

POLICY & PRACTICE

Mass. Medicaid Waiver Extended

The Centers for Medicare and Medicaid Services has granted Massachusetts a 3-year, \$21.2 billion Medicaid waiver that will allow the state to continue to expand access to care through its health reform law. The agreement represents a \$4.3 billion increase over the current waiver and fully preserves existing eligibility and benefit levels as well as federal matching funds for all government health insurance programs, Massachusetts Gov. Deval Patrick (D) said in a statement. The waiver allows the state to continue to subsidize health

coverage for residents with incomes up to 300% of the poverty level. "In less than 2 years, health care reform in Massachusetts has made a difference," he said. "Nearly 440,000 adults and children are newly insured, and total system costs have begun to level off."

Cephalon Pays \$425 Million

Cephalon Inc. has agreed to pay more than \$425 million to settle claims that it inappropriately marketed three drugs for off-label uses, according to the U.S. Justice Department. The settlement will resolve civil

and criminal complaints alleging that the company marketed Gabitril (tiagabine), Actiq (oral transmucosal fentanyl), and Provigil (modafinil) for off-label uses. Between 2001 and 2006, Cephalon allegedly promoted Actiq, which is an approved pain treatment in opioid-tolerant cancer patients, as a treatment for migraine, sickle-cell pain, and injuries. Gabitril was allegedly promoted for treatment of anxiety, insomnia, and pain. Provigil, which was originally approved to treat excessive daytime sleepiness associated with narcolepsy, was allegedly promoted off-label as a nonstimulant drug for sleepiness, tiredness, decreased activity, and fatigue. Under

the settlement, Cephalon has entered into a 5-year agreement with the Health and Human Services Office of Inspector General that requires the company to notify physicians of the settlement terms and to begin disclosing any payments made to physicians on its Web site by Jan. 31, 2010.

Consumers Like Flat Rx Pricing

Pharmacy customers who take advantage of flat-rate generic prescription drug prices have higher levels of satisfaction than those who don't, according to the second annual J.D. Power and Associates National Pharmacy Study. Nearly one-fourth of pharmacy customers participate in a \$4 generic or similar flat-rate pricing program, with the greatest participation rate among customers 44 years and older, the study said. Satisfaction among "bricks-and-mortar" pharmacy customers who participate in flat-rate prescription pricing programs averages 826 on a 1,000-point scale, compared with 817 among those customers who don't participate in the programs.

Nationwide RAC Launched

CMS has launched its national recovery audit contractor program as part of its "aggressive new steps to find and prevent waste, fraud and abuse in Medicare." The new RACs, which will be paid on a contingency fee basis, soon will begin to contact providers about the program, CMS said. The 3-year RAC demonstration program in Arizona, California, Florida, Massachusetts, New York, and South Carolina collected more than \$900 million in overpayments, according to CMS. However, the program has drawn strong criticism from physician groups, who have maintained that RAC audits were overly burdensome. In addition to implementing the RACs, CMS said it will begin to work directly with beneficiaries to make certain they receive the durable medical equipment or home health services for which Medicare has been billed, and that the items or services were medically necessary.

Many Drug Studies Unpublished

Studies on new prescription drugs are less likely to be published if they conclude that the medication is ineffective, researchers reported in the journal PLoS Medicine. The researchers found that only 43% of all clinical trials submitted to the Food and Drug Administration to support drug approvals between 1998 and 2000 had been

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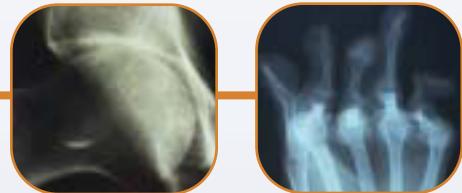
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CLINICAL HIGHLIGHTS

