Prior Authorization Information

Practice Fusion

Patient 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.

Practice Fusion supports the ability to print a Patient Summary, 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

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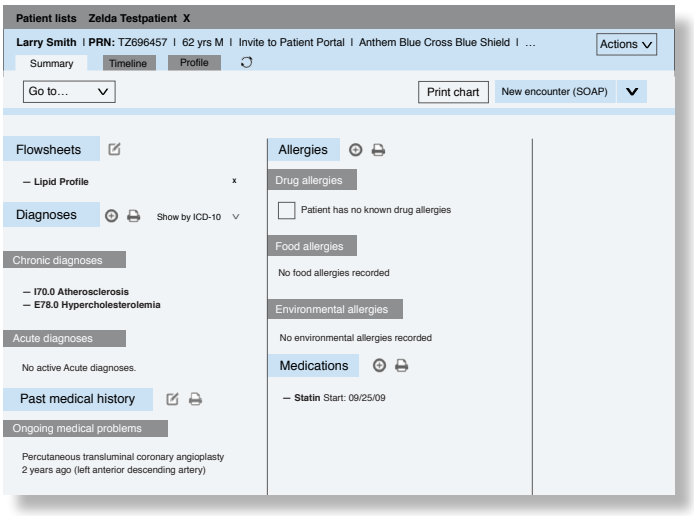
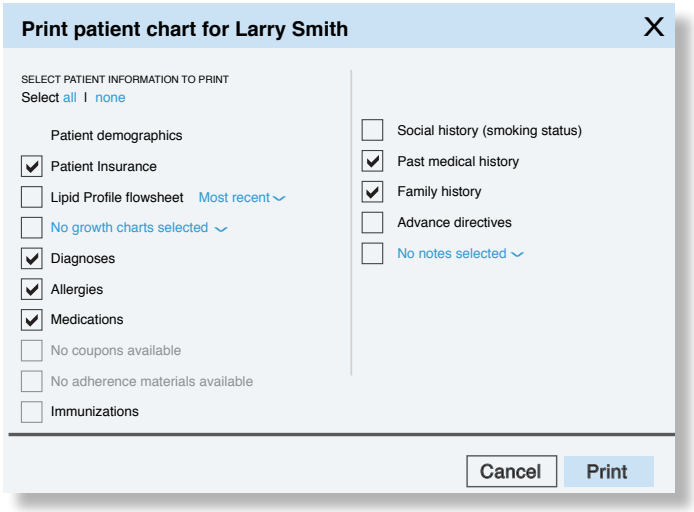
To Create a Patient Summary:

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

1. Navigate to a patient chart. Select the **Summary** tab



2. Click **Print chart.** Check sections to include and click **Print**



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

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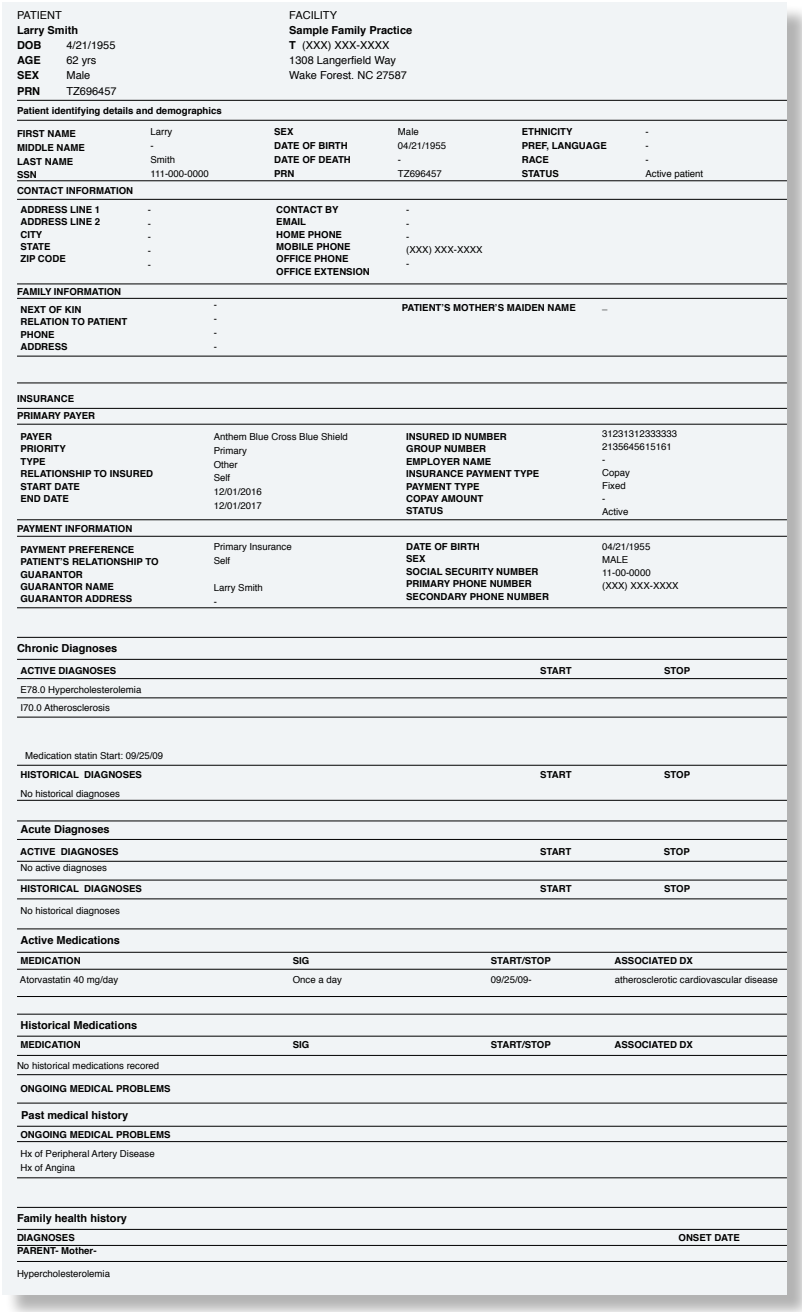
Example of the Summary document:



