

Date: March 16, 2006

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 02/16/06 meeting, the Drug Review Committee considered the potential toxicity and therapeutic roles of targeted immune modulators for rheumatoid arthritis, juvenile rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, and Crohn's disease.

**Targeted immune modulators under consideration include the following:**

Humira (adalimumab)  
Amevive (alefacept)  
Kineret (anakinra)  
Raptiva (efalizumab)  
Enbrel (etanercept)  
Remicade (infliximab)

Based upon the bulk of the best available evidence pertaining to the aforementioned agents the Committee concluded the following:

Because there is insufficient information about alefacept and efalizumab to reach conclusions about their safety and adverse-event profiles relative to the other drugs, they should be excluded from further consideration. Of the remaining four drugs, there is insufficient evidence to conclude that one is superior to the other in terms of safety considerations or frequency of adverse events.

In the treatment of rheumatoid arthritis there insufficient information to conclude that any of the following are superior: Humira (adalimumab), Kineret (anakinra), Enbrel (etanercept) and Remicade (infliximab). At least two of these agents should be available.

In the treatment of juvenile rheumatoid arthritis, Enbrel (etanercept) should be available as there insufficient information to recommend Humira (adalimumab), Kineret (anakinra), and Remicade (infliximab). At least two of these agents should be available.

Enbrel (etanercept) and Remicade (infliximab) should be available for treatment of ankylosing spondylitis.

For the treatment of psoriatic arthritis at least two of the following should be available: Humira (adalimumab), Enbrel (etanercept) and Remicade (infliximab). Kineret (anakinra) should be excluded for this indication due to lack of evidence.

Remicade (infliximab) should be available for the treatment of Crohn's disease.

Humira (adalimumab) and Kineret (anakinra) should be available for the treatment of patients with congestive heart failure.

A majority of committee members felt that the targeted immune modulators should be prescribed only by physicians who routinely treat patients with chronic inflammatory disorders that are refractory to traditional therapy.

Henry F. Simmons, Jr.  
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