

High cholesterol

treatment with PCSK9 inhibitors

CONDITION GUIDE



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How to use this guide

We know the diagnosis of high cholesterol can be overwhelming. This guide can help answer your questions about your diagnosis, and give you important information to share with family or friends.

Your doctor has suggested that you start treatment. This means that your doctor believes you have a good chance of responding to medicine. We're here to help, every step of the way.

Remember, taking your medicine as prescribed will help you live a healthy life. Please don't stop taking your medicine without checking with your doctor.

Today's treatments are individualized, so each person has the best chance of responding. Your treatment may differ from the treatment of other people with high cholesterol. This is one of the reasons it is so important that you talk to your doctor, or your pharmacist, about your questions or concerns.

There are four parts to this guide

1 Understanding high cholesterol

We're here to help you become better informed. In this chapter we'll discuss how to live your best life with a high cholesterol diagnosis.

2 Taking care of your body

Find ways to take charge of your health — both physically and mentally — with proactive changes.

3 High cholesterol treatment approaches

Learn more about the treatment options that your doctor or specialty pharmacy care team might suggest. Find out about possible treatment plans, including medicine and other approaches to help manage high cholesterol in a way that works best for you.

4 Understanding side effects

Know when to call your doctor and what tips can help reduce side effects.



Understanding high cholesterol

According to the Centers for Disease Control and Prevention (CDC), over 102 million American adults have high cholesterol levels.¹ In fact, over half of Americans have cholesterol that's higher than recommended.²

Whether you're newly diagnosed, or you've been living with high cholesterol for a while, this guide is designed to help you learn more about cholesterol and your options for staying healthy.

What is cholesterol?^{3,4}

Cholesterol is a waxy, fat-like substance that's found in all the cells in the body. Cholesterol travels through your bloodstream in small packages called lipoproteins. These packages are made up of fat on the inside and proteins on the outside.

Our bodies need some cholesterol to make hormones, vitamin D and substances that help to digest foods.⁵ But, too much cholesterol can build up on the walls of arteries and cause blood flow to slow. This can lead to a serious health event like a stroke or a heart attack.

Different types of cholesterol

There are two kinds of cholesterol— low-density lipoprotein and high-density lipoprotein.⁵ Having healthy levels of both types of cholesterol is important. A test called a lipid profile helps your doctor understand the levels of cholesterol in your body.



Low-density lipoprotein (LDL): LDL is also called “bad” cholesterol. It carries fat and small amounts of protein to the liver and body. This kind of cholesterol can raise your risk of heart disease, heart attack and stroke.



High-density lipoprotein (HDL): HDL is also called “good” cholesterol. HDL carries bad cholesterol out of the body, to be processed by the liver. Your liver removes cholesterol from your body. A higher HDL level means you have a lower risk for heart disease.

Understanding triglycerides

Triglycerides are the most common type of fat in the body. Normal levels of triglycerides vary by age, sex or genetic factors. A high triglyceride level combined with either low HDL or high LDL is associated with build-up of fat in the linings of arteries, which can lead to heart attacks, heart disease or stroke.^{1,2}

● *Fast facts on cholesterol*⁶

- High blood cholesterol puts you at risk of heart disease, the leading cause of death in the United States.
- People with higher cholesterol have twice the risk for heart disease as people with ideal cholesterol levels.
- Only 1 out of 3 adults have their high cholesterol under control.

