



Statin Use in Persons with Diabetes (SUPD)

The Centers for Medicare & Medicaid Services (CMS) Drug Safety and Accuracy of Drug Pricing Measure

To lower their risk of developing heart disease, most people with diabetes should take cholesterol medication.¹ The American Diabetes Association recommends the following statin intensities for patients ages 40 and older who have been diagnosed with diabetes.^{2*}

Presence of atherosclerotic cardiovascular disease	Recommended statin intensity
No	Moderate-intensity statin [^]
Yes	High-intensity statin
ASCVD with LDL \geq 70 mg/dL despite maximally tolerated statin dose	Maximally tolerated statin dose plus ezetimibe or PCSK9 inhibitor

*Lifestyle modifications should be incorporated into all treatments.

[^]High-intensity statin may be considered based on risk-benefit profile and presence of ASCVD risk factors, such as LDL cholesterol \geq 100 mg/dL, high blood pressure, smoking, chronic kidney disease, albuminuria and family history of premature ASCVD.

Measure definition

Patients ages 40 to 75 in the measurement year who were dispensed at least two diabetes medication fills and who received a statin medication fill in the current measurement year.¹

Exclusions from the measure

Patients are excluded if they:

- Are diagnosed with end stage renal disease.
- Are a patient in hospice any time in the measurement year.

Information patient medical records should include

The statin prescribed and the date it was prescribed.

Moderate-intensity and high-intensity statins
Amlodipine-atorvastatin
Atorvastatin
Ezetimibe-atorvastatin
Fluvastatin
Fluvastatin XL
Lovastatin
Pitavastatin
Pravastatin
Rosuvastatin

Tips to overcome barriers

There are many reasons why statins are not being prescribed. Here are some solutions:

Barrier	Solution
Patient has Type 1 diabetes	The American Diabetes Association and the American College of Cardiology/American Heart Association guidelines recommend statin therapy for primary prevention of ASCVD events for both Type 1 and Type 2 diabetes. ^{2,3}
Patient's LDL is within normal range	Statin should be considered in all patients diagnosed with diabetes ages 40 and older regardless of LDL levels, according to current ADA guidelines. ² LDL levels should still be monitored, since an elevated LDL is a risk factor for CVD and monitoring can help assess patient adherence to treatment.
Myalgia	Myalgias are common and may not be medication related. Try a brief period of discontinuation. Consider a re-challenge with a reduced dose of the same or a different statin if myalgia resolves. ³ Try a different statin that is more hydrophilic, such as pravastatin, rosuvastatin or fluvastatin. ^{4,5} These statins may be less likely to cause myalgia. Try lower or less frequent dosing. Evidence supports the use of a very low dose or less than daily regimen, such as simvastatin every other day or rosuvastatin once weekly. ^{6,7,8,9} Consider the maximally tolerated statin dose for patients with ASCVD. ²
ACC/AHA ASCVD risk calculator estimates a <7.5% 10-year atherosclerotic ASCVD risk	This tool has limited use in patients with diabetes since diabetes itself confers an increased risk for ASCVD and all diabetics over the age of 40 should be taking a statin. ²
Drug interaction with concomitant medication	Simvastatin, lovastatin and atorvastatin are susceptible to the most drug interactions. ¹⁰ If initiating a medication that interacts, consider switching to a different statin with less potential for drug interactions, such as rosuvastatin, pravastatin or fluvastatin. ¹⁰

