Step One Foods

WHICH CHOLESTEROL LOWERING OPTION IS RIGHT FOR ME?

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TABLE OF CONTENTS

WHY WE CREATED THIS GUIDE

This guide was created to help you gain a better understanding of cholesterol, the medications that are used to manage it, how those medications work, their potential downsides, and the critical impact nutrition has on cholesterol levels. The guide also covers cholesterol lowering supplements.

We hope you find this information useful, and that you are inspired to take more control over your own health.

However, this guide is NOT intended to replace individual medical advice and we never advocate that you stop or reduce any medications before talking with your physician.

WHY CHOLESTEROL MATTERS

Cholesterol is a waxy, fat-like substance found in every cell wall of our bodies. We also use cholesterol to make hormones, bile acids, vitamin D, and other substances. So cholesterol is important to our bodies' structure and function.

However, if there is too much cholesterol circulating in the bloodstream, some of the excess can become trapped in artery walls. This build-up is called plaque. If enough of that accumulates, plaque can narrow vessels and make them less flexible, causing "hardening of the arteries".

Plaque accumulation can happen in blood vessels anywhere in the body, including the coronary arteries of the heart. If the coronary arteries become partially blocked by plaque, blood flow to the heart muscle can become reduced enough that people experience chest pain or unusual shortness of breath with activity. This is called angina.

Some cholesterol-rich plaques can also become unstable. Because they have a thin covering, they can burst, triggering the formation of a blood clot at the site of plaque rupture. If the blood clot is big enough, it can end up blocking blood flow through the artery—causing a heart attack.

Lowering cholesterol (especially LDL (bad) cholesterol) has been shown to reduce the risk of developing blockages and to stabilize plaque that is already there. There is even data showing REVERSAL of blockages with lifestyle change and lowering LDL to very low levels. No wonder there's so much effort expended on making sure everyone's LDL is under control.

In general, most cardiologists would say that an LDL below 130 mg/dL is acceptable for otherwise healthy individuals. As you accumulate risk factors for heart disease (such as high blood pressure, family history of heart disease, smoking, low HDL (good) cholesterol), aiming for an LDL below 100 mg/dL is preferable. If you already have heart disease or have diabetes, getting your LDL below 70 mg/dL is ideal. Achieving an LDL below 50 mg/dL appears to confer additional health benefits without causing harm.

As points of reference, in communities where heart disease is rare, LDL cholesterol among community members averages around 90 mg/dL. Some people are genetically blessed and spend their entire lives with LDL cholesterols below 30 mg/dL. These individuals never get heart disease and display no increased risk of other health conditions.

The bottom line, when it comes to LDL cholesterol, the lower the better.

WHAT CAUSES HIGH LDL?

There are three main reasons LDL is high:

1. We make too much of it:

We all have an enzyme in the liver, called **HMG-CoA reductase**, that tells the liver to make LDL. That enzyme can be stimulated by weight gain, inactivity, and/or high insulin levels (due to type 2 diabetes, prediabetes or eating highly processed foods). Therefore, losing weight, increasing physical activity and eating a less processed diet can reduce HMG-CoA reductase activity and help bring LDL levels down - by 10% on average.

We all have a unique genetic floor below which HMG-CoA reductase activity cannot be influenced by lifestyle any further. And this is where statins can help. Statins are HMG-CoA reductase inhibitors. But here's what's really important: statins will work much better - meaning you will need lower doses of the drugs to get to your LDL goal - if you increase exercise, lose weight (if you need to) and avoid highly processed foods. Statin side effects are dose-dependent, so needing less medication because you eliminated lifestyle drivers of HMG-CoA reductase, means a lower likelihood of developing those side effects.

2. **We don't eliminate enough of it:**

We also all have a natural elimination pathway for LDL which is related to **making bile and digesting food.** Bile is vital to breaking down food and is secreted into the digestive system every time we eat. Bile is also very cholesterol rich and is made using LDL. Picture an exit funnel directing LDL from the bloodstream to the liver where it gets turned into bile, dumped into the intestines every time we eat, used up during digestion and then eliminated through the colon.

Some of us are quite efficient and we re-absorb any bile not used up in the digestive process so it can be available for the next meal. That means the funnel bringing LDL to the liver to make bile for the next meal doesn't need to be as big and LDL can remain in the bloodstream (keeping levels high). This is the process that the original cholesterol lowering drugs leveraged. Called bile acid sequestrants, these medications bound bile in the digestive system so it couldn't be reabsorbed, keeping the LDL elimination funnel wide. These medications yielded significant cholesterol reductions. Unfortunately, they also required complex dosing schedules and were associated with a lot of digestive side effects, so they are not used much anymore.

