The OAR Advocate
Ohio Association of Rheumatology
January 2011
A Newsletter for Rheumatologists in the State of Ohio

About *The OAR Advocate*

Welcome to *The OAR Advocate*, the publication of the Ohio Association of Rheumatology (OAR). Published semiannually, its aims are: (1) to inform our members of news, events and trends in Ohio and nationally relevant to the practice of rheumatology; (2) to opine on issues that impact the practice of rheumatology; and, (3) to entertain our membership. In broadly defining our goals, we do not have a predetermined concept of what *The OAR Advocate* should be; rather, we seek your input and want it to be your publication. In that spirit, as editor I invite you to contribute articles, opinion pieces, stories about your practice, or even brief, informative cases. Please see the May 2009 *OAR Advocate* on our website for details about how to submit your contributions.

Gary M. Kammer, M.D., editor

SAVE the DATE

OAR 6th Annual Meeting

September 23 and 24, 2011

Location TBD

Another Outstanding Meeting...And More

by Gary M. Kammer, M. D.

In September OAR held its fifth annual meeting at the Cherry Valley Lodge in Newark, OH. And what a meeting it was! Like 2009's meeting, we had a record attendance. The rustic ambiance of the lodge with its flaming hearth warmed our spirits and prompted fireside chats. And—no hyperbole here—the meeting was truly outstanding.

Here are some details that tell the story. Of the 34 folks in attendance, 30 (88%) were physicians. Twenty-nine were rheumatologists, one was a P.A., and four included a Ph.D. and J.D. Of those physicians responding to our questionnaire, all reported that the course description listed in our brochure was accurate and felt that the material was presented in a balanced, unbiased manner without any commercial tilt. Several offered the following comments: "Well balanced discussion of advocacy….Very good broad based program."

We asked our attendees to grade speakers from 0 to 4.0 based on the several criteria. These included (1) meeting learning objectives; (2) relevance to clinical practice of rheumatology; (3) quality, clarity and organization of presentation; and, (4) audience participation. Of the three morning talks on advocacy, the ratings ranged from 3.5 to 3.9. Attendees commented on the speakers' overall knowledge, insights and understanding of the broad array of health care reform issues discussed. Specific comments included: "Wonderful talk…I learned more detailed information about the ACA (Affordable Care Act of 2010)… the option to 'opt out' [of Medicare] is novel to me…what's going on with changes and legislation [affecting the practice of medicine in Ohio]."

Our line-up of clinical speakers in the afternoon fared as well. All speakers were rated 3.5 to 4.0. It doesn't get better than that! Attendees were particularly fascinated to hear how translational research has yielded such major therapeutic advancements in the rheumatic diseases, especially in biologic therapies, as well as understanding the pathophysiologic mechanisms of inflammatory myopathies and osteoarthritis. Of particular interest were the following comments: "New intracellular signal transduction inhibitors and their potential for use in RA [are exciting]….MTX monotherapy is still an impressive option….Inflammatory aspect of osteoarthritis [and the importance of] cytokines in the pathophysiology of OA…Incredibly complex subject [OA] made relatively understandable….[The review on inflammatory myopathies] was a very timely [one] for me [since] I have had a 'run' on these rare diseases….Reinforced the need for a DAM [Disease Activity Measurements]…Well done."

Our informal Friday evening dinner and Saturday noon luncheon provided quality time for attendees to renew acquaintances, meet new members, and, importantly, to talk with speakers. I just happened to walk up as Dave Racer, our keynote speaker on health care reform, was waxing elegantly on what really is ailing our health care system. It was a fascinating tour de

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Another Outstanding Meeting
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force, essentially a mini-lecture. (By the way, I recommend Dave's booklet entitled "What really ails the U.S. health care system" for a forceful, no-holds-barred discussion of the facts and myths of our health care system.)

If you didn't have an opportunity to join us for this exhilarating meeting, please consider attending our sixth annual meeting next Fall. More about that in the near future from Stephanie Ott, M. D. (Lancaster, OH) and Wael Jarjour, M. D. (Columbus, OH), who will be co-chairing the meeting.

