

POLICY & PRACTICE

CBO Casts Doubt on Health IT Savings

Health information technology, when coupled with other reforms, can help reduce health spending in certain settings, according to a Congressional Budget Office report. But the adoption of health IT alone will not produce significant savings, the report concludes. Institutions that have successfully used health IT to lower costs are generally integrated health care systems like Kaiser Permanente's. "Office-based physicians in particular may see no benefit if they purchase [an electronic health record]—and may even suffer financial

harm," the CBO said. Recent studies by the RAND Corporation and the Center for Information Technology Leadership estimate savings from health IT at around \$80 billion annually. The CBO takes issue those estimates, noting that the savings figures are derived by assuming changes to the health care system. But without changes to the current payment system, providers would not be incentivized to reduce costs to the system, according to the report (available at www.cbo.gov). The CBO report also outlines possible policy options for the federal government to encourage

the adoption of health IT by physicians and hospitals. CBO analysts found that a subsidy to providers could increase health IT adoption but would be costly to the government; a mandate for adoption or a penalty for lack of adoption would be effective but costly for providers.

MD Cash Payments Cut Spending

Giving physicians cash payments for reduced hospital spending can help control costs without sacrificing quality or access to care, researchers reported in the policy journal *Health Affairs*. In a 5-year study of more than 220,000 patients who received coronary stents, Arizona State University researchers showed that "gainsharing" programs, in which physicians are paid for reducing hospital spending, cut costs by more than 7%, or \$315 per patient. If these experiences are representative, the report said, nationwide use of gainsharing would cut hospital costs for stent patients by about \$195 million a year. Most savings from the gainsharing programs were attributed to lower prices for coronary stents, the study said. The researchers found that the programs did not increase the risk of in-lab complications, and were associated with significant decreases in three specific types of complications.

Group Calls for Obesity Action

The advocacy group Campaign to End Obesity, in concert with the American College of Gastroenterology, the American Heart Association, the American Diabetes Association, and others, has issued a call to action outlining what it said Congress must do to address the obesity epidemic. "It is time for the government to take a more comprehensive policy approach to the problem—to look holistically at factors that influence obesity and to look for ways to support people in preventing, managing and treating the disease," the report said. The call to action said that there is much more that lawmakers can do about improving school nutrition and physical activity standards, and that Congress also should consider reimbursement for providers who manage and treat obesity.

Family Spending Up 8%

The average annual medical cost for a typical American family of four increased by nearly 8% from 2007 to 2008, according to consulting firm Milliman Inc.'s fourth annual study of medical spending. Although the \$1,109 increase is a lot, the rate of increase was down for the second straight year and is the lowest rate of increase in the past 5 years. This was the second consecu-

tive year of double-digit increase for the employee's share of spending on health care, the report said. Medical costs in 2008 for a typical American family of four will be \$15,609, compared with \$14,500 in 2007, the report found. Milliman also found wide variation across the country: Among the 14 metropolitan areas studied, health care costs varied by more than 35%.

Few Americans Are Health Literate

Just 12% of America's 228 million adults have the skills to manage their own health care proficiently, according to the Agency for Healthcare Research and Quality. Those deemed proficient in health literacy skills can obtain and use health information to make appropriate health care decisions, can weigh the risks and benefits of different treatments, know how to calculate health insurance costs, and are able to fill out complex medical forms. AHRQ found that about 53% of U.S. adults have intermediate health literacy skills, such as being able to read instructions on a prescription label and determine the right time to take medication. Meanwhile, 22% had basic skills, such as being able to read a pamphlet and understand two reasons why a disease test might be appropriate despite a lack of symptoms, according to the report. And 14% had less than basic skills, meaning they could accomplish only simple tasks, such as understanding a set of short instructions or identifying what is permissible to drink before a medical test, AHRQ said.