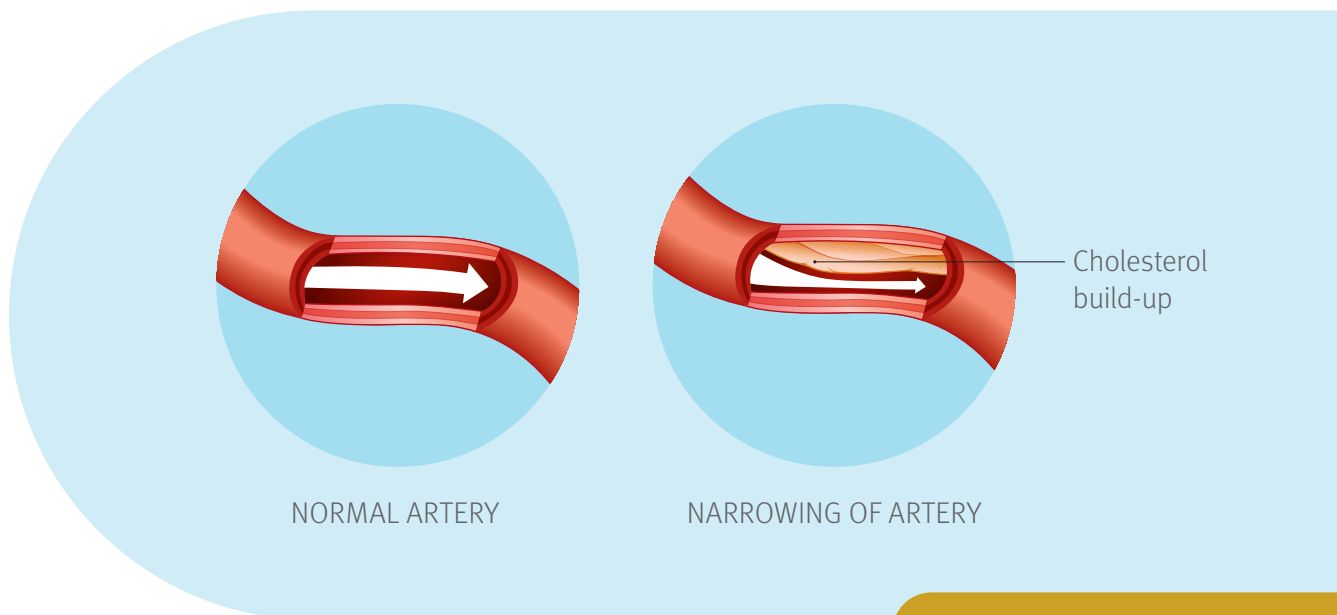
Complications from high cholesterol

If tests show that your cholesterol levels are higher than normal, and you don't start treatment, your health may be affected.

When you have high cholesterol, you have a much higher risk of cardiovascular disease. This disease is caused by blockages and narrowing of the blood vessels.

Conditions related to high cholesterol include:

- ❖ Heart attack
- ❖ Chest pain
- ❖ High blood pressure
- ❖ Kidney disease
- ❖ Stroke



Know your cholesterol levels⁷

It's important to keep your heart healthy and to lower your chances of getting heart disease or having a stroke. Your new medicines can help you avoid these conditions. It's important you understand and educate yourself about your cholesterol levels and ways you can lower your risk. Cholesterol levels are determined by a variety of factors.

Healthy cholesterol levels for adults (aged 20 and over)

TYPE	HEALTHY LEVEL
Total cholesterol	Less than 200 mg/dL
HDL cholesterol	40 mg/dL or higher
LDL cholesterol	Less than 100 mg/dL
Triglycerides	Less than 150 mg/dL

● *Symptoms of high cholesterol⁸*

High cholesterol has no symptoms, but your doctor can perform a simple test to check your levels. Talk to your doctor to find out how often he or she wants to test your cholesterol.



*What are the risk factors?**

High cholesterol can affect anyone. Many factors may affect your risk for high cholesterol. Some factors, like lifestyle choices, are in your control. Other factors, like heredity, are outside your control.

Factors in your control

- ❖ **Diet:** Some foods contain fats that can make your cholesterol levels rise.
- ❖ **Weight:** People who are overweight may have higher cholesterol levels. Weight gain can raise triglycerides, and can lead to other conditions.

Factors outside your control

- ❖ **Genetics:** High cholesterol can run in families. You can take precautions and work with your doctor to minimize your risk.
- ❖ **Age:** After age 20, blood cholesterol begins to rise.
- ❖ **Gender:** In women, LDL, or bad cholesterol levels often rise during menopause.

Helping your family and friends understand a high cholesterol diagnosis

It's up to you to decide when and how to tell your friends and family about your diagnosis. The people who care about you may have questions, and may be worried. If these questions seem overwhelming, or you're having trouble responding, consider saying, "I'll share more information when I learn more from my doctor."

Your family and friends will want to find the best ways to support your emotional and physical needs. It's okay to ask for help and receive help.



Taking care of your body

There's nothing worse than feeling like your body is out-of-control. Luckily, there are ways you can lessen stress on your physical body and mental health by being proactive in a few areas. These areas include a healthy diet, regular exercise, smart sleep schedule and a great support network. Keep reading to find out more.

Take charge of your health

People who actively manage their condition report better outcomes, fewer visits to the doctor and better quality of life. High cholesterol treatment also means you must take lifestyle changes seriously.

