

Kineret is given by self-injection once a day. Pre-filled syringes are supplied together with a convenient injection tool called 'simpleject.'

**Side effects?** The most common side effect of Kineret was injection site reactions (ISR). These usually occur during the first 4 weeks of treatment. They tend to disappear within days to weeks, and usually don't require any additional treatment. ISRs can include redness and swelling, but not itching. Low white cell count occurred in some people when Kineret was used together with Enbrel. Therefore it is strongly recommended that Kineret not be used together with Enbrel or Remicade.

**Costs.** Kineret is not as expensive as Enbrel or Remicade, but it is still very expensive, costing in the neighborhood of \$9,000 per year. Because it is self-injected, Medicare will not cover the cost of this treatment. Most other insurance companies should cover Kineret therapy.

## BEXTRA® APPROVED BY FDA FOR INFLAMMATION AND PAIN: USEFUL IN RA, OA, AND FIBROMYALGIA

BEXTRA® (generic name: valdecoxib) was the second drug approved by the FDA in November 2001. Bextra, a non-steroidal anti-inflammatory drug (NSAID) of the COX-2 class, is approved for the treatment of the pain and inflammation associated with conditions such as RA, osteoarthritis and fibromyalgia (pain only). NSAIDs are usually divided into two classes: COX-1 and COX-2.

Although the distinction can be complicated, the main practical difference between these two drug classes is that COX-2 NSAIDs are thought to have less stomach side effects (ulcers). The COX-2 NSAIDs are Vioxx, Celebrex, and now Bextra. Studies submitted to the FDA show that Bextra has the same effectiveness as other NSAIDs but does not increase stomach ulcers compared to placebo.

Bextra is expected to be available early in 2002. It has its full effect when taken once a day. If you need to take a COX-2 NSAID, Bextra may be more convenient and less expensive than the twice a day Celebrex. Costs are expected to be in the same range as the other two COX-2 NSAIDS.

## NOTES FROM THE DIRECTOR- ABOUT OUR RESEARCH: COST AND EFFECTIVENESS

Evaluating costs and effectiveness of Treatments: what works and who pays? You may have noticed that drugs are getting more expensive. Although Enbrel, Remicade and Kineret are potent new agents, and the COX-2 drugs Celebrex, Vioxx and Bextra appear to have reduced ulcer-related side effects, all of this comes at a price. As an example, NDB researchers presented Figure 2 at the 2001 American College of Rheumatology (ACR) annual meeting. It shows that the major increase in the cost of arthritis treatment over the last few years was due entirely to the increase in drug costs.

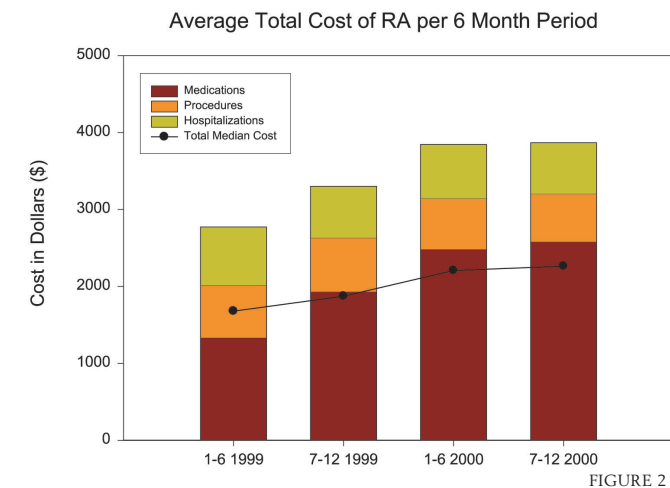
If you have arthritis these costs can be quite real. You may have to pay drug costs directly, in whole or in part, and your insurance may not pay any of the costs. If you have a co-payment requirement, the expense of drugs such as Remicade, Enbrel, and Kineret may be so much that you just can't afford to take them. Insurance companies are also concerned about costs. One way they have of dealing with costs is by reducing benefits.

**What is the benefit and who benefits?** Costs are but one side of the equation. What about the benefit you may get from treatment? In the end the value of treatment represents some balance between cost and effectiveness. Let's take some easy examples. If a drug barely helps at all then neither you nor your insurance company would want to pay for it. If a drug cures (or almost cures) arthritis, then everyone would want to have it and pay for it. It is when drug effectiveness is less than complete that creates complications.

First, there is the issue of determining how effective the drug is. For example, if a drug reduces pain by 10% or 20% or it eliminates two swollen joints, how shall its effectiveness be rated? Next, suppose that a drug can prevent work disability or slow it down. Should we also take that benefit into account; and how do we convert the ability to work into terms of 'effectiveness'? In the NDB questionnaires we try to measure effectiveness by asking about function, pain, joints, and quality of life. In addition, by asking about your work, your work disability and your income, we can measure the extent to which arthritis related factors can predict and be associated with these long-term measures of effectiveness (and costs).