Barrier	Solution
Patient believes that red yeast rice is superior to statins	Red yeast rice may contain a chemical identical to the active ingredient in lovastatin, but, as a supplement, it can only contain trace amounts. ¹¹ Furthermore, the FDA has issued warnings against taking this supplement due to the lack of standardized preparation and efficacy or safety data. ^{11,12,13}
Elevated liver enzymes	Elevated liver enzymes in diabetes are often due to non-alcoholic fatty liver, which may improve with better glycemic control. It is reasonable to re-initiate the same statin at a lower dose or try a different statin once liver function returns to normal. ¹⁴ This can be safely done with routine liver function test monitoring.
Patient is at high risk for myopathy	Risk factors include: female gender, advanced age, low body mass index, hepatic dysfunction, kidney dysfunction, human immunodeficiency virus, pre-existing myopathy, Asian ancestry, excess alcohol intake, high levels of physical activity, trauma and drug interactions. ^{15,16,17} To minimize the risk of myopathy, a lower dose of a hydrophilic statin (e.g., pravastatin, rosuvastatin, fluvastatin) may be considered in patients with multiple risk factors. ¹⁷
Statins increase HgbA1c	Increased HgbA1c and fasting serum glucose have been reported with statin use. ^{18,19,20} This risk is considered minimal compared to the cardiovascular benefits seen with statin therapy. ² The ADA recommends performing the HgbA1c test at least two times per year in patients who are meeting their treatment goals and have stable glycemic control, and performed quarterly in patients whose therapy has changed or who are not meeting glycemic goals. ¹
Statins cause dementia	There is no definitive data to support the claim that statins cause dementia. Conversely, statin use may even be associated with a reduction in incidence of dementia. ^{21,22,23} There have been some rare post-marketing reports of cognitive impairment associated with statin use. These events weren't serious and reversed upon statin discontinuation. ²⁴ The evidence associating statins with cognitive impairment is not well-established and health care providers should note if a patient is taking another medication that can cause cognitive impairment, such as over-the-counter antihistamines, sedative-hypnotics, antipsychotics and pain medications. ²⁵

Sources**:

1. Medicare 2019 Part C & D Star Ratings Technical Notes (Centers for Medicare & Medicaid Services), 82-84
2. American Diabetes Association. Standards of Medical Care in Diabetes 2018. *Diabetes Care*. 2018; 40 Suppl 86-104
3. Stone NJ, Robinson JG, Lichtenstein AH, 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. *Circulation* 2014; 129 (25 Suppl 2): S1-45. doi: 10.1016/j.jacc.2013.11.002.
4. Bitzur R, Cohen H, Kamari Y, et al. Intolerance to Statins: Mechanisms and Management. *Diabetes Care*. 2013; 36(Supplement 2): S325- S330. doi: 10.2337/dcS13-2038.
5. McTaggart F, Buckett L, Davidson R, et al. Preclinical and clinical pharmacology of rosuvastatin, a new 3-hydroxy- 3-methylglutaryl coenzyme A reductase inhibitor. *Am J Cardiol*. 2001; 87(suppl): 28B-32B. doi: 10.1016/S0002-9149(01)01454-0
6. Backes JM, Venero CV, Gibson CA, et al. Effectiveness and tolerability of every-other-day rosuvastatin dosing in patients with prior statin intolerance. *Ann Pharmacother*. 2008; 42(3): 341. doi: 10.1345/aph.1K604.
7. Meek C, Wierzbicki AS, Jewkes C, et al. Daily and intermittent rosuvastatin 5 mg therapy in statin intolerant patients: an observational study. *Curr Med Res Opin*. 2012; 28: 371-378. doi: 10.1185/03007995.2012.657302.