- Autoimmunity Unbound: New Insights Into the Pathogenesis of Rheumatoid Arthritis
Daniel E. Furst, MD
- What's Ahead: New Therapies for the Treatment of Rheumatoid Arthritis
Tore K. Kvien, University of Oslo, Past President EULAR 2005-2007
- New Frontiers: Therapeutic Options in Juvenile Idiopathic Arthritis
Charles H. Spencer, MD, Nationwide Children's Hospital/Ohio State University
- MRI in Rheumatology
Norman B. Gaylis, MD, Private Practice, University of Miami
- Assessing Cardiac Complications in Connective Tissue Diseases
Daniel Edmundowicz, MD, University of Pittsburgh Medical Center
- New Advances in the Treatment Options in SLE
Susan Manzi, MD, MPH, University of Pittsburgh School of Medicine
- Autoimmune Threats to Kidney Function
Jonathan Ashley Jefferson, MD, MRCP, University of Washington
- Clinical Manifestations and Complications of Systemic Scleroderma
Daniel E. Furst, MD
- Gout: What's Ahead in Disease Management
Robert L. Wortmann, MD, Dartmouth-Hitchcock Medical Center
- New Paradigms in Managing and Treating Ankylosing Spondylitis
Tore K. Kvien, University of Oslo, Past President EULAR 2005-2007
- Crohn's Disease and Ulcerative Colitis: Challenges of Inflammatory Bowel Disease
Sunanda V. Kane, MD, Mayo Clinic College of Medicine
- Panel Discussion: Collaborative Care of Patients with Immunologic-Based Diseases: A Rheumatology/Dermatology Perspective
Daniel E. Furst, MD, Moderator, Kenneth B. Gordon, MD, Christopher T. Ritchlin, MD

DERMATOLOGY ESSENTIALS FOR THE RHEUMATOLOGIST

- More Than Skin Deep: Understanding and Managing the Patient With Psoriasis
Kenneth B. Gordon, MD
- Therapeutic Advances in the Treatment of Psoriatic Arthritis
Christopher T. Ritchlin, MD, University of Rochester School of Medicine and Dentistry
- Rashes, Erythema, and Spots: Common Skin Disorders
Michael D. Tharp, MD, Rush University Medical Center
- Weird and Worrisome: Uncommon Skin Diseases
Francisco Kerdel, MD, University of Miami

PROGRAM OVERVIEW

New treatment modalities are being developed in rheumatology based on scientific research breakthroughs in immunology, cytokines, T lymphocytes, B lymphocytes, as well as genetic studies that may result in gene therapies. Rheumatologists and other health care professionals need comprehensive knowledge of the latest developments and techniques in diagnosing and treating rheumatic disorders to ensure the highest standards of patient care. Rheumatologists need to have an understanding of dermatologic co-morbidities that often appear in their patients.

*Program subject to change.

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HHS Committee Calls for Medical Home Funding

BY MARY ELLEN SCHNEIDER
New York Bureau

Support for the concept of the patient-centered medical home continues to grow, with the latest nod coming from the federal Advisory Committee on Training in Primary Care Medicine and Dentistry.

The committee, which provides policy advice to Congress and the Health and Human Services secretary, is finalizing a report that recommends that policy makers invest in training physicians on how to operate within the medical home model and evaluate the health outcomes associated with this model of care.

A failure to invest in the medical home model now will impair efforts to improve quality and control costs, the committee wrote. The United States "faces a watershed moment when it can restructure health care to focus on prevention and coordinated, comprehensive care through the adoption of this promising new model of care," the committee wrote in the draft report.

The report, which is expected to be released in its final form in late 2008, calls for changes to Title VII, Section 747 of the Public Health Service Act. For example, the committee is recommending that the

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published 5 years after the drug in question was approved. Among all the trials, those with statistically significant results were nearly twice as likely to have been published as those without statistically significant results, and pivotal trials were three times more likely to have been published as nonpivotal trials. But the study revealed "selective reporting" of results, the authors said. "A pivotal trial in which the new drug does no better than an old drug is less likely to be published than one where the new drug is more effective, a publication bias that could establish an inappropriately favorable record for the new drug in the medical literature," the authors wrote.

Florida Files Vioxx Suit

Florida Attorney General Bill McCollum has sued Merck & Co. on behalf of state agencies he said were damaged by "the company's allegedly deceptive marketing and promotion" of Vioxx. The lawsuit follows a 3-year investigation of Merck's promotional practices of Vioxx (rofecoxib) and alleges that, due to the company's marketing practices, numerous Florida agencies approved the inclusion of Vioxx as a covered or approved drug. Vioxx purchases by the Florida Medicaid program exceeded \$80 million between 1999 and 2004, according to Mr. McCollum, who argued that, if the facts about Vioxx had been known earlier, physicians and their Medicaid patients would have chosen other, less expensive prescriptions. Eight other states have filed similar lawsuits, according to Merck spokesman Ronald Rogers, who said in an interview that Merck acted responsibly on Vioxx and will defend against the suits.

—Jane Anderson

HHS secretary expand the authority of that law to include directing continuing medical education programs to train currently practicing physicians in aspects of the medical home, including interdisciplinary team-based care, care of disadvantaged and vulnerable populations, and the use of information technology.

It also calls on the HHS secretary to promote dissemination of the best practices related to providing a medical home that have been identified by researchers.