Gary M. Kammer, M. D. is the current president of OAR, chair of the Agenda Committee for the Annual Meeting, and a practicing rheumatologist in suburban Cleveland.

About RheumPAC

by Ed Herzig, M. D.

There are many kinds of political speech: debates, editorials, letters to Congress or newspapers, political contributions. Rheumatology has a small number of practitioners when compared to primary care, orthopedics, hematology - oncology and other subspecialties. As rheumatologists, we have a number of issues that impact our patients, practice and research before Federal agencies or Congress. These include the Arthritis Prevention and Control Act, the SGR issue, evaluation and management codes, among several others. A timely and important question for rheumatologists is: How do we bring our concerns to light when there are so many others competing for attention? The American College of Rheumatology (ACR) does this through both the Government Affairs Committee (GAC) and RheumPAC.

RheumPAC, a committee of the ACR, is the only political action committee for rheumatologists. It accepts donations from American or resident alien members of the ACR, and distributes these funds as contributions to members of Congress. The distribution is not random. The RheumPAC committee has developed a questionnaire to gauge and evaluate the position of the Representative or Senator concerning our issues. The committee then votes whether to donate and how much. There are two important points in this: First, we do not contribute based on party affiliation, but rather on the member's perceived attitudes and philosophy about rheumatic disease issues.

Second, these donations are usually done during a fundraising event. Many of these events only have 15-20 attendees, allowing our representative to gain face time. This is very important since we can personalize our message. Then, we have an open door for future contacts. Thus, our political voice is amplified and we stand out from the crowd.

Please join me in donating to RheumPAC. It is easy to do. Go to the ACR web site and then to the Advocacy tab. RheumPAC is on the lower left.

Edward Herzig, M. D., FACP, FACR is treasurer of RheumPAC, an OAR Board member, and a practicing rheumatologist in suburban Cincinnati.

Who We Are . . .

Gary M. Kammer, M. D. (Willoughby, Ohio), president;

Stephanie J. Ott, M. D. (Lancaster, Ohio), vice-president;

Ed Goldberger, M.D. (Toledo, Ohio), secretary-treasurer.

OAR Board members are:
Ed Herzig, M. D. (Fairfield, Ohio) and
William Treuhaft, M. D. (Toledo, Ohio).

OAR
Ohio Association of Rheumatology

Meetings
We hold regular meetings, usually monthly, that can be easily accessed from your office or home by teleconferencing. We announce these meetings one month in advance in our meeting minutes that are posted on our website, and we remind you with an e-mail announcing the agenda. Lasting about an hour, these meetings discuss works in progress and introduce new business. We welcome your input, so please plan to join the meetings. The teleconference phone number is 1-888-557-8511; pass code is 8455129.

An Open Letter to OAR Membership

By Gary M. Kammer, M. D.

Recently, I received an e-mail from a representative of a pharmaceutical company that manufactures biologic agents informing me of a significant change in Cigna medical coverage policy of biologic agents used for the treatment of rheumatic diseases. Although he did not indicate when this change in policy took place, he urged me to go to the company's website and to review these coverage changes for the biologic agents that rheumatologists prescribe and administer daily to our patients.

What I found were separate Cigna medical coverage policies for each of the nine biologic agents from Actemra to Simponi. I must admit upfront that I rarely go to insurance company websites to peruse their coverage policies, so I was stupefied to learn that Cigna's policies dictate to physicians the order in which specific agents have to be administered in order for beneficiaries to receive coverage. For example, Cigna's medical coverage policy for infliximab states the following:

- Used in combination with methotrexate, for active rheumatoid arthritis (RA in Adults ≥ 18 yr of age) for EITHER of the following indications:

1. History of a beneficial clinical response to infliximab therapy for RA condition

2. Inadequate response, intolerance, or contraindication to at least one disease-modifying anti-rheumatic drugs (DMARDs)(i.e., methotrexate (MTX), azathioprine, gold, hydroxychloroquine, penicillamine, sulfasalazine) AND to TWO self-administered preferred tumor necrosis factor (TNF) antagonists [adalimumab (Humira) and etanercept (Enbrel)].