Half of America on Drugs

Medco Health Solutions Inc. has determined that 51% of insured Americans—children and adults—were taking prescription medications for at least one chronic condition in 2007. The pharmacy benefit management company analyzed a representative sample of 2.5 million people from its database. A surprise: In all, 48% of women aged 20-44 years are being treated for a chronic condition, compared with 33% of men their age. Antidepressants were the most common prescription for this age group, whereas the top therapies overall were antihypertensives and cholesterol cutters. Hormone therapy use by women aged 45-64 years declined from 30% in 2001 to 15% in 2007. The data "paint a pretty unhealthy picture of America," Dr. Robert Epstein, Medco's chief medical officer, said in a statement. "But there is a silver lining: It does show that people are receiving treatment which can prevent more serious health problems down the road."

—Jane Anderson

LEXAPRO® (escitalopram oxalate) TABLETS/ORAL SOLUTION

(5% and 4%); Fatigue (5% and 2%). **Psychiatric Disorders:** Insomnia (9% and 4%); Somnolence (6% and 2%); Appetite Decreased (3% and 1%); Libido Decreased (3% and 1%). **Respiratory System Disorders:** Rhinitis (5% and 4%); Sinusitis (3% and 2%). **Urogenital:** Ejaculation Disorder^{1,2} (9% and <1%); Impotence² (3% and <1%); Anorgasmia² (2% and <1%). ¹Events reported by at least 2% of patients treated with Lexapro are reported, except for the following events which had an incidence on placebo > Lexapro: headache, upper respiratory tract infection, back pain, pharyngitis, inflamed injury, anxiety. ²Primarily ejaculatory delay. ³Denominator used was for males only (N=225 Lexapro; N=188 placebo). ⁴Denominator used was for females only (N=490 Lexapro; N=404 placebo). **Generalized Anxiety Disorder Table 3** enumerates the incidence, rounded to the nearest percent of treatment-emergent adverse events that occurred among 429 GAD patients who received Lexapro 10 to 20 mg/day in placebo-controlled trials. Events included are those occurring in 2% or more of patients treated with Lexapro and for which the incidence in patients treated with Lexapro was greater than the incidence in placebo-treated patients. The most commonly observed adverse events in Lexapro patients (incidence of approximately 5% or greater and approximately twice the incidence in placebo patients) were nausea, ejaculation disorder (primarily ejaculatory delay), insomnia, fatigue, decreased libido, and anorexia (see TABLE 9). **TABLE 9. Treatment-Emergent Adverse Events: Incidence in Placebo-Controlled Clinical Trials for Generalized Anxiety Disorder (Percentage of Patients Reporting Event) Body System/Adverse Event Lexapro (N=429) and Placebo (N=427): Autonomic Nervous System Disorders:** Dry Mouth (9% and 5%); Sweating Increased (4% and 1%). **Central & Peripheral Nervous System Disorders:** Headache (24% and 17%); Paresthesia (2% and 1%). **Gastrointestinal Disorders:** Nausea (18% and 8%); Diarrhea (8% and 6%); Constipation (5% and 4%); Indigestion (3% and 2%); Vomiting (3% and 1%); Abdominal Pain (2% and 1%); Flatulence (2% and 1%); Toothache (2% and 0%). **General:** Fatigue (8% and 2%); Influenza-like symptoms (5% and 4%). **Musculoskeletal:** Neck/Shoulder Pain (3% and 1%). **Psychiatric Disorders:** Somnolence (13% and 7%); Insomnia (12% and 6%); Libido Decreased (7% and 2%); Dreaming Abnormal (3% and 2%); Appetite Decreased (3% and 1%); Lethargy (3% and 1%); Yawning (2% and 1%). **Urogenital:** Ejaculation Disorder^{1,2} (14% and 2%); Anorgasmia² (6% and <1%); Menstrual Disorder (2% and 1%). ¹Events reported by at least 2% of patients treated with Lexapro are reported, except for the following events which had an incidence on placebo > Lexapro: inflamed injury, dizziness, back pain, upper respiratory tract infection, rhinitis, pharyngitis. ²Primarily ejaculatory