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Meeting the Challenge of Incorporating Injectable Biologics Into Managed Care: Multiple Sclerosis and Psoriasis

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Supplement Policy Statement

Standards for Supplements to the *Journal of Managed Care Pharmacy*

Supplements to the *Journal of Managed Care Pharmacy* are intended to support medical education and research in areas of clinical practice, health care quality improvement, or efficient administration and delivery of health benefits. The following standards are applied to all *JMCP* supplements to assure quality and assist readers in evaluating potential bias and determining alternate explanations for findings and results.

1. Disclose the principal sources of funding in a manner that permits easy recognition by the reader.

2. Disclose the existence of all potential conflicts of interest among supplement contributors, including financial or personal bias.

3. Describe all drugs by generic name unless the use of the brand name is necessary to reduce the opportunity for confusion among readers.

4. Strive to report subjects of current interest to managed care pharmacists and other managed care professionals.

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6. Subject all supplements to expert peer review.

FACULTY

Imelda C. Coleman, PharmD, is currently the clinical pharmacist at BlueCross and BlueShield of Louisiana. She received her BS in pharmacy from the University of Mississippi and PharmD from Xavier University of Louisiana. Upon completion of her pharmacy practice residency at the University of Mississippi Medical Center, she worked at the Ochsner Clinic Foundation, New Orleans, Louisiana, managing pharmacy risk for the 500-physician group. Coleman is a member of the Academy of Managed Care Pharmacy, where she serves on the Special Projects Committee.

Richard Cook, PharmD, is manager, clinical and quality programs, Blue Care Network of Michigan, Grand Rapids.

Jay N. Gade, MD, PhD, is in private practice in southern Oregon at the Dermatology and Laser Center of Roseburg. In addition, he is the clinical director of research at the center. He is also a Seminars in Psoriasis faculty member at the University of Alabama, Birmingham. Gade is a member of the Oregon Dermatology Association, Oregon Medical Association, and American Academy of Dermatology. He received his PhD in biochemistry and molecular biology from the Oregon Health Sciences University. His research focused on protein crosslinking systems in artificial skin development. Gade received his medical degree from the Oregon Health Sciences University and completed his residency in dermatology at Wake Forest University, serving as chief resident.

Douglas S. Hum, RPh, is director of pharmacy services at Medica, Minneapolis, having served in that capacity since 2001. The department was nominated for a 2003 company-sponsored service/performance excellence award for achieving significant medical cost savings toward overall company goals in 2003. Hum is a graduate of the University of Minnesota College of Pharmacy, where he was awarded a Samuel W. Melendy undergraduate research scholarship in pharmacology. He has 24 years of practice as a pharmacist in hospital, retail, and managed care settings, including 8 years at AdvancePCS, now Caremark.

Ben Johnson, RPh, MBA, is pharmacy contract manager for Intermountain Health Care, Salt Lake City, Utah. He is responsible for all pharmacy contracting in the integrated delivery system. Johnson works on several clinical committees including asthma, lower respiratory tract infection, cardiology, multiple sclerosis, and preventive medicine. He served as the pharmacy director for the 2002 Olympic Winter Games in Salt Lake City.

Terry Maves, RPh, has been a community and pharmacy leader in northeast Wisconsin for more than 25 years. He is the pharmacy director for Touchpoint Health Plan, based in Appleton, Wisconsin, which, for the second consecutive year, has been named by the National Committee for Quality Assurance as the number one health plan in the nation in delivering preventive care and managing chronic diseases.

Maves has recognized the pharmacist's ability to intervene on the patient's behalf to improve patient therapies. He helped create the Everyone Teaching Compliance program, which helps health care providers coordinate care to improve medication utilization for 12 disease states. This program earned Maves recognition as the Innovative Pharmacist of the Year in 2000 for the state of Wisconsin. In addition to increasing pharmacist's involvement in the delivery of health care, he has created and implemented a cognitive reimbursement program and made this program available to all pharmacies in the Touchpoint Health Plan area. A leader in patient consultation and education, his role as a well-known preceptor, professional, and public speaker also demonstrates his commitment to the field of pharmacy.