In other words, Cigna can deny coverage to your patients if you fail to follow their protocol.

You might immediately wonder: How can an insurance company dictate to me how to treat my RA patients? The answer is unsurprisingly simple: because they can; they hold the purse strings.

In David Mandel, M.D.'s Open Letter to OAR Members on page 6, he lays out for you the significance of such a policy as only David can do. I urge you to read and heed his letter. In addition, I recommend you read Michael Schweitz, M. D.'s letters from the Coalition of State Rheumatology Organizations (CSRO) to Cigna's chief medical officer and president regarding their coverage policies. To find these letters, go to our website (www.ohiorheumatology.org), click on Rheumatology News, next click on CSRO, and, once on the CSRO website, look to the right and you will find the links to the two letters.

Check our website regularly for updates on this and other vital advocacy issues. This topic will be a subject of an upcoming President's Blog.

An Open Letter to OAR Membership

Dear Colleagues:

I'm writing to provide an update to our members in the rheumatology community regarding the new 'fail first policy' by Cigna Insurance to first use Humira and Enbrel for patients with inflammatory forms of arthritis prior to using an infusible biologic medication.

There are many important consequences and issues that we need to consider and discuss among ourselves, with our patients and ultimately speak out to Cigna Insurance regarding this.

This intrusive policy usurps the primary physician/patient role to decide which biologic medications are most suitable and appropriate and the timing sequence in which they should be initiated.

This policy also limits equal access of certain biologic medications that may be more medically appropriate for certain types of patients with systemic rheumatic diseases.

We rheumatologists are in the ideal and best position to help guide our patients to make these important medical decisions.

We recognize the many medical co morbid illnesses that face our patients and which of these medications would be best to prescribe.

I have enclosed a letter from the Coalition for Society of Rheumatology Organizations (CSRO) crafted by its leadership to Jeffrey Cane, M.D., M.Ph. the chief medical officer of Cigna as well as Mr. David M. Cordani, president and CEO of Cigna Corporation.

I would invite you to read these letters and strongly encourage you to write your own response to each of these gentlemen.

Currently our Congress passed the wide reaching health care reform legislation in March of 2010.

Within that legislation contains a 'short cut process' for the approval of generic versions of biologic medications (biosimilars).

There are a number of important issues that need to be actively debated and discussed about this legislation.

Concepts such as interchangeability vs. biosimilarity are an important part of the development and manufacturing of these complex molecules and are included in this new legislation. I will be reviewing these in more detail in future newsletters.

We and our patients are fortunate to have these new families of biologic medications available at this time. They are truly 'life changing' for our patients.

We must be vigilant to be able to prescribe these in a safe and responsible way. Please remember that you can communicate with us by email or contacting Michelle Pohl with those patient issues and problems you might be having with Cigna or other insurance carriers. This is an important service that the OAR can offer our membership.

David R. Mandel, M.D.

David Mandel, M. D. is a founding member and emeritus president of OAR, chair of the advocacy committee of OAR, and a practicing rheumatologist in suburban Cleveland.

The Choices of Rheumatology

by Stephanie Ott, M. D.

I will start out by saying hello to all of the OAR members that I have not had the opportunity to meet yet. My name is Stephanie Ott MD and I am the newly elected (and slightly wet behind the ears in this new position) vice-president of OAR. Our OAR president asked me to write an article for this newsletter and I gave this a lot of thought. Where to start and what to choose! There are so very many topics, but in the choosing came the name of this article. In our very existence as rheumatologists we make a myriad of choices just to become physicians, and then navigating our way through the training until we decide to choose our subspecialty as our path in medicine. I wanted to give you a brief taste of who I am and where I practice and then briefly touch on how I chose out of fellowship to work where I do and what I hope to accomplish as vice-president.