However, we can still leverage this mechanism through what we eat. Consuming diets high in fiber and plant sterols, naturally present in whole, plant based foods can increase LDL elimination by helping trap bile in the digestive system (fiber), or competing with bile for re-absorption (plant sterols). On average, high fiber diets can reduce LDL levels by 5% while plant sterols can reduce LDL by as much as 10%.

WHAT CAUSES HIGH LDL?

3. We can't clear it from our bloodstream:

We use LDL to make all sorts of substances in our bodies. We make hormones with it, we create cell walls from it, we turn it into bile, etc. However, we can make most of the LDL we need to accomplish these tasks inside our cells. We don't actually need much LDL cholesterol circulating around. But if it's in the bloodstream already, why waste energy making it inside cells - just grab it and use it.

The grabbing part requires receptors that can bring LDL from outside the cell to inside the cell, and the activity of these receptors is determined by another enzyme, **PCSK9**. When PCSK9 levels are very high, like in Familial Hypercholesterolemia, LDL receptors are mostly inactive and LDL levels are sky high (190 mg/dL or higher). In individuals who have absent or defective PCSK9, LDL receptors are very active and LDL levels run in the 30s and below. PCSK9 is the target of the latest cholesterol lowering drugs, called PCSK9 inhibitors which will be covered later in this guide.

Saturated fats (as found in butter, cheese, meat and chicken, as well as coconut and palm oils) interfere with LDL receptor function and can result in high LDL levels. People who follow a ketogenic diet can see their LDL levels skyrocket as a result. Unsaturated fats (like olive oil, the oils in nuts and seeds, fish and avocados) help LDL receptors work better so LDL levels fall.

The critical role of nutrition:

You many have noticed that every biochemical pathway that leads to elevated LDL levels can be influenced by what we eat. This means diet is **critical** if we're interested in reducing cholesterol and keeping it under control. However, there's much more to this than just "eating better." To measurably lower LDL cholesterol with food, you really have to know what you're doing. This requires consuming fiber, plant sterols, complex carbohydrates and polyunsaturated fats **from the right sources and in the right amounts**. And, for most people, trying to do this on their own can get overwhelming.

This is where Step One Foods comes in. We make it easy to eat in a way that helps lower cholesterol without having to turn your life upside down. And this food-based solution has been rigorously tested by Mayo Clinic and University of Manitoba and found to be highly effective for lowering cholesterol in as little as 30 days.

But before we get to Step One Foods, let's first go over the various medications, how they work, who should use them, and what their potential side effects are. We will also cover all the options available to lower your cholesterol without (or in addition to) medications, so you have a full understanding of all your choices. After all, Step One Foods doesn't exist just to sell you our products. We are here to help you achieve your best health while minimizing the need for medications.

STATINS

Statins are a group of medications used to lower cholesterol. They are some of the most frequently prescribed drugs on the planet. The category includes Crestor® (rosuvastatin), Lipitor® (atorvastatin), Zocor® (simvastatin), Pravachol® (pravastatin), Mevacor® (lovastatin) Lescol® (fluvastatin), and Livalo® (pitavastatin). 94 million Americans have high cholesterol, and a great majority of them are candidates for statin drugs. So if you have high cholesterol and have been advised to take statins, you are not alone.

WHO SHOULD BE ON STATINS?

It's important to point out that there is almost universal agreement that **some people SHOULD take these medications**, because the data consistently demonstrates that their health outcomes (not just cholesterol numbers) improve. The 4 groups that have been shown to benefit from taking statin medications include:

- Those with **known coronary artery or vascular disease** (people who have a stent, have had a heart attack, stroke, or bypass surgery, and those with otherwise documented atherosclerosis)
- Those with **Familial Hypercholesterolemia** (LDL > 190 mg/dL)
- Those with **diabetes**
- Those with a **7.5% or greater risk of experiencing a heart or vascular event** over the next 10 years, as determined by a risk calculator

Note that individuals with known coronary or vascular disease should be on statins REGARDLESS OF THEIR CHOLESTEROL NUMBERS.

But for the other 3 groups, modifying lifestyle, and especially **diet**, can have a large impact on whether or not they need to remain on statin drugs. In fact, lifestyle modification can reverse diabetes, markedly impact your calculated risk, and even bring very high LDL levels below 190 mg/dL.

