Drug Utilization Review (DUR) Newsletter

COLORADO
Department of Health Care Policy & Financing

Select HCPF Medication Use Policy Updates

SUMMER 2024

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The Basics of Secondary Prevention of Atherosclerotic Cardiovascular Disease

DON'T FORGET THE STATIN!

Robert L Page II, PharmD, MSPH

The Problem

Millions of adults in the United States are affected by cardiovascular events each year, reducing their quality of life and increasing their risk for death.[1] Hyperlipidemia is a significant risk factor for the development of atherosclerotic cardiovascular disease (ASCVD), which is present in 47% of young adults with ASCVD.[1,2] Lipid-lowering therapy remains a cornerstone of secondary ASCVD prevention, but many patients remain untreated. Data from the Cholesterol Treatment Trialists' Collaboration show that for every 38.7 mg/dL (1 mmol/L) reduction in low-density lipoprotein cholesterol (LDL-C) on statin therapy, adults with ASCVD experience a 21% reduction in the risk of major vascular events (first nonfatal myocardial infarction [MI], coronary death, stroke, or coronary revascularization procedure).[3]

Despite 40 years of robust, randomized evidence demonstrating their safety, efficacy, and reduced risk of major atherosclerotic cardiovascular events (MACE), many patients with ASCVD are not prescribed a statin, and among those who are, many are not using the guideline-recommended statin intensity.[4-12] Furthermore, utilization of non-statin therapy with ezetimibe and proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitors has also been shown to be low. To date, most analyses of statin utilization derive from either prospective cohort studies or registries with selected populations, or from insurance databases that include individuals with certain health plans. In an analysis from the PALM registry, 83.6% of patients with ASCVD were on a statin but only 47.3% were on a high-intensity statin.[4] A more recent analysis by Nelson et al found that of patients with ASCVD participating in a commercial health plan half (50.1%) were not on any statin and only 22.5% were on a high-intensity statin. By contrast, this study identified markedly higher rates of statin utilization (71.7% overall) and high-intensity statin use (39.4%).[5] Finally, using data from the ACTION Registry linked to Medicare claims, Wang et al identified 11,046 MI patients aged ≥ 65 years who were discharged alive on a statin from 347 hospitals (2007–2009).[6] Only 21% of MI patients were discharged on a high-intensity statin. By 90 days after MI, 44% of patients discharged on a statin underwent lipid testing (43% on low- or moderate-intensity statins and 49% on high-intensity statins; P=0.001). Of note, the investigators estimated that only ~66% of all patients discharged on a statin in our study population would reach the guideline-recommended LDL-C goal of <70 mg/dL.

The Goals of Treatment

In terms of approaching statin therapy for secondary prevention, the definition of ASCVD based on a patient's past medical history (Table 1), as well as the appropriate level of LDL reduction or "statin intensity," which is based on specific statin and dose (Table 2), are both critical.[1] The definition of clinical ASCVD comes from the populations enrolled in the randomized trials, and includes acute coronary syndromes, history of MI, stable or unstable angina, coronary or other arterial revascularization, stroke, transient ischemic attack, or peripheral arterial disease presumed to be of atherosclerotic origin (Table 1).[1] In addition to evaluation of potential cardiovascular risk factors, consideration should also be given risk-enhancing factors, especially those which are modifiable (Table 3).[1]

Table 1. Definition of ASCVD Stratified by Risk.

Major ASCVD Events	• ACS within the past year • History of MI (other than ACS event listed above) • History of ischemic stroke • Symptomatic peripheral arterial disease (history of claudication with ABI <0.85, or previous revascularization or amputation)
High-Risk Conditions	• Age ≥ 65 years • Heterozygous familial hypercholesterolemia • History of prior CABG or PCI outside of major ASCVD events • Diabetes • Hypertension • CKD (eGFR: 15-59 ml/min/1.73m^2) • Current smoking • History of heart failure • Persistently elevated LDL (LDL >100 mg/dl) despite maximally tolerated statin therapy and ezetimibe
Very High Risk Category	• History of multiple major ASCVD events or 1 major ASCVD event and multiple high-risk conditions.

