Medicare Expands Coverage for Bariatric Surgery

BY JENNIFER LUBELL

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edicare's national coverage decision on bariatric surgery expands Lthe population for which the program will cover the procedure, but specifies that the procedure must be done at a highly qualified center.

The Centers for Medicare and Medicaid Services originally proposed to exclude patients aged 65 years and older from coverage, based on the significant surgical risks seen in studies of this population. But in reviewing new data and analyses, the agency determined that similar outcomes could be obtained in patients of all ages, provided that the surgery was done in facilities capable of handling large numbers of these procedures and was performed by highly qualified surgeons.

This means that patients must seek care in facilities certified by certain medical organizations, the agency said.

In its national coverage decision, CMS said it had evaluated the certification programs of the American College of Surgeons (ACS) and the American Society for Bariatric Surgery and determined that facilities deemed Centers of Excellence by either organization would be able to produce the best surgical results.

In announcing the national coverage decision, Dr. Mark B. McClellan, CMS administrator, said that bariatric surgery "is not the first option for obesity treatment, but when performed by expert surgeons, it is an important option for some of our beneficiaries. While we want to see more evidence on the benefits and risks of this procedure, some centers have demonstrated high success rates, and we want to ensure access to the most up-to-date treatment alternatives for our beneficiaries,' Dr. McClellan added.

The ACS devised its standards "for anybody performing this surgery in adults of any age," Dr. R. Scott Jones, the ACS's di-

Ambien CR™© idem tartrate extended-release tablets) BRIEF SUMMARY

red. Intentional overdosage is more common in this group of patier fore, the least amount of drug that is feasible should be prescribed for It at any one time. mation for patients: Patient information is printed at the end of this ins sure safe and effective use of Ambien CR, this information and instruction led in the patient information section should be discussed with patient ratory tests: There are no specific laboratory tests recommended.

Since the systematic evaluations of Ambien CR in combination with other CNS-active drugs have been limited, careful consideration should be given to the pharmacology of any CNS-active drug to be used with zolpidem. Any drug with CNS-depressant effects could potentially enhance the CNS-depressant

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There are no adequate and well-controlled studies in pregnant women. Ambien CR should be used during pregnancy only if the potential benefit justi-lies the potential risk to the fetus. Montarelagenic effects: Studies to assess the effects on children whose moth-ers took zolpidem during pregnancy have not been conducted. However, chil-dren bron of mothers taking seaditive/hypnotic drugs may be at some risk for withdrawal symptoms from the drug during the postnatal period. In addition, neonatal flaccidity has been reported in infants born of mothers who received sedative/hypnotic drugs during pregnancy.

ur is nave not been established.

Geriatric Use: A total of 99 elderly (≥ 65 years of age) received daily doses of 6.25 mg Ambien CR in a 3-week placebo-controlled study. The adverse event profile of Ambien CR 6.25 mg in this population was similar to that of Ambien CR 1.25 mg in younger adults (≤ 64 years of age). Dizziness was reported in 8% of Ambien CR-treated patients compared with 3% of those treated with placebo.

treated with placebo.

ADVERSE REACTIONS

Associated with discontinuation of treatment: In clinical trials with Ambien CR, 3.5% of 201 patients receiving 6.25-mg or 12.5-mg of Ambien CR discontinued treatment because of an adverse event. Events most commonly associated with discontinuation were somnolence (1.0%) and dizziness (1.0%). Data from a clinical study in which selective serotonin reuptake inhibitor (SSRI)-treated patients were given immediate-release zolpidem tartrate revealed that four of the seven discontinuations during double-blind treatment with zolpidem (n=93) were associated with impaired concentration, continuing or aggravated depression, and manic reaction; one patient treated with placebo (n=97) was discontinued after an attempted suicide.

Incidence in controlled clinical trials

Most commonly observed adverse events in controlled trials: During treat-

Adverse events observed at an incidence of ≥1% in controlled trials of Ambien CR: The following enumerates treatment-emergent adverse event frequencies that were observed at an incidence equal to 1% or greater among patients with insomnia who received Ambien CR in placebo-controlled trials. Events reported by investigators were classified utilizing the MedDRA dictionary for the purpose of establishing event frequencies. The prescriber should be aware that these figures cannot be used to predict the incidence of side effects in the course of usual medical practice in which patient characteristics and other factors differ from those that prevailed in these clinical trials. Similarly, the cited frequencies cannot be compared with figures obtained from other clinical investigators involving related drup products and uses, since each group of drug trials is conducted under a different set of conditions. However, the cited figures provide the physician with a basis for estimating the relative contribution of drug and nondrug factors to the incidence of side effects in the population studied.

