Clinical Policy Title: Home cholesterol management/lipid panel screening

Clinical Policy Number: 04.01.06

Effective Date:	**December 1, 2014**
Initial Review Date:	July 16, 2014
Most Recent Review Date:	June 5, 2018
Next Review Date:	June 2019

Policy contains:

- Home Cholesterol Management.
- Cardiac Risk Factors.

Related policies:

None.

ABOUT THIS POLICY: *AmeriHealth Caritas has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas' clinical policies are based on guidelines from established industry sources such as Centers for Medicare and Medicaid (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer reviewed professional literature. These clinical policies, along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state or plan specific definition of "medically necessary", and the specific facts of the particular situation are considered by AmeriHealth Caritas when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. AmeriHealth Caritas' clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. AmeriHealth Caritas' clinical policies are reflective of evidence based medicine at the time of review. As medical science evolves, AmeriHealth Caritas will update its clinical policies as necessary. AmeriHealth Caritas' clinical policies are not guarantees of payment.*

Coverage policy

AmeriHealth Caritas considers the use of home cholesterol monitors to be investigational/experimental and, therefore, not medically necessary.

Limitations:

The value of home testing over standard laboratory testing has not been established.

Alternative covered services:

Age specific, periodic lipid panels as recommended by the National Heart, Lung and Blood Institute.

Background

Elevated cholesterol levels are common among Americans. High levels (over 200 mg/dL total cholesterol) exist for each by race and gender (Mozzafarian, 2015):

White men	40%
White women	46%
Black men	37%
Black women	41%
Hispanic men	46%
Hispanic women	43%

High cholesterol is a known risk factor for cardiovascular conditions such as heart attack and stroke, which are common among Americans. The annual number of heart attacks and strokes in the U.S. are estimated at 790,000 and 795,000, respectively (Benjamin, 2017).

Despite the high rates of cholesterol, and the recommendation of the American Heart Association that adults should have their cholesterol level measured every five years (AHA, 2018), about one-third of Americans haven't had a cholesterol check in the most recent 4-6 years (Carroll, 2013).

There are no signs or symptoms of high cholesterol. The only way to detect the disorder is to have a simple blood test, which helps to indicate the risk for cardiovascular disease. The American Heart Association recommends that cholesterol testing should be considered for children and adolescents with a 1) parent or grandparent with evidence of coronary atherosclerosis, peripheral vascular disease or cerebrovascular disease; 2) parent or grandparent who had a coronary artery procedure, suffered a heart attack or sudden cardiac death before age 55, or 3) parent who has or had a history of total cholesterol levels 240 mg/dL or higher (AHA, 2017). The AHA also recommends that all adults age 20 or over have their cholesterol, and other traditional risk factors, checked every 4 - 6 years (AHA, 2018).

These tests have traditionally been done in a lab. In 1993, the U.S. Food and Drug Administration (FDA) approved the first home test kit to measure blood cholesterol (Cimons, 1993). Today, there are dozens of such test kits available to consumers.

Results from home testing kits approved by the FDA should be as accurate as those obtained through a laboratory certified by the Clinical Laboratory Improvement Amendments. Under controlled conditions, such home kits for measurement of serum cholesterol have demonstrated this level of accuracy, but in real world experience have not produced valid and reliable results. However, results of home lipid panel tests are about 95 percent accurate in comparison to commercial laboratories (Davis, 2007). Kits sold to consumers may include tests for total cholesterol, high density lipid cholesterol and/or triglycerides. However, these tests require three needle sticks and don't measure low density lipids (Harvard Medical School, 2017).

Checking blood pressure or blood sugar at home can assist the ambulatory patient in making appropriate adjustments in medication, diet and lifestyle. Home cholesterol test kits don't substitute for a cholesterol test performed by medical professionals. The accuracy of home cholesterol test kits varies, and results can't offer a complete picture of risk of developing heart disease. A doctor should always review results in combination with other risk factors even if a sophisticated test is purchased. The American College of Cardiology and American Heart Association did not address these home tests in its 2013 guideline (Stone, 2013).

Several home devices exist for measuring blood cholesterol levels. Some of these devices are operated similarly to the blood glucose level testing devices. Examples include the Cholestech LDX, Cardio Chek, and the Life Stream® Three Minute Cholesterol Monitor ® professional devices.

The CardioChek analyzers are one of the fastest, most cost-efficient and most user-friendly methods to determine lipid values. Handheld and battery-powered, CardioChek analyzers require a small blood sample from a simple finger stick. In as little as ninety seconds, CardioChek test systems provide values and measurements, using the same technology as clinical laboratories.

An alternative test methodology is illustrated with the CholesTrak® Total Cholesterol Test. The CholesTrak® test is a manual system that does not employ an electronic meter. Rather, the person using the CholesTrak® device visually compares the "color" of the reacted test analyte with a colorant-containing result chart, to determine the cholesterol level.