First, as we all do, we list where we trained and worked before and this is a good a place to start. So: I did my undergraduate training at OSU; then, I worked in a research lab for two years before moving to New Mexico. I spent eight years running a fetal alcohol research lab for a PI at the School of Medicine (SOM) at the University of New Mexico (UNM) while working on my Master's in Water Resource Administration. After finishing my Master's I went to the UNM SOM, and then stayed to do my internship and residency. I worked as a hospitalist, then returned to OSU for my rheumatology fellowship. Talk about a big circle to get back home!

When my fellowship ended, if you asked me I would have answered that I intended to remain in academia. Life had other plans and more choices ensued. I accepted a position in Lancaster Ohio. For those not sure where Lancaster is, it is about 35 minutes southeast of Columbus and just over an hour from Athens. It is a relatively small town of about 39,000, but we have a very large catchment area and a 233 bed hospital. So, why Lancaster Ohio? In the end, just like many physicians, I moved closer to home to serve the underserved rural individuals I grew up around and who needed a rheumatologist. In my training in UNM, serving the underserved was emphasized and my upbringing, via my parents and family who volunteered frequently and often, showed me the importance of "giving back and helping others". Therefore, after a long internal debate and wading through more choices, I elected to take a position on staff rather than open my own office and that is where part of this article comes from: my choice to not be in private practice but to be on staff with an institution. Partially, my decision stems from really having no interest in burying myself further in debt, but there is more to it than that. By choosing to work for the hospital there are certain benefits; but, of course, there are drawbacks as well and I will try to balance both sides in this discussion. One of the gains from being employed is that I do not need to make the difficult choices about which insurance to accept and how many from each of those patient groups I can see and still keep the doors open. Whichever insurance our hospital takes my office accepts and this removes that hard choice. It also means, though, that I do not negotiate on remuneration for services rendered from office visits, hospital consults, procedures or infusions. I still need to cover all of the bills for my office and meet the hospital's budget that has been created for my office. By not having more input into this process there are times it can be difficult to "please" everyone. However, I can practice medicine without the guilt of needing to turn patients away due to insurance issues. Many of you, I know, frequently struggle with this tough decision, so this is at least one of the major benefits for me. As my lead office staff person tells me often I have a "bleeding heart" and should toughen up, but I am not ready to walk that path if I do not have to. Another of the benefits, and often a drawback as well, is not splitting my time with running a business and practicing medicine. My staff are all hired, trained and managed by the hospital. Great most days, on others it would have been better to have more say in selecting of my staff. The hospital has most of the day to day say and their rules are mine as well; this again is a blessing and a curse as well on any given day. One major drawback to being employed by the hospital is that there is little room to "grow the practice" within my vision and I need to take everything. For example, doing research, adding or changing staff, working through hospital boards, and renegotiating my contract to better reflect my vision of how the practice should be is problematic. If I could give any advice to a fellow or colleague who may be considering signing on with a hospital instead of private practice, I would advise a long piece of paper to list all the pros and cons you can think of. Then, choose wisely and carefully. Overall, although I love what I do and where I am doing it, there are several things I would change. I am always willing to talk about this with someone if you want some advice before making the decision.

Speaking of contracts, I now have one also with the OAR by taking on the position of vice-president. I would like to use this time to improve membership and to reach out to the fellows in Ohio and encourage more participation in OAR from them. I hope to meet most of our members face to face and to help our other colleagues who have not joined yet to choose to "sign on" with our OAR group. I am working on our next meeting for 2011 and hope to see it become the biggest and best yet. I am also hoping to be a part of next year's "Fly In" with the ACR; I had participated in 2009 but regrettably had to sit out in 2010. Advocacy for our profession and our patients cannot be overemphasized in today's health care world. Let's face it, most of our patients, and for that matter our health system in general, have very little idea who or what a Rheumatologist is and why our specialty and our patients hold any importance. Arthritis is generally accepted as

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"just something that happens" and the other diseases that we treat are frequently regarded as "rare" even if they are far from it. I am deeply committed to advocating for my patients and for my specialty and respectfully ask each of you to choose to join me in some way with this. I look forward to serving the OAR members as vice president and I hope to continue after that as well.

In my next article for the OAR Advocate, I will talk about the "joys" of choosing and utilizing an EMR within my practice.

