

Medicaid Substance Abuse Funds Going Unused

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WASHINGTON — More than \$260 million in Medicaid funds set aside to pay physicians to conduct brief screening and interventions for substance abuse are practically untouched, according to federal experts in the White House Office of National Drug Control Policy.

The Centers for Medicare and Medicaid Services designated the matching funds in January for states that adopt Medicaid codes for substance abuse Screening and Brief Intervention (SBI). But so far, only nine states (Iowa, Indiana, Maine, Maryland, Minnesota, Montana, Oklahoma, Oregon, and Virginia) have begun using the codes, Bertha Madras, Ph.D., deputy director for demand reduction at the White House Office of National Drug Control Policy (ONDCP) said at a meeting to discuss the program. Wisconsin and Washington are reimbursing for SBI in limited circumstances.

The CMS established G codes for SBI in 2006 and followed with H codes. Last year, the American Medical Association established current procedural terminology codes for SBI; they were published for the first time in the 2008 CPT manual.

For CPT 99408, which involves screening and a brief intervention of 15-30 minutes, the reimbursement is \$33.41. For SBI longer than 30 minutes (CPT 99409), the rate is \$65.51.

Dr. Madras did not say how much money has been reimbursed by Medicaid and Medicare, but indicated that the codes are vastly underused.

The ONDCP has been seeking ways to encourage more physicians to conduct SBIs. At the meeting, Dr. Madras cited recently released figures from the Substance Abuse and Mental Health Services Administration showing that 19.9 million people abuse drugs in the United States, but that 93% of those who are addicted do not seek treatment.

Dr. Madras said that so far, about 700,000 people have been screened. Almost a quarter were positive for alcohol or drug use; 70% needed a brief intervention and about 16% were referred to treatment, she said. According to self-reports 6 months later, at least a third of those who received treatment said their health status improved.

Citing several recent developments, she said that screening is gaining currency.

At the beginning of 2008, the Federal Employees Health Benefits Plan, which covers 8 million employees and dependents, notified its carriers that the CPT codes for screening and intervention were added and available for use.

In June, the Department of Veterans Affairs directed all VA medical centers to routinely screen for alcohol use and provide brief interventions.

Screening for alcohol intoxication is required at level I and II trauma centers; patients with positive screens should be offered interventions, according to criteria adopted by the American College of Surgeons' Committee on Trauma. The committee decided to institute SBI because al-

cohol use is the single most important risk factor associated with serious injury, said Dr. John Fildes, who represented the ACS committee at the meeting.

Screening and brief intervention protocols are also incorporated into the latest edition of the Advanced Trauma Life Support manual, which was released in October, said Dr. Fildes, professor of surgery at the University of Nevada, Las Vegas.

The ACS Committee on Trauma hopes to expand SBI to all level II and III trauma

centers and have drug and alcohol intoxication data included in the National Trauma Data Bank, Dr. Fildes said.

Health insurer Aetna Inc. is aiming to have more of its participating primary care physicians offer screening and brief interventions, said Dr. Hyong Un, national medical director for behavioral health at the company. According to Dr. Un, Aetna has the systems in place to pay claims with the SBI codes and its behavioral health specialists will work with primary care physi-

cians in an effort to encourage screening.

The National Institute on Drug Abuse is developing a resource guide for physicians that will be posted on the agency's Web site, said Dr. Wilson Compton, NIDA director of the division of epidemiology, services, and prevention research.

Some online training is already available at www.mdalcoholtraining.org. The curriculum is sponsored by the National Institute on Alcohol Abuse and Alcoholism and Boston University. ■

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

An advertisement in professional journal publications for EFFEXOR XR® (venlafaxine HCl) 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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