William J. Mazanec, PharmD, MBA, is vice president, clinical and formulary management, of CuraScript Inc., based in Orlando, Florida. He is responsible for support of its strategic clinical mission by providing clinical support to client account management. Mazanec works with managed care partners to develop and implement programs that integrate pharmacy activities with health plan management to control costs and utilization of pharmaceuticals. In his role, he conducts pipeline monitoring for product development within the biotechnology and pharmaceutical industry.

For the past 15 years, Mazanec has served in various capacities in managed care, including director of pharmacy for AvMed Health Plan and director of pharmacy operations, Aetna U.S. Healthcare, where he oversaw Integrated Pharmacy Solutions Inc., a business component of Prudential Healthcare. Mazanec received his doctor of pharmacy degree from the University of Florida College of Pharmacy, with a special emphasis on disease state management and clinical interventions. He earned an MBA from the Crummer Graduate School of Business at Rollins College and a bachelor's degree in pharmacy with a minor in radiopharmacy, in cooperation with the Harvard University joint program in nuclear medicine, from the Massachusetts College of Pharmacy.

James R. Miller, MD, has recently retired after serving as director of the Multiple Sclerosis Center of Columbia-Presbyterian Medical Center in New York City for 20 years. He has lectured widely on the pathogenesis and treatment of multiple sclerosis and allied diseases as well as in the field of infections of the central nervous system. He has also written a variety of articles on these subjects and contributed chapters to several standard neurological textbooks. In retirement, Miller continues to lecture both to medical and patients groups concerning multiple sclerosis.

Woodrow J. Proveaux, PharmD, is the clinical pharmacy director at CareFirst BlueCross BlueShield in Baltimore, Maryland, and precepts a post-PharmD resident and a pharmacoeconomics fellow each year. He has extensive experience in teaching and coordinating clinical pharmacy practices at both West Virginia University and King Saud University. His research and scholarly activities include 14 journal publications as well as various chapter and book reviews and presentations to local, state, national, and international groups. He received his doctor of pharmacy degree from the University of Michigan after completing undergraduate work at the University of Georgia and the Southern Technical Institute.

Sheldon J. Rich, RPh, PhD, is president of SJR Associates, LLC, a health care consulting company in West Bloomfield, Michigan. He has more than 20 years experience in the pharmacy field, having practiced in hospital, retail, and managed care pharmacy. Nationally recognized as a lecturer and moderator, his recent consulting assignments have included acting as interim pharmacy director at a large managed care plan, developing a pharmaceutical manufacturer rebate program for a large group purchasing organization, assisting numerous physician practice groups in managing pharmacy costs and shared risk contracts, providing managed care training for various pharmaceutical manufacturers, and developing and moderating clinical advisory boards.

Prior to starting his own consulting practice, Rich was director of pharmacy programs at SelectCare, Troy, Michigan, where he developed a nationally recognized, cost-effective pharmacy program and pharmacy network. He was responsible for development of drug utilization review programs, served as the chairperson of the pharmacy and therapeutics committee, and developed a comprehensive drug formulary. Rich earned his pharmacy degree from the University of Michigan. He also holds a doctorate in theocentric business ethics. He has held the position of clinical assistant professor at the University of Michigan since 1982 and has held a dual appointment as an adjunct assistant professor with the College of Pharmacy and Allied Health Professions at Wayne State University since 1994.

Rich has moderated more than 100 meetings and advisory boards, published numerous journal articles, and contributed to 2 textbooks. He served for 8 years on the Michigan Board of Pharmacy, 3 years as chairperson. Rich has received numerous professional awards and honors and is a member of several professional organizations.

Howard S. Rossman, DO, FACN, is a senior partner of the Michigan Institute of Neurological Disorders (MIND) in Farmington Hills, an organization with which he has been associated since 1978. He is medical director of the Multiple Sclerosis Center at MIND and has been involved in 10 major clinical trials for potential new MS therapeutics since 1999, 7 of which are currently ongoing. In addition, Rossman is a clinical professor of neurology at Michigan State University and chairman of the neurology department at Botsford General Hospital, an affiliate of Michigan State University, where he directed the residency training program for 19 years until 2002. He is still actively involved in the training of medical students, interns, and neurology residents.