Things you can do include:

- Eating healthy foods
- Exercising regularly
- Supporting your emotional health
- Taking medicine on time and following your doctor's orders

If you find that your family or friends are unsupportive of your healthier habits, try seeking out resources and groups that can help.



ASK YOUR DOCTOR

Ask your doctor if there are vitamins or minerals that could help to manage your symptoms and keep you healthy. Also, note how your diet affects your symptoms and discuss any diet changes with your doctor or nutritionist.

Talk to your doctor before you take any nutritional supplements. These can be harmful or life-threatening under some circumstances.

Eat healthy

The most important thing you can do for your body is to eat well and maintain a healthy weight.

A balanced diet includes plenty of fruits, vegetables and whole grains. It also limits salt, sugar, saturated fat and alcohol. It may include daily vitamins and minerals. Studies have shown that a diet low in saturated fat but high in omega-3 fatty acids may be beneficial.

Tips for safe and healthy eating

- ❖ Eat small meals or snacks every three to four hours instead of three large meals each day
- ❖ Do not eat raw or undercooked fish or shellfish
- ❖ Drink at least eight glasses of water or clear, caffeine-free fluids every day
- ❖ Ask your doctor if you would benefit from dietary supplements

Some foods may lower cholesterol¹⁰

- ❖ **Nuts like almonds, walnuts and pistachios:** Eating a handful a day can help lower cholesterol. They are a great substitute for cheese or croutons in a salad as well.
- ❖ **Olive oil:** Instead of using vegetable-based oils, consider cooking with olive oil. Not only is it better for your heart, olive oil has antioxidant benefits, too.
- ❖ **Oatmeal:** Oatmeal is a great heart-healthy food because of its natural fiber. Studies show that eating just five to ten more grams of fiber a day may cut your bad cholesterol risk.

● *We believe in you*

Making many changes at once can be overwhelming. If it's necessary, incorporate changes into your routine slowly, over time. In some cases you may find that you need to change the way you do some things sooner, in order to reduce pain.



Saturated fats and trans fats¹¹

Food has different types of fats. Two of the main types of “bad” fats are saturated fats and trans fats.

- ❖ **Saturated fats** are found in animal meat, full-fat dairy products, butter, chocolate and palm oil. Saturated fats can increase blood cholesterol. It’s best to limit saturated fats in your diet.
- ❖ **Trans fats** occur naturally, but can also be added to our food in a chemical process. They are often labeled as, “partially hydrogenated oils.” According to the American Heart Association, trans fats may raise levels of LDL cholesterol and lower HDL cholesterol.

The best way to avoid these types of fats is to look at ingredient lists, focus on eating healthy (whole) food like fruits, vegetables and whole grains, and limit processed foods.

Maintain a healthy weight

A healthy weight is one that allows your body to function at its best. To find out if your weight is at a healthy level, you should know your body mass index (BMI). Here are four ways to maintain your weight:

- 1 Overeating can interfere with your treatment.**
Choose healthy options, such as the ones featured on **ChooseMyPlate.gov**, a website that can help you plan healthy meals.
- 2 Listening to your body** is an important step in managing your high cholesterol journey and in living a healthy lifestyle. Creating a meal-time plan that allows you to focus on your food with little distraction can help you feel satisfied, full and nurtured.
- 3 Accountability partners** can be a great tool to keep your goals on track. It may seem hard to eat healthier or lose weight on your own. Pair up with a workout buddy or a friend to help you discuss hurdles and share celebrations and keep you accountable for your goals.
- 4 Create weight loss goals that are sustainable and realistic.**
Talk about your weight loss goals with your doctor. Finding a nutritionist may also help you to change habits that are blocking your path to success.



Sleep well

Your body needs rest to heal and recharge. One of the best things you can do for yourself is to make sure you get eight or more hours of sleep every night. If your body is telling you that you're tired and you're having trouble falling asleep, make sure to mention it to your doctor.

*Exercise regularly*¹²

Exercise may actually boost your energy level. It may also help you cope with your condition and manage your weight. Try to exercise regularly.

Exercising, for even as little as 10 minutes at a time, can dramatically impact your mood and health.

Use these ideas to add exercise in your life

- ❖ **Take a walk:** During your lunch hour at work, or at home, take a walk around the block or building. Raising your heart rate and allowing your body to move has great long-term effects.
- ❖ **Find a team sport:** Join people you already know or people you have yet to meet. Sign up for a team sport. It's more fun to exercise when it feels like a social activity.
- ❖ **Don't give up:** New changes take time to feel like a regular routine. Reward yourself when you do choose to exercise so you have something to look forward to.

