Peak Development for … Medication Administration©

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Cholesterol-Lowering Agents: PCSK9 Inhibitors

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After completion the learner should be able to:

1. Identify appropriate indications for use of PCSK9 inhibitors.
2. Relate general characteristics of PCSK9 inhibitors to specific patient situations.
3. Apply nursing process considerations for PCSK9 inhibitors to specific patient situations.

Hyperlipidemia is a metabolic disorder characterized by increased serum cholesterol and triglycerides, two of the lipids found in the blood. Cholesterol is normally present in cell membranes and is necessary in the formation of steroid hormones and bile acids which aid in digestion of fats. Triglycerides provide an energy source for cellular metabolism. Hyperlipidemia may be caused by familial (genetic) or secondary (diet, diabetes, liver disease, medications) factors. It is associated with increased risk for atherosclerosis, coronary artery disease (CAD), MI and stroke.

Lipids are transported in the blood by lipoproteins, a combination of the plasma protein albumin or globulin, and cholesterol and/or triglycerides. Lipoproteins are classified and measured in the blood according to their density. In general, the more protein contained in the lipoprotein, the higher the density. The major lipoproteins include:

- Very-low-density lipoprotein (VLDL): mostly triglycerides, and makes up 10-15% of total serum cholesterol; delivers triglycerides from the liver to fat and muscle tissues
- Low-density lipoprotein (LDL): comprises 60-70% of total serum cholesterol; known as "bad" cholesterol, since it delivers cholesterol to body tissues and is associated with development of atherosclerosis and heart disease
- High-density lipoprotein (HDL): comprises 20-30% of total serum cholesterol; known as "good" cholesterol because its primary function is to deliver cholesterol from the peripheral tissues to the liver to be metabolized and excreted

Since 1987, when they were first approved for use by the FDA, statin drugs have been the most commonly used drugs to treat elevated cholesterol levels. Other drugs, such as niacin and fenofibrate, have also been found useful. In 2015, the FDA approved two monoclonal antibodies, the PCSK9 inhibitors alirocumab (Praluent) and evolocumab (Repatha), to lower LDL-C levels in certain patients. LDL-C is the calculation or measurement of the amount of cholesterol in the LDL particles.

Indications

Evolocumab and alirocumab are indicated to:

- reduce the risk of MI, stroke, and angina or the need for coronary revascularization in adults with established coronary artery disease (CAD).
- along with diet, lower LDL-C in patients with elevated cholesterol, including heterozygous familial hypercholesterolemia. May be taken alone or with other cholesterol-lowering medications.
- lower LDL-C in patients with homozygous familial hypercholesterolemia.

The American College of Cardiology recommends statin drugs as first-line treatment for elevated LDL-C levels. PCSK9 inhibitors may be used in patients who are unable to tolerate statin drugs, and in those whose LDL-C remain high despite the maximum dose of statins.

Pharmacodynamics

There are LDL receptors on liver cells that collect LDL and transport it into the liver for breakdown. The liver enzyme PCSK9

(proprotein convertase subtilisin kexin type 9) inactivates these receptors. This causes more LDL particles to remain in circulation, resulting in higher LDL levels. Evolocumab and alirocumab act by binding to PCSK9. This allows for more LDL receptors to remain active on the hepatocytes, reducing LDL-C levels.

Pharmacokinetics

Absorption: High bioavailability, with peak concentrations occurring in 3-4 days.

Distribution: The volume of distribution is low, meaning that these agents remain primarily in circulating blood.

Metabolism: Monoclonal antibodies are proteins, and break down into protein components, such as peptides and amino acids.

Elimination: Some of the agent is used up in binding to PCSK9, and the rest breaks down as protein components.

Major Interactions

There are no clinically significant drug interactions with these agents.

Adverse Effects/Toxicity

Common adverse reactions include nasopharyngitis, injection site reactions, influenza, respiratory tract infections, diarrhea, and myalgia. Severe allergic reactions, including angioedema and anaphylaxis, have also been reported.

