Cholesterol Management (Hyperlipidemia)

OBJECTIVE

The objective of this Clinical Practice Guideline (CPG) is to provide evidence-based practice recommendations for cholesterol management. The CPG discusses treatment options as well as behavioral health implications. In addition, the CPG outlines the organizations that WellCare aligns with regarding cholesterol management and relevant Measureable Health Outcomes.

OVERVIEW

Heart and blood vessel disease — cardiovascular disease, also called heart disease — includes numerous problems, many of which are related to a process called atherosclerosis. Atherosclerosis is a condition that develops when a substance called plaque builds up in the walls of the arteries. This buildup narrows the arteries, making it harder for blood to flow through. If a blood clot forms, it can stop the blood flow. These diseases include **Coronary Heart Disease, Cerebrovascular Disease, Peripheral Artery and Aortic Atherosclerosis.** As HTN continues, the arteries thicken and become less flexible. Cholesterol deposits in the arteries further narrow the ability of blood flow easily. To compensate for the additional force needed to pump blood, the heart gets thicker and enlarges. Some of the risk factors that can lead to cardiovascular disease include:

- Smoking
- Diabetes
- Genetics
- Hypertension
- Congenital heart conditions
- Arterial stiffness and/or calcification Left ventricular hypertrophy (LVH)*
- Atherosclerotic vessels due to high lipids in the blood
- Collagen vascular disease (such as Lupus or Scleroderma)

* The heart uses electrical impulses to generate a heartbeat. This electrical activity can be measured using an electrocardiogram (ECG). When the heart is enlarged due to ventricular hypertrophy, the path that the electrical impulse takes is affected. This effect can be seen on an ECG.

Hierarchy of Support

GUIDELINE HIERARCHY

CPGs are updated annually or as necessary due to updates made to guidelines or recommendations by the American College of Cardiology (ACC) and the American Heart Association (AHA). When there are differing opinions noted by national organizations, WellCare will default to the member's benefit structure as deemed by state contracts and Medicaid / Medicare regulations. If there is no specific language pertaining to cholesterol management, WellCare will default (in order) to the following:

- National Committee for Quality Assurance (NCQA);
- United States Preventive Services Task Force (USPSTF), National Quality Strategy (NQS), Agency for Healthcare Research and Quality (AHRQ);
- Specialty associations, colleges, societies, etc. (e.g., American Academy of Family Physicians, American Congress of Obstetricians and Gynecologists, American Cancer Society, etc.).

Original Effective Date: 6/2008 Revised: 6/2009, 7/2010, 7/5/2012, 7/31/2014, 8/7/2014, 2/5/2015, 7/24/2017, 12/7/2017

Links to websites within the CPGs are provided for the convenience of Providers. Listings do not imply endorsement by WellCare of the information contained on these websites. NOTE: All links are current and accessible at the time of MPC approval.

WellCare aligns with the ACC and AHA on the topic of cholesterol management. Highlights from their respective publications are noted below.

AMERICAN COLLEGE OF CARDIOLOGY (ACC) AND AMERICAN HEART ASSOCIATION (AHA)

The American College of Cardiology (ACC) and the American Heart Association (AHA)[1] updated the guideline on the treatment of blood cholesterol to reduce atherosclerotic cardiovascular risk in adults. Highlights of the report include:

- Encouraging adherence to a heart-healthy lifestyle
- Prescribing statin therapy for adults in groups demonstrating potential benefit. Statins have an acceptable margin of safety when used in properly selected individuals and appropriately monitored.
- Engaging in a clinician-patient discussion before initiating statin therapy, especially for primary prevention.
- Utilizing the newly developed Pooled Cohort Equations for estimating 10-year atherosclerotic cardiovascular disease (ASCVD) risk.
- Initiating the appropriate intensity of statin therapy to reduce ASCVD risk.
- Monitoring patients regularly for adherence to lifestyle and appropriate intensity of statin therapy.
- Using non-statin drug therapy may be considered in selected individuals.