Rossman received his undergraduate degree from the University of Michigan and his medical training at the Michigan State University College of Osteopathic Medicine. He completed his residency in neurology at Botsford General Hospital, an affiliate of Michigan State University. Rossman is a member of the Consortium of MS Centers and a fellow of the American College of Neuropsychiatrists, where he served as president from 1994 to 1995.

William H. Stuart, MD, received his medical degree from Northwestern University Medical School and completed an internship at Cleveland Metropolitan General Hospital and a residency in internal medicine at Northwestern. He subsequently served as an epidemic intelligence service officer at the Communicable Disease Center (CDC) in Atlanta, Georgia, and completed a fellowship in neurology at Emory University Medical School. Upon completion of this training and serving at the National Institute of Neurological Disorders and Stroke, Rockville, Maryland, he entered private practice in the Atlanta area, forming the Atlanta Neurological Clinic, subsequently renamed the Peachtree Neurological Clinic in 1990.

One of the founding members of the American Society of Neuroimaging in 1975, Stuart served as its president in 1984 and 1985. In 1980, he became a member of the Practice Committee of the American Academy of Neurology, (AAN), remaining active on that committee until 1991 and serving as its chairman from 1985 through 1991. He was a member of the Executive Committee of AAN for several years and served as treasurer. His most recent activity with AAN was aiding in the formation of the academy's MS section and serving on the Long-Range Planning Committee.

Stuart began his focused interest in multiple sclerosis in 1988, developing the Multiple Sclerosis Comprehensive Care and Research Center at Shepherd Center, Atlanta, in 1991. In 2001, he became medical director of the MS Center of Atlanta and the MS Research Network of Georgia. His interest in MS has focused on early treatment and aggressive combination therapy for patients with breakthrough disease.

He has maintained a broad interest in education and served as a clinical professor of neurology at Emory University Medical School from 1987 to 2003. He was named Clinical Teacher of the Year at Piedmont Hospital in 1987 and 1988. He has lectured widely in evolving treatments in MS. Stuart's board certification includes the American Board of Internal Medicine and the American Board of Psychiatry and Neurology. He serves on the boards of the National MS Society—Georgia Chapter (and its Medical Advisory Board) and Millennium Medical Communications, Inc.

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Meeting the Challenge of Incorporating Injectable Biologics Into Managed Care: Multiple Sclerosis and Psoriasis

Target Audience:

This program has been designed to meet the educational needs of pharmacists and other health care practitioners in a managed care environment.

Learning Objectives

After completing this continuing education module, the pharmacist will be able to

1. verbalize the importance and long-term potential of injectable biologic therapies for the treatment of multiple sclerosis (MS) and psoriasis;
2. describe strategies and considerations that optimize treatment success and ensure appropriate resource utilization for biologic therapies in MS and psoriasis;
3. recognize the complexity of treating MS and the importance of individualizing therapy and planning for long-term management of the disease;
4. employ (a) treatment protocols developed by neurologists for appropriate use of biologics in MS and (b) interventions for managing MS symptoms and treatment side effects;
5. describe an MS treatment algorithm developed by managed care professionals that provides guidelines for long-term disease management, including treatment initiation, recommended evaluations, and disease progression;
6. understand current clinical data concerning alefacept's use in the treatment of patients with moderate-to-severe psoriasis, including long-term benefits and safety and tolerability considerations; and
7. identify key considerations for evaluating the cost implications and drug utilization for biologic therapies in psoriasis.

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*A total of .20 CEUs (2 contact hours) will be awarded for successful completion of this continuing education program (Program No. 233-000-04-040-H04).

SHELDON J. RICH, RPh, PhD

The development of injectable biologic agents has revolutionized the treatment of numerous diseases, including multiple sclerosis (MS) and psoriasis. These agents have the potential for long-term benefits, including reduced disease activity, improved quality of life, and decreased utilization of total health care services. As newly approved biologics for the treatment of MS and psoriasis become available, managed care decision makers must determine the appropriate use of these agents based on long-term efficacy, safety, and cost. The goal of this supplement is to provide information from clinical trials and from the experience of renowned specialists to aid in this endeavor.

