



**Indian Health Service**  
**Closed Class – HMG CoA Reductase Inhibitors**  
**IHS National Pharmacy and Therapeutics Committee**  
**Last Reviewed: February 2009**



**Background:**

In February 2009, the IHS National Pharmacy and Therapeutics Committee (NPTC) reviewed the HMG CoA Reductase Inhibitors (Statins) class and voted to maintain simvastatin and lovastatin, to remove fluvastatin and atorvastatin 80mg, and to add pravastatin and rosuvastatin 20 mg to the IHS National Core Formulary (NCF). Furthermore, the committee concluded that the breadth of the current agents on the NCF and the cost advantages over other non-formulary agents supported maintaining the closed class status.

**Clinical Review:**

The Adult Treatment Panel III of the National Cholesterol Education Program has established guidelines for the treatment of hyperlipidemia, and has established low density lipoprotein cholesterol (LDL-C) as the primary target of therapy. Goals for LDL-C lowering have been established according to risk categories; those with the highest risk levels have the lowest recommended LDL-C targets. Statins are among the best studied cholesterol lowering drugs. They work by blocking the HMG CoA reductase enzyme that is the rate-limiting step in cholesterol production. Statins also lower triglycerides, improve endothelial function, decrease platelet aggregation, and reduce inflammation. Each of the six statins currently on the market has been associated with a reduction in cardiovascular events.

According to the Oregon Evidence-based Practice Center's drug class review of the statins, patients requiring LDL-C reductions of up to 35% will achieve results with any of the statins. Patients requiring 35-50 percent reductions will meet these goals with atorvastatin 20 mg or more, lovastatin 80 mg, rosuvastatin 10 mg or more, and simvastatin 20 mg or more. Studies of statins have not proven definitively that one is superior to another in increasing high density lipoprotein cholesterol (HDL-C) when they are prescribed at doses found to achieve near equivalence in LDL-C lowering.

Regarding the safety and tolerability of the statins, there is insufficient evidence to conclude which agents are safer with regard to liver and muscle toxicity. Because the statins are metabolized by different enzymes in the liver, they are affected differently by various drugs, and these interactions need to be considered when prescribing statins to patients on drugs such as itraconazole, clarithromycin, fluconazole, amiodarone, and many others. For example, simvastatin and lovastatin are metabolized by the CYP3A4 system in the liver and are affected by the drugs mentioned above; atorvastatin is metabolized less by this enzymatic system. Pravastatin is not significantly metabolized by the cytochrome system, and rosuvastatin is only minimally metabolized by the CYP2C9 system.

The IHS National Pharmacy and Therapeutics Committee, after completing a review of the statin class, placed four statins on the national formulary: lovastatin, simvastatin, pravastatin, and rosuvastatin 20 mg, and maintained the statin class' "closed class" designation. This decision was made after a complete review of the data revealed that these drugs provided the needed clinical benefits in the most cost-efficient way for the majority of patients.

**Cost Avoidance Potential:**

With a strong collaborative effort from all I/T/U facilities and enhanced compliance of the statin's closed class status on the IHS National Core Formulary, the IHS has the potential to realize a significant amount of cost avoidance annually.

If you have any questions regarding this document, please contact the NPTC at [nptc1@ihs.gov](mailto:nptc1@ihs.gov).

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**References:**

1. Helfand, Carson, and Kelley. "Drug Class Review on HMG-CoA Reductase Inhibitors (Statins) Final Report." August 2006.
2. Ridker, et al. "Rosuvastatin to Prevent Vascular Events in Men and Women with Elevated C-Reactive Protein." New England Journal of Medicine. Vol. 359, no. 21, pp. 2195-2207.
3. Brunzell, et al. "Lipoprotein Management in Patients with Cardiometabolic Risk: Consensus Conference Report from the American Diabetes Association and the American College of Cardiology Foundation." Journal of the American College of Cardiology. January 6, 2009.
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