

Date: March 21, 2005

Subject: DRC Recommendations to DCC and DHS

To: DHS, DCC, Dean's Office

From: Henry F. Simmons, Jr., MD, Ph.D.
Chairman DRC

At its 03/18/05 meeting, the Drug Review Committee considered the potential toxicity and therapeutic roles of atorvastatin, fluvastatin, pravastatin, rosuvastatin, simvastatin and lovastatin. Dr. McDonough of the EPC addressed the Committee telephonically regarding her organization's views on the statins and responded to questions.

The voting members of the Committee made the following formal recommendations based upon their perception of the bulk of the best available evidence with the understanding that comparable doses of each drug are used.

1. None of the six drugs differ significantly in either the incidence or the nature of clinically evident complications in patients of a particular sex, age or race when appropriately dosed.
2. None of the six drugs have been proven more efficacious for patients of a particular sex, age or race.
3. Atorvastatin, simvastatin, pravastatin, fluvastatin and lovastatin all improve some health outcomes.
However, lovastatin lacks data on secondary health outcomes, fluvastatin on primary and rosuvastatin on both primary and secondary.
Because of these gaps in the data base, the Committee excluded rosuvastatin, lovastatin and fluvastatin from further consideration.
4. Atorvastatin, simvastatin and pravastatin are all three effective in reducing LDL cholesterol in patients with moderate elevations. Furthermore, all three have both primary and secondary health outcome data.
5. Atorvastatin or simvastatin should be available for patients who need more than 40% reduction in LDL cholesterol from the outset or who fail control with a less potent agent such as pravastatin. In particular a patient with a need for more than 40% reduction at the initiation of treatment should not have to fail control with pravastatin before being switched to atorvastatin or simvastatin. Therefore, a minimum of two drugs would have to be available if one of them were pravastatin.

In addition, the Committee offers the following considerations:
It is not possible to make generic recommendations for individuals having certain co-morbidities, taking potentially interacting drugs or experiencing refractory hyperlipidemias. However, pravastatin was considered a good potential choice for patients taking cytochrome P450 inhibitors and atorvastatin a potential drug for those with refractory LDL-c elevations. Such cases will quite possibly need to be addressed in the prior authorization process.

Respectfully,
Henry F. Simmons, Jr., MD, Ph.D.