## WIN \$1000

Return your research questionnaire electronically or by paper within two weeks of receiving it and be eligible for one of three \$1,000 awards. The research data bank can best contribute to research when the mailed questions are complete and returned as soon as possible. Anyone who completes the questionnaire within two weeks of receiving it will be eligible for the drawing for the award - given as a token of our gratitude in help with arthritis research. **The winners from the last questionnaire were Betty Spittler of Peoria, AZ; Elizabeth Meyer of Ambler, PA; and Jeanette Blakely of Cleveland, OH. Congratulations to all!**



**Effectiveness for whom?** Then there is the issue of 'effectiveness for whom?' If you have arthritis, a 10% reduction in pain may be welcome, but if you are an insurance company you may not think 10% is worth paying for. Also, insurance companies may not pay much attention to work disability if it is something that may happen in the future. Finally, if we make all drugs available to all people, then costs of premiums (or government services) will go up.

**Side effects.** Side effects of treatment are another aspect of drug effectiveness, cost, and quality of life that must be considered. For example, some NSAIDs can cause ulcers, and the TNF- $\infty$  drugs can be associated with side effects like infection. These types of problems can lead to increased costs due to unexpected office visits, hospitalizations, or lost work days. *So how do we know whether it is worth it, and what does this have to do with NDB research?*

*The major increase in the cost of arthritis treatment over the last few years was due entirely to the increase in drug costs.*

**Establishing costs.** The direct medical costs of arthritis can be due to drugs, medical visits, and/or hospitalizations. When you complete a questionnaire we look up the costs of all of the drugs that you take, and we apply government-based costs to your doctor visits, outpatients services, and hospitalizations. Though not all costs are easy to measure. For example, if someone helps you with your work tasks, home tasks, or your self-care, these are also costs of arthritis that you or your helper pay directly or indirectly. Here are some other costs that are not so easy to measure: reduced income related to physical disability, income loss due to early retirement and/or work disability. There are also some other things you may give up when you have arthritis -recreational activities, travel and participation in social and civic events. Not all of these things may apply to you, but overall they are also a part of the real costs of arthritis.

**Working and Arthritis.** In the January 2002 questionnaire, the NDB together with Dr. Saralynn Allaire of Boston University has added a series of questions designed for persons with RA who are working. This detailed section asks about all aspects of your work in an effort to understand how having arthritis affects your ability to work, affects your ability to earn income, and describes factors that might lead to or protect against future work disability. In the July 2001 questionnaire and again in this questionnaire we asked about your work limitations. Figure 3 is the result of one analysis of this series of questions. Although reported for persons with fibromyalgia, we found almost exactly the same results for persons with RA and OA. To summarize, persons with arthritis or fibromyalgia who were working had limitations in almost all work activities, but especially in physical activities, as might be expected. We also reported at the 2001 ACR annual meeting that these limitations were associated with reduced income.

**Putting it all together: costs, effectiveness, and quality of life.** Once we have all of the costs related to having arthritis, including direct medical costs and indirect costs related to work and self-care, we add up measures of effectiveness of treatment (as well as measures of ineffectiveness) including those related to pain, function, side effects, arthritis surgery and work problems. When all of this information is at hand we try to determine how much actual benefit can be obtained from the treatments that are available, and how much it costs to get that benefit.

**Measuring Quality of Life.** The last step in assessing the value of treatment is to measure the actual quality of life (QOL) of persons with arthritis. One way to do this is with the questionnaire scale which asks you to tell us how you rate the quality of your life on a 0-100 numeric scale. The best way to determine QOL is through a detailed interview. We have set up such an interview on the Internet. It takes about 10 minutes to complete. We hope that you will be interested in helping us learn more about quality of life by completing this Internet interview after you complete the NDB regular questionnaire. The QOL interview can be found at [www.arthritis-research.org](http://www.arthritis-research.org). Please click on the "QOL Interview" button.

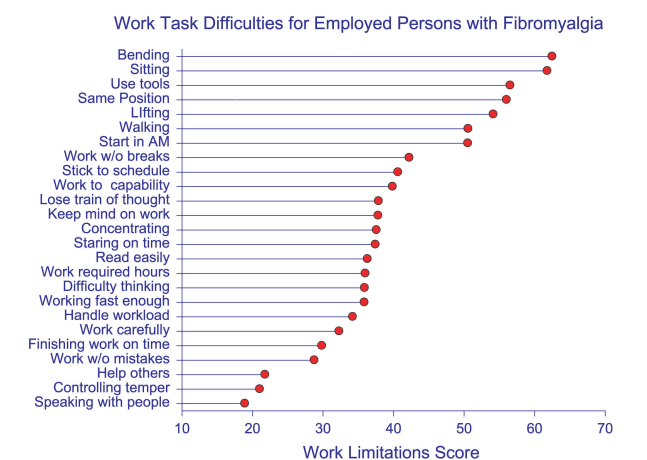


FIGURE 3