ASCVD: atherosclerotic cardiovascular disease; CABG: coronary artery bypass graft; CKD: chronic kidney disease; eGFR: estimated glomerular filtration rate; LDL-C: low density lipoprotein; MI: myocardial infarction; PCI: percutaneous coronary intervention

Table 2. Definition of Statin Intensity

Intensity	High Intensity	Moderate Intensity	Low Intensity
LDL-C Lowering	**>50%**	**30-49%**	**<30%**
Statins	**Atorvastatin** (40 mg‡) 80 mg **Rosuvastatin** 20 mg (40 mg)	**Atorvastatin** 10 mg (20 mg) **Rosuvastatin** (5 mg) 10 mg **Simvastatin** 20–40 mg§ **Pravastatin** 40 mg (80mg) **Lovastatin** 40 mg (80 mg) Fluvastatin XL 80 mg **Fluvastatin** 40 mg BID Pitavastatin 1–4 mg	Simvastatin 10 mg **Pravastatin** 10-20 mg **Lovastatin** 20 mg Fluvastatin 20-40 mg

BID: twice daily; LDL-C: low-density lipoprotein cholesterol; RCT: randomized controlled ; XL: extended release.

Boldface type indicates specific statins and doses that were evaluated in RCTs

‡ Evidence from 1 RCT only: down titration if unable to tolerate atorvastatin 80 mg in the IDEAL (Incremental Decrease through Aggressive Lipid Lowering) study (S3.1.1-18)

§ Although simvastatin 80 mg was evaluated in RCTs, initiation of simvastatin 80 mg or titration to 80 mg is not recommended by the FDA because of the increased risk of myopathy, including rhabdomyolysis.

Table 3. Risk-Enhancing Factors for Clinician–Patient Risk Discussion.

- Family history of premature ASCVD (males, age <55 years; females, age <65 years)
- Primary hypercholesterolemia (LDL-C, 160–189 mg/dL [4.1–4.8 mmol/L); non–HDL-C 190–219 mg/dL [4.9–5.6 mmol/L])
- Metabolic syndrome (increased waist circumference, elevated triglycerides [>175 mg/dL], elevated blood pressure, elevated glucose, and low HDL-C [<40 mg/dL in men; <50 in women mg/dL] are factors; tally of 3 makes the diagnosis)
- Chronic kidney disease (eGFR 15–59 mL/min/1.73 m^2 with or without albuminuria; not treated with dialysis or kidney transplantation)
- Chronic inflammatory conditions such as psoriasis, RA, or HIV/AIDS
- History of premature menopause (before age 40 y) and history of pregnancy-associated conditions that increase later ASCVD risk such as preeclampsia
- High-risk race/ethnicities (e.g., South Asian ancestry)
- Lipids/biomarkers associated with increased ASCVD risk
  - ✓ Persistently elevated primary hypertriglyceridemia (≥175 mg/dL);
  - ✓ If measured:
    - Elevated high-sensitivity C-reactive protein (≥2.0 mg/L)
    - Elevated Lp(a): A relative indication for its measurement is family history of premature ASCVD. An Lp(a) ≥50 mg/dL or ≥125 nmol/L constitutes a risk-enhancing factor especially at higher levels of Lp(a)
    - Elevated apoB ≥130 mg/dL: A relative indication for its measurement would be triglyceride ≥200 mg/dL. A level ≥130 mg/dL corresponds to an LDL-C ≥160 mg/dL and constitutes a risk-enhancing factor
    - ABI <0.9