The following was derived from results of two placebo-controlled efficacy trials involving Ambien CR. These trials involved patients with primary insomnia who were treated for 3 weeks with Ambien CR at doses of 12.5 mg (Table 1) or 6.25 mg (Table 2), respectively, Included are only adverse events occurring at an incidence of at least 1% for Ambien CR patients and with an incidence greater than that seen in the placebo patients.

Incidences of Treatment-Emergent Adverse Events in a 3-Week Placebo-controlled clinical Trial is Madius (sevents penanged has allegated).

who were treated for 3 weeks with Ambien Ch at doses of 12.5 mg (Table 1) or 6.25 mg (Table 2), respectively. Included are only adverse events occurring at an incidence of at least 1% of Ambien Ch patients and with an incidence greater than that seen in the placebo patients and that a microscopic of a factor of the patients and with an incidence greater than that seen in the placebo patients. A microscopic of Treatment-Emergent Adverse Events in a 3-Week Placebo-Controlled Clinical Trial in Adults (events reported by at least 1% of patients treated with Ambien CR 12.5 mg In=102] and at greater frequency than in the placebo group (n=110). Infections and infestations: Influenza (3% vs. 0%). Sastroenterist (1% vs. 0%). Labyrinthist (1% vs. 0%). Psychiatric disorders: Appetite disorder (1% vs. 0%). Psychiatric disorders: Alphotic (including hallucinations Nos as well as visual and hypnogoic hallucinations) (4% vs. 0%). Disorientation (3% vs. 2%); Anxiety (2% vs. 0%). Supersonalization (1% vs. 0%); Dispinishibition (1% vs. 0%). Depression (2% vs. 0%); Psychomotor retardation (2% vs. 0%); Biago eating (1% vs. 0%). Depression (2% vs. 0%); Wood swings (1% vs. 0%); Bigo including memory impairment, amnesia, anterograde amnesia) (3% vs. 0%); Bigo including memory impairment, amnesia, anterograde amnesia) (3% vs. 0%); Bigo is disturbance (2% vs. 0%); Vs. Ver endess (2% vs. 0%); Vs. Vs. 0%); Astronesia (2% vs. 1%); Ataxia (1% vs. 0%); Psyc redness (2% vs. 0%); Frequent bowel movements (1% vs. 0%); Ladician (1% vs. 0%); Balance disorder: Answer (1% vs. 0%); Balance disorder: Sack pain (4% vs. 0%); Balance disorder (1% vs. 0%); Balance (1% vs. 0%); Balance (1% vs. 0%); Balance disorders and administration site conditions: Fatigue (3% vs. 0%); Skin and subcutaneous issue disorders: Rash (1% vs. 0%); Balance disorders and administration site conditions: Fatigue (3% vs. 2%); Asthenia (1% vs. 0%); Balance (1% vs. 0%); Balance

ison trials suggesting a dose relationship for many of the adverse events associated with zolpidem use, particularly for certain CNS and gastrointestinal adverse events.

Other Adverse Events Observed During the Premarketing Evaluation of Ambien CR: Other treatment-emergent adverse events associated with participation in Ambien CR studies (those reported at frequencies of <1%) were not different in nature or frequency to those seen in studies with immediate-release zolpidem tartrate, which are listed below.

Adverse Events Observed During the Premarketing Evaluation of Immediate-Release Zolpidem Tartrate: Immediate-release zolpidem tartrate, was administered to 3,660 subjects in clinical trials throughout the U.S. Canada, and Europe. Treatment-emergent adverse events associated with clinical trials participation were recorded by clinical trials throughout the U.S. Canada, and Europe. Treatment-emergent adverse events susing terminology of their own choosing. To provide a meaningful estimate of the proportion of individuals experiencing treatment-emergent adverse events, similar types of untoward events were grouped into a smaller number of standardized event categories and classified utilizing a modified World Health Organization (WHO) dictionary of preferred terms. The frequencies presented, therefore, represent the proportions of the 3,660 individuals exposed to zolpidem, at all doses, who experienced an event of the type cited on at least one occasion while receiving immediate-release zolpidem. All reported treatment-emergent adverse events are included, except those coding terms that are so general as to be uninformative and those events where a drug cause was remote. It is important to emphasize that, although the events reported did occur during treatment with immediate-release zolpidem, they were not necessarily caused by it. Adverse events are further classified within body system categories and enumerated in order of decreasing frequency using the following definitions: frequents are sevents are those

dementia, depersonalization, dysphasia, feeling strange, hypokinesia, hypotonia, hysteria, intoxicated feeling, manic reaction, neuralgia, neuritis, neuropathy, neurosis, panic attacks, paresis, personality disorder, somnambulism, sucided attempts, tetany, vawning.