Further, the ACC/AHA guideline states that evidence is inadequate to support treatment to specific LDL-C or non-HDL-C treatment goals. The ACC/AHA identified four statin benefit groups:

1. Clinical ASCVD
2. LDL-C ≥190 mg/dL, Age ≥21 years
3. Primary prevention - Diabetes: Age 40-75 years, LDL-C 70-189 mg/dL
4. Primary prevention - No Diabetes†: ≥7.5%‡ 10-year ASCVD risk, Age 40-75 years, LDL-C 70-189 mg/dL

†Requires risk discussion between clinician and patient before statin initiation
‡Statin therapy may be considered if risk decision is uncertain after use of ASCVD risk calculator

For members not in a statin benefit group, those for whom a risk decision is uncertain, providers should discuss the following with the member to help inform clinical decision making:

- Family history of premature ASCVD
- Elevated lifetime risk of ASCVD
- LDL-C ≥160 mg/dL
- hs-CRP ≥2.0 mg/L
- CAC score ≥300 Agaston units
- ABI <0.9

Evidence Based Practice

AGENCY FOR HEALTHCARE RESEARCH AND QUALITY (AHRQ)

The Agency for Healthcare Research and Quality (AHRQ) has not published any report on cholesterol management.

MEASUREMENT OF COMPLIANCE

WellCare is committed to adhering to the measures and standards published by the Centers for Medicare and Medicaid Services (CMS) and the National Committee for Quality Assurance (NCQA). Please reference WellCare's Clinical Policy Guiding Document titled *Measures of Compliance.*

NOTE: To access Clinical Policy Guiding Documents visit www.wellcare.com – select the Provider tab, then "Tools" and "Clinical Guidelines".

Care Management

Original Effective Date: 6/2008 Revised: 6/2009, 7/2010, 7/5/2012, 7/31/2014, 8/7/2014, 2/5/2015, 7/24/2017, 12/7/2017

The goals for Care Management are to support the member's ability to self-manage their disease, minimize risks factors, and remove barriers preventing them from achieving those goals. Integrated Care Management:

- Coaching related to making lifestyle changes
- Ensuring member's understanding of medication dosing and adherence to medications, refilling timely
- Supporting the member's weight loss and tobacco cessation efforts as appropriate
- Regular screening for co-morbities (e.g., hypertension, obesity, cardiovascular disease)
- Assess for risk of depression and share with appropriate provider(s) if risks identified

DETERMINING RISK

The presence of clinical atherosclerotic disease that confers high risk for coronary heart disease (CHD) events include: symptomatic carotid artery disease, peripheral arterial disease, and abdominal aortic aneurysm. Suggested levels are outlined below:[2]

LDL Cholesterol – Primary Target of Therapy (mg/dL)[3]	
< 100	Optimal
100-129	Near optimal / above optimal
130-159	Borderline high
160-189	High
≥ 190	Very High

Total Cholesterol	
< 200	Desirable
200-239	Borderline high
≥ 240	High

HDL Cholesterol	
< 40	Low
≥ 60	High

Other major risk factors include:

- Cigarette smoking
- Hypertension (BP > 130 / 80 mmHg or an antihypertensive medication)
- Low HDL cholesterol (<40 mg/dL)*
- Family history of premature CHD (CHD in male first degree male relative <55 years; CHD in female first degree relative <65 years)
- Age (men ≥45 years; women ≥55 years)

NOTE: HDL cholesterol ≥60 mg/dL counts as a "negative" risk factor; its presence removes one risk factor from the total count.

TREATMENT AND LIFESTYLE MODIFICATIONS

Along with weight management and increasing physical activity, patients can follow a cholesterol-reducing diet. Balance calories taken in and calories burned to keep desirable body weight and prevent weight gain.[3]

Saturated Fat	Less than 7% of total calories
Polyunsaturated Fat	Up to 10% of total calories
Monounsaturated Fat	Up to 20% of total calories
Carbohydrate	50% to 60% of total calories
Fiber	20 to 30 grams per day
Protein	Approximately 15% of total calories
Cholesterol	Less than 200 mg per day

Initial LDL Level	**Initiation of Drug Therapy**
>130 mg/dl	Start statin therapy simultaneously with lifestyle modification.
100-129 mg/dl	Consider starting statin therapy simultaneously with lifestyle modification. Definitely start statin therapy if still >100 mg/dl after 3 months of lifestyle modification.** In patients hospitalized with an acute cardiovascular or coronary event, initiate statin therapy prior to discharge.
<100 mg/dl	Statin therapy is not required, but may further lower risk in some patients. Lowering to <70 mg/dl in very high-risk patients is an option.