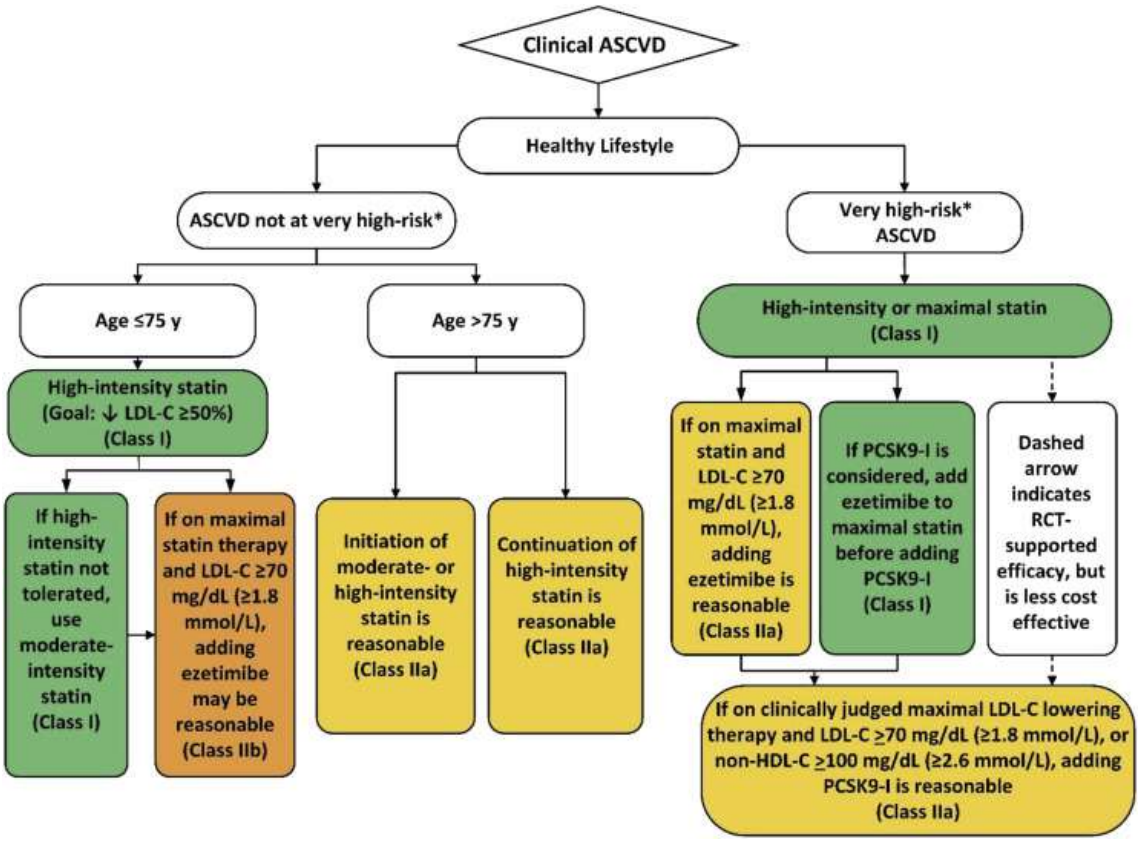
AIDS: acquired immunodeficiency syndrome; **ABI**: ankle-brachial index; **apoB:** apolipoprotein B; **ASCVD**: atherosclerotic cardiovascular disease; **eGFR**: estimated glomerular filtration rate; **HDL-C**: high-density lipoprotein cholesterol; **HIV**: human immunodeficiency virus; **LDL-C**: low-density lipoprotein cholesterol; **Lp(a):** lipoprotein (a); and **RA**: rheumatoid arthritis.

Overall, all patients with clinical ASCVD should receive a statin unless they have a contraindication.

As seen in Figure 1 below, in patients less than or equal to 75 years of age with clinical ASCVD, high-intensity statin therapy should be initiated or continued to achieve ≥50% reduction in LDL-C. In patients with very high-risk ASCVD, a high-intensity (or maximally-tolerated) statin) should be considered, and a non-statin such as ezetimibe and/or a PCSK9 inhibitor can be added if LDL-C reduction is <50% and LDL-C level is ≥55 mg/dL. In patients without very high-risk ASCVD, a high-intensity statin (atorvastatin 80 mg or rosuvastatin 20 mg) can be started up to (and including) age 75 years unless there are safety concerns.

