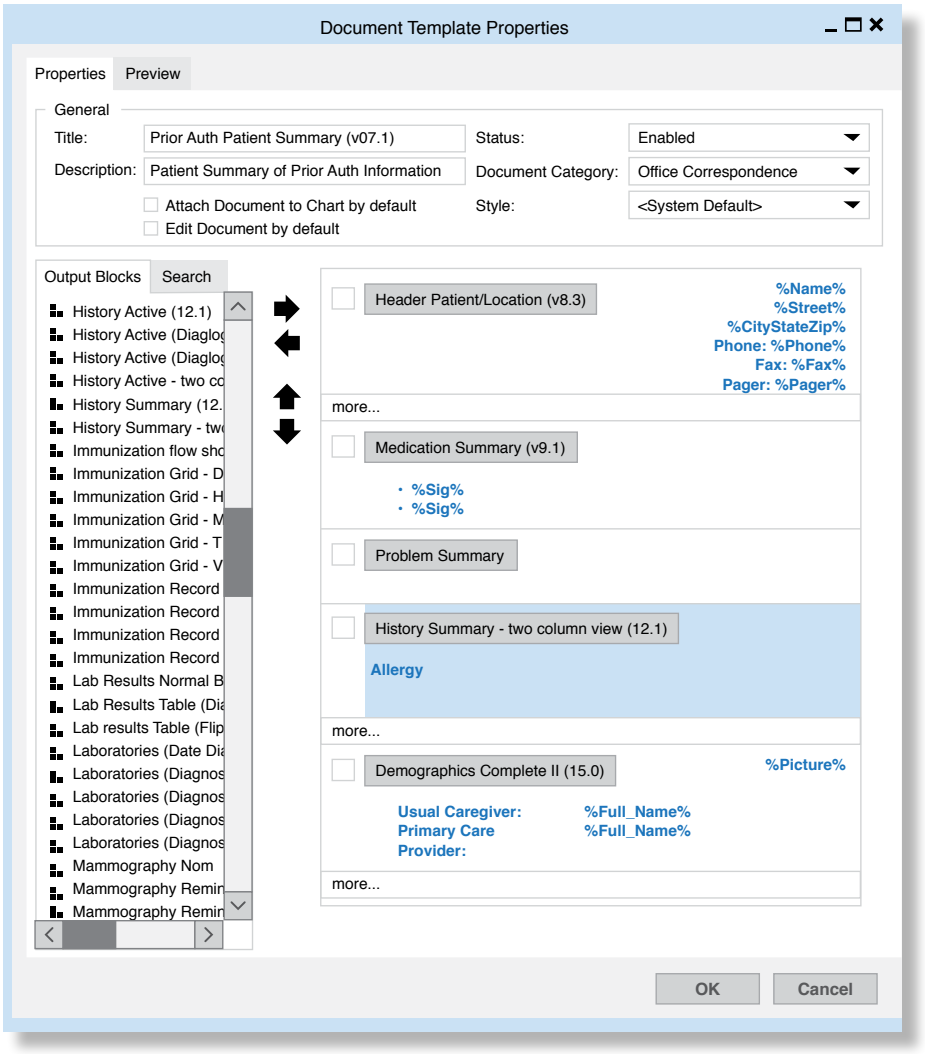
Prior Authorization Information

Allscripts Professional

5. To add Lab Results to the summary, from the **Output Blocks** tab, navigate to the **System Defaults, Patient Chart.** Choose the desired **Laboratory** block, for example Laboratory Results Table. Select the **Right Arrow** to include the block in the template.

6. To include insurance information, add a **Demographics Complete** block, to include data such as DOB, Gender, Address, Active Insurance Policies, Active Insurance Subscriber.