HOW STATINS WORK

Cholesterol is packaged and processed in the liver and statins inhibit a liver enzyme involved in LDL production, called HMG-CoA reductase. When HMG-CoA reductase is inhibited, cholesterol production in the liver slows down.

When cholesterol production in the liver falls, circulating levels of LDL (bad) cholesterol drop. In general, at maximum dose, **statins can lower LDL by 30-50%**.

STATIN SIDE EFFECTS

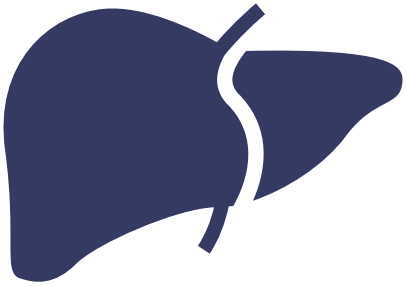
People who develop side effects after trying at least 2 different statins are referred to as "statin-intolerant". It is estimated that approximately 15-20% of people run into difficulties while taking these medications.

If you look around the internet, you will be overwhelmed by stories of horrible things happening because someone went on a statin. Remember – no one takes time to write how well they're doing on a drug. The information is therefore fundamentally slanted.

However, statin side effects are real and you need to be aware of what they are. Here's the rundown:

LIVER

Statins work in the liver, where they're only supposed to affect the HMG-CoA reductase system. But in some people, statins have a broader liver effect and that gets translated into elevated liver enzyme tests. This is not something you would feel – rather it is something that would show up in a blood test.



If they are to be affected, liver function tests (LFTs) tend to become abnormal early after starting a statin or after increasing the dose. Sometimes, they go up slightly as you start and then settle down over time. This is not the sort of situation where you are on a statin for years and then all of a sudden your liver starts to malfunction.

The liver effect is almost always reversible but is **more likely with higher statin doses**. The LFTs go right back down to baseline if you stop the statin medication.

It's important to point out that marked LFT abnormalities related to statin use are very uncommon. And if you do see a liver effect with one statin, it does not mean you will see it with a different statin preparation. Each statin preparation is unique in its chemical structure (which is why each of them had a patent at one point in time), so each can have its own unique biologic impact.

For monitoring purposes, **you should have a baseline LFT assessment before you go on statin medications** and then periodically once you're on them (especially after starting on the medication or going up on the dose). Long-term, LFT monitoring (for statin treatment alone) is not required if your LFT numbers have been stable.

MUSCLE

Muscle side effects are the most common reason people stop taking these medications. Although very few patients experienced muscle side effects during the clinical trials that led to the medications getting approved, in real-world practice, about 10 to 20% of patients taking the medications report achiness.

The achiness tends to affect large muscle groups and tends to be symmetrical. Patients most commonly complain of back pain or bilateral leg pain or shoulder/upper arm pain. A sore left index finger, for example, is unlikely to be caused by statins. The achiness may be felt more in the joints than in the muscles, but still tends to affect larger joints – and on both sides of the body.

The achiness can vary in severity from person to person. For some people it's very subtle – it just takes them longer to recover from strenuous exercise. For others, it's much more extreme and actually interferes with their ability to move without pain.

The reason why some people develop muscle side effects and others don't is not clear. Having a slight build, having a history of muscle achiness, having low thyroid function, and/or having a low vitamin D level all increase the likelihood that muscle side effects will occur. But even people without any of those risk factors can develop achiness.

Certain medication combinations can make achiness (and other statin side effects) more likely. Be sure to always ask your doctor or pharmacist if a new medication being prescribed has the potential to interact with your statin. Consuming grapefruit/grapefruit juice in large amounts can also increase the risk of statin toxicity.

One thing is clear – the higher the statin dose, the more likely the muscle achiness. So minimizing the dose you need helps reduce your chances of developing muscle side effects.

Finally, not all muscle achiness is due to statins. Sometimes it's difficult to know if you're sore because you just engaged in a new physical activity, because you have arthritis, or because you're on a new cholesterol-lowering medication. In some situations, this can be really challenging to sort out and require stopping and starting the statin several times.

MUSCLE CONT.

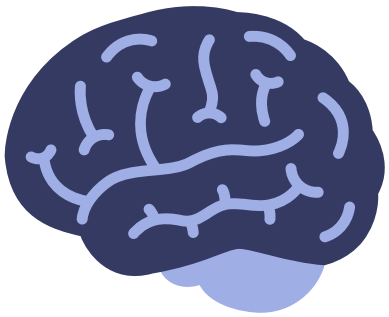
The good news is that achiness caused by statins tends to go away very quickly once the medication is stopped. People usually report marked improvement within days, and being back to their baseline within 2-4 weeks of stopping the drug.