Stephanie Ott, M.D. is vice-president of OAR, co-chair of the 6th annual OAR meeting committee, and a practicing rheumatologist in Lancaster, Ohio.

OAR Mission

From its inception in 2003, OAR has been a non-profit, 501 C3 organization composed of rheumatologists dedicated to the advancement of quality arthritis and musculoskeletal health care for all persons in the State of Ohio.

Our mission is to:

- Advocate and protect patient access to all appropriate treatments for rheumatic diseases,
- Establish and maintain clinical guidelines defining appropriate treatment of arthritis and rheumatic diseases,
- Nurture the interest and development of medical students and trainees in the field of rheumatology,
- Augment and support other organizations involved in arthritis care in order to enhance the quality of rheumatology services for all patients.

Why the Cimzia Imbroglio?

By Gary M. Kammer, M. D.

Originally released in 2008, Cimzia (certolizumab pegol) is the first PEG ylated anti-TNF agent FDA-approved for the treatment of moderately to severely active rheumatoid arthritis (RA) and Crohn's disease. Administered as a subcutaneous injection, this novel biologic agent provides a new and innovative tool in the armamentarium of rheumatologists and gastroenterologists in the treatment of two debilitating chronic diseases. The molecule is a recombinant, humanized monoclonal antibody Fab' fragment that is conjugated to a ~40 kDa polyethylene glycol structure. Manufactured in two forms, it is available as a 200 mg lyophilized powder for reconstitution and a 200 mg/mL single-use prefilled syringe.[1] The manufacturer anticipated that the lyophilized powder would be reconstituted in the physician's office for subcutaneous administration. By contrast, the prefilled syringe is manufactured for patient self-administration or injection in the home by a health care professional or trained non-health care individual.

Unexpectedly, Ohio Medicare carrier Palmetto GBA placed Cimzia (certolizumab pegol) on its Self-Administered Drug (SAD) list in May 2010. According to sources at UCB[2], the pharmaceutical manufacturer of Cimzia (certolizumab pegol), Palmetto GBA's Contractor Medical Directors (CMDs) concluded that the drug was determined to be "usually self-administered" based on Medicare Benefit Policy Manual. During my recent interview with Robert Kamps, M. D., Palmetto GBA's Ohio CMD, he confirmed that a group of the CMDs had initially voted to categorize and subsequently to maintain Cimzia (certolizumab pegol) on the SAD list. [3]

Pausing momentarily, it is both insightful and instructive to cite the specific regulations in chapter 15 of the Medicare Benefit Policy Manual pertaining to this issue. First, the term 'administered' in this circumstance refers to an injectable agent. Second, "for the purposes of applying this exclusion, the term 'usually' means more than 50 percent of the time for all Medicare beneficiaries who use the drug. Therefore, if a drug is self-administered by more than 50 percent of Medicare beneficiaries, the drug is excluded from coverage and the contractor may not make any Medicare payment for it. In arriving at a single determination as to whether a drug is usually self-administered, contractors should make a separate determination for each indication for a drug as to whether that drug is usually self-administered.

After determining whether a drug is usually self-administered for each indication, contractors should determine the relative contribution of each indication to total use of the drug (i.e., weighted average) in order to make an overall determination as to whether the drug is usually self-administered. For example, if a drug has three indications, is not self-administered for the first indication, but is self-administered for the second and third indications, and the first indication makes up 40 percent of total usage, the second indication makes up 30 percent of total usage, and the third indication makes up 30 percent of total usage, then the drug would be considered usually self-administered." [4]

Because placement of Cimzia (certolizumab pegol) on Palmetto GBA's SAD list means that the agent cannot be reimbursed by Medicare B when it is administered by a health care professional in the physician's office, both physicians and UCB concluded that physician determination of optimal patient care would necessarily be hindered. What followed was a series of communications between UCB and Palmetto CMDs resulting in an agreement to survey prescribing rheumatologists and gastroenterologists to "better understand the patterns of use for Cimzia in the Medicare population" [2]. To this end, UCB contracted with C1 Consulting during the summer of 2010 to survey physicians in Palmetto GBA's service jurisdiction of California, Hawaii, Ohio, Nevada, South Carolina and West Virginia.