[5] ** In people younger than 40 years with diabetes but without CVD, lifestyle modification alone may be sufficient; however, data for this subpopulation are limited. Use clinical judgment based on other cardiovascular risk factors to guide whether or when to start drug therapy if the LDL goal of <100 mg/dl is not met by lifestyle modification alone.

Lifestyle modifications are important when managing cholesterol. Provider should encourage the following:[4]

- **Healthy diets** should be low in saturated fat and cholesterol but high in fiber; transfat should be avoided.

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- **Weight management** should be gradual, with a goal of losing 1-2 pounds per week.
- **Physical activity** should be ≥30 minutes of moderate physical activity (e.g., a brisk walk) ≥5 times/week.
- **Smoking cessation** should include a quit date and plan to carry out the goal.
- To increase **medication adherence**, encourage patients to:
  - Use a pill box
  - Carry a list of all medications*
  - Understand that lipid-lowering medication(s) should be taken **every day** – even when feeling well.
  - Be aware that adverse effects such as muscle soreness, tenderness or pain, headache or dyspepsia can occur and should immediately be reported to their healthcare provider.
  - Appreciate that a lipid-lowering medication and treatment regimen if typically lifelong and multifaceted, including diet, lifestyle modification and medication(s).

* Each and every office visit should include a reconciliation of the medications currently being used.

MEASURABLE HEALTH OUTCOMES

Targeted Health Outcomes (Extended Program Goals) result from successful member self-management (see Case Management Objectives).

1. Maintaining a healthy diet. Compare member's knowledge and dietary habits pre and post engagement at 6-12 months. In absence of documentation, Provider and/Member narrative/HRA data may be used.
2. A moderate physical activity regimen to include a minimum of 30 minutes on most days of the week .Compare physical activity level documented in provider records, assessments and care plans, and monitoring data pre and post engagement 6-12 months. In the absence of these data sources, CM may use Provider and/or Member narrative and/or HRA data may be used.
3. Adherence to medication regimen, when appropriate, as evidenced by pharmacy claims pre and post engagement at 6-12 months. In absence of documentation, Provider and/Member narrative/HRA data may be used.

CASE MANAGEMENT GOALS

Case Goals should target specific care gaps and/or adherence issues, and measure the member's progress towards self-management and adherence which will lead to the targeted health outcomes above. Examples:

1. The member will increase their level of physical activity by 2-5 minutes each week. Member self-reports exercise regime over the last 30 days that demonstrates improved adherence to physical recommendation.
2. The member will be able to identify healthy eating patterns. Member self-reports grocery shopping and diet regime over the last 30 days that demonstrate improved adherence to guideline and or provider recommendation.
3. The member will be adherent to medication regimen as evidenced by pharmacy claims over last 30 days.
4. Specific for Members requiring hospitalization: The Member participates in provider follow-up visit within 7 days of hospital discharge.

CASE MANAGEMENT OBJECTIVES

Case Management Objectives should focus on improving the Member's self-management skills up including:

1. Lifestyle change skills
2. Increasing physical activity to at least 150 minutes/week or as otherwise prescribed by physician
3. Following a diet low in saturated fat and cholesterol but high in fiber
4. Taking medications including statins as prescribed
5. Adhering to Provider visit(s) as scheduled
6. Tobacco cessation
7. Avoiding second-hand smoke
8. Early identification of symptoms to manage, report to physician and / or call for emergency services

The care team should also conduct screening for and treatment of anxiety and/or depression, as appropriate.

MEDICAL BEHAVIORAL INTEGRATION

Some studies have suggested that lower serum cholesterol levels (below 160 mg/dL), while reducing the risk of deaths caused by heart attacks and cardiovascular disease, may be associated with increased rates of depression and

mortality due to suicide and violence. More studies needed to investigate the causal relationship between suicidality, violence and lower cholesterol levels.[5,6]

MEMBER EDUCATIONAL RESOURCES

WellCare contracts with Krames/StayWell for Member educational materials utilized by Case Managers. Items are available to review with Members to address knowledge gaps. Case Managers verbally educate Members on the topics below related to asthma. (Titles may also be sent to the member).