Unlike liver side effects, muscle side effects do not necessarily appear right away. Instead, they tend to appear sometime during the first 6 months of starting the medication (or increasing the dose). But some people are on statins for well over a year before they notice this side effect. Nevertheless, if you do not get achy within the first 6 months of treatment, chances are high you will not experience this side effect going forward.

Just because you see this effect with one statin does not mean you will see it with a different statin preparation. But if you've experienced muscle achiness with 3 different statins, chances are high that you will experience achiness with the remaining preparations.

BRAIN

Neurologic side effects are rare but can occur and are also **dose dependent**. People tend to report fogginess, being "less sharp" or more forgetful. This again reverses with stopping or changing the medication.



However, when looking at long term statin use, on balance, published studies have shown that statins appear to be protective against dementia. This is probably because people on statins experience lower rates of strokes and mini-strokes.

DIABETES

The association between statin therapy and a higher risk of developing diabetes is something that has only recently been appreciated. The reason for this association is not fully understood, but it does not appear to be entirely explained by background lifestyle factors. In other words, there is something unique to statins alone that are driving higher rates of diabetes in statin users. **The risk of diabetes is higher with higher doses of statins used.**

It's important to point out that the chance of developing diabetes is not overwhelming, and the general consensus is that the cardiovascular benefits of statins far outweigh diabetes risk. However, if you are on these medications it behooves you to be sure you are attending to any other risk factors for developing diabetes - and that you are following a very strategic eating plan.

OTHER CONDITIONS

If you search the internet, you will find lots of other potential associations between statins and unwanted health effects including digestive problems, hair loss, cataracts, tendon rupture, kidney damage, myositis (dangerous inflammation of the muscles, different from the simple achiness described above), and even cancer.

All of these side effects are possible – because we are all completely individual. But it is important to point out that they appear to be very rare. That's not to say a ruptured tendon or cancer is minor. But the chance that anyone taking a statin will experience one of these side effects is truly small.

Nevertheless, your body on a statin is different from your body off of a statin.

For many people, being on a statin makes sense because the benefits far outweigh the risks. If you have known coronary artery disease, you are diabetic, or you have a very high LDL level (>190 mg/dL) that remains high despite your best lifestyle efforts, taking a statin makes sense.

For those without heart disease, diabetes, or genetically driven very high LDL levels, lowering cholesterol and reducing the risk of heart disease can often be accomplished without adding medications to the mix.

STATIN ALTERNATIVES

As many as 20% of people who have been prescribed statins cannot take them because they develop one or more side effects. 30-40% of people prescribed statins never fill the prescription in the first place. Clearly, there are a lot of people who are looking for something different to improve their cholesterol numbers. Here are some options.

STEP ONE FOODS

After all, this is why these products were created. We have combined real food ingredients -- all of which have been shown to lower cholesterol and improve cardiovascular health in their own right -- into a suite of convenient snacks. **Just eat them twice per day in exchange for something similar you're eating now. That's it**. You don't have to become a vegan or start training for marathons. This is meant to be a real-life solution for real people. Not only are these products effective, they are also unapologetically delicious.

Step One Foods are unique because, in those two servings, they supply scientifically validated levels of four critical nutrients needed to improve cholesterol profiles and cardiovascular health:

- **Whole Food Fiber** – enhances cholesterol elimination through the digestive tract and helps reduce insulin levels
- **Plant Sterols** – block biliary and food cholesterol absorption in the digestive tract.
- **Omega-3 fatty acids** – upregulate LDL receptor activity, reduce inflammation, help raise HDL and lower triglycerides
- **Antioxidants** – reduce LDL toxicity and plaque inflammation, helping prevent build-up of cholesterol in blood vessels and reducing risk of plaque rupture.

You might wonder if such a small dietary change - that tastes this good - could have much of an effect. After all, it's just 2 snacks per day. And the answer is YES! In a randomized controlled clinical trial (the highest level of scientific scrutiny), on average, Step One Foods lowered LDL cholesterol by 9% in just 30 days, with many individuals experiencing 20, 30, even close to 40% LDL reductions. The trial was performed at Mayo Clinic and University of Manitoba and the results have been peer reviewed and published.

Other than incorporating Step One Foods twice per day into their usual diets, subjects were instructed to change nothing else. And not only did 80% of participants see a positive response, 95% really enjoyed the foods and were able to stick with the twice per day use instructions.

