

## Defining the Great Debate

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Specialty pharmaceuticals represent a growing challenge to managed care pharmacy. The policies dictating use and reimbursement for these innovative and expensive biologic therapies are under increased scrutiny. Where should these policies originate? Who decides which patients get which therapies? In this supplement to *The American Journal of Managed Care*, 2 experts on pharmaceutical use in managed care settings will debate the question that lies at the heart of myriad controversies in managed care pharmacy settings today: Should specialty pharmaceuticals be managed with consensus guidelines or left largely to specialist discretion?

This summary of the debate between John Golenski, EdD, and Sean Sullivan, PhD, was based on a moderated session held at the annual meeting of the Academy of Managed Care Pharmacy (AMCP) in San Francisco on April 2, 2004. Attendees at this lively AMCP session also participated by asking questions of the debaters and by responding to quick-polling questions posed by the moderator.

Similar debates about specialty pharmaceuticals are occurring every day within hundreds of health plans and hospitals across the country. In these institutional settings, however, the debate's agenda is limited and time is short. Policy choices are driven more by the specific drug than by a guiding set of principles. Naturally, the question of guidelines versus physician discretion informs and drives these local drug-specific conversations, but this central question is usually never given a forum of its own. The objective of this program was to provide such an open forum for this common but often subliminal debate. By outlining the advantages and disadvantages of consensus guidelines in various specialty pharmaceutical situations, this program was

designed to provide managed care professionals with a more self-aware approach to their future discussions of prescribing and reimbursement policies for the growing universe of specialty drugs.

In this introductory article, the debate will be framed with a review of the specialty pharmaceutical marketplace and a sampling of recent opinions from medical and pharmacy directors in managed care organizations (MCOs). Also, examples of current specialty pharmacy policies from major MCOs for biologics and injectables will be described to illustrate the current wide spectrum of policies used to manage these innovative agents. The role of treatment guidelines and product labeling in shaping these MCO policies is also discussed.

### **Specialty Pharmaceuticals: Not So Special Anymore**

Many of the innovative biologics and injectable agents approved over the past decades have provided life-saving or disease-modifying benefits with relatively benign side effect profiles. Over 250 million people have already benefited from medicines and vaccines developed with biotechnology.<sup>1</sup> Although expensive, the biologics approved in the 1980s and 1990s mainly targeted comparatively rare disease states, such as hemophilia, hereditary emphysema, autoimmune disorders, or Gaucher's disease (Table 1). In managed care settings, this low incidence of the target disease within the covered population essentially negated the high per-patient treatment costs. Thus, specialty pharmaceuticals such as imiglucerase for injection for Gaucher's disease and clotting factor for hemophilia entered into the mainstream of clinical use with less-than-expected controversy. Guidance on proper clinical use was typically provided by managed care groups' own physician specialists, who in some cases

## SUMMARY

**Table 1.** Examples of Specialty Pharmaceuticals

Product	Chemical Name or Action	Company	Primary Use	Mode of Administration
Amevive	Alefacept	Biogen Idec	Psoriasis	IV infusion or IM injection
Aranesp	Darbepoetin alfa	Amgen	Anemia	IV infusion or SC injection
Avonex	Interferon $\beta$ -1a	Biogen Idec	Multiple sclerosis	IM injection
Betaseron	Interferon $\beta$ -1b	Berlex	Multiple sclerosis	SC injection
Copaxone	Glatiramer acetate	Teva Neuroscience	Multiple sclerosis	SC injection
Enbrel	Etanercept	Amgen	Rheumatoid arthritis	SC injection
Forteo	Teriparatide (rDNA origin)	Eli Lilly	Osteoporosis	SC injection
Gamimune N	Immune globulin intravenous	Bayer	Immunodeficiency	IV infusion
Humira	Adalimumab	Abbott	Rheumatoid arthritis	SC injection
Leukine	Sargramostim	Berlex	Cancer	IV infusion or SC injection
Prolastin	$\alpha_1$ -proteinase inhibitor	Bayer	Hereditary emphysema	IV infusion
Raptiva	Efalizumab	Genentech	Psoriasis	SC injection
Remicade	Infliximab	Centocor	Rheumatoid arthritis, Crohn's disease	IV infusion
Synagis	Palivizumab	Medimmune	Respiratory syncytial virus	IM injection
Xolair	Omalizumab	Genentech/Novartis	Allergic asthma	SC injection

IV indicates intravenous; IM, intramuscular; SC, subcutaneous; rDNA, ribosomal deoxyribonucleic acid.

used selective billing codes to profit from the sale of an injectable administered in their office.<sup>2</sup> However, payers generally accepted the costs without much scrutiny.