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Why the Cimzia Imbroglio?
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In order to achieve 95% participation of prescribing physicians in these six states, two back-to-back surveys were performed. Of the 687 physicians surveyed, 196 (28.5%) met eligibility criteria. Of the 1,080 Medicare patients taking Cimzia (certolizumab pegol), 686 (64%) have the agent administered by a health care professional; 142 (13%) have the agent administered by a spouse or other caregiver; 49 (5%) have the agent administered by a home health nurse; and, 203 (18%) self-administered the agent. Considering Ohio patients with RA specifically, 89% had Cimzia (certolizumab pegol) administered by others and just 11% self-administered.[5] These data, made public in October 2010, clearly demonstrated that only a small minority of RA patients self-administer Cimzia (certolizumab pegol).

As this process was unfolding during the summer of 2010, the Board of OAR discussed the issue by a teleconference call. In consequence of our discussion, I wrote to Dr. Kamps to inform him that OAR favored exclusion of Cimzia (certolizumab pegol) from the SAD list. In part I opined: "Since the first anti-TNF biologic agent was released more than a decade ago, we have gained significant knowledge and experience with these agents and understand their benefits and risks. In particular, we understand their mechanism of action relative to the immune system, and are always vigilant for adverse effects such as infections. One highly successful way in which we have limited such adverse reactions is by performing a history and examination prior to each in-office administration of these agents." Our practice's anecdotal experience in the past decade has repeatedly shown us that a detailed history and examination have remarkably limited our infection rate. To date, however, I am unaware of any published data addressing this observation. Finally, I pointed out that "the Board believes that patients and physicians should have the choice of determining where the drug is administered."[6]

These surveys were designed and carried out by the consulting firm, and appeared to be performed incisively and without treacle. Notwithstanding, the studies have some inherent limitations. First, the study was confined to the Palmetto GBA service area, limiting the analysis to 1,080 Medicare beneficiaries. Extending the study to several different contractor service jurisdictions would obviously have enlarged the study population and allowed the consulting firm to have compared data between these areas. Second, no statistical analyses were performed to decisively establish significant differences in the data sets. However, it could be argued that, based on the criteria cited in the Medicare Benefit Policy Manual above, the data are sufficient to prove that within the Palmetto GBA service area that >50% of RA patients do not self-administer Cimzia (certolizumab pegol). Third, the survey did not parse which preparation of drug was administered under the conditions analyzed. Based on the cited regulations, this is a serious flaw because it does not allow the consulting firm to calculate an appropriate weighted average for each preparation of Cimzia (certolizumab pegol). Finally, a concern could be raised because the studies were funded by the pharmaceutical manufacturer and could, therefore, open the door to unintended bias of the data. However, the obvious response to this objection is: What other entity would fund such a study other than the manufacturer? Surely such an objection is rendered hollow by the recognition that the FDA often requests manufacturers to perform various additional analyses of their products prior to its rigorous assessments of the clinical data for final approval of an agent.

So, considering the strength of the data UCB provided, why did Palmetto GBA's CMDs conclude that Cimzia (certolizumab pegol) should remain on the SAD list? One objection was that the data did not derive from "all Medicare beneficiaries who use the drug". According to one CMD: "The entire Medicare population must be taken into account, not simply a sub-set of physicians responding to a survey in a contractor's state…." Again, one might vociferously respond by posing the question: How can Palmetto GBA reasonably expect the manufacturer to survey the entire U. S. Medicare population being treated with Cimzia (certolizumab pegol)? There is neither a precedent nor expectation for such an approach. Indeed, in both the basic and clinical sciences, conclusions are based on representative populations in rigorously constructed experiments in which appropriate statistical testing determines the validity of the results. So, perhaps the expectation should be scaled down to just two or three contractor service areas. In that way, "all Medicare beneficiaries" in those jurisdictions could be studied and, therefore, the requirement amply and reasonably satisfied.