A big benefit of Step One Foods is that you can objectively determine how well this approach is working for you by checking your cholesterol levels. All you need to do is eat Step One Foods twice per day for at least 30 days right up until the day of the blood test. It doesn't get easier than that!

Not everyone who changes their diet will see a dramatic change in their cholesterol – just like not everyone who reduces salt in their diet will see a dramatic drop in blood pressure. But profound changes are possible. And when you eat in a way that helps lower cholesterol, you are also eating in a way that helps lower blood pressure, improve blood sugar levels, and support a healthy weight. So you are impacting several risk factors for heart disease all at once.

Food is the comprehensive solution - not only to cholesterol lowering but to improving your health overall. No single drug can do all that.

EZETIMIBE

Ezetimibe, also known as Zetia®, is a medication that can be added to statins to boost their effects. So, strictly speaking, it's not really a statin substitute, but it does facilitate lower statin dosing – and this is important since statin side effects are more likely the higher the statin doses.

Zetia® affects the activity of intestinal cholesterol receptors directly and can be taken as a stand-alone prescription medication or can be part of a combination tablet, like Vytorin®, (ezetimibe with simvastatin).

This is where Step One Foods fits in again. Step One Foods also affect intestinal cholesterol absorption, helping to reduce the dose of statins needed to get to LDL goal. We know that real food has profoundly positive effects on health above and beyond cholesterol reduction. Combining strategic food intake with lower statin doses is, therefore, a better option than relying on combinations of medications.

PCSK9 INHIBITORS

This is a whole new category of cholesterol drugs approved by the FDA in the last few years. PCSK9 inhibitors (like **Praluent®** and **Repatha®**) are monoclonal antibodies that neutralize PCSK9.

PCSK9 is a protein that controls the number of cholesterol receptors in the liver. If PCSK9 levels are lowered, the number of liver cholesterol receptors increases, allowing more LDL to get removed from the bloodstream. In other words, if PCSK9 is destroyed by antibodies, LDL levels fall.

Praluent® and Repatha® need to be injected under the skin once to twice per month and are extremely effective in lowering LDL (by as much as 70%). They are also extremely expensive (around $6,000 per patient per year).

Although they appear to be relatively safe, these medications are new and we are still learning about all their possible side effects. So far, runny nose, sore throat, or flu-like symptoms appear to be most common. But muscle aches, diarrhea, and urinary tract infections are also being seen.

With more extensive use of these medications, we're learning that lowering LDL to very low levels does not appear to be associated with any untoward effects – at least in the near term.

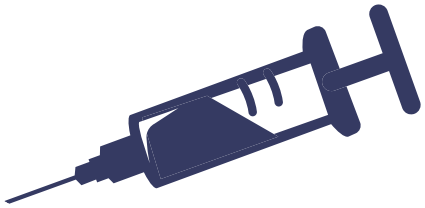
Given the cost, insurance companies have been very selective in granting approval for PCSK9 inhibitor use. Many patients find that even when "covered" the associated deductibles can still be prohibitively expensive.

INCLISIRAN

This drug was recently approved for treatment of high LDL and goes by the name **Leqvio®**. It also lowers PCSK9 levels but does this by affecting genes that control PSCK9 production – thus preventing PCSK9 from being made in the first place.

Inclisiran requires injection under the skin only twice per year – which is a significant advantage over PCSK9 inhibitors, especially for patients who don't like needles. A disadvantage is that it can only be administered by a healthcare provider, so it requires a visit to your doctor's office. So far it appears well tolerated and trials looking at long-term outcomes are under way.

Inclisiran costs close to $3,500 per dose, so it's also difficult to obtain insurance approval for use of this drug without first demonstrating that other approaches have failed to achieve desired cholesterol results.



BEMPEDOIC ACID

Bempedoic acid blocks an enzyme in the liver called adenosine-triphosphate citrate lyase (ACL), which is part of the same cholesterol production cascade as HMG-CoA reductase (the enzyme that is blocked by statin drugs). Fortunately, blocking ACL is not associated with the same side effects that can be experienced by people taking statins.

The drug, approved in early 2020 is sold under the name **Nexletol®**, and lowers LDL by 18%, on average. A combination drug, **Nexlizet®** (bempedoic acid with ezetimibe) is also available and has been shown to lower LDL by 38% when added to maximally tolerated statin doses. Both Nexletol® and Nexlizet® come in pill form and are taken once per day.