delay. ³Denominator used was for males only (N=182 Lexapro; N=195 placebo). ⁴Denominator used was for females only (N=247 Lexapro; N=232 placebo). **Dose Dependency of Adverse Events:** The potential dose dependency of common adverse events (defined as an incidence rate of ≥ 5% in either the 10 mg or 20 mg Lexapro groups) was examined on the basis of the combined incidence of adverse events in two fixed-dose trials. The overall incidence rates of adverse events in 10 mg Lexapro-treated patients (66%) was similar to that of the placebo-treated patients (61%), while the incidence rate in 20 mg/day Lexapro-treated patients was greater (86%). **Table 4** shows common adverse events that occurred in the 20 mg/day Lexapro group with an incidence that was approximately twice that of the 10 mg/day Lexapro group and approximately twice that of the placebo group. **TABLE 4: Incidence of Common Adverse Events* in Patients with Major Depressive Disorder Receiving Placebo (N=311), 10 mg/day Lexapro (N=310), 20 mg/day Lexapro (N=125); Insomnia (4%, 7%, 14%); Diarrhea (5%, 6%, 14%); Dry Mouth (3%, 4%, 9%); Somnolence (1%, 4%, 9%); Dizziness (2%, 4%, 7%); Sweating Increased (<1%, 3%, 8%); Constipation (1%, 3%, 6%); Fatigue (2%, 2%, 6%); Indigestion (1%, 2%, 6%).** ^{*}Adverse events with an incidence rate of at least 5% in either the Lexapro groups and with an incidence rate in the 20 mg/day Lexapro group that was approximately twice that of the 10 mg/day Lexapro group and the placebo group. **Male and Female Sexual Dysfunction with SSRIs** Although changes in sexual desire, sexual performance, and sexual satisfaction often occur as manifestations of a psychiatric disorder, they may also be a consequence of pharmacologic treatment. In particular, some evidence suggests that SSRIs can cause such untoward sexual experiences. Reliable estimates of the incidence and severity of untoward experiences involving sexual desire, performance, and satisfaction are difficult to obtain, however, in part because patients and physicians may be reluctant to discuss them. Accordingly, estimates of the incidence of untoward sexual experience and performance cited in product labeling are likely to underestimate their actual incidence. **Table 5** shows the incidence rates of sexual side effects in patients with major depressive disorder and GAD in placebo-controlled trials. **TABLE 5: Incidence of Sexual Side Effects in Placebo-Controlled Clinical Trials [In Males Only: Adverse Event: Lexapro (N=407) and Placebo (N=383)];** Ejaculation Disorder (primarily ejaculatory delay) (12% and 1%); Libido Decreased (6% and 2%); Impotence (2% and <1%). [In Females Only: Adverse Event: Lexapro (N=737) and Placebo (N=636)]; Libido Decreased (3% and 1%); Anorgasmia (3% and <1%) There are no adequately designed studies examining sexual dysfunction with escitalopram treatment. Priligal has been reported with all SSRIs. While it is difficult to know the precise risk of sexual dysfunction associated with the use of SSRIs, physicians should routinely inquire about such possible side effects. **Vital Sign Changes** Lexapro and placebo groups were compared with respect to (1) mean change from baseline in vital signs (pulse, systolic blood pressure, and diastolic blood pressure) and (2) the incidence of patients meeting criteria for potentially clinically significant changes from baseline in these variables. These analyses did not reveal any clinically important changes in vital signs associated with Lexapro treatment. In addition, a comparison of supine and standing vital sign measures in subjects receiving Lexapro indicated that Lexapro treatment is not associated with orthostatic changes. **Weight Changes** Patients treated with Lexapro in controlled trials did not differ from placebo-treated patients with regard to clinically important change in body weight. **Laboratory Changes** Lexapro and