Multiple sclerosis is a chronic, multifocal, demyelinating disease of the central nervous system (CNS). The onset of MS typically occurs in early adulthood,[1] and MS is the leading cause of nontraumatic CNS morbidity in young and middle-aged adults.[2] In the United States, the annual per-patient cost of MS has been estimated at $34,000, with a total lifetime per-patient cost of $2.2 million; a conservative estimate of the national annual cost is $6.8 billion.[3] MS is a complex and heterogeneous disease, with high intrapatient and interpatient variability in its clinical course and manifestations. Consequently, physicians who treat patients with MS must tailor treatment to individual patients and actively plan for the long-term management of the disease.

Four articles in this supplement focus on the role of biologics in the management of MS. The first article, by James R. Miller, MD, provides an overview of the 4 biologic agents that are available in the United States for the treatment of relapsing-remitting MS as well as the complexities involved in the diagnosis and clinical course of MS. Data supporting early treatment of patients at high risk for MS also are discussed. The second article, by Howard S. Rossman, DO, FACN, reviews data on the development of neutralizing antibodies (NAbs) to biologic agents used to treat MS. Studies show that differences exist among biologics regarding the risk of developing NAbs and that these NAbs reduce or abolish the therapeutic effects of biologics. The article also discusses the implications of NAbs for neurologists and managed care professionals.

The third article, by William H. Stuart, MD, presents an MS treatment algorithm recently developed by a panel of neurologists who are MS experts. This algorithm provides best-practice guidelines on choosing the appropriate biologic agent for initiating therapy, managing occasional relapses, and selecting agents that can be added to biologics in patients whose disease progresses while they are on treatment. The fourth article, by my colleagues and me, provides a model treatment algorithm for use in the managed care setting, which was developed by a group of managed care professionals. This model MS algorithm provides health care professionals with guidelines on the following disease management issues: when to initiate treatment, how to select a biologic agent as the initial therapy, the use of magnetic resonance imaging in the diagnosis and management of patients with MS, when to test for NAbs and how to manage patients who have positive test results for NAbs, and how to manage patients who experience progression during treatment. An algorithm for NAb testing also has been proposed that, while recognizing the authority of the physician to make ultimate prescribing decisions, can be incorporated into a patient's care path to ensure the quality of care without placing a burden on the patient.

An estimated 4.5 million adults in the United States have psoriasis, and approximately one third (1.5 million) of these individuals have moderate-to-severe disease.[4] The financial burden of psoriasis is substantial, with annual U.S. economic costs estimated at $4.3 billion.[5] Patients with moderate-to-severe psoriasis typically require chronic treatment with systemic therapy or phototherapy. Although conventional systemic agents can be effective in producing short-term reductions in disease severity, the long-term, chronic use of these treatments is limited by safety and tolerability concerns. Novel injectable biologics, which have been developed based on an understanding of the role of T cells in the pathogenesis of psoriasis, have advanced the treatment of moderate-to-severe psoriasis.

Alefacept was the first biologic therapy approved for the treatment of moderate-to-severe chronic plaque psoriasis in the United States, and it has been available here for more than 1 year. Two articles in this supplement review the use of alefacept in the treatment of psoriasis. The article by Jay N. Gade, MD, PhD, provides an update on the clinical efficacy and safety of alefacept in patients with psoriasis. Alefacept has proven to be an effective intermittent therapy for psoriasis that offers patients extended treatment-free and disease-free periods. As a result of prolonged remissions, overall drug utilization may be reduced.

In the second article, I review key considerations for the long-term assessment of biologic therapies in psoriasis. These considerations establish the importance of efficacy, safety, and cost parameters measured over a longer course of therapy than the traditional 3-month or 6-month time period utilized to date.

It is hoped that the timeliness and clinical relevance of the information provided in this *Journal* supplement will assist you in improving the care of your patients with MS or psoriasis and will ensure the use of biologic therapies in the most cost-efficient manner.

Author

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