Reported side effects include liver function abnormalities, flu-like symptoms, elevations in uric acid levels (a significant concern for those with a history of gout), and tendon rupture. In fact, bempedoic acid preparations are probably not the best choice in people over age 60 as this is the group at the highest risk of tendon complications.

BILE ACID SEQUESTERANTS

These drugs were the first to be used to help lower cholesterol. They come in powder and pill formats and include formulations like cholestyramine (Questran®), colesevelam (Welchol®), and colestipol (Colestid®). They work by binding bile cholesterol in the intestinal tract, preventing its reabsorption, ultimately leading to lower circulating LDL levels. Because their action is dependent on bile being present in the digestive system, these medications are taken with food, typically multiple times per day.

Bile acid sequesterants have many potential side effects, which is why they are not used much in clinical practice. Digestive upset, constipation, liver function abnormalities, as well as weakness, chest pain and fatigue are just some of a long list. In addition, interference with absorption of various vitamins and drugs makes timing of dosing of these medications challenging.

Having said all that, these are generic medications, don't get absorbed, and can lower LDL by 15 to 30% at full dose. So for those who can tolerate them, don't take a lot of medications or vitamins that might cross-react, and don't have other options for lowering cholesterol, these medications can be a viable option.

NIACIN

Niacin, a B vitamin, when taken in high doses, lowers LDL cholesterol. But just because it is a vitamin (and "natural") does not mean it is without side effects when consumed in massive doses.

The recommended daily allowance for niacin (for optimal nutrition) is around 15-20 mg per day. The amount of niacin prescribed to meaningfully lower LDL cholesterol can be as high as 2000 mg per day.

When you take niacin at those doses, you can develop flushing, itching, digestive issues, liver enzyme abnormalities and muscle side effects. So you need to be monitored as closely as if you were on statin medications.

The form of niacin that is active for cholesterol lowering is nicotinic acid. Nicotinamide, another form of niacin, has no effect on cholesterol levels. Although niacin has been shown to not only lower LDL cholesterol but also raise HDL (good) cholesterol and lower triglycerides, the data on improved outcomes (including rates of heart attack and stroke) based on niacin use are less impressive. Nevertheless, this is a reasonable option for people who cannot tolerate statin medications and have exhausted all dietary options.

Note that niacin can worsen blood sugar control, which probably accounts for the less robust outcomes data. Diabetics should be especially careful when using niacin for cholesterol management.

RED YEAST RICE

Red yeast rice, an over-the-counter supplement has been shown to lower LDL cholesterol. The reason for this is that red yeast rice contains a compound structurally identical to lovastatin (one of the statin drugs). Because of this, be aware that red yeast rice can cause the same side effects as statins and if you take this supplement you should be monitored in the same way as if you were on a prescription cholesterol-lowering medication.

The main problem with red yeast rice (above and beyond the fact that it can have the same side effects as statins) is that the supplement industry is not well regulated. Which means the dose of the active ingredient can vary from bottle to bottle and from pill to pill. In addition, other substances can be present in the pill that are not listed or monitored, affecting safety and efficacy.

Food is monitored and regulated by the same agency as medications - the Food and Drug Administration. That means food ingredient lists and nutrition content must be truthful and transparent. Another good reason to try Step One Foods before scouring the supplement aisle.

FIBER AND PLANT STEROL SUPPLEMENTS

To see a cholesterol benefit, you need to add at least 10 grams of fiber and 2 grams of plant sterols to your diet, spread out throughout the day. You should take both fiber and plant sterol supplements WITH your meals so that you obtain the most benefit.

Fiber and plant sterol supplementation has been shown to help improve cholesterol levels. However, the data for improved heart outcomes is strongest when higher fiber intakes come from dietary transformation rather than from supplements. Step One Foods provides at least 10 grams of whole food fiber and 2 grams of plant sterols in just 2 servings per day and those nutrients come as part of a whole food package.

By the way, there is no evidence that taking CoQ 10, cayenne, or garlic supplements lowers LDL cholesterol.

BERGAMOT

Bergamot is a fragrant citrus fruit. The essence from its peel gives Earl Grey tea its distinct flavor.

Bergamot has also been shown to lower cholesterol in small clinical trials. The dose most frequently studied was 1000 mg per day.

Although bergamot is considered relatively safe, it shares some biochemical properties with grapefruit. This means people on statins should avoid using bergamot due to the potential for a toxic interaction.