placebo groups were compared with respect to (1) mean change from baseline in various serum chemistry, hematology, and urinalysis variables, and (2) the incidence of patients meeting criteria for potentially clinically significant changes from baseline in these variables. These analyses revealed no clinically important changes in laboratory test parameters associated with Lexapro treatment. **ECG Changes** Electrocardiograms from Lexapro (N=625), racemic citalopram (N=351), and placebo (N=527) groups were compared with respect to (1) mean change from baseline in various ECG parameters and (2) the incidence of patients meeting criteria for potentially clinically significant changes from baseline in these variables. These analyses revealed (1) a decrease in heart rate of 2.2 bpm for Lexapro and 2.7 bpm for racemic citalopram, compared to an increase of 0.3 bpm for placebo and (2) an increase in QTc interval of 3.9 msec for Lexapro and 3.7 msec for racemic citalopram, compared to 0.5 msec for placebo. Neither Lexapro nor racemic citalopram were associated with the development of clinically significant ECG abnormalities. **Other Events Observed During the Premarketing Evaluation of Lexapro** Following is a list of WHO terms that reflect treatment-emergent adverse events, as defined in the introduction to the ADVERSE REACTIONS section, reported by the 1428 patients treated with Lexapro for periods of up to one year in double-blind or open-label clinical trials during its premarketing evaluation. All reported events are included except those already listed in Tables 2 & 3, those occurring in only one patient, event terms that are so general as to be uninformative, and those that are unlikely to be drug related. It is important to emphasize that, although the events reported occurred during treatment with Lexapro, they were not necessarily caused by it. Events are further categorized by body system and listed in order of decreasing frequency according to the following definitions: frequent adverse events are those occurring on one or more occasions in at least 1/100 patients; infrequent adverse events are those occurring in less than 1/100 patients but at least 1/1000 patients. **Cardiovascular - Frequent:** palpitation, hypertension. **Infrequent:** bradycardia, tachycardia, ECG abnormal, flushing, varicose vein. **Central and Peripheral Nervous System Disorders - Frequent:** light-headed feeling, migraine. **Infrequent:** tremor, vertigo, restless legs, shaking, twitching, dysequilibrium, tics, carpal tunnel syndrome, muscle contractions involuntary, sluggishness, coordination abnormal, faintness, hyperreflexia, muscular tone increased. **Gastrointestinal Disorders - Frequent:** heartburn, abdominal cramp, gastroenteritis. **Infrequent:** gastroesophageal reflux, bloating, abdominal discomfort, dyspepsia, increased stool frequency, belching, gastritis, hemorrhoids, gagging, polyposis gastric, swallowing difficult. **General - Frequent:** allergy, pain in limb, fever, hot flushes, chest pain. **Infrequent:** edema of extremities, chills, tightness of chest, leg pain, asthenia, syncope, malaise, anaphylaxis, fall. **Hemic and Lymphatic Disorders - Infrequent:** bruise, anemia, nosebleed, hematoma, lymphadenopathy cervical. **Metabolic and Nutritional Disorders - Frequent:** increased weight. **Infrequent:** decreased weight, hyperglycemia, thirst, bilirubin increased, hepatic enzymes increased, gout, hypercholesterolemia. **Musculoskeletal System Disorders - Frequent:** arthralgia, myalgia. **Infrequent:** jaw stiffness, muscle cramp, muscle stiffness, arthritis, muscle weakness, back discomfort, arthropathy, jaw pain, joint stiffness. **Psychiatric Disorders - Frequent:** appetite increased, lethargy, irritability, concentration impaired. **Infrequent:** jitteriness, panic reaction, agitation, apathy, forgetfulness, depression aggravated, nervousness, restlessness