Searches

AmeriHealth Caritas searched PubMed and the databases of:

- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality's National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare and Medicaid Services (CMS).

We conducted searches on April 12, 2018. The search terms were: "cholesterol management," "cholesterol monitor," "lipid panel," "cholesterol test," "CardioChek," "CholesTrak," and "Cholestech," plus the term "home."

We included:

- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use pre-determined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- **Guidelines based on systematic reviews**.

- **Economic analyses,** such as cost-effectiveness and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

Findings

No clinical guidelines on the use of community based cholesterol management currently exist, and thus no recommendations have been made for or against their use in the U.S. In the U.K., as part of an effort to reduce inequalities in racial minorities, 406 high risk South Asians were screened for lipids using the Cholestech LDX point-of-care model. Biases in results were small at higher levels often observed in high-risk populations, and authors agreed that Cholestech LDX is adequate for the National Health Service health check (Jain, 2011). Cholestech LDX was also judged adequate for lipid screening in Australia (Shephard, 2009).

The Adult Treatment Panel III of the National Cholesterol Education Program issued an evidence-based set of guidelines on cholesterol management in 2001 (Pasternak, 2003). AllPanel reports have identified low-density lipoprotein cholesterol as the primary target of cholesterol lowering therapy. Home testing kits have not been fully evaluated under the circumstances for which they are marketed. The results are secured in minutes, which does provide privacy. However, home kits only measure one component of the cholesterol panel and may give a false sense of security, because they do not assess all risks; home testing does not provide a full lipid profile.

To date, no systematic reviews or meta-analyses addressing efficacy of home cholesterol management and lipid panel screening have been published in the peer-reviewed literature.

An article compared home monitoring of low density lipids ("bad" cholesterol) and feedback with the usual method of checking lipids six weeks after initiation of statin therapy. The reduction in low density lipids for the home measure group in six months was significant (186 to 117 mg/dL), as was the group employing the usual method (162 to 105 mg/dL). Because there was no significant difference in the two methods, the authors conclude lipid home monitoring is a feasible way to improve cholesterol levels (Alkouli, 2013).

In a sample of 30 patients, measurements of total cholesterol, high-density lipids, and triglycerides using two popular home screening devices (CardioChek and Cholestech) were compared with those using two standard laboratory models (Integra analyzer and Roche Cobas analyzer). Results given below show that all correlation coefficients between the home and lab models fall within the industry standard variation (Bastianelli, 2017):

Measure	Total Cholesterol	HDL	Triglycerides
Industry standard variation	+/- 10.0%	+/-12.0%	+/-15.0%

CardioChek vs. Integra Analyzer	- 7.8%	- 6.2%	+ 5.1%
Cholestech vs. Integra Analyzer	+ 0.5%	- 4.5%	- 3.3%
CardioChek vs. Roche Cobas Analyzer	- 4.2%	+ 0.8%	+ 7.0%
Cholestech vs. Roche Cobas Analyzer	+ 4.6%	+ 2.6%	- 1.6%

A comparison of blood samples measuring high density lipids and triglycerides in 516 persons showed that the agreement between the CardioChek home screening device and the COBAS reference analyzer used in laboratories demonstrated a good agreement (between 94.6 and 97.7 percent) of samples, depending on the category of lipid measurement (total cholesterol, triglycerides, high density lipids, and low density lipids) (Ferreira, 2015).

In a Chinese journal, the consistency of measuring cholesterol levels between the CardioChek device with a clinical laboratory mechanism was attempted. Based on 325 patients tested using both methods, a good consistency was found for 97.0, 92.9, 92.4, and 83.7 percent for total cholesterol, high density lipids, triglycerides, and low density lipids; all findings were highly statistically significant (Gao, 2016). In western Kenya, blood samples were collected from 246 persons and tested using the CardioChek test and in a laboratory. CardioChek results was significantly lower than lab results, for total cholesterol (-15.9 percent), high density lipid (-8.2 percent), and low density lipid (-25.9 percent). These deviated from the industry standards of +/- 5, 5, and 3 percent, respectively. Authors concluded that CardioChek was "substantially inaccurate and unsuitable" for use (Park, 2016).

A comparison of the Cholestech LDX Lipid Profile and CardioChek Lipid Panel was conducted using blood samples from 57 persons. Results showed that, compared to reference methods, samples from Cholestech were more accurate for low density lipids, while CardioChek was more accurate for high density lipids (Donato, 2015). An analysis from the prior year found CardioChek accuracy to be superior, and authors conclude home-based tests make widespread population screening for cholesterol levels feasible (Whitehead, 2014). Cholestech accuracy was found to be superior to CardioChek in measuring cholesterol (Dale, 2008; Shephard, 2007).