ICOSAPENT ETHYL

Icosapent ethyl, marketed under the name **Vascepa®**, is a very pure pill form of EPA omega-3 fatty acid. It is designed to help lower serum triglyceride levels. It does not lower LDL per se, but one trial demonstrated lower heart event rates in patients at high risk of heart disease using these medications regardless of triglyceride level reductions. Although that trial has come under fire for how it was designed, this drug is now being prescribed more and more in patients with established heart disease, even if they're on statins and even if their LDL is well controlled.

Side effects of Vascepa® include muscle and joint pain, ankle swelling, constipation, gout, and heart rhythm abnormalities (specifically, atrial fibrillation). In addition, Vascepa® can increase the risk of bleeding, especially in patients who take blood thinners.

SUMMARY: WHICH OPTION IS BEST FOR ME?

Clearly there are many options for managing high LDL cholesterol. So which is the best option for you? Here is my perspective based on treating thousands of patients:

- **Regardless of whether you need medications, attending to nutrition and getting that part right is paramount in controlling cholesterol and minimizing the doses of cholesterol lowering medications needed to get you to goal.**
- Statins are well established first line cholesterol lowering medications. They have been around for decades, have a known long term track record and have been shown to improve outcomes, especially in people with known heart and vascular disease. They are also low cost and simple to use. And, should you develop them, their side effects are almost always reversible. If you need medications to lower cholesterol, statins are the drugs to try first.
- Some people cannot tolerate statins at all or can't achieve their cholesterol goal on the highest doses they can tolerate. Assuming dietary factors have already been addressed, ezetimibe in combination with statins or as a standalone medication is the reasonable next option.
- If food (+statin) + ezetimibe is still not enough, adding a PCSK9 inhibitor should come next. These are generally well tolerated medications that yield impressive LDL reductions. Be aware that insurance approval can take time.
- Bempedoic acid carries a price tag similar to that of PCSK9 inhibitors, yields less impressive LDL reductions and has a side effect profile which is not necessarily benign or reversible (tendon rupture). It should be considered as an add on or alternative after PCSK9 inhibitors.
- Bile acid sequestrants are difficult to use and interact with several medications. In those who are able to follow the more complex dosing schedules and have no contraindications, these generic drugs are a reasonable choice at any point in this treatment cascade, especially if drug costs are a major consideration.
- Although some supplements have been shown to affect cholesterol levels, unlike food and pharmaceuticals the supplement industry is poorly regulated, making this approach the option of last resort
- Icosapent ethyl has no role in managing high LDL levels.

Getting nutrition right, the foundation of cholesterol management, can seem daunting. But we've made it easy with Step One Foods. Our solution was created specifically to help you succeed at changing your diet in a way that maximizes your chances of lowering cholesterol naturally. All our foods contain the precise levels of nutrients your body needs to improve heart health and lower cholesterol. Simply incorporate 2 servings of Step One foods each day.

That's it!

LEARN HOW STEP ONE WORKS

SUMMARY: WHICH OPTION IS BEST FOR ME?

	LOWERS LDL	NO SIDE EFFECTS	CAN USE WITH STATINS	QUALITY STRICTLY REGULATED	DELIVERS OPTIMAL NUTRITION
STEP ONE FOODS	✓	✓	✓	✓	✓
STATINS	✓	✗	N/A	✓	✗
EZETIMIBE	✓	✗	✓	✓	✗
PCSK9 INHIBITORS	✓	✗	✓	✓	✗
INCLISIRAN	✓	✗	✓	✓	✗
BEMPEDOIC ACID	✓	✗	✓	✓	✗
BILE ACID SEQUESTERANTS	✓	✗	✓	✓	✗
NIACIN	✓	✗	✓	✗	✗
RED YEAST RICE	✓	✗	✗	✗	✗
FIBER & PLANT STEROL SUPPLEMENTS	✓	✓	✓	✗	✗
BERGAMONT	✓	✓	✗	✗	✗
ICOSAPENT ETHYL	✗	✗	✓	✓	✗

LEARN HOW STEP ONE WORKS

STEP ONE FOODS

Each non-pharmaceutical dose of Step One Foods targets the root cause of high cholesterol for proven reduction without major lifestyle changes.

The only ready-to-eat food clinically proven to actively block cholesterol absorption, choose Step One Foods twice each day for lower cholesterol in as little as 30 days.

