# ASHP Statement on Pharmacist Prescribing of Statins

**Position**

The American Society of Health-System Pharmacists (ASHP) believes that existing models for over-the-counter (OTC) dispensing do not provide the safeguards required to ensure the safe and effective use of 3-hydroxy-3-methylglutaryl coenzyme A (HMG-CoA) reductase inhibitors ("statins") as part of a multimodal approach to preventing atherosclerotic cardiovascular disease (ASCVD). ASHP supports the goal of more widespread use of ASCVD-preventive therapies, including statin therapy, and encourages consideration of pharmacist prescribing models for statins that would advance ASCVD prevention.

ASHP launched the Practice Advancement Initiative (PAI) in 2015 with the objective of significantly advancing the health and well-being of patients in hospitals and health systems by developing and disseminating optimal pharmacy practice models that are based on the effective use of pharmacists as direct patient care providers.[1] In 2020, ASHP updated the initial PAI recommendations with the ASHP PAI 2030 recommendations.[2] These recommendations included 59 recommendations focused on patient-centered care; pharmacists' and pharmacy technicians' roles, education, and training; technology and data science; and leadership in medication use and safety. Recommendation B2 states that pharmacists should leverage and expand their scopes of practice, including prescribing, to optimize patient care. ASHP believes statins are an ideal candidate for dispensing under pharmacist prescribing models.

**Background**

ASHP supports the use of statins to lower cholesterol and reduce morbidity and mortality in patients at risk for cardiovascular events. Elevated cholesterol, specifically low-density lipoprotein cholesterol (LDL-C), is an important risk factor for the development of ASCVD. ASHP has recommended that evaluation and management of lipid disorders be guided by the recommendations of the American Heart Association/American College of Cardiology (AHA/ACC) guidelines on the management of blood cholesterol.[3] Statins are considered the drug of choice for most patients with dyslipidemia who require lipid-lowering therapy for both

primary and secondary prevention of ASCVD. Statins are effective in lowering elevated LDL-C, and studies have demonstrated that statins reduce the risk of ASCVD events in patients without known ASCVD (primary prevention). In addition, statins have been shown to reduce ASCVD events and mortality in patients with ASCVD (secondary prevention). Cardiovascular disease is the leading cause of death for both men and women in the United States, and ASCVD is responsible for nearly 80% of all deaths from cardiovascular disease.[4] Individuals with multiple cardiovascular risk factors and a low LDL-C derive an absolute benefit in reducing risk of ASCVD for a given milligram-per-deciliter lowering of LDL-C. In patients being treated for primary prevention with intermediate risk (7.7-19.9% 10 year predicted risk) of an ASCVD event, the percent LDL-C lowering is targeted at 30-49% and ≥50% for high-risk patients (≥20% 10-year predicted risk).[5] Further, for secondary prevention in patients with established ASCVD, the percent LDL-C lowering is targeted at ≥50% along with an LDL-C threshold of <70 mg/dL to consider adding nonstatin therapy to maximally tolerated statin therapy.

The effectiveness of statins in reducing LDL-C has prompted calls for more widespread use, including suggestions for a reclassification of statins as an OTC medication. Although ASHP does not support reclassification to OTC status as that status is currently constructed, ASHP does support alternative approaches that expand pharmacists' scopes of practice, including prescribing of statins, to optimize patient care to reduce risk of ASCVD.

**Current OTC Model**

To approve a reclassification to OTC status, Food and Drug Administration reviewers must find that (1) a drug is safe and effective in its proposed use(s), (2) the benefits of the drug outweigh its risks, and (3) consumers will be able to use the drug's labeling (e.g., its package insert) to safely use the medication in an OTC setting.[6] Because statins do not meet the third criterion of this test, they are not suitable for OTC status as that class is currently regulated.

ASHP believes that any statin dispensing model should be based on AHA/ACC guidelines for primary and secondary prevention of ASCVD.[3] These guidelines provide both disease-specific and risk-factor-based prescribing criteria to achieve safe and effective use. ASHP

believes that *before* a patient begins statin therapy, a cardiac risk assessment should be performed by a competent healthcare professional in order to

- Determine the patient's LDL-C value, which can be used as a baseline value if the patient is a candidate for treatment.
- Assess the individual for other cardiovascular risk factors such as smoking, diabetes, hypertension, diet, weight, amount of exercise, and family history of cardiovascular disease.
- Assess patient with the 10-year ASCVD risk score if a primary prevention patient.

ASHP believes that *after* a patient begins statin therapy, there should be an assessment with the patient to evaluate for both safety and effectiveness of the statin therapy in order to

- Determine the patient's LDL-C lowering seen with the statin therapy at 4-12 weeks post-initiation to evaluate if the patient achieved the desired response.
- Assess the individual for any potential adverse effects from the statin therapy (e.g., statin-associated muscle symptoms, hyperglycemia) and develop a plan for further monitoring and management if an ADE occurs.
- Counsel the patient on the importance of medication adherence with statin therapy to achieve the goal of lower ASCVD risk.

One of the studies that has examined the use of statins in a simulated OTC setting, the CUSTOM study,[7] was an open-label study designed to observe consumers' initial and continued use of a statin to lower LDL-C. Although the results may indicate that some individuals in the study sample were able to use an OTC statin as directed, the study was, by the investigators' own admission, not designed to evaluate clinical outcomes and therefore not able to demonstrate efficacy. The study certainly did not prove that the existing OTC model would provide the level of counseling required to reduce cardiovascular risk factors other than LDL-C levels.