In patients older than 75 years of age, ezetimibe (first line) and/or a PCSK9 monoclonal antibody (second line) can be considered if LDL-C reduction with current statin therapy is <50% and LDL-C level is ≥70 mg/dL. After initiating statin therapy, patients should return within 4 to 12 weeks for a fasting lipid panel to assess response to therapy and adverse effect, at which time statin dose can be increased or addition non-statin therapies added. Monitoring should continue at a 3-to-12-month schedule thereafter.[1]

Figure 1. Secondary Prevention in Patients with Clinical ASCVD.



Colors correspond to Class of Recommendation. ACS: acute coronary syndrome; ASCVD, atherosclerotic cardiovascular disease; LDL-C: low-density lipoprotein cholesterol; HDL-C: high-density lipoprotein cholesterol; MI: myocardial infarction; and PCSK9i: PCSK9 inhibitor.* See text and Table 1 for definitions.

Non-statin Therapy

When considering the addition of a non-statin, ezetimibe is often preferred for additional LDL-C lowering because of its favorable risk-benefit and cost-benefit profile. Ezetimibe lowers LDL-C by approximately 20% when added to a statin and was shown to reduce ASCVD events in a large, long-term ASCVD outcomes trial (IMPROVE-IT).13 While still higher-cost, PCSK9 inhibitors (alirocumab or evolocumab) can reduce LDL by up to about 65% when added to a statin with or without other lipid-lowering therapy in patients with and without heterozygous familial hypercholesterolemia (HeFH). Evolocumab and alirocumab have been shown to significantly reduce the incidence of ASCVD events in the FOURIER and ODYSSEY OUTCOMES trials, respectively.[14,15] The anti-PCSK9 siRNA inclisiran lowers LDL-C by approximately 50% in combination with a statin regimen in patients with ASCVD, or ~40% in patients with HeFH (ORION-2,ORION-3); no data are yet available on its efficacy for ASCVD event reduction (ORION-4).[16-18] Finally, bempedoic acid, also a higher-cost medication, provides an additional 12-16% of LDL-C reduction when added to a background statin therapy, and ~40% in combination with ezetimibe and a background statin therapy. As this drug targets hepatic cholesterol synthesis upstream from the same enzyme that statins inhibit, this therapy can be considered in those who may be statin intolerant. In the CLEAR trial, treatment with bempedoic acid among statin-intolerant patients was associated with a lower risk of major adverse cardiovascular events (death from cardiovascular causes, nonfatal MI, nonfatal stroke, or coronary revascularization).[19] In patients with very high-risk ASCVD who do not achieve ≥50% LDL-C reduction and whose LDL-C level is ≥55 mg/dL, consider adding ezetimibe and/or a PCSK9 inhibitor as first-line non-statin therapy and bempedoic acid or inclisiran as second-line non-statin therapy.

In patients with ASCVD without very high-risk features who do not achieve ≥50% LDL-C reduction and whose LDL-C level is ≥70 mg/dL, consider adding ezetimibe as a first-line option, an a PCSK9 inhibitor as a second-line option, or bempedoic acid or inclisiran as a third-line option.

Additional Considerations

In addition to statin therapy, all patients, including those with clinical ASCVD, should be counseled to adhere to healthy lifestyle habits (physical activity, a heart-healthy diet) and maintain a healthy weight. Smokers should be strongly advised to quit. Other risk factors (Table 3) should be controlled and antiplatelet agents should be administered according to current guidelines.[1]

Health First COLORADO
Colorado's Medicaid Program

In May 2024 there were 1,085,224 members enrolled in Health First Colorado (Colorado's Medicaid Program)

Population Health/DUR Interns

Doctor of Pharmacy candidates at the University of Colorado Skaggs School of Pharmacy who have an interest in public health policy, managed care, and population health management have a unique opportunity to gain one or two years of faculty mentoring and real-world experience as members of the intern team that skillfully supports Health First Colorado DUR activities.