Another objection, as alluded to above, is that the consulting firm did not parse the preparations used and, therefore, could not provide the appropriate weighted average for each. This remains a limitation of the study design.

In the end, we may never understand precisely how the Palmetto GBA CMDs made their final decision to maintain Cimzia (certolizumab pegol) on the SAD list in response to the survey results. And, so, this presents a Cimzia imbroglio. What we do know, however, is that Sections 50.2 I and J of chapter 15 in the Medicare Benefit Policy Manual leaves the door open to beneficiary appeals. "If a beneficiary's claim for a particular drug is denied because the drug is subject to the 'self-administered drug' exclusion, the beneficiary may appeal the denial. Because it is a 'benefit category' denial and not a denial based on medical necessity, an Advance Beneficiary Notice (ABN) is not required. A 'benefit category' denial (i.e., a denial based on the fact that there is no benefit category under which the drug may be covered) does not trigger the financial liability protection provisions of Limitation On Liability (under §1879 of the Act). Therefore, physicians or providers may charge the beneficiary for an excluded drug."[4] However, considering the expense of biologic agents, how many beneficiaries can afford to pay for these agents out of pocket?

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How OAR Works

We accomplish our mission by developing and implementing achievable goals. In 2003, OAR recognized that the administration of office-based therapies by all specialists was being targeted for reform by Congress in a bill entitled HR 1622 Quality Cancer Care Preservation Act. This bill contained language regarding reimbursement policies for the use of biological agents. In response to this Act and the recognition that burdensome future regulations would follow, OAR authored a pivotal position paper recommending, among several items, the renaming of the bill to include non-oncologists who administer biologic agents as well as recommendations on reimbursements. OAR stated: "The administration of biologics, as well as the follow-up and maintenance care, is complicated in a variety of conditions such as Rheumatoid Arthritis and Crohn's disease. There should be equal, fair, and comprehensive reimbursement at a higher level for patients receiving biologic therapy for all specialties that use biologics."

In addition to position papers, we frequently correspond with our elected officials in the Ohio legislature and in Congress. Shortly after the Ohio Revised Code Title LVII Chapter 5751 Commercial Activity Tax (CAT) was implemented in 2005, OAR learned that this bill provides an exclusion for the gross receipts attributable to the administration of infusible chemo-therapeutic, biologic and therapeutic agents and supporting drugs for patients with cancer. OAR recognized that this law carved out an unfair exclusion for oncologists while including all other physicians who administer biologic agents in their offices, including rheumatologists. In an effort to level the playing field, former OAR president David R. Mandel, M. D. (Chardon, OH) wrote to tax commissioner William Wilkins in February 2006 advising him of this inequity in the law and asking for redress. Dr. Mandel wrote: "The Ohio Association of Rheumatology believes it is imperative that the Ohio Department of Taxation amend the CAT Law immediately to correct this inequity. Specifically, we recommend that the Ohio Revised Code 5751.01 (S) (2) (v) be amended to drop the last two words "with cancer" from this paragraph. This would allow the exclusion of gross receipts to extend to any physician who administers chemotherapeutic, biologics or therapeutic medications in his office." Although this thorny issue has not yet been resolved by the Legislature, OAR continues to meet with Ohio legislators and to communicate our concern.

These are among many examples of the work OAR continues to pursue on behalf of Ohio rheumatologists.

Why the Cimzia Imbroglio?
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Gary M. Kammer, M. D. is the current president of OAR, editor of the OAR Advocate, and a practicing rheumatologist in suburban Cleveland.

[1] Full prescribing information for Cimzia (certolizumab pegol), revised 10/2010, UCB Inc., Smyrna, GA.
[2] UCB Inc., 2010-2011.
[3] Robert Kamps, M. D., verbal communication, 1/18/2011.
[4] Medicare Benefit Policy Manual, chapter 15, section 50.2. http://www.cms.gov/manuals/Downloads/bp102c15.pdf. Accessed 1/22/11.
[5] Summary of Survey Findings in Palmetto's Service Jurisdiction and Overview of Medicare Coverage Determination Process. 10/7/2010. Performed by C1 Consulting and funded by UCB Inc. Obtained from (2).
[6] Gary M. Kammer, M. D. e-mail communication with Robert Kamps, M. D., 7/1/2011. Archived by author.