A more recent study by Nissen et al.[8] evaluated whether a technology-assisted, self-selection process for nonprescription statin therapy had concordance with a clinician assessment for statin eligibility. In this study of 500 patients, 96.2% concordance was seen between the patient and clinician selection as either "OK to use," "not right for you," or "ask a doctor." Further, 91.6% of the 96.2% concordance was for the "not right for you" or "ask a

doctor" category, indicating that this tool may help determine when a patient is statin ineligible. However encouraging those results might seem, caution should be exercised in extrapolating such information to a larger population, especially information regarding safety. An accompanying article pointed out several shortcomings of the study:

- the study population was self-selected and may differ from the general population;
- the study cohort was relatively young, and few participants had actual indications for primary prevention statin therapy;
- the study tool did not consider the complex algorithms required for evaluation of different statin doses or nonstatin lipid therapies;
- the study could not assess the impact of the tool on actual patient initiation of or adherence to statin therapy, the latter of which has proven especially problematic.[9]

The adverse effects of drugs should always be assessed, especially if the drugs that cause them are easily available to the public. A system that relies on the voluntary reporting of such adverse effects by patients may be inadequate to protect the public or detect subtle signals. It is imperative that the decision to reclassify a statin to nonprescription status include a wide margin of safety. After statin therapy starts, ongoing evaluations should assess the patient's response, reassess risk factors, and monitor for and report adverse drug events. The existing model for OTC medications would place the entire burden for performing this evaluation and reassessment on the patient. Most patients are likely to be unfamiliar with the system used to report an adverse drug event (ADE), if the ADE is even recognized. Although ADEs from prescription statins are rare, particularly at lower doses, they can occur months or years after therapy is initiated. Since OTC status would encourage wider use of statins, these drugs might be used by individuals with multiple disease states or those taking potentially interacting medications (e.g., cyclosporine, diltiazem, verapamil, macrolide antibiotics, azole antifungals, or protease inhibitors). Because statins are a chronic therapy, new risks may be introduced as the patient's health varies, requiring vigilance on the part of the patient as well as healthcare providers.

ASHP concludes, for these reasons, that reclassification of statins to OTC status as currently constructed is not advisable but advocates that alternative models for dispensing these valuable drugs be explored.

**Pharmacist prescribing models**

ASHP supports the role of pharmacists in developing collaborative practice agreements (CPAs) with licensed providers to optimize care for care for patients. A CPA has been defined as "...a formal agreement in which a licensed provider makes a diagnosis, supervises patient care, and refers patients to a pharmacist under a protocol that allows the pharmacist to perform specific patient care functions."[10] Collaborative drug therapy management (CDTM) with physicians and other healthcare providers via CPAs allows qualified pharmacists with an advanced scope of practice to initiate, adjust, and discontinue medications; order and monitor laboratory studies; and perform limited physical assessments for various conditions (e.g. diabetes, hypertension, hyperlipidemia).[11] The privileges of pharmacists vary by state, practice site, and payer. For example, in some states they are recognized as an Advanced Practice Pharmacist (APP), a Clinical Pharmacist Practitioner (CPP), or a Pharmacist Clinician (PhC).

A number of pharmacist-led programs to increase statin prescribing both for the primary and secondary prevention of ASCVD have demonstrated significant improvements in statin use across different clinical settings through use of CPAs, CDTM, or statewide protocols.[12-13] One study that evaluated the impact of a pharmacist population health initiative across 10 primary care clinics in Washington demonstrated that a protocolized prescribing authority initiative resulted in a 50% increase in initiation of statin therapy for secondary prevention of ASCVD.[14] This literature not only shows the impact that pharmacists with statin prescribing authority through CPAs, CDTM, and statewide protocols can have, but also highlights the need to expand these prescribing models to reduce patients' CV risk through primary and secondary prevention of ASCVD.

**Pharmacogenomics of statin therapy**

Muscle toxicities are among the most common side effects of statins. Statins' effects on muscles range from mild myalgias to life-threatening rhabdomyolysis. Statins exert their effect in the liver by active transport of the drug into hepatocytes by *SLCO1B1* (also known as *OATP*). People who have poor *SLCO1B1* function are at increased risk for the development of myopathies to life-threatening rhabdomyolysis. Atorvastatin, fluvastatin, lovastatin, pitavastatin, pravastatin, rosuvastatin, and simvastatin have the most evidence for alterations in pharmacotherapy based on *SLCO1B1* genotype. The Clinical Pharmacogenomics Implementation Consortium guideline for statins discusses the risk of statin-associated musculoskeletal symptoms in patients who have been genotyped for *SLCO1B1, CYP2C9*, or *ABCG2*.[15] Knowledge of a person's *SLCO1B1* genotype test result prior to initiation of statin therapy can help in initial agent and dosage selection. Identification of a clinical laboratory performing *SLCO1B1* genotyping can be done by reviewing the National Center for Biotechnology Information genetic testing registry resource.[16]

**Conclusion**

ASHP supports pharmacist prescribing models for statins that ensure their safe and effective use as part of a multimodal approach to ASCVD prevention. Given the complexities of therapies to prevent ASCVD, ASHP encourages consideration of pharmacist statin prescribing models rather than any OTC distribution for statins.

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**Additional Information**

Approved by the ASHP Board of Directors on March 23, 2022, and by the ASHP House of Delegates on May 19, 2022. Developed through the ASHP Council on Therapeutics. Supersedes the ASHP statement on the over-the-counter availability of statins dated June 14, 2005.

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**Disclosures**
The authors have declared no potential conflicts of interest.