This honeymoon phase for specialty pharmaceuticals is over. Already, the accelerating pace of injectable introductions over the past 5 years has forced many commercial payers to exert greater control over specialty product-driven expenses. And there are more to come. Although the number of new molecular entities in development has decreased in recent years (from 50 applications in 1995 to 23 in 2002), this trend does not apply to biologics.<sup>3</sup> In 2002, 178 biotechnology medicines were in clinical development for cancer alone.<sup>1</sup>

But it is not only the sheer numbers of high-tech biologic medications that alarms payers. It is also the shifting targets of these new agents. Increasingly, specialty pharmaceuticals treat very common conditions

rather than rare genetic disorders. Some of the newest products, for example, are intended for patients with rheumatoid arthritis, psoriasis, or asthma—conditions with US prevalence estimates as high as 2 million, 5 million, and 15 million, respectively (Table 2). Compared with the prevalence for Gaucher's disease, hemophilia, and other classic rare disorders, these high numbers command attention, especially in the context of discussions about expensive life-long therapy.

Further, in contrast to the first generation of agents, many of these new or soon-to-be-marketed products target disorders that usually do not impose any near-term mortality. Examples of such conditions are psoriasis and immunoglobulin E (IgE)-mediated allergic disorders. Payers are especially concerned about reimbursing expensive therapies that neither extend survival nor modify disease progression.

Another new worry with the current crop of specialty pharmaceuticals is that many lack efficacy as monotherapy. In many cases, new specialty pharmaceuticals are no longer meant to replace another treatment or to create a completely new treatment where once there was none, but, in fact, to be combined with another expensive agent. This paradigm of combination therapy thrives in oncology research in particular.

The bottom line is increased costs. The average cost of a specialty pharmaceutical is \$71 000 per year.<sup>4</sup> The size of the specialty pharmaceutical market overall was estimated by Intercontinental Marketing Services to be \$35 billion in 2002, with a predicted growth of 20% per year. In terms of injectable medications alone, the US market is expected to reach \$26 billion by 2006.<sup>5</sup> Obviously, even if a drug costs only one tenth of imiglucerase for injection (\$200 000-\$250 000/year), its total cost to an MCO will be much greater if the target patient population is 100 or 1000 times the size of the Gaucher's disease population. This is why the costs for pegylated interferon for hepatitis C, the many biologics for multiple sclerosis (MS), and etanercept for rheumatoid arthritis—although all cost about one tenth of imiglucerase injections—are bright on the radar screens of MCOs. The prospect of combining expensive agents to treat a single disease—for example, bevacizumab plus cetuximab to treat colon cancer—heightens these concerns over increasing costs. And finally, the long-standing practice of physicians receiving excessive reimbursement for in-office administration of injectables has also come under increased scrutiny as the public and MCOs are now pressuring physician groups to consider alternative management policies for injectables.<sup>2</sup>

### How MCOs Are Responding to Specialty Pharmaceuticals

One response to the high costs of medical injectables has been implementation of specialty pharmacy networks.<sup>6,7</sup> The market for specialty pharmacy providers is highly dynamic, with a range of plans for specific conditions and for different services and systems. Options today include not only large

**Table 2.** Prevalence of Selected Conditions Now Treated With Specialty Pharmaceuticals

Target Diseases	US Prevalence
Gaucher's disease	2500
Hemophilia	20 000
Crohn's disease	380 000-480 000
Multiple sclerosis	400 000
Rheumatoid arthritis	2.1 million
Hepatitis C infection	3.9 million
Psoriasis	5.8 million-7.5 million
Asthma	14.9 million

