

New Agents for Arthritis

Cody K. Wasner, MD

Introduction

"It was the age of wisdom, it was the age of foolishness, . . . it was the spring of hope, it was the winter of despair." These comments could apply to the present state of rheumatology just as easily as Dickens applied them to the French Revolution. In the last ten years, treatments have been developed which dramatically slow the progression of rheumatoid arthritis. With early diagnosis and appropriate medications, joint damage and physical disability are no longer inevitable. Yet, because of the change in the medical landscape, these effective new medications are often unavailable due to restricted formularies and preauthorization hassles. Patients may continue to suffer, not from lack of effective treatment, but due to lack of access to treatment. Truly these are the best of times and the worst of times.

As chronic care specialists, our expertise lies in managing chronic, complex musculoskeletal diseases. Where we once coordinated a team of professionals including physical and occupational therapists, diagnostic radiologists, orthopedic surgeons and rehabilitative medicine practitioners, we now spend a substantial amount of energy justifying our patient's right to use these services. While we should be expanding our services to an aging and enlarging pool of patients, instead we are spending increasing amounts of time justifying these services and treatments.

In the worst cases, HMOs and insurance providers have evolved from patient advocates, (if they ever were), to advocates for their stockholders; from protectors of the patient's health and well-being to protectors of a shibboleth, "the rising cost of medical care."

ACR Introduces Position Statement

Nowhere in the practice of rheumatology is this change more obvious than in the use of the new cytokine blockers or the so-called "biological" medications. One month's supply of one of the new biological medications can average approximately

\$1000. The cost has caused many third party payers to place barriers to these treatments, in spite of the overwhelming evidence of their effectiveness and relative safety. Other systems, such as Medicare, limit use based on legislatively-mandated delivery restrictions.

Recognizing these increasing problems and responding to the numerous complaints from physicians and patients, the ACR ratified a Position Statement on this class of agents in March 2003. This Position Statement, reproduced within on pages 2 and 3, represents the input of members from around the country, members of the Committee on Rheumatologic Care and the Board of Directors. In addition to stating the College's position, we added a section to this "Practice View" which identifies problem areas involved with obtaining these medications. Attempted restriction of care often takes multiple and convoluted forms and identifying different maneuvers may prove helpful to you.

Problem Areas

Access

The "Access" section addresses medication equivalency and access. Third party providers may develop favorable purchasing arrangements or rebate structures with a specific pharmaceutical company, making it more profitable for one biologic to be used over another. They may attempt to mandate a selection based on these factors under the guise of some guideline or criteria, often developed by pharmacists or pharmacy benefit committees. Insurers sometimes argue that these medications are equivalent, in an attempt to defend their preferred choice limitations. In other cases, to justify their selection, they may maintain that the medications are clinically different and ignore individual patient preferences and physician input. Within Medicare, the distinction is made by method of delivery.

In each case, the attempt by the organization making the reimbursement decision restricts the physician's options and place non-clinical judgments ahead of physician choice, and, ultimately, patient care.

AMERICAN COLLEGE OF RHEUMATOLOGY

POSITION STATEMENT

SUBJECT: New Agents for Arthritis

PRESENTED BY: Committee on Rheumatologic Care

FOR DISTRIBUTION TO: Members of the American College of Rheumatology
Medical Societies
Members of Congress
Centers for Medicare and Medicaid Services
Managed Care organizations/Third-Party Carriers
Arthritis Foundation

BACKGROUND

A new group of DMARDS (disease modifying anti-rheumatic drugs) has been developed with the purpose of interfering with inflammatory cytokine biology. They represent a significant advance in the treatment of rheumatic diseases. These so called "biologics" or biologic response modifying agents have proved to be very effective and offer the possibility of controlling rheumatic diseases to an extent not previously possible. Currently approved representatives are anakinra, etanercept, infliximab and adalimumab. These agents are considered by the FDA to inhibit the progression of structural damage and improve physical function in RA. The number of diseases in which these agents are useful continues to expand as do the number and types of agents available.

The clinical improvement with these drugs is often quite dramatic and several years of data show that these responses are long lasting. However, the production of these medications is significantly more complicated than our previous treatments and their cost is significantly higher. Because of cost, access to these medications has become increasingly difficult for our patients and a clarification on the American College of Rheumatology's policy on these medications is needed.

POLICY:

We believe that all patients with serious rheumatic disease must have these new "biologic" medications available when clinically appropriate.

Access

Attempts to restrict their use by guidelines or criteria that are outside the patient-physician relationship should be discouraged, and cost based substitutions within this group are inappropriate. The differences in ACR response rates, route and frequency of administration, antigen target and possible side effect profiles prevent any consideration of these drugs as equivalent agents.

29 Decision Making

30 The choice for any individual patient should be determined by the treating rheumatologist who,
31 as an expert in the field, will take into consideration not only the above medication differences
32 but logistics, patient willingness or aversion to various medication delivery systems,
33 contraindications, co-morbidities, concomitant medication, susceptibility to infection, and other
34 factors which can only be individualized on a patient-by-patient basis. Third party payers should
35 not attempt to mandate the use of one agent over another based on population-based studies nor
36 predetermined algorithms. To do so ignores the complexity of decision making by the
37 rheumatologist, preempts the expertise of the physician and blindly intrudes on the patient-
38 physician relationship.