Other draft recommendations from the committee include the following:

- Funding pilot programs that contribute to the development and evaluation of the medical home, with priority given to those programs that address the needs of underserved populations.
- Developing measures to evaluate the medical home in terms of accessibility and patient satisfaction, health status, quality of care, health disparities, and cost.
- Implementing key components of the

medical home model in academic medical centers, in an effort to prepare faculty educators.

The committee's next report, due out in May 2009, will explore how primary care training would need to be redesigned to further the concept of the medical home. It will also address the difficulties in hand-offs between pediatric and adult medicine specialists when patients with chronic illnesses reach adulthood, as well as on workforce issues and medical school debt. ■

IMPORTANT CORRECTION OF DRUG INFORMATION ABOUT EFFEXOR XR® (VENLAFAXINE HCI) EXTENDED-RELEASE CAPSULES

An advertisement in professional journal publications for EFFEXOR XR® (venlafaxine HCI) Extended-Release Capsules for the treatment of major depressive disorder was the subject of a Warning Letter issued by the U.S. Food and Drug Administration (FDA) in December 2007. The FDA stated that the journal ad was misleading because it overstated the efficacy of EFFEXOR XR, made unsubstantiated superiority claims, and contained other unsubstantiated claims regarding EFFEXOR XR.

Wyeth would like to take this opportunity to clarify the content of the advertisement.

Claims that Reference the Baldomero et al Study and Other Related Claims

The FDA objected to the claim, "In an open-label study of patients who failed previous antidepressant treatment, nearly 60% achieved remission when changed to EFFEXOR XR." The FDA determined that the Baldomero study (the cited reference for this claim) could not be relied upon as substantial evidence to support the claim due to the following reasons: (1) the study was an open-label study, which is not an appropriate study design to measure subjective end points because it fails to minimize potential bias; (2) the study did not include a placebo group, so there was no way to determine the actual effect size of the drug; and (3) the study did not provide information about whether EFFEXOR XR was superior to failed therapy because study subjects were not randomized to their previously failed therapy. Therefore, the FDA stated that the study failed to support the 60% remission rate claim as well as any conclusion that EFFEXOR XR is superior to other antidepressant treatments. In addition to the above claim, the FDA stated that other claims added to the misleading impression that patients who have failed previous antidepressant therapy can expect improvement when switching to EFFEXOR XR.

Claims from the PREVENT Study

The FDA objected to the claim, "In the PREVENT study, the probability of preventing a new episode of depression was 92% with EFFEXOR XR in maintenance year 2 vs. 55% with placebo." The FDA stated that the cited claim overstated the efficacy of EFFEXOR XR by implying that the general patient population suffering from major depressive disorder can expect a 92% probability of preventing a recurrent depressive episode after two years of treatment when this is not supported by substantial evidence.

The cited study for this claim was a randomized, multicenter, double-blind study (n=1096) comparing EFFEXOR XR with placebo. The study was designed to provide efficacy data regarding recurrence prevention with EFFEXOR XR after two years of maintenance

treatment. It followed patients through 4 different time periods: a 10-week acute period, a 6-month continuation period, an initial 12-month maintenance period (maintenance year 1), and a second 12-month maintenance period (maintenance year 2). At the end of each period, patients were only considered eligible for inclusion in the next period if they were still responding to the drug. Patients dropped out of the study during each of the periods for different reasons (eg, lack of efficacy, adverse events). At the start of each maintenance period, the remaining patients who still showed a response to EFFEXOR XR were re-randomized to EFFEXOR XR or placebo. Because a high percentage of EFFEXOR XR patients were either re-randomized to placebo or were discontinued from the study before entering maintenance year 2 and because only patients who responded to EFFEXOR XR were selected to continue to the next phase of treatment, the FDA determined that the results of the study could not be extrapolated to the general patient population suffering from major depressive disorder.

Claim Regarding Clinical Experience and Number of Patients

The FDA objected to the claim, "More than 12 years of clinical experience and over 20 million patients treated with EFFEXOR/EFFEXOR XR." The claim of 20 million EFFEXOR/EFFEXOR XR patients was estimated from the number of U.S. prescriptions, average daily consumption, and average length of therapy. The FDA determined that this claim was misleading based on the referenced data because the calculations used did not reflect the number of "unique" patients. Because there are no unique patient-level data available for the entire 14-year period during which EFFEXOR/EFFEXOR XR has been on the U.S. market, the claim is no longer used in EFFEXOR XR promotional materials.

Please see brief summary of Prescribing Information on adjacent page.

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