Precautions/Contraindications

Contraindicated in patients having a previous serious allergic reaction to these agents. No dosage adjustment is required in patients with mild to moderate renal or hepatic impairment. Results in patients with severe renal or hepatic impairment are unknown. The needle cover on the prefilled syringe and auto-injector form of evolocumab (Repatha) is made of a latex derivative. Patients with latex allergies should be made aware of this, and discuss the choice with the prescriber.

Nursing Process

Assessment

Determine baseline status: Lab values for total cholesterol, HDL, LDL, VLDL, and triglycerides should be obtained prior to beginning therapy with evolocumab or alirocumab. This lipid panel should be drawn following 8-12 hours of fasting. A full cardiovascular and lifestyle history and physical assessment should be performed to identify any current or potential factors that contribute to development of atherosclerosis and CAD. Specific risk factors that should be assessed include smoking, obesity, family history of coronary artery disease, hypertension, and diabetes. A complete dietary history is essential in developing a teaching plan for assisting patients who will need dietary modifications.

Identify risk factors: The patient's medication and allergy history should be assessed, and specifically for previous use of PCSK9 inhibitors and allergic reaction to them.

Age-specific considerations: Safety and effectiveness have not been established for use in pregnant or breastfeeding women. Evolocumab is considered safe and effective for treatment of homozygous familial hypercholesterolemia in patients age 13 years and older. Safety and effectiveness have not been established for any other use in the pediatric population for either agent. There are no known drug issues specific to the geriatric population, and reduced drug dosage is not required.

Planning and Analysis

The goal of therapy with PCSK9 inhibitors is to lower LDL–C values to desired levels.

Intervention

Medication administration: Evolocumab and alirocumab are administered subcutaneously every two or four weeks. Acceptable sites include the abdomen, thigh, and upper arm, with regular rotation of sites.

Observe for therapeutic effects: LDL-C levels should decrease within four weeks of starting therapy. Fasting lipid studies should be done periodically to assess drug effects.

Observe for adverse effects: Monitor for adverse effects, such as allergic reaction, muscle pain, injection site reactions and respiratory infection.

Patient/Family teaching: Patient and family teaching for patients focuses on medication use and administration, as well as lifestyle and dietary changes aimed at reducing risks associated with CAD. These include:

- thorough instruction in dosage, scheduling, and subcutaneous administration of these agents.
- the importance of dietary modification, regular exercise, and stopping smoking in supporting cardiovascular health. Overweight and obese patients benefit from a weight loss program. Counseling with a dietician may be necessary.
- the importance of continued therapy. If medication is discontinued, cholesterol levels will increase to pre-therapy values.
- seeking immediate medical attention for allergic reaction.

Evaluation

Thorough education and careful monitoring of patients taking PCSK9 inhibitors help to promote the outcomes of reducing LDL cholesterol and preventing chronic conditions associated with atherosclerosis and CAD for each patient.

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Competency Assessment Tool

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PEAK DEVELOPMENT RESOURCES LLC

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NAME:_____ DATE: _____ UNIT:_____

Directions: Place the letter of the one best answer in the space provided.

_____1. Hyperlipidemia is associated with increased risk for:
A. coronary artery disease
B. atherosclerosis
C. stroke
D. all of the above

_____2. HDL particles are considered high-density because they contain a higher percentage of:
A. triglycerides
B. protein
C. assorted fats
D. cholesterol

_____3. Which of the following drugs is considered first-line treatment for elevated LDL-C levels by the American College of Cardiology:
A. statins
B. niacin
C. PCSK9 inhibitors
D. fenofibrate

_____4. HDL is considered “good” cholesterol because it brings cholesterol to the liver to be excreted
A. True
B. False

_____5. PCSK9 inhibitors act to lower LDL-C by:
A. attaching to cholesterol particles in the blood
B. activating substances in brown adipose tissue
C. inhibiting absorption of LDL in the small intestine
D. increasing active LDL receptors in liver cells