7. Use the arrows to reorder or remove information blocks as desired.



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

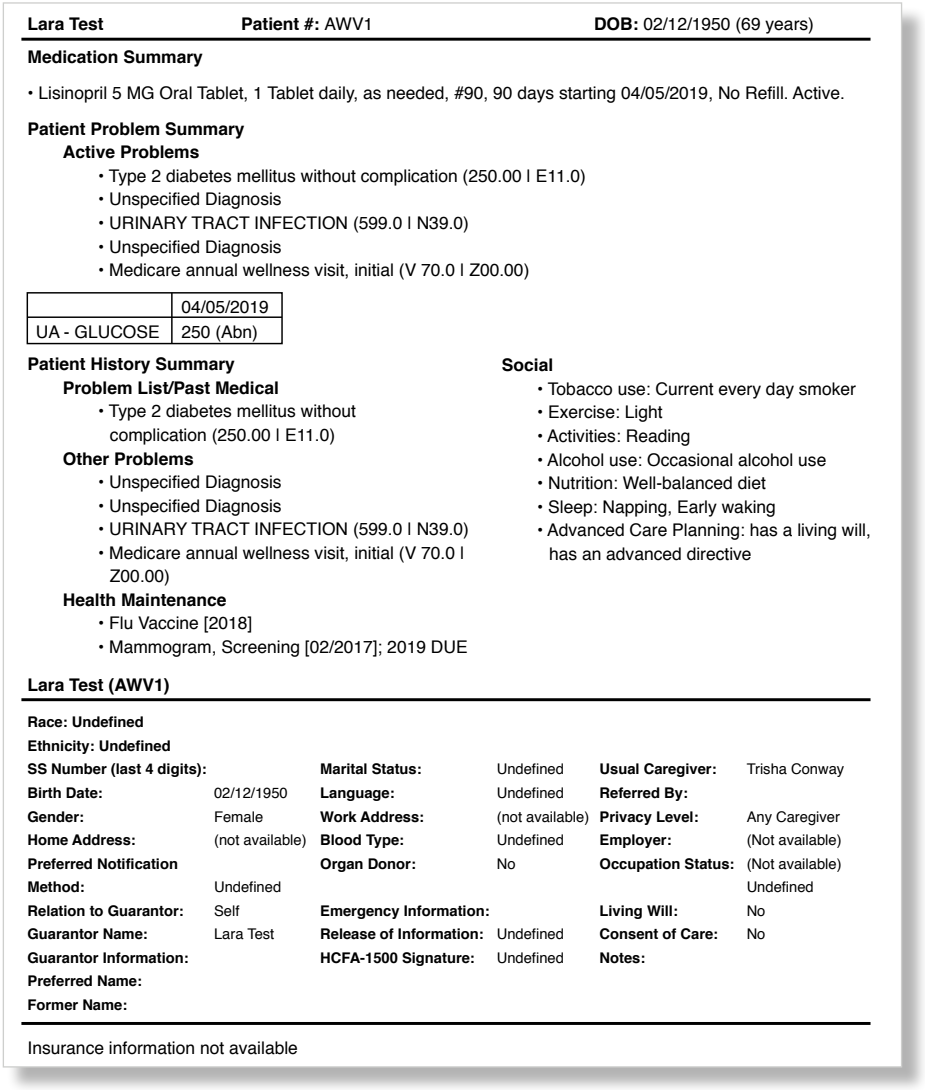
Prior Authorization Information

Allscripts Professional

8. From the **Preview tab,** ensure that appropriate Information is included from:

   - **Problem Summary** (to include specific active diagnoses, such as E78)
   - **Medications Summary** (to include current and historical statins)
   - **Laboratory Results Table** (for example, LDL-C – Most recent result value and date to be included)

The customized patient summary can be printed from the patient chart. Choose **Print.** Select the Prior Auth Patient Summary template from list.



Lara Test **Patient #:** AWV1 **DOB:** 02/12/1950 (69 years)

Medication Summary

• Lisinopril 5 MG Oral Tablet, 1 Tablet daily, as needed, #90, 90 days starting 04/05/2019, No Refill. Active.

Patient Problem Summary

Active Problems

- Type 2 diabetes mellitus without complication (250.00 I E11.0)
- Unspecified Diagnosis
- URINARY TRACT INFECTION (599.0 I N39.0)
- Unspecified Diagnosis
- Medicare annual wellness visit, initial (V 70.0 I Z00.00)

	04/05/2019
UA - GLUCOSE	250 (Abn)

Patient History Summary

Problem List/Past Medical

- Type 2 diabetes mellitus without complication (250.00 I E11.0)

Other Problems

- Unspecified Diagnosis
- Unspecified Diagnosis
- URINARY TRACT INFECTION (599.0 I N39.0)
- Medicare annual wellness visit, initial (V 70.0 I Z00.00)

Health Maintenance

- Flu Vaccine [2018]
- Mammogram, Screening [02/2017]; 2019 DUE

Social

- Tobacco use: Current every day smoker
- Exercise: Light
- Activities: Reading
- Alcohol use: Occasional alcohol use
- Nutrition: Well-balanced diet
- Sleep: Napping, Early waking
- Advanced Care Planning: has a living will, has an advanced directive

Lara Test (AWV1)

Race: Undefined					
Ethnicity: Undefined					
SS Number (last 4 digits):		**Marital Status:**	Undefined	**Usual Caregiver:**	Trisha Conway
Birth Date:	02/12/1950	**Language:**	Undefined	**Referred By:**	
Gender:	Female	**Work Address:**	(not available)	**Privacy Level:**	Any Caregiver
Home Address:	(not available)	**Blood Type:**	Undefined	**Employer:**	(Not available)
Preferred Notification Method:	Undefined	**Organ Donor:**	No	**Occupation Status:**	(Not available) Undefined
Relation to Guarantor:	Self	**Emergency Information:**		**Living Will:**	No
Guarantor Name:	Lara Test	**Release of Information:**	Undefined	**Consent of Care:**	No
Guarantor Information:		**HCFA-1500 Signature:**	Undefined	**Notes:**	
Preferred Name:					
Former Name:					

Insurance information not available

IMPORTANT SAFETY INFORMATION

- 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

Please see accompanying full Prescribing Information

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

Prior Authorization Information

Allscripts Professional

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

Please see accompanying full Prescribing Information

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

Prior Authorization Information

Allscripts Professional

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