OAR Membership Form

Those interested in OAR membership, please complete the form below and return with your $50 annual membership fee.

Name: _____

Title: _____ MD/DO: _____

Address: _____

City/State: _____

Zip: _____ Phone: _____

Email: _____

Return your OAR membership form to:

Ohio Association of Rheumatology
36100 Euclid Avenue #170
Willoughby, OH 44094

If you have any questions regarding the Ohio Association of Rheumatology, please contact Gary Kammer, M.D. at gmkammer@hotmail.com or Michelle Pohl at michelle.pohl@lhs.net.

A Quarter Century of Rheumatology Wisdom

By Sanford Wolfe, D.O.

I have been in private practice in Dayton, Ohio for 24 years and I have certainly seen lots of changes over this time. When I initially began to practice, I had thought about whether to purchase an x-ray machine or try to establish an in-office lab as an adjunct service. The choice I made was for the x-ray machine and that turned out to be the best choice and has been useful to me over the years. We have been able to do films in-house for clinical trials and for instant feedback on practice patients during their initial and follow-up exams.

In-office labs for small practices basically quickly went away within five years of my starting practice due to the rising cost of maintaining the equipment, increased and expensive regulatory requirements like CLIA, and significantly sinking reimbursement for the lab tests. Unfortunately, as time has passed, reimbursements for the x-rays has diminished considerably and the cost of the new equipment, like digital systems, makes medical imaging in-office virtually impossible to do and be able to make a profit of some sort, for a new small practice. The newer imaging modalities like in-office extremity MRI is a fascinating technology, but the difficulty with prior authorization, with some of the insurance carriers and refusal by others to pay at all, plus the huge costs, makes it fairly unattractive. I do think musculoskeletal ultrasound may be a sound future for us and may be a good idea for a new practice. The learning curve is somewhat steep, but the applications are potentially numerous and the cost is not gigantic. I don't have this equipment and I'm not sure I'm going to go there, but it is potentially useful even for us older guys. (You probably can teach an old dog a new trick.)

I also wanted to discuss another area of interest that Dr. Mandel discussed at the last OAR meeting: the topic of rheumatology metrics (measuring responses and outcomes). I think that developing some type of user friendly system to measure progress and response in RA is important, and I think will gather importance as insurers may demand proof that our expensive therapies are working. I have developed my own template for RA and am working on templates for other conditions we see and would be happy to send anyone a copy if they are interested. We are submitting claims for RA for the Medicare PQRI (finally got around to it) and the template I use pretty much provides all the documentation needed for getting this bonus some day.

Also, an area of daily concern and irritation in my practice is the flood of Prior Authorizations we have. The biggest problem is with Celebrex and PPI's, and seems sometimes that Celebrex is a harder to get Prior Authorized than a biologic. We have even had trouble with Voltaren Gel and the most ridiculous example is Methotrexate Prior Authorization. I have one person who concentrates on Prior Authorization and it does take a lot of her time and is often a waste of our time, but I would advise pursuing these especially if you think its right for your patients. I do not want a specialty pharmacy or insurer to get away with these denials that are often not based on correct medical decision making, but simply on cost. I will sometimes get on the telephone to argue my case (not always politely) and even though it is time consuming for the physician I think it's important for the third parties to sometimes hear it directly from us.

Finally, I wanted to discuss billing. I would advise our younger members starting out to try and do their own internal billing if they can afford a good coding and billing specialist as opposed to a billing service because the billing service may not fight for your claims like you would, especially high ticket items such as infusible drugs. There is too much at stake to not get paid on a timely basis. We still have problems with some insurers over these issues and I doubt we could have had a satisfactory response or resolution if we didn't do the billing ourselves.

I'm sure there are lots of other issues and concerns to our members and these are just a few of the things we deal with almost daily.

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