aggravated, suicide attempt, amnesia, anxiety attack, bruxism, carbohydrate craving, confusion, depersonalization, disorientation, emotional lability, feeling unreal, tremulousness nervous, crying abnormal, depression, excitability, auditory hallucination, suicidal tendency. **Reproductive Disorders/Female - Frequent:** menstrual cramps, menstrual disorder. **Infrequent:** menorrhagia, breast neoplasm, pelvic inflammation, premenstrual syndrome, spotting between menses. ¹% based on female subjects only. **Respiratory System Disorders - Frequent:** bronchitis, sinus congestion, coughing, nasal congestion, sinus headache. **Infrequent:** asthma, breath shortness, laryngitis, pneumonia, tracheitis. **Skin and Appendages Disorders - Frequent:** rash. **Infrequent:** pruritus, acne, alopecia, eczema, dermatitis, dry skin, folliculitis, lipoma, furunculosis, dry lips, skin nodule. **Special Senses - Frequent:** vision blurred, tinnitus. **Infrequent:** taste alteration, earache, conjunctivitis, vision abnormal, dry eyes, eye irritation, visual disturbance, eye infection, pupils dilated, metallic taste. **Urinary System Disorders - Frequent:** urinary frequency, urinary tract infection. **Infrequent:** urinary urgency, kidney stone, dysuria, blood in urine. **Events Reported Subsequent to the Marketing of Escitalopram** - Although no causal relationship to escitalopram treatment has been found, the following adverse events have been reported to have occurred in patients and to be temporally associated with escitalopram treatment during post marketing spontaneous and clinical trial experience and were not observed during the premarketing evaluation of escitalopram: Blood and Lymphatic System Disorders: hemolytic anemia, leukopenia, thrombocytopenia. Cardiac Disorders: atrial fibrillation, cardiac failure, myocardial infarction, torsade de pointes, ventricular arrhythmia, ventricular tachycardia. Endocrine Disorders: diabetes mellitus, hyperprolactinemia, SIADH. Eye Disorders: diplopia, glaucoma. Gastrointestinal Disorders: gastrointestinal hemorrhage, pancreatitis, rectal hemorrhage. General Disorders and Administration Site Conditions: abnormal gait. Hepatobiliary Disorders: fulminant hepatitis, hepatic failure, hepatic necrosis, hepatitis. Immune System Disorders: allergic reaction. Investigations: electrocardiogram QT prolongation, INR increased, prothrombin decreased. Metabolism and Nutrition Disorders: hypoglycemia, hypokalemia. Musculoskeletal and Connective Tissue Disorders: rhabdomyolysis. Nervous System Disorders: akathisia, choreoathetosis, dysarthria, dyskinesia, dystonia, extrapyramidal disorders, grand mal seizures (or convulsions), hypoesthesia, myoclonus, neuroleptic malignant syndrome, nystagmus, seizures, serotonin syndrome, tardive dyskinesia. Pregnancy, Puerperium and Perinatal Conditions: spontaneous abortion. Psychiatric Disorders: acute psychosis, aggression, anger, delirium, delusion, nightmare, paranoia, visual hallucinations. Renal and Urinary Disorders: acute renal failure. Reproductive System and Breast Disorders: priapism. Respiratory, Thoracic and Mediastinal Disorders: pulmonary embolism. Skin and Subcutaneous Tissue Disorders: angioedema, ecchymosis, erythema multiforme, photosensitivity reaction, Stevens Johnson Syndrome, toxic epidermal necrolysis, urticaria. Vascular Disorders: deep vein thrombosis, hypotension, orthostatic hypotension, phlebitis thrombotic. Forest Pharmaceuticals, Inc. Subsidiary of Forest Laboratories, Inc. 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UPCOMING MEETINGS

Endocrine Society

American Society for Metabolic and Bariatric Surgery

Society of Obstetricians and Gynecologists of Canada

American Headache Society

Society of Geriatric Cardiology

Canadian Dermatology Association

Research Society on Alcoholism

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