

SPEAKER: Well, there has been a confluence of events. We have a new set of guidelines which, these are no longer just a pathway, consensus pathway. These are actual guidelines that says, particularly to the lipidology cardiology community, those high-risk patients who keep coming back. They're having multiple events.

They've got ASCVD, and they've got multiple risk factors. Those are individuals who should be on a high-intensity statin or on a maximum tolerated statin. And we know, in real life, unfortunately, that may not be a very high dose, but you've tried everything you can. If they have an LDL over 70, we have a recommendation now to add non-statin therapy, and there's considerations-- ezetimibe and PCSK9 inhibitors.

Now some things have also changed the equation here. We've had, finally, the publication of ODYSSEY Outcomes, a second trial, longer duration, high risk population. And some very interesting data in regards to some of the individuals who are at the highest risk, high LDLs, favorable impact in terms of mortality.

Then, we have an announcement of, basically, pricing, putting it into a range that's going to be in this-- we've seen that if you get down to around \$6,000, that, in fact, these therapies, in high-risk individuals, are in the cost-effective approach. And there's also been some improvement in regards to access. And I think this is an important thing. If you have the correct information, particularly for these patients-- there's not-- and that's actually true even for FH. As long as you use these criteria and you put in your note, patient has heterozygous familial hypercholesterolemia, there's an ICD-10 code for that. You can make a diagnosis by just family history and an LDL over 190. That's usually going through without problems.

And in the patient where you've got clinical ASCVD, now you need to say not just CBD disease. You need to say, EMI, cabbage, put down what the clinical event was. You need to have a recent LDL level. They're on maximum targeted statin. There are a few key words. What we're saying is, it's much easier in terms of getting these through. So I think we're going to see some real changes in terms of people being more aggressive.

I've been involved with multiple registries, with my colleague, [INAUDIBLE], looked at the pinnacle registry. And I'll tell you the data in regards to-- these are good cardiology practice, people having LDLs over 190. And the amount of non-statin usage is minimal. And we're involved with something called the GOULD registry.

So it's really shocking. And it's something that's-- we're just starting to improve, but it hasn't yet. But there's lots of people who really, on maximum tolerated statins are poorly controlled. And it's really time that we do something about that. This is a disease that's treatable, preventable in terms of making a big impact. And I think, with this confluence of events, hopefully, we'll see up a lot better progress in this area.