A three-year monitoring of the accuracy of Cardiochek compared to the reference standard generated in labs found that the underestimate of total cholesterol declined from 6.5 to 1.3 percent from Year 1 to Year 3 (Matteucci, 2014).

Engineers at Cornell University developed a smart phone application allowing for the quantification of blood cholesterol levels. They claim their system can accurately quantify total cholesterol within 60 seconds by imaging standard test strips, which optimizes reliability across different smart phones (Onescu, 2014).

Policy updates:

A total of one guideline/other and four peer-reviewed references were added to this policy in April, 2018.

Summary of clinical evidence:

Citation	Content, Methods, Recommendations
Bastianelli (2017) Comparison of two point of care cholesterol monitors	**Key points:** • 30 patients with blood analyzed by home cholesterol monitors CardioChek and Cholestech, and compared with standard lab devices (Integra analyzer and Roche Cobas analyzer). • Correlation coefficients +/- industry standards are 10% for total cholesterol, 12% for high-density lipoprotein/HDL, 15% for triglycerides. • Average differences CardioChek vs. Integra -7.8%, -6.2%, +5.1%. • Average differences Cholestech vs. Integra +0.5%, -4.5%, -3.3%. • Average differences CardioChek vs. Roche Cobas -4.2%, +0.8%, +7.0%. • Average differences Cholestech vs. Roche Cobas +4.6%, +2.6%, -1.6%.
Ferreira (2015) Correlation of point of care and lab cholesterol monitors	**Key points:** • Study of 516 patients age 20-85. • Correlation between CardioChek home monitor and Cobas standard lab analyzer. • Correlation was between 94.6% and 97.7% for total cholesterol, HDL, and triglycerides. • CardioChek is a reliable lipid testing system, can use anywhere in the home.
Donato (2015) Comparison of two point of care cholesterol monitors	**Key points:** • Study of 57 adults, point of care monitors compared to standard lab device. • Cholestech was more accurate for LDL. • CardioChek was more accurate for HDL.
Alkouli (2013) Comparing reduction in LDL (“bad” cholesterol levels) via home monitoring vs. usual method	**Key points:** • 33 patients, one group measuring LDL with a home device and following up with phone call, other group measuring LDL with usual method. • Six weeks after initiation of statin therapy, subjects checked at 6, 12, 24 weeks. • At 24 weeks, home group reduction in average LDL (186 to 117 mg/dL) was significant, as was usual group (162 to 105 mg/dL). • No significant differences between two group in LDL, HDL, triglyceride, liver function tests, and blood pressure. • Authors conclude that lipid home monitoring is feasible in measuring cholesterol changes, but not superior to usual method.

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Professional society guidelines/other:

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CMS National Coverage Determinations (NCDs):

Medicare law expanded coverage to cardiovascular screening services on January 1, 2005.

Local Coverage Determinations (LCDs):

No LCDs identified as of the writing of this policy.

Commonly submitted codes

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill in accordance with those manuals.

CPT Code	Description	Comment
N/A	No Applicable Codes	

ICD-10 Code	Description	Comment
E71.30	Disorder of fatty-acid metabolism, unspecified	
E75.21	Fabry (-Anderson) disease	
E75.22	Gaucher disease	
E75.240	Niemann-Pick disease type A	
E75.241	Niemann-Pick disease type B	
E75.242	Niemann-Pick disease type C	
E75.243	Niemann-Pick disease type D	
E75.248	Other Niemann-Pick disease	
E75.249	Niemann-Pick disease, unspecified	
E75.3	Sphingolipidosis, unspecified	
E75.6	Lipid storage disorder, unspecified	

ICD-10 Code	Description	Comment
E77.0	Defects in post-translational modification of lysosomal enzymes	
E77.1	Defects in glycoprotein degradation	
E77.8	Other disorders of glycoprotein metabolism	
E77.9	Disorder of glycoprotein metabolism, unspecified	
E78.0	Pure Hypercholesterolemia	
E78.1	Pure hyperglyceridemia	
E78.2	Mixed hyperlipidemia	
E78.3	Hyperchylomicronemia	
E78.4	Other hyperlipidemia	
E78.5	Hyperlipidemia, unspecified	
E78.6	Lipoprotein deficiency	
E78.70	Disorder of bile acid and cholesterol metabolism, unspecified	
E78.79	Other disorders of bile acid and cholesterol metabolism	
E78.81	Lipoid dermatoarthritis	
E78.89	Other lipoprotein metabolism disorders	
E78.9	Disorder of lipoprotein metabolism, unspecified	
E88.1	Lipodystrophy, not elsewhere classified	
E88.2	Lipomatosis, not elsewhere classified	
Z13.220	Encounter for screening for lipoid disorders	

HCPCS Level II Code	Description	Comment
N/A	No Applicable Codes	