HOW TO USE STEP ONE FOODS TO MINIMIZE STATIN DOSE

If you are thinking of using Step One Foods in the hopes of reducing your reliance on statin medications, here's what you should do:

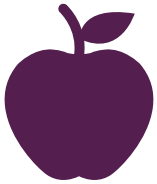
- **Confirm with your physician** that you are in a group of patients for whom it is reasonable to try to reduce your statin dose.
- Make sure you've already had a cholesterol check on your current medication dose, so that there is a baseline to compare to.
- Eat Step One Foods twice per day as a substitute for something you are eating already for at least 30 days. You will need 5 boxes of food for every 30 days of use. You can mix and match products as you like.
- While still using Step One Foods, have your cholesterol profile rechecked at least 30 days after starting the food program. Blood work should be obtained fasting.
- If your cholesterol is stable or improved, cut the statin dose in half and continue to eat Step One Foods twice per day for an additional 30-60 days and repeat instructions #4 and #5.
- Continue repeating instructions #4 and #5 until you have reached your lowest possible statin dose or you are off the medication altogether.

Even if you can't get off of your statin altogether – or even if you don't see much of a cholesterol improvement with the foods – you will still be making a positive impact on your health with Step One.

Remember, heart disease is caused by more than just high cholesterol. Eating better means you are helping to lower blood pressure, lose weight, improve blood sugar control and reduce inflammation inside your body.

And all of that adds up to better health regardless of the cholesterol response.

READ STEP ONE SUCCESS STORIES



ABOUT THE AUTHOR, DR. KLODAS

Dr. Klodas is a cardiologist and founder of Step One Foods. She trained at Mayo Clinic and Johns Hopkins, and practices in Minneapolis, Minnesota. She is also author of the American College of Cardiology's, "Slay the Giant: The Power of Prevention in Defeating Heart Disease," a comprehensive educational guide on heart disease prevention designed for patients.

Dr. Klodas has dedicated her career to helping people prevent and reverse heart disease without relying solely on medications.

Step One Foods was founded based upon Dr. Klodas' work that demonstrated most cholesterol abnormalities can be markedly improved through dietary change. Step One's foods were formulated scientifically to deliver the precise levels of nutrients needed to improve heart health and lower LDL (bad) cholesterol. Backed by a rigorous randomized controlled clinical trial, Step One Foods have been shown to yield highly significant cholesterol reductions in as little as 30 days, with many individuals experiencing medication-level results.

Dr. Klodas writes a weekly blog on the Step One Foods website to help educate and empower people to be their own best health advocates.

SEE IF YOU'RE A FOOD RESPONDER WITH OUR 30 DAY STARTER PACK

FREQUENTLY ASKED QUESTIONS ABOUT STEP ONE FOODS:

How does the program work?
Our array of snacks and meals are designed to fit easily into your everyday life. Just eat two servings a day of your favorite Step One Foods products as a substitute for something you're eating now. You can choose whichever products you like as they are interchangeable in terms of nutrients of interest. That's it. No additional dietary changes or daily workouts are required (although we won't stop you if you also decide to add a little exercise and a few more fruits and vegetables!).

How do the products taste?
Unapologetically delicious. We want to help you change your health through food that you love to eat. So we make Step One Foods products with premium whole-food ingredients - like the highest quality Belgian chocolate, and the finest walnuts, almonds and pecans. Because food made with great ingredients tastes.....well....great!

How much do the foods cost?
Two servings per day will cost somewhere between $4 and $4.50 in total, depending on product mix. However the net cost is much lower because these are substitutes for something you are eating already. Our program is extremely economical - if you were going to try and obtain the key nutrients in Step One Foods through supplements, you would spend $4 per day or more... before taking even one bite of food.

Can I eat these products if I don't have high cholesterol?
Step One Foods products are made with all-natural ingredients that are known to posess multiple health-promoting properties. These foods would be considered appropriate for anyone trying to improve their heart health in general or their overall well-being.

Where can I buy these products?
Step One Foods products are a premium brand of foods formulated specifically to support cardiovascular disease care and prevention. As such, they are not typical of foods available in regular grocery stores. You can find them online at steponefoods.com.

Are these products gluten free? GMO free? Are there any allergens?
Step One Foods products are made exclusively with certified gluten free and non-GMO ingredients. All Step One Foods products contain tree nuts. The Pancake Mix contains egg whites. The Chocolate Peanut Butter Bar contains peanuts.

Should I stop my statin when I use Step One Foods products?
No. If you have been prescribed a statin by your physician, you should not discontinue it unless you consult with them. To most accurately assess how Step One Foods is impacting your cholesterol, you should take your statin in conjunction with Step One Foods twice per day. After at least 30 days of consistent use, you can test your cholesterol levels; if there is improvement (or even similar readings) you and your healthcare provider can discuss adjusting your prescription.

QUESTIONS?

We're here to help!

help@steponefoods.com

(952) 303-4265