Sources: National Gaucher Foundation (Gaucher's disease); National Heart, Lung, and Blood Institute (hemophilia); Calkins BM et al. *Epidemiol Rev*. 1986;8:60-91 (Crohn's disease); National Multiple Sclerosis Society (multiple sclerosis); National Institute of Arthritis and Musculoskeletal and Skin Diseases (rheumatoid arthritis and psoriasis); *MMWR*. 1998;47(RR-19):p1 (hepatitis).

pharmacy benefit management organizations, such as Medco Health Solutions and Express Scripts, but disease management companies focusing on specific complex conditions (eg, CuraScript, Accredo), niche pharmacy services groups devoted to 1 category (eg, ivpCare, Nova Factor), and home care companies (eg, Caremark). Such specialty pharmacy groups help reduce costs through a combination of greater purchasing power, just-in-time delivery, and strong patient oversight. The Zitter Group's Managed Care Injectables Index, a semi-annual survey of medical and pharmacy directors from more than 100 large managed care plans, shows that about two thirds (64%) of surveyed organizations currently use a specialty pharmacy provider or vendor to manage some or all of their injectables, biologics, or oncology products.<sup>8</sup> The survey also shows that specialty pharmacy vendors have reduced the acquisition costs to commercial plans to a level about 13% to 18% below the average wholesale price—a real savings of as much as 30% if the reimbursement environment for specialists is considered.<sup>8</sup>

Patient self-administration of injectables has also been fostered by MCOs as a method

to reduce office visit costs, limit physician billing for injectables, and improve patient convenience. Although insulin and triptans are the classic self-injected agents, the MS agents, low-molecular-weight heparins, and pegylated interferons are examples of newer agents now commonly being self-administered. The main criteria used by pharmacy or medical directors to determine whether a drug can be self-administered are subcutaneous administration (95%), presence of a trained caregiver in the house (66%), and the availability of a support network for the patient (54%).<sup>8</sup>

Two other MCO responses to specialty pharmaceuticals involve benefit design and copayment structures. First, payers are increasingly shifting injectable and biologic products from under the medical or mixed benefit umbrella into the pure pharmacy benefit category. Although only 10% of specialty products are currently administered via the pharmacy benefit, medical and pharmacy directors say that 24% of these products will be handled this way 12 to 18 months from now.<sup>8</sup> Second, most MCOs today are also collecting copayments for injectable or biologic products. In 62% of plans, the patient cost sharing includes tiered copayments—typically set at \$10, \$20, and \$40. Some plans have even set a fourth tier for specialty injectables at \$75.<sup>9</sup> Of the plans not currently using tiered copays for injectables and biologics, 63% say they will be using them 12 to 18 months from now.<sup>8</sup>

These evolving strategies to deal with specialty pharmaceuticals are indeed reshaping the patterns of use of biologic agents within MCOs. Coverage alone no longer determines access and uptake. Instead, usage is driven by specialty pharmacies, by coinsurance and copays, and by policies on self-administration. Another variable defining use of specialty agents is the set of “use rules” adopted by each MCO for each agent. These rules determine, for example, whether prior approval is required for physicians or specialists, how closely the approved uses and dosing match the product labeling, and whether prior failure with another class or agent is required. This collection of rules can be founded on treatment

guidelines, specialist input, product labeling, or published peer-reviewed studies. The advisability and practicality of using guidelines for specialty pharmaceuticals is the subject of this supplement’s debate. Definitions, background, and samples of treatment guidelines are provided here to introduce the debate.

### **Treatment Guidelines and Specialty Pharmaceuticals: Opportunities and Challenges**

Treatment guidelines are recommendations for care based on the best available evidence and other relevant knowledge. Especially in the area of specialty pharmaceuticals, guidelines often cover diagnosis and patient selection as well as treatment. They usually specify what should be done; they may also spell out what should not be done. The purpose of guidelines is to reduce inappropriate care, increase appropriate care, reduce variation, and make better use of healthcare resources.