8. Ruisinger JF - Once-a-week rosuvastatin (2.5 to 20 mg) in patients with a previous statin intolerance. *Am J Cardiol.* 2009; 103: 393-4. doi: 10.1016/j.amjcard.2008.09.095.
9. Degreef LE, Opdam FL, Teepe-Twiss IM, et al. The tolerability and efficacy of low-dose simvastatin in statin-intolerant patients. *Eur J Intern Med.* 2010; 21(4): 293-6. doi: 10.1016/j.ejim.2010.03.015.
10. Zhelyazkova-Savova M, Gancheva S, Sirakova V. Potential statin-drug interactions: prevalence and clinical significance. *SpringerPlus.* 2014; 3:168. doi: 10.1186/2193-1801-3-168.
11. Klimek M, Wang S, Ogunkanmi A. Safety and efficacy of red yeast rice (*Monascus purpureus*) as an alternative therapy for hyperlipidemia. *P&T: A Peer-Reviewed Journal for Formulary Management.* 2009; 34(6): 313–327.
12. Dujovne CA. Red Yeast Rice Preparations: Are They Suitable Substitutions for Statins? *Am J Med.* 2017 Jun 7. pii: S0002-9343(17)30591-0. doi: 10.1016/j.amjmed.2017.05.013.
13. Gordon RY, Cooperman T, Obermeyer W, et al. Marked variability of monacolin levels in commercial red yeast rice products: buyer beware! *Archives of Internal Medicine.* 2010; 170(19): 1722–1727.
14. Calderon RM, Cubeddu LX, Goldberg RB, Schiff ER. Statins in the Treatment of Dyslipidemia in the Presence of Elevated Liver Aminotransferase Levels: A Therapeutic Dilemma. *Mayo Clinic Proceedings.* 2010; 85(4): 349-356. doi:10.4065/mcp.2009.0365
15. Feng Q, Wilke RA, Baye TM. Individualized risk for statin-induced myopathy: Current knowledge, emerging challenges, and potential solutions. *Pharmacogenomics.* 2012; 13(5): 579-594. doi:10.2217/pgs.12.11.
16. Mancini GB, Tashakkor AY, Baker S, Bergeron J, Fitchett D, Frohlich J, Genest J, Gupta M, Hegele RA, Ng DS, Pearson GJ, Pope J. Diagnosis, prevention, and management of statin adverse effects and intolerance: Canadian Working Group Consensus update. *Can J Cardiol.* 2013 Dec; 29(12): 1553-68. Epub 2013 Sep 29.
17. Husband A. Managing statin-induced myopathy. *Clinical Pharmacist.* <http://www.pharmaceutical-journal.com/learning/learning-article/managing-statin-induced-myopathy/10970792.article>. Published July 14, 2009. Accessed August 29, 2017.
18. Rajpathak SN, Kumbhani DJ, Crandall J, Barzilai N, Alderman M, Ridker PM. Statin therapy and risk of developing type 2 diabetes: a meta- analysis. *Diabetes Care.* 2009; 32: 1924–1929
19. Sattar N, Preiss D, Murray HM, et al. Statins and risk of incident diabetes: a collaborative meta-analysis of randomised statin trials. *Lancet.* 2010; 375: 735–742
20. Ridker PM, Pradhan A, MacFadyen JG, Libby P, Glynn RJ. Cardiovascular Benefits and Diabetes Risks of Statin Therapy in Primary Prevention. *Lancet.* 2012; 380(9841): 565-571. doi:10.1016/S0140-6736(12)61190-8.
21. Cramer C, Haan M N, Galea S, et al. Use of statins and incidence of dementia and cognitive impairment without dementia in a cohort study. *Neurology.* 2008 Jul 29; 71(5): 344–350. doi: 10.1212/01.wnl.0000319647.15752.7b.
22. Jick H, Zomberg G L, Jick S S, et al. Statins and the risk of dementia. *Lancet.* 2000 Nov 11; 365: 1627-1631.
23. Wanamaker, B. L., Swiger, K. J., Blumenthal, R. S. and Martin, S. S. (2015), Cholesterol, Statins, and Dementia: What the Cardiologist Should Know. *Clin Cardiol*, 38: 243–250. doi:10.1002/clc.22361.
24. Lipitor (atorvastatin) package insert. NY, NY. *Pfizer Inc*; 2017 Jul.
25. Rojas-Fernandez C, Goldstein L, Levey A, et al. An assessment by the Statin Cognitive Safety Task Force: 2014 update. *Journal of Clinical Lipidology.* 2014; 8, S5–S16. doi:10.1016/j.jacl.2014.02.013.

**Blue Cross Blue Shield of Michigan and Blue Care Network don't own or control this website.