A special thanks to outgoing interns Renee Sapasap and Jordan Hahn as they undertake their P4 advanced clinical practice training year.

Centers of Excellence in Pain Management

As a provider, are you interested in pain management training and support?

The Centers of Excellence in Pain Management program offers free training and peer-to-peer consultations with pain specialists for Health First Colorado primary care medical providers. The program also includes a benefit specialist who serves as a care coordinator for members receiving Home and Community Based Services (HCBS) and helps coordinate appropriate referrals to behavioral health services, substance use disorder (SUD) programs, or chronic pain providers.

For more information about how to connect with this program, contact judy.shepard@state.co.us

DUR Spotlight

by Nicole DeLeon
PharmD Candidate
DUR Intern

Rachele Poissant, PharmD

Dr. Rachele Poissant, Clinical Lead for Physician Administered Drugs, is a key member of the Pharmacy Office at the Colorado Department of Health Care Policy and Financing. She completed a rigorous six-year pharmacy doctorate program at Albany College of Pharmacy and Health Sciences in 2015 directly out of high school. She then relocated to Colorado to explore career prospects and has been a Coloradoan since. Initially drawn to community pharmacy, Dr. Poissant's interests evolved towards specialty pharmacy, where it now lies in ensuring equitable access to healthcare for Health First Colorado members. She truly finds fulfillment in actively contributing to community wellness.

Since joining HCPF in 2020, Dr. Poissant has played a pivotal role in developing and implementing clinical criteria for medications administered across various healthcare settings, including clinics, offices, and hospitals. When asked about her favorite aspect of her current role, she expressed joy for the collaborative partnerships with providers and the meaningful clinical impact.

Beyond her professional endeavors, Dr. Poissant cultivates a balanced lifestyle by engaging in outdoor activities that include gardening flowers and vegetables, hiking, and running. She cherishes moments spent with her husband, human baby, and beloved fur babies, Charles Barkley and Purrl Washington, a playful homage to her love of basketball

May 2024

PDL Drug Classes reviewed by the DUR Board

- Pulmonary Arterial Hypertension Therapies
- Anti-Psoriatic Agents
- Topical Immunomodulators
- Atopic Dermatitis & Antineoplastic Agents
- Bile Salts
- Antiemetics
- Chronic GI Motility Agents
- Hemorrhoidal, Anorectal, and related Topical Anesthetic Agents
- Anticoagulants
- Anti-Platelet Agents
- Colony Stimulating Factors
- Tetracyclines
- Alpha Blockers
- Beta Blockers
- Calcium Channel Blockers
- Angiotensin Converting Enzyme (ACE) Inhibitors & Combinations
- Angiotensin Receptor Blockers (ARBs) & Combinations
- Renin Inhibitors & Combinations
- Lipotropic Agents
- Statins & Combinations
- Topical Acne Agents
- Acne Agents – Oral Isotretinoins
- Rosacea Agents
- Topical Steroids
- *H. Pylori* Treatments
- Pancreatic Enzymes
- Proton Pump Inhibitors
- Non-Biologic Ulcerative Colitis Agents
- Erythropoiesis Stimulating Agents
- Movement Disorder Agents ***(NEW)***

Announcement Column

New PBM System Coming in 2025

The Department recently reprocured its pharmacy benefit management system (PBMS) with a contract awarded to MedImpact. Work to transition to MedImpact's system has already begun, with an anticipated completion date of Fall 2025.

SMART Asthma Therapy Coverage

Single Maintenance and Reliever Therapy (SMART) is an evidence based approach in which a single inhaler containing both a corticosteroid and a long-acting beta$_2$ agonist is used in both daily maintenance and as-needed relief of asthma symptoms. By involving only one metered dose inhaler, SMART simplifies the process of asthma management and makes it easier for members to properly use their medications.