This working definition of guidelines reflects the firm belief of payers that for a given patient with a given set of characteristics, there is a best treatment strategy. In an ideal world, of course, all medical practice would be evidence-driven as spelled out in guidelines. This deep-seated faith in a codified approach to the delivery of medical care is revealed in the results of our quick poll of AMCP attendees before the debate (**Table 3**). As shown, not surprisingly, in these responses, most attendees say they want more guidelines and less physician preference.

But is that the end of the debate? Clearly, the gap between the ideal of evidence-driven medicine and the reality of current guideline use is wide. The barriers to universal use of treatment guidelines, for specialty or non-specialty drugs, include the following.

**Insufficient Evidence.** For each therapy or condition, the quantity and the quality of the evidence base will vary. In some cases, especially with newer agents with smaller target populations, the evidence base has not yet accrued to the point where expert panels can reach consensus on best use. In other cases, evidence from several solid

**Table 3.** Snapshot of Opinions on Guidelines\*

	Strongly Disagree 1	Disagree 2	Neutral/ No Opinion 3	Agree 4	Strongly Agree 5
My organization is more likely to use adherence to treatment guidelines as a basis for reimbursement for injectables and biologics versus traditional small molecule therapies.	14%	12%	5%	51%	19%
My organization is more likely to use adherence to treatment guidelines as a basis for specialty pharmaceutical reimbursement in competitive classes than in noncompetitive classes.	14%	12%	5%	51%	19%
I believe that an MCO or PBM is better off using credible treatment guidelines as a basis for specialty pharmaceutical reimbursement than it is relying primarily on specialist discretion.	9%	0%	6%	40%	45%
My organization does not consider existing treatment guidelines when determining reimbursement policy for biologic and injectable therapies.	48%	40%	2%	10%	0%
I am familiar with credible provider treatment guidelines for most of the major classes of specialty pharmaceuticals.	7%	27%	20%	40%	7%

\*Based on an instant poll of attendees at "The Great Debate" satellite symposium held at AMCP Annual Meeting, April 2, 2004, San Francisco (n = 65, self-selected participants in audience). AMCP indicates Academy of Managed Care Pharmacy; MCO, managed care organization; PBM, pharmacy benefit management.

studies may be available, but inconsistent. Thus, there is always room for clinical interpretation and judgment.

**Credibility Issues.** Because human judgment is inevitable in their development, guidelines will never be bias-free. The perceived credibility of individual guidelines often determines the level of their acceptance by MCOs. For example, guidelines issued by specialty societies, if followed, rarely would reduce income for that group. Similarly, consensus guidelines issued under the sponsorship of a drug or device manufacturer might be received with some natural skepticism by MCOs.

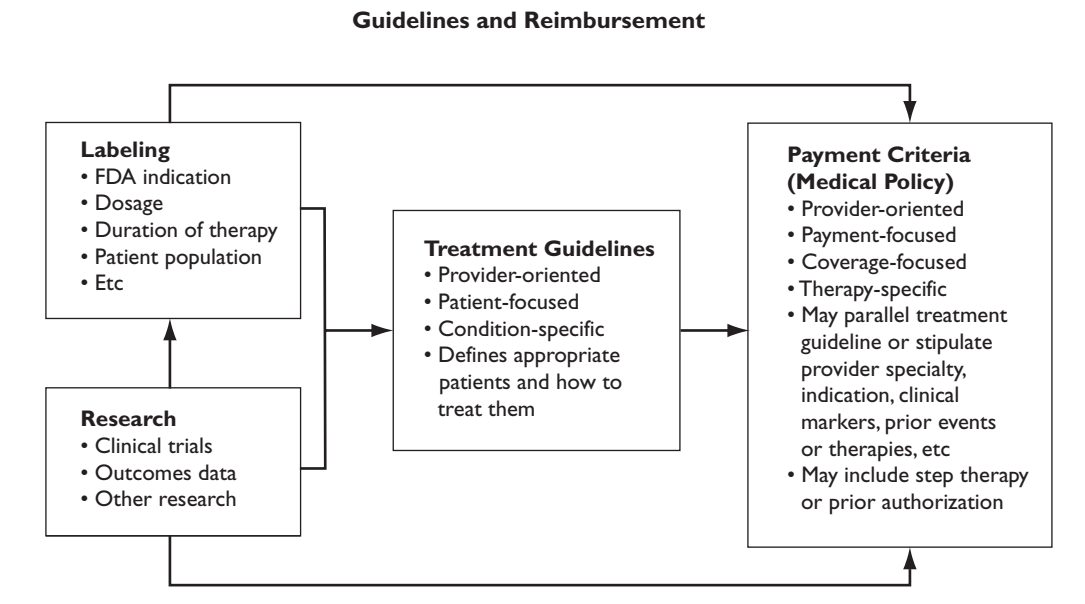
**Difficulty Keeping Up to Date.** The logistics of assembling a team of experts to review the current evidence base and write guidelines are considerable. By the time the detailed guidelines have been drafted, reviewed, edited, and published, they are all too often out of date. This is acknowledged