Stop smoking

It's time to think about stopping smoking. Within 20 minutes of quitting, your heart rate and blood pressure will decrease. In one year, your risk of heart disease is cut to half.¹³ As hard as it may be, quitting smoking is one of the best things you can do for your health. Talk about your options for quitting with your doctor, or look online for ideas on how to quit.




- ❖ **Smokefree.gov:** A stop-smoking initiative by the U.S. Department of Health and Human Services.
- ❖ **Cancer.org:** Initiatives around support for those stopping smoking, cravings and ways to remain tobacco-free.

Supporting your emotional health

Maintaining your emotional health can help to maintain your physical health. Some people become overwhelmed with their diagnosis and the life adjustments they need to make. This is normal. Managing your stress and asking for help from friends, family or professionals are important aspects of staying healthy. Many people also benefit from in-person or online support groups.

Stress

Any diagnosis of a long-term condition can be very stressful. This stress may make the challenges of life difficult to handle — especially when it comes to your body. Here are three great ways you can manage your stress:

-  **Write it down:** Record your thoughts in a journal and read through it often. Celebrate daily successes and share opportunities and challenges to help your brain recognize the many sides of your life.
-  **Take a break:** When you're in the midst of a particularly difficult moment, take a step back and take a deep breath. Even taking a small nap or watching something you enjoy on TV may help brighten your mood.
-  **Find a support group:** Every individual needs a healthy balance of people that are able to help in stressful situations. Keep phone numbers handy for family or friends you trust. Reach out to them as often as needed.



Depression

Depression is not a character flaw or weakness. It's a health problem that starts from a chemical imbalance in the brain. If you have thoughts of suicide or of harming yourself or others, call 911 or go to the emergency room.

FOR SUPPORT

**National Suicide
Prevention Hotline**
1.800.273.8255

Crisis Textline
Text "GO" to 741-741

**American Heart Association
Support Line**
www.supportnetwork.heart.org

National 211 Helpline
www.211.org

● *A note on depression*





Everyone feels sad now and then. Sometimes a deep sadness or loss of interest in activities you usually enjoy can actually be a medical illness called depression. Depression can cause deeply sad feelings or high anxiety around everyday activities, and may make it hard to live your life in the way you want.

If you think you may be depressed, talk with your doctor. Your doctor may prescribe an antidepressant medicine to help with your symptoms. It may take several weeks for you to feel the full benefit of antidepressants. Your doctor may also recommend counseling with a mental health professional.

High cholesterol treatment approaches



Taking an active role in your health care includes paying careful attention to both symptoms and treatment. It also means talking openly with your doctor. This part of the guide can help you:

-  Track your disease symptoms and medicine side effects
-  Understand more about how your condition might affect your quality of life
-  Understand more about how to get the most from your medicine therapy
-  Record questions or concerns to discuss with your doctor

Staying on track with your medicines

Here is what you can do to help get good results from your high cholesterol medicine therapy:

DO

- ❖ Call your doctor or pharmacist with any questions you may have concerning your high cholesterol medicines.
- ❖ Educate yourself about your medicines, especially risks and warnings.
- ❖ Keep a list of the names and amounts of medicines you are taking.
- ❖ Stick to the medicine schedule your doctor has prescribed.
- ❖ Add taking your medicines into your normal routine.
- ❖ Check with your doctor before starting any new medicines, including vitamins, supplements, herbal remedies, prescription medicines and over-the-counter products.
- ❖ Drink plenty of fluids. The best choices are water, clear fruit juices and other caffeine-free drinks.

DON'T

- ❖ Skip or change doses. By taking your medicine as prescribed, you will improve your chances for a positive treatment outcome.



Treatment strategies and goals

Treatment options have improved over the last few years. New medicines, (monoclonal antibodies that target a specific protein that regulates LDL receptors) may be prescribed for people who just can't take traditional statins. Some people who take statins stop them or reduce the dose, primarily because of complaints of muscle pain, which is not only unpleasant but can even be debilitating. These people may be potential candidates for the new drugs. These new medicines may be prescribed in addition to statins. Some people who can take statins find that their LDL levels remain stubbornly high. People with an inherited form of high cholesterol and associated high risk for premature cardiovascular events can have very high levels of LDL. Lifestyle changes along with statins may not be enough to reduce high levels of LDL.