NOTE: Links are internal for WellCare Care Management staff. Please see below for public links.

- Managing High Cholesterol (Fast Guide)
- Understanding Food and Cholesterol
- Cholesterol Quiz
- Exercise Fitting It Into Your life
- Weight Management Overcoming Your Barriers
- Understanding Body Mass Index
- Cholesterol Medications
- Low Fat Cooking Tips
- Eating Healthy
- Understanding Fat and Cholesterol
- Losing Weight

Providers may wish to research the titles above related to asthma that Case Managers utilize with Members.

PHARMACOLOGY

To access the Preferred Drug List (PDL) and directions on how to submit a drug exception request, visit www.wellcare.com and select the applicable state. From there, visit the Provider section where you will find the PDL and related Pharmacy items.

Related WellCare Guidelines

In addition to the information contained in this document, reference the following CPGs: *Cardiovascular Disease (HS-1002)* and *Congestive Heart Failure (HS-1003).* Information on prevention can be found in the following age-specific Preventive Health CPGs: *Adolescent (HS-1051), Adult (HS-1018), Older Adult (HS-1063)*, and *Pediatric (HS-1019).*

NOTE: Clinical Policies can be accessed by going to www.wellcare.com – select the Provider tab, then "Tools" and "Clinical Guidelines".

References

1. Stone NJ, Robinson J, Lichtenstein AH, Bairey Merz CN, Blum CB, Eckel RH, & et al. 2013 ACC/AHA guideline on the treatment of blood cholesterol to reduce atherosclerotic cardiovascular risk in adults: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. http://circ.ahajournals.org/content/early/2013/11/11/01.cir.0000437738.63853.7a.full.pdf. Published 2013. Accessed July 10, 2017.
2. Third report of the expert panel on detection, evaluation, and treatment of high blood cholesterol in adults (Adult Treatment Panel III). National Heart Lung and Blood Institute Web site. https://www.nhlbi.nih.gov/health-pro/guidelines/current/cholesterol-guidelines/final-report. Published 2002. Accessed July 17, 2017.
3. Therapeutic lifestyle changes (TLC) diet for high cholesterol – overview. WebMD and Healthwise Web site. http://www.webmd.com/cholesterol-management/tc/therapeutic-lifestyle-changes-tlc-diet-for-high-cholesterol-. Accessed July 17, 2017.
4. Lipid control: preventing cardiovascular events in patients with atherosclerotic disease or diabetes. New York City Department of Health and Mental Hygiene Web site. https://www1.nyc.gov/assets/doh/downloads/pdf/chi/chi25-5.pdf. Published 2006. Accessed July 17, 2017.
5. Greenblatt, James M. "Low Cholesterol and Its Psychological Effects: Low Cholesterol is Linked to Depression, Suicide, and Violence." Psychology Today. June 10, 2011. https://www.psychologytoday.com/blog/the-breakthrough-depression-solution/201106/low-cholesterol-and-its-psychological-effects. Accessed July 19,2017.
6. Lake, James. "Cholesterol and Mood: What's the Link?" Psychiatric Times. October 08, 2010. http://www.psychiatrictimes.com/depression/cholesterol-and-mood-what%E2%80%99s-link. Accessed July 19, 2017.

Disclaimer

Medical Policy Committee Approval History

Date	History and Revisions by the Medical Policy Committee
12/7/2017	• Approved by MPC. Updated guidelines on hypertension.
7/24/2017	• Approved by MPC. Added sections on Care Management and Health Equity, Health Literacy, and Cultural Considerations.
2/5/2015	• Approved by MPC. Additions from Heart Disease Care Management training.
8/7/2014	• Approved by MPC. Included CMS STAR metric.
7/31/2014	• Approved by MPC. No changes.
7/5/2012	• Approved by MPC. Incorporated items from the USPSTF (2008) and NHLBI (2004).
12/1/2011	• New template design approved by MPC.
7/2010	• Approved by MPC.