as a major flaw of guidelines. Innovations to speed up guideline development, such as mail-in expert updates, have been tested,<sup>10</sup> but the problem remains.

**Difficulty Implementing.** Even if the guidelines are rigorous, credible, and current, implementation among providers always remains a roadblock. To overcome the inherent challenges in changing physician behavior, strategies such as tying incentives to adherence or denial of reimbursement for nonadherence have been employed.

In fact, the translation of treatment guidelines into specific medical policies and reimbursement criteria is one of the most delicate and highly charged tasks of any MCO. Although treatment guidelines are typically patient-focused and condition-specific, the medical policies based on these guidelines are necessarily provider-oriented and therapy-specific (Figure). This difference in focus is important to remember when considering the guidelines

**Figure.** Evidence...to Guidelines...to Payment Criteria



The research evidence base and product labeling typically inform the payment criteria and therapy-specific rules established by most managed care organizations. As depicted here, the core evidence can also be interpreted in treatment guidelines that provide an interim step on the path to medical policy. Note that the perspectives of the treatment guidelines may differ from those of the payment criteria. FDA indicates US Food and Drug Administration.

adopted by various MCOs for specific conditions. It means, for example, that even if 2 different MCOs accept the same set of published guidelines for a given condition, they may translate these guidelines into widely varying payment criteria for a specific treatment.

**A Sampling of Current Medical Policies for Specialty Pharmaceuticals**

Given the generally immature evidence base behind most biologics, it is not surprising that most MCO policies are consistent with product labeling. Our recent survey of 22 MCO medical policies showed that about 50% to 70% of these policies adhered very closely to the approved label. In some cases, the MCO policy was more restrictive than labeling (eg, including more quantifiable definitions for package insert phrases like “if not well controlled on current therapy”). Less often, the policies were less restrictive than labeling, such as in allowing use in patients above or below a certain age. Off-label uses of biologics can significantly

increase pharmacy costs. However, off-label use of drugs is also a widespread practice, especially in therapeutic areas where clinical testing is difficult or where the treatments are evolving rapidly (eg, anticancer therapy<sup>11</sup> or pediatric diseases).<sup>12</sup> At least half of all cancer patients<sup>13</sup> and many seriously ill children and others lacking treatment alternatives are prescribed drugs off label, and government agencies such as the US Food and Drug Administration and Centers for Medicare and Medicaid Services as well as insurers have issued policies that acknowledge the need and set guidelines for such prescribing in such situations.

Overall, however, current medical policies on the use of specialty pharmaceuticals tend to track the labeling very closely. In our quick poll at this AMCP session, 33% of attendees indicated that the product labeling was the most important factor in their organization’s payment criteria for specialty pharmaceuticals. Response rates to the other potential answers were 22% for published peer-reviewed studies (whether or not

