

Food-based approach to lowering cholesterol provides significant healthcare cost savings

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Dr. Elizabeth Klodas, cardiologist and founder of Step One Foods, says that even though lipid-lowering drugs like statins are routinely subsidized by insurers, many people can't or don't want to take them, leaving a large number of people at a persistently increased risk of cardiovascular events. Credit: Step One Foods



A new study is the first to show a food-based approach using clinicallyproven diet interventions to lower cholesterol levels, such as Step One Foods, provides significant healthcare cost savings.

The study, publishing online in the journal *Current Cardiology Reports*, analyzed the healthcare <u>costs</u> associated with having elevated <u>low-density</u> <u>lipoprotein cholesterol</u> (LDL-C) levels among commercially insured people 50 years old and over and Medicare users. The analysis found those with high LDL-C levels with commercial insurance incurred a medical cost of \$242 per member per month (PMPM), or 44% higher than those with normal <u>cholesterol levels</u>, and a medical cost of \$449 per member per month, or 66% higher those with normal <u>cholesterol</u> levels, in the Medicare target population.

"Nearly 1 in 3 American adults has hyperlipidemia, including 2 of 3 persons over age 65. LDL-C is a major risk factor for <u>coronary heart</u> <u>disease</u> which ultimately leads to much higher healthcare costs," said Dr. Elizabeth Klodas, cardiologist, author of the study and founder of Step One Foods. "Even though lipid-lowering drugs like statins are routinely subsidized by insurers, many people can't or don't want to take them, leaving a large number of people at a persistently increased risk of cardiovascular events. That's why I created Step One Foods, which are designed for those who are intolerant to statins, are unwilling to take them, or have not achieved the desired results despite maximally tolerated statin doses."

Step One Foods is a twice per day dosed eating system with products precisely formulated to help lower LDL cholesterol. In a randomized controlled clinical trial, the foods were demonstrated to reduce LDL cholesterol by an average of 9% in 30 days, with some individuals experiencing nearly 40% LDL cholesterol reductions, without other dietary or lifestyle changes.



The actuarial study conducted by Wakely Consulting Group, identified the correlation between cholesterol issues and higher medical costs, and quantified the potential savings in medical costs for insurers if the high cholesterol population is more effectively managed. Potential savings were derived via the exploration of various scenarios for reductions in medication costs, lower heart attacks rates, hospital readmissions, and other material health care metrics.

The study also estimated the savings from mitigating the need for injectable cholesterol medications, called PCSK9 inhibitors that cost nearly \$6,000 per person per year. For the Medicare population, the study estimated a potential reduction in healthcare costs of \$297 PMPM for target plan members, if the clinical results expected from Step One Foods interventions are achieved. Reduction in costs could be as high as \$444 PMPM. After accounting for the cost of Step One Foods, which is \$130 per month, successfully lowering LDL-C for the affected population among the entire Medicare privately insured population of 24 million could lead to billions of medical savings annually.

While previous clinical studies have shown medication-driven reductions in LDL-C and major cardiovascular events and, therefore, healthcare costs, this is the first study to show a dietary intervention to lower LDL-C, when effective, may also lead to medical cost savings. Unlike pharmaceuticals, food products have not been typically designed to address a specific health condition, lack cost analysis data, and are not "dosed" making it difficult to separate any effect of a particular food from the effects of diet in general, and as a result, food has never enjoyed full or partial insurance coverage status. As a dosed eating system designed specifically to help assist in the management of hyperlipidemia, Step One Foods is uniquely positioned to have served as a model of this type of analysis.

"Failing to address the root cause of high cholesterol, which for most



people is their diet, makes no sense. This has created a scenario where heavily insurance subsidized pharmaceuticals are utilized as the only clinical option to treat a condition driven in whole or in part by the consumption of unsubsidized poor quality foods," said Klodas. "However, this study shows that managing hyperlipidemia at its source with Step One Foods can significantly lower healthcare costs and should therefore be eligible for insurance-based incentives—especially in patients who can't or won't take statin drugs or who are not at goal despite maximal tolerated doses."

"There exists a consistent and compelling correlation between diagnosed cholesterol issues, heart disease, and higher <u>medical costs</u>, which indicates significant cost savings potential if health insurance plan sponsors focus efforts on recognizing and better managing cholesterol issues as a potential key driver of health and cost," said Tim Murray of Wakely Consulting Group.

Provided by Step One Foods

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