SMART was included in the most recent updates to the National Asthma Education Program (NAEPP) Asthma Management Guidelines and it is the preferred treatment for patients 4 years and older who have moderate to severe persistent asthma and are already using a low or medium inhaled corticosteroid dose.

SMART therapy is covered for Health First Colorado members when billed with the appropriate days' supply. For claim rejections related to dose and days' supply, pharmacies may contact the Magellan Helpdesk for overrides.

DUR Spotlight

by Jordan Hahn
PharmD Candidate
DUR Intern

Robert Page, PharmD, MSPH

Dr. Robert Page grew up in Charleston, South Carolina and later attended Furman University in Greenville, South Carolina. He originally planned to attend medical school. However, this path didn't sit right with him and he decided to pursue a PharmD degree at the Medical University of South Carolina (MUSC). He was on the track toward traditional pharmacy practice, but fate had other plans because his mentor was pioneering a two-year post-doctoral residency program. Dr. Page became one of the first residency-trained pharmacotherapy experts in the country.

After residency, Dr. Page planned to stay in South Carolina; however, at his mentor's urging, he decided to look for opportunities outside of his home state. Ultimately, he came to Colorado and the University of Colorado Skaggs School of Pharmacy. Although he had not expected it as part of his career path, he began teaching at the school. And, since clinical pharmacy had not yet taken root in Colorado, he began his professional practice on the medical floor of the UCHealth University of Colorado Hospital (UCH). A year later, Dr. Page began making significant contributions to build the UCH cardiology program into what it is today.

Dr. Page earned a Master of Science in Public Health in 2009 which pushed him into health policy and research. He also joined the DUR Board and the first P & T committee for Health First Colorado. He has enjoyed the close partnership between the State of Colorado and the CU Skaggs School of Pharmacy to manage Colorado's Medicaid program. For many years, Dr. Page has contributed to a robust DUR program with an expert staff and excellent intern team.

Dr. Page describes himself as a foodie and particularly likes Indian cuisine. He also loves the outdoors and enjoys running, hiking, biking, and Pokémon GO. While his varied career has been fulfilling, Dr. Page believes that his identity as an educator has become the most meaningful aspect. He is a pioneer who has been instrumental in building Colorado's robust practice of pharmacy.

The Health First Colorado Drug Utilization Review (DUR) Board

The Health First Colorado DUR Board is composed of four physicians, four pharmacists, and one industry representative. Despite busy schedules, these experienced professionals offer their clinical insight and expertise to serve in an advisory capacity to the Colorado Department of Health Care Policy & Financing.

This quarter we welcome Dr. Marshal Ash to a two-year term.

Physicians and pharmacists are recruited on a continuous basis to fill positions on the Colorado DUR Board. If you or a colleague are interested in learning more about this professional opportunity, send an email inquiry at any time to SSPPS.co-dur@cuanschutz.edu. If there are no Board openings at the time you apply, the Department will keep your information on file and may contact you in the future as openings arise.

The DUR Board meets quarterly in February, May, August and November. To observe a Board meeting or to learn more, visit https://hcpf.colorado.gov/drug-utilization-review-board.

Thank you, current DUR Board members, for your important service to the State of Colorado!

Brian Jackson, MD, MA *(Chair)*	Patricia Lanius, BSPharm, MHA
Liza Claus, PharmD, BCACP *(Vice Chair)*	Todd Brubaker, DO
Shilpa Klocke, PharmD, BCPS	Kenneth MacIntyre, DO
Marshal Ash, DO	Ingrid Pan, PharmD, BCPPS

Our mission is to improve health care equity, access and outcomes for the people we serve while saving Coloradans money on health care and driving value for Colorado.
https://hcpf.colorado.gov

The July 1, 2024
Colorado Preferred Drug List (PDL)
is available at
https://www.colorado.gov/hcpf/pharmacy-resources

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The Basics of Secondary Prevention of Atherosclerotic Cardiovascular Disease: DON'T FORGET THE STATIN!

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SMART Asthma Therapy Coverage

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Images

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