**Table 4.** How Consensus Guidelines Can Inform Payment Criteria

From Treatment Guidelines to Payment Criteria			
Consensus Panel Treatment Considerations	Blue Cross/Blue Shield North Carolina	Aetna	Paramount Health Care (ProMedica)
Moderate-to-severe persistent asthma	Moderate-to-severe persistent asthma	Moderate-to-severe persistent asthma	Moderate to severe persistent asthma
≥12 years old	≥12 years old	≥12 years old	≥6 years old
Reversible disease	IgE level 30-700 IU/mL	Positive test for allergic sensitivity	Positive test for allergic sensitivity
IgE level ≥30 IU/mL	Positive test for allergic sensitivity	Inadequate control despite ≥3 months of high-dose ICS:	Inadequate control despite ≥3 months of high-dose ICS:
Positive test for allergic sensitivity	Inadequate control despite ≥3 months of high-dose ICS or oral steroids	<ul style="list-style-type: none"> <li>• Daily symptoms affecting activity and sleep and:                             <ul style="list-style-type: none"> <li>—Daily use of rescue med</li> <li>—PEF variation &gt;30%</li> <li>—PEF &lt;80% of best, or</li> <li>—Multiple ED visits for asthma over 12 months</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• Hospitalization</li> <li>• Oral/parenteral CS needed</li> <li>• 4 times daily use of rescue meds, or</li> <li>• Dx precluding steroid use</li> <li>• Pulmonologist or allergist prescribes</li> </ul>
Inadequate control despite ≥3 months of high-dose ICS plus LABA or LT:	Pulmonologist or allergist prescribes		
<ul style="list-style-type: none"> <li>• Emergency room/hospital/UC visits or</li> <li>• Excessive use of rescue med or OS or</li> <li>• ADL impairment</li> </ul>			
Systemic CS or high-dose ICS required for control			
Nonadherence			

Note how these examples of omalizumab payment criteria from 3 managed care organizations are similar to the Consensus Treatment Guidelines as published by Rosenwasser LJ, Nash DB. *Pharmacy & Therapeutics*. 2003;28:400-414 ([www.ptcommunity.com/ptjournal](http://www.ptcommunity.com/ptjournal)). IgE indicates immunoglobulin E; ICS, inhaled corticosteroids; LABA, long-acting β-agonists; LT, leukotriene inhibitors; UC, usual care; OS, oral steroids; ADL, activities of daily living; CS, corticosteroids; PEF, peak expiratory flow; ED, emergency department; Dx, dexamethasone.

within labeling), 13% for specialty physician input, 24% for national provider treatment guidelines, and 8% other.

To illustrate the range of issues related to medical policies for specialty pharmaceuticals, we reviewed specific examples of published MCO policies in the categories of rheumatoid arthritis, allergic asthma, MS, and psoriasis. (Please note that MCO policies may have changed since the time of this analysis.)

**Rheumatoid Arthritis and Etanercept.** MCOs have had years to develop policies for the use of etanercept since this was the first tumor necrosis factor-α inhibitor introduced for rheumatoid arthritis. Our review showed

that Aetna offers detailed and surprisingly rigid criteria (eg, specific numbers of swollen joints, duration of morning stiffness) defining the markers and conditions for etanercept reimbursement. At the opposite end of the spectrum, AmeriHealth policy simply states that the patient must have either rheumatoid arthritis or psoriatic arthritis and be treated by an appropriate specialist (ie, rheumatologist or dermatologist). This is a classic specialist discretion policy. Between these 2 extremes is Wellmark, which generally endorses etanercept use based on physician discretion but also tightens certain criteria by saying, for example, that patients with juvenile arthritis first need to have had an inadequate response to

disease-modifying antirheumatic drugs. This range of prescribing rules for a single drug illustrates how varying interpretations of the same literature and the same package insert can produce widely divergent reimbursement policies.