39

40 Cost Considerations

41 Because these newer agents are costly, the rheumatologist has added responsibility in selecting
42 appropriate treatment for rheumatic patients. Financial considerations are not limited to the direct
43 cost of medication, however; they range from the loss of present and future earning capacities if
44 treatment is omitted to the potential consequences of adverse effects of treatment. The optimal
45 management for a given patient may be complex, but these decisions are to be made within the
46 patient-physician relationship. It is not justifiable for third party payers to attempt to influence
47 these medication selections by pre-authorization requirements, "preferred drug status" (such as
48 cost discounts negotiated by third party payers) or tiered levels of co-pays.

49

50 Spectrum of Use

51 Presently the new "biologic" medications are FDA approved for use in rheumatoid arthritis.
52 Etanercept is indicated for psoriatic arthritis as well. It must be recognized however, that many
53 rheumatic diseases, because of small numbers or other factors, may never have FDA approval for
54 biologic treatment, but have adequate evidence-based data to justify such treatment. For
55 example, at the present time ankylosing spondylitis and other spondyloarthropathies and
56 inflammatory arthritides, such as reactive arthritis, Reiter's Syndrome, and inflammatory bowel
57 disease arthritis meet this requirement. The fact that these are non-FDA approved indications
58 should not be justification of third party denial for this treatment. Rheumatologists have a
59 responsibility to provide what they consider to be the safest and most effective treatment option
60 for the patient's illness, even where full FDA approval may never be obtained.

61

62 Approved by Committee on Rheumatologic Care: 01/11/03

63 Approved by the Board of Directors 03/07/03

NEW AGENTS FOR ARTHRITIS

The ACR maintains that it is completely inappropriate to mandate or restrict the rheumatologist's prescribing options. There are many individual factors that may influence a rheumatologist's choice of a biological medication and there are no major head-to-head comparison studies substantiating insurer-based decisions.

If and when comparison studies become available, the individual details of a case will still make the treating rheumatologist's professional expertise and opinion most important in selecting the appropriate medication. Some individual factors that are taken into account are listed in the section on decision-making.

Decision-Making

New biological medications are undoubtedly more expensive than our previous treatments. In perspective however, they are not any more expensive than the biological treatments for other diseases such as hepatitis C, multiple sclerosis or lymphoma. They are cost-saving in many aspects as well, in allowing patients to return to work, improving earning capacity and avoiding costly joint replacement surgeries. Conversely, the social and emotional costs of inadequate rheumatic treatments are high. When insurers use the excuse of high cost to refuse biological treatment, they are often operating on a very limited and often short-sighted view of costs, and not including the societal or patient-centered costs. In fact, it is accepted practice in the private insurance industry to make policy decisions that impact the future of merely one or two fiscal quarters. For the patient, the physician (who bears responsibility for the therapy) and for society, this is unacceptable.

Cost Considerations

Elaborate "preauthorization requirements" such as qualifying HAQ scores or other tests used in research studies, or failure of numerous less expensive medications in a specific sequence (so-called "step therapy") are not justified. Reserpine failure is not required before one can use a newer anti-hypertensive. Rheumatologists deserve no less degree of professional prescribing authority than other physicians such as cardiologists. Furthermore, prescribing a less effective medication because a third party payer requires it may be ethically and legally compromising the physician-patient relationship.

Spectrum of Use

Lastly, the new biological medications are effective for an ever-increasing list of rheumatic diseases that are cytokine dependent. Third party payers have tried to restrict biologic use by restrictive criteria that demand FDA approval before utilization. Even when there is substantial medical literature testifying to a biologic's efficacy, the payer may consider it investigational if FDA approval is lacking and, therefore, deny access. Many of the rare rheumatic diseases may never have a specific FDA indication for their treatments, so to demand FDA approval before allowing use is unwarranted. One can

only imagine how many Wegner's patients would have died if we had restricted our treatments to only FDA-approved medications for this disease.

Conclusion

The delivery of rheumatic care is becoming increasingly complex as it becomes more effective. The American College of Rheumatology is committed to protecting the physician-patient relationship and to continued advocacy for the patient, the rheumatologist and society. We hope that dissemination of this document can make those goals more reachable. We encourage you to duplicate and use this official ACR Position Paper (pages 2 and 3) when dealing with biological medication problems and keep us informed of your successes and failures so we can direct our continuing advocacy efforts. Our specialty's unparalleled expertise in developing and evaluating new treatments must go hand in hand with our ability to champion for the patient. Educating the payers and advocating for the patient are part of our societal role.

This Position Paper is available at www.rheumatology.org/position/dmard.html, or through the homepage of www.rheumatology.org by following the Publications/Position Papers/Access and Coverage links.

PRACTICEview

Cody K. Wasner, MD

Chair, Committee on Rheumatologic Care
Editor

Teresa Fitzgerald Ogden, CAE

Vice President, Socioeconomic Affairs
Managing Editor

Practice View is published periodically by the Committee on Rheumatologic Care of the American College of Rheumatology. Copyright 2003, American College of Rheumatology.

American College of Rheumatology
1800 Century Place, Suite 250
Atlanta, GA 30345-4300
Phone: (404) 633-3777
Fax: (404) 633-1870
E-mail: acr@rheumatology.org
www.rheumatology.org

The ACR does not guarantee, warrant or endorse any commercial product or service.

Printing of this issue is supported by an unrestricted educational grant from Pfizer Inc.