Try the following steps to help stay on time with your medicine schedule

- ❖ Consider using a medicine reminder system or app to help track your medicines, their dosages and the time you should be taking them
- ❖ Make taking your medicine part of your daily routine
- ❖ To help you remember your medicine, take your pills at the same time as another routine task, like when brushing your teeth
- ❖ Set an alarm on a watch or cell phone, or set a timer to remind you to take your medicine

● *Administering your medicine*

Traditional medicines for high cholesterol are taken by mouth. However, the type of medicine you've been prescribed is administered by injection.

You must inject this medicine into a muscle or into the vein. If you're worried about giving yourself an injection, your doctor, nurse or pharmacist can talk to you about any concerns. They will take the time to demonstrate how to inject your medicine properly. Sometimes, they can give you a device that can help make it easier for you to inject yourself.

PCSK9 inhibitors^{14,15}

PCSK9 inhibitors are a new class of medicines. The Food and Drug Administration (FDA) recently approved these for people with very high levels of LDL (or, bad) cholesterol. They can lower LDL levels when traditional cholesterol medicines haven't worked. These medicines can also help people who have already experienced heart attacks or strokes.

DRUG NAME	AVAILABLE FORMS	POSSIBLE SIDE EFFECTS	IMPORTANT INFORMATION
Praluent ^{®17} (alirocumab)	Injection	<ul style="list-style-type: none"> ● Redness, pain, swelling, bruising, irritation at injection site ● Bronchitis, influenza, sinusitis, cough ● Memory impairment ● Muscle aches 	<ul style="list-style-type: none"> ● In pre-marketing trials, Praluent had few side effects. ● Available in pre-filled syringes.
Repatha ^{™18} (evolocumab)	Injection	<ul style="list-style-type: none"> ● Redness, pain, swelling, bruising, irritation at injection site ● Bronchitis, influenza, sinusitis, cough ● Hypertension ● Muscle aches ● Headaches 	<ul style="list-style-type: none"> ● In pre-marketing trials, Repatha had few side effects. ● Available in pre-filled syringes.

*Understanding side effects*¹⁵



You may have concerns about possible side effects of your high cholesterol medicine. That concern can sometimes make it hard to stay on track. It helps to set realistic expectations about how your treatment may affect you. Remember that medicine you're taking now may be different from medicines you've taken before. Your current medicines may have fewer, less severe or completely different side effects. Talk with your doctor about any side effect that doesn't go away after a little while.

Possible side effects

- 1 If you're having trouble sleeping,** consider avoiding large meals or caffeine too close to bedtime. You may also consider developing a peaceful bedtime routine that can help your body and mind better relax in the evening. Many people have found that relaxation techniques such as yoga, meditation or deep breathing can help with alleviating sleep problems.
- 2 If headaches are becoming more regular,** consider drinking more fluids — especially water. Some people have also found that dark rooms or warm baths can help reduce some headache symptoms. Make sure to speak to your doctor or pharmacist before you use an over-the-counter pain reliever.
- 3 If you are experiencing a fever,** make sure you are drinking plenty of fluids. Remember that a high fever or a fever lasting more than 48 hours needs to be addressed with your doctor immediately.
- 4 If you're lacking an appetite,** consider eating smaller and more frequent meals. Taking a walk before and after meals also may help stimulate the appetite and aid digestion. Practice good self-care and indulge in a few of your favorite meals. Try taking supplements or drinking meal replacement shakes to help provide the nutrition your body needs.
- 5 If you have a bad taste in your mouth, or you have dry mouth,** it's recommended to start each day with a glass of water. Make sure to get regular dental check-ups and let your dentist know about any medicines you may be taking.



Bronchitis, cough and influenza

Coughing and flu-like symptoms are common side effects of PSCK9 inhibitors. Call your doctor to see if you need prescription or over-the-counter medicines to treat your symptoms and prevent a secondary infection.