PATIENT
Larry Smith
DOB 4/21/1955
AGE 62 yrs
SEX Male
PRN TZ696457

FACILITY
Sample Family Practice
T (XXX) XXX-XXXX
1308 Langerfield Way
Wake Forest. NC 27587

Patient identifying details and demographics

FIRST NAME	Larry	**SEX**	Male	**ETHNICITY**	-
MIDDLE NAME	-	**DATE OF BIRTH**	04/21/1955	**PREF, LANGUAGE**	-
LAST NAME	Smith	**DATE OF DEATH**	-	**RACE**	-
SSN	111-000-0000	**PRN**	TZ696457	**STATUS**	Active patient

CONTACT INFORMATION

ADDRESS LINE 1	-	**CONTACT BY**	-
ADDRESS LINE 2	-	**EMAIL**	-
CITY	-	**HOME PHONE**	-
STATE	-	**MOBILE PHONE**	(XXX) XXX-XXXX
ZIP CODE	-	**OFFICE PHONE**	-
		OFFICE EXTENSION	

FAMILY INFORMATION

NEXT OF KIN	-	**PATIENT'S MOTHER'S MAIDEN NAME**	_
RELATION TO PATIENT	-		
PHONE	-		
ADDRESS	-		

INSURANCE

PRIMARY PAYER

PAYER	Anthem Blue Cross Blue Shield	**INSURED ID NUMBER**	31231312333333
PRIORITY	Primary	**GROUP NUMBER**	2135645615161
TYPE	Other	**EMPLOYER NAME**	-
RELATIONSHIP TO INSURED	Self	**INSURANCE PAYMENT TYPE**	Copay
START DATE	12/01/2016	**PAYMENT TYPE**	Fixed
END DATE	12/01/2017	**COPAY AMOUNT**	-
		STATUS	Active

PAYMENT INFORMATION

PAYMENT PREFERENCE	Primary Insurance	**DATE OF BIRTH**	04/21/1955
PATIENT'S RELATIONSHIP TO GUARANTOR	Self	**SEX**	MALE
		SOCIAL SECURITY NUMBER	11-00-0000
GUARANTOR NAME	Larry Smith	**PRIMARY PHONE NUMBER**	(XXX) XXX-XXXX
GUARANTOR ADDRESS	-	**SECONDARY PHONE NUMBER**	

Chronic Diagnoses

ACTIVE DIAGNOSES	START	STOP
E78.0 Hypercholesterolemia		
I70.0 Atherosclerosis		

Medication statin Start: 09/25/09

HISTORICAL DIAGNOSES	START	STOP
No historical diagnoses		

Acute Diagnoses

ACTIVE DIAGNOSES	START	STOP
No active diagnoses		

HISTORICAL DIAGNOSES	START	STOP
No historical diagnoses		

Active Medications

MEDICATION	SIG	START/STOP	ASSOCIATED DX
Atorvastatin 40 mg/day	Once a day	09/25/09-	atherosclerotic cardiovascular disease

Historical Medications

MEDICATION	SIG	START/STOP	ASSOCIATED DX
No historical medications recored			

ONGOING MEDICAL PROBLEMS

Past medical history

ONGOING MEDICAL PROBLEMS

Hx of Peripheral Artery Disease
Hx of Angina

Family health history

DIAGNOSES	ONSET DATE
PARENT- Mother-	
Hypercholesterolemia	

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

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- 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

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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

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SANOFI REGENERON