_____6. PCSK9 inhibitors may be taken alone or concurrently with other cholesterol-lowering medications.
   A. True
   B. False

_____7. Common adverse reactions of PCSK9 inhibitors include all of the following EXCEPT:
   A. diarrhea
   B. nasopharyngitis
   C. tremors
   D. influenza

_____8. Dosage reductions for evolocumab and alirocumab are required for:
   A. mild to moderate liver disease
   B. moderate to severe renal disease
   C. patients over the age of 70
   D. none of the above

_____9. Due to their complex structure, the monoclonal antibodies evolocumab and alirocumab have many interactions with other drugs.
   A. True
   B. False

_____10. Patient education for PCSK9 inhibitors should include all of the following EXCEPT:
   A. administer subcutaneously once daily
   B. continued use is required to maintain therapeutic effect
   C. focus on lifestyle changes to reduce risk of atherosclerosis and coronary artery disease
   D. LDL levels should decrease within four weeks of starting therapy

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Month: September 2021
Issue: Cholesterol-Lowering Agents: PCSK9 Inhibitors

Group Tracking Log

Employee Name	Unit	Test Date	Score

Peak Development Resources©

Contact Hour Application for Medication Administration

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PLEASE COMPLETE EACH SECTION LEGIBLY. INCOMPLETE APPLICATIONS CANNOT BE PROCESSED.

1. Issue: **Cholesterol-Lowering Agents: PCSK9 Inhibitors**
Month: **September 2021** **Contact Hours Awarded Through: September 2023**

2. Facility Information
(provide information about the subscribing facility):
Facility Name: _____
Address: _____
_____
City: _____ State: _____ Zip: _____

3. Applicant Information
(provide information about yourself)
Name: _____
Address: _____
City: _____ State: _____ Zip: _____
Daytime Phone Number:_____
Nursing License #: _____
Licensing State: _____
Previous Peak Development Contact Hours: Yes No

4. Test Answers: Darken the appropriate circle below to answer each test question.

	A	B	C	D
1.	0	0	0	0
2.	0	0	0	0
3.	0	0	0	0
4.	0	0	0	0
5.	0	0	0	0
6.	0	0	0	0
7.	0	0	0	0
8.	0	0	0	0
9.	0	0	0	0
10.	0	0	0	0

5. Contact Hour Information:
One contact hour is awarded for each test grade of 70% or higher from an issue of Peak Development for Medication Administration. The applicant must be an employee of a subscribing institution. The application fee is nonrefundable, regardless of test grade.

6. PAYMENT INFORMATION:
APPLICATIONS MUST INCLUDE PAYMENT
Cost: $10 per test — nonrefundable
Check Payment method - Provide all information
_____ Check Payable to Peak Development Resources
($40.00 service fee for returned checks)
_____ Credit Card (circle one):
VISA MASTERCARD
Credit Card Number: _____
Credit Card Expiration Date: _____
Print Name on Card: _____
Authorized Signature: _____
Billing Address for credit card:
Address: _____ _____
_____
State: _____ Zip: _____

7. EVALUATION
A. How long, in minutes, did it take you to complete this educational packet? _____minutes.

B. Please rate each of the following categories by circling the number that best reflects your experience with this self-study packet:
1=Strongly agree
2=Agree
3=Disagree
4=Strongly disagree

1. I met the stated course objectives.	1	2	3	4
2. Subject matter was accurate.	1	2	3	4
3. Content reflected current information.	1	2	3	4
4. This self-study packet was an effective way for me to learn.	1	2	3	4
5. Reading level and content were appropriate for me.	1	2	3	4
6. Test reflected the stated course objectives.	1	2	3	4
7. Completing this self-study packet was an effective use of my time.	1	2	3	4
8. This packet met my educational needs.	1	2	3	4

8. Mail completed application and payment to:

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