Gastrointestinal system: Frequent: abdominal pain, diarrhea, dyspepsia, hiccup, nausa. Infrequent: anorxia, constipation, dysphagia, flatulence, gastroenteritis, vomiting. Rare: enteritis, eructation, esophiagospasm, gastritis, hemorrhoids, intestinal obstruction, rectal hemorrhage, tooth carries, hematologic and lymphatic system: Rare: anemia, hyperhemoglobinemia, leukopenia, lymphadenopathy, macrocytic anemia, purpura, thrombosis. Immunologic system: Infrequent: ahnormal hepatic function, increased SGPT. Rare: bilirubinemia, increased SGPT. Metabolic and nutritional: Infrequent: ahnormal hepatic function, increased SGPT. Metabolic and nutritional: Infrequent: and sulfiance simple system: Infrequent hyperlycemia, thirst. Rare: gout, hypercholesteremia, hyperlipidemia, increased alkaline phosphatase, increased BUN, periorbital edema.

Musculoskeletal system: Frequent: arthralgia, myalgia. Infrequent: arthritis. Rare: arthrosis, muscle weakness, scalacia, tendinitis.

Reproductive system: Infrequent: menstrual disorder, vaginitis. Rare: breast

hare. artnrosis, muscle weakness, sciatica, tendinitis. Reproductive system: Infrequent. menstrual disorder, vaginitis. Rare: breast fibroadenosis, breast neoplasm, breast pain.

Respiratory system: Frequent: pharyngitis, sinusitis, upper respiratory infection. Infrequent bronchitis, coupling, dyspnea, rhinitis. Rare: bronchospasm, epistaxis, hypoxia, laryngitis, pneumonia.

Skin and appendages: Frequent: rash. Infrequent: pruritus. Rare: acne, bullous eruption, dermatitis, furunculosis, injection-site inflammation, photosensitivity reaction, urticaria.

DRUG ABUSE AND DEPENDENCE
Controlled substance. Zolpidem tartrate is classified as a Schedule IV of
rolled substance under the Controlled Substances Act. Examples of
rugs placed in Schedule IV include benzodiazepines (diazepam, alporazol
tic) and the non-benzodiazepine hypnotics (zaleplon and eszopiclone).

DOSAGE AND ADMINISTRATION

The dose of Ambien CR should be individualized.

Ambien CR is available as extended-release tablets containing 6.25 mg or 12.5 mg of 20 policiem tartrate for oral administration. Ambien CR extended-release tablets should be swallowed whole, and not be divided, crushed, or chewed. The effect of Ambien CR may be slowed by ingestion with or immediately after a meal.

The recommended dose of Ambien CR for adults is 12.5 mg immediately before bedtime.

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Ambien CR™ (zolpidem tartrate extended-release tablets)

Group AMB-SEP05-B-Ab

rector of the division of research and optimal patient care, said in an interview.

'We've got a big problem with obesity, so it's important for the public to know that they can go to a hospital that meets standards that are subject to scrutiny."

Evidence regarding the benefits of the surgery is more limited for the over-65 population, Cynthia A. Brown, director of advocacy and health policy at ACS, said in an interview.

Nevertheless, she said, "the procedure is valuable, and ought to be covered as part of the process that includes data collection and quality monitoring. And that's what CMS is doing."

The college started its certification program, "because of concerns on what happens when new technology gets disseminated into the community and used in specialized facilities," Ms. Brown said. "Our certification program addresses those issues, as well as data collection, to monitor outcomes."

The national coverage decision also expands the types of procedures Medicare covers for its beneficiaries. Previously, only gastric bypass was covered; now the

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list also includes open or laparoscopic Roux-en-Y bypass, laparoscopic adjustable gastric banding, and open or laparoscopic biliopancreatic diversion with duodenal switch.

Further, coverage is limited to obese patients with one or more comorbidities, such as hypertension, type 2 diabetes, osteoarthritis, or coronary heart disease, according to CMS.

More information on the ACS's bariatric surgery certification program is available at www.facs.org/cqi/bscn/index.html. Medicare's coverage decision is available at www.cms.hhs.gov/center/coverage.asp.

UPCOMING MEETING COVERAGE **American Academy of Dermatology** American Academy of Allergy, Asthma, and Immunology **American Association for Geriatric Psychiatry American College of Cardiology** Society for Healthcare Epidemiology of America Society for Adolescent Medicine **Anxiety Disorders Association of America** We Are There For You