Injection-site reactions

When you inject a medicine, a reaction may occur at the injection site. Reactions may include:

- ❖ Redness
- ❖ Rash
- ❖ Stinging
- ❖ Tingling
- ❖ Swelling
- ❖ Itching
- ❖ Pain
- ❖ Discomfort

The following steps may help reduce or prevent these reactions

STEP	EXPLANATION
Preparation	<ul style="list-style-type: none">● Make sure the medicine is at room temperature before injection. Applying ice to the site before and after injection may lessen injection-site reactions.
Method	<ul style="list-style-type: none">● Ensure that you are using the correct injection method for your medicine.
Placement	<ul style="list-style-type: none">● Rotate each new injection site at least one inch apart.● Avoid injecting into areas that are swollen, red or hard.● Record when and where you inject each time to help keep track.
Supplies	<ul style="list-style-type: none">● Use a new needle for each injection.



Skin rash

Some injections can cause dry, itchy skin. Constant scratching can lead to infection. Try the following to keep your skin in optimal shape:

- ❖ Use an oatmeal bath to protect your skin and prevent itching.
- ❖ Wash with an unscented moisturizing soap.
- ❖ Use lukewarm water instead of hot.
- ❖ Drink plenty of fluids to keep your skin hydrated.

Pregnancy, breastfeeding and fertility

It is currently not known how PCSK9 inhibitors affect pregnancy, breastfeeding and fertility. Talk to your doctor if you're pregnant or breastfeeding.

When it's time to call the doctor

Chest pain

This includes discomfort in your chest, esophagus (throat) or lungs. This may feel like a burning or aching chest pain. Seek emergency treatment immediately if you develop chest pain while taking your medicine, especially if the pain is:

- ❖ Very severe
- ❖ Different from pain you have had before
- ❖ Occurs when you are doing a strenuous activity, such as climbing stairs

Shortness of breath

If you feel short of breath, call your doctor. Your doctor will determine if it is related to your cholesterol medicine, or another medical problem that requires prompt attention.



Also call your doctor right away if you experience:

- ❖ Swelling in your legs, feet or ankles
- ❖ Severe diarrhea lasting for more than 48 hours
- ❖ Blood in your stool
- ❖ Fever higher than 100.5° F at any time, or you have a fever lasting longer than 48 hours
- ❖ Extreme fatigue
- ❖ Allergic-type reactions such as trouble breathing, hives, etc.



ASK YOUR DOCTOR

If you are experiencing a symptom or side effect that is worrying you, it is always best to call your doctor. Your doctor will determine if you need immediate attention and the next steps.



Resources

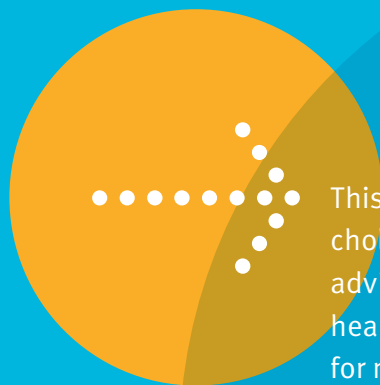
ORGANIZATION	DESCRIPTION
American Heart Association heart.org	<ul style="list-style-type: none"> The American Heart Association is a national non-profit focused on education around heart disease and lowering deaths related to heart disease.
CDC Million Hearts Campaign millionhearts.hhs.gov	<ul style="list-style-type: none"> The Centers for Disease Control is offering the public education to save one million hearts and empower better knowledge around heart disease and heart conditions.
The National Heart, Lung, and Blood Institute nhlbi.nih.gov/health/public/heart/index.htm	<ul style="list-style-type: none"> This is the U.S. Department of Health and Human Services' initiative for better education around issues of the heart, lungs and blood.
Mayo Clinic mayoclinic.com	<ul style="list-style-type: none"> The Mayo Clinic is a non-profit medical practice and medical research group based in Minnesota.
Patient Advocate Foundation patientadvocate.org	<ul style="list-style-type: none"> Patient Advocate Foundation (PAF) is a national 501 (c)(3) non-profit organization which provides professional case management services to Americans with chronic, life threatening and debilitating illnesses.

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This guide provides an overview of high cholesterol. It is not meant to replace medical advice from your doctor, pharmacist or other health care provider. Please contact them for more information. This guide is intended to be accurate. However, Prime Therapeutics is not responsible for loss or damage due to reliance on this guide.

ABOUT PRIME THERAPEUTICS

Purpose-built, mission-driven — we're committed to helping people get the medicine they need to feel better and live well. This mission fuels our passion and drives every decision we make.

Prime Therapeutics LLC is URAC-accredited for Pharmacy Benefit Management. Prime Therapeutics LLC holds NCQA Certifications for Utilization Management and Health Information Product — Pharmacy Benefit Information.



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