**Allergic Asthma and Omalizumab.** The use of omalizumab in allergic asthma offers an interesting case study for several reasons. First, it is a recently introduced (mid-2003) specialty pharmaceutical. Health systems are still refining their medical prescribing policies for this IgE blocker. Second, although the core set of National Institutes of Health (NIH) guidelines for asthma are among the most exhaustively researched and well accepted of any therapeutic area, these national guidelines have not been revised since the introduction of omalizumab and thus do not mention the product. And third, anticipating this gap in the NIH guidelines, an expert panel of asthma experts, researchers, and managed care advisors was convened under the sponsorship of the manufacturer to develop a consensus on where omalizumab fits within the existing guideline framework. The consensus guidelines on omalizumab, which were published last year in a peer-reviewed journal around the time the product was approved,<sup>14</sup> basically defined the criteria that establish when this agent should be used in suboptimally controlled patients with moderate-to-severe asthma. Specific criteria included, for example, patients 12 years of age or older, with a positive test for allergic sensitivity, and with IgE levels >30 IU/mL or higher. Despite the natural cynicism that should attend any recommendations coming from a panel convened and funded by industry,<sup>15</sup> these consensus guidelines have apparently been perceived by MCOs as credible and useful. As shown in **Table 4**, many of the consensus panel recommendations are currently reflected in the actual published usage policies from Blue Cross/Blue Shield (BCBS) North Carolina, Aetna, and Paramount (part of ProMedica). Although there are some variations in policies (eg, the need for IgE testing, the controllability of the disease with high-dose inhaled or systemic corticosteroids), the

major usage policies of these MCOs mirror those recommended by the consensus group. The degree to which these MCO policies were shaped by the consensus guidelines versus the evidence itself is unclear, although the BCBS groups specifically cites the *Pharmacy and Therapeutics* article in its published policy. This side-by-side comparison of MCO omalizumab policies shows how a manufacturer-sponsored treatment-specific consensus guideline can—if developed properly—help fill the temporary gap in the evidence/guideline base that occurs soon after the introduction of a specialty pharmaceutical.

**MS and Its Many Biologic Treatments.** The disease-modifying agents now available to treat relapsing-remitting MS include interferon  $\beta$ -1b, interferon  $\beta$ -1a, and glatiramer acetate (copolymer-1). Policies dictating use of these agents vary widely across the country. One of the most restrictive sets of medical policies is found in the Aetna system, where physician discretion is sharply minimized with definitions for the number of attacks and lesions needed to qualify for treatment. Aetna provides exacting criteria for clinically definite and/or laboratory-supported attacks and lesions. By contrast, the BCBS Tennessee medical policy on these agents endorses the more patient-oriented National Multiple Sclerosis Society's 1998 Consensus Statement by stating that "the frequency of relapses, age, or level of disability should not limit an individual's access to medication." Although the policy certainly also covers its bases in terms of standard contraindications and other package insert guidance, this BCBS approach definitely maximizes physician discretion by maintaining flexibility in treating MS. These divergent approaches to the prescribing of biologic response modifiers in MS reveal 2 fundamentally separate attitudes about physician discretion with specialty pharmaceuticals. It is unknown whether the extra efforts required to establish and police the more restricted approach translates into reductions in inappropriate use, cost savings, or reduced side effects.

**Psoriasis and Alefacept.** The payment criteria adopted by various MCOs for use of



alefacept in plaque psoriasis also vary widely by region and system. Alefacept is the first of many agents in this class to block immune system components. Interestingly, the agent appears to be effective in many patients for only a limited duration of time. Policies on retreatment are therefore of interest. Although MCOs such as The Regence Group and HGSA (Medicare Part B for Pennsylvania) agree on many restrictions for initial use of this agent (eg, disease definition, previous treatments, CD4+ T lymphocyte counts, a 12-week course) the HGSA policy on retreatment specifies that the patients should have had a meaningful clinical response in the initial treatment course while the Regence policy is silent on this issue. This example highlights how MCO medical policies can be similar in their overall approach but markedly different in a specific aspect of a specialty pharmaceutical's use.

### Summary

Treatment guidelines offer a credible approach to MCO management of specialty pharmaceuticals by basing decisions on the best available scientific evidence. Drawbacks to using guidelines include lack of available evidence, bias on the part of the expert team, a lack of currency, and difficulties in implementation. Treatment guidelines can and often do serve, along with product labeling, as the basis for reimbursement and usage rules as specified in MCO medical policies. The relationship between provider-oriented guidelines and payment criteria varies by payer, with implications for care quality, cost, and access. Increased awareness of the advantages and disadvantages of using treatment guidelines to shape prescribing policies for specialty pharmaceuticals may lead to worthwhile non-product-specific discussions within MCOs about

sources and methods used in medical policy development.

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