

Prepare for Medicare Part D Launch in January

BY ELAINE ZABLOCKI
Contributing Writer

SAN DIEGO — Physicians will face many questions about the new Medicare Part D benefit in coming months as patients decide whether to enroll and which plan to select in the voluntary prescription drug program, Elizabeth Carder-Thompson said at the annual meeting of the American Health Lawyers Association.

CMS has begun posting informational

resources on its Web site, and additional materials will become available over the next few months. The best resource at this time is the "Outreach Toolkit," available by download or on CD-ROM, said Ms. Carder-Thompson, a lawyer with Reed Smith LLP.

"The Outreach Toolkit doesn't answer all the questions we want answered, but it's a good start," she said.

Enrollment for Part D begins on Nov. 15, 2005, and patients are required to enroll by May 15, 2006, or face a financial penalty when they do.

The new coverage goes into effect Jan. 1, 2006, and the interim discount drug card program ends at that time. This means Medicare beneficiaries will need to make fairly complicated choices within a short time.

There will be at least two part D prescription drug plans available in each geographic area, and plans may include several subplans.

A Kaiser Family Foundation survey, conducted March/April 2005, found that seniors are more likely to turn to their doctor (49%) or pharmacist (33%) for help in making these decisions, rather than to

Medicare information sources (23%). About two-thirds (68%) of those surveyed said they did not have a good understanding of the new benefit.

In October 2005, Part D plans will start to send marketing materials. CMS will distribute its "Medicare and You," handbook to all beneficiaries via mail, with a description of the new benefit. A "Plan Comparison Web Tool" and "Medicare Personal Plan Finder" will be posted at www.Medicare.gov, and there will be special mailings for low-income beneficiaries.

"CMS says it will provide materials they did for the drug discount card but this is far more complicated than the card," Ms. Carder-Thompson said.

According to Robert J. Hill, also of Reed Smith LLP, the CMS marketing guidelines on Part D include a great deal of material that will affect physicians. For example, enrollment cannot be taken at the point of care, such as a physician's office. If physi-

cians offer their patients information on any Part D plan then they must offer information on all available Part D plans.

CMS has not released the final version of its marketing guidelines, and Mr. Hill expects these issues to be dealt with in more detail in the second part.

Once Part D becomes effective, doctors will face a different set of concerns, Ms. Carder-Thompson said.

When a plan does not cover a prescribed drug, physicians will need to provide supporting statements in order to get an exception, but many details are not clear at this time.

"The regulation is confusing," Ms. Carder-Thompson said. "CMS says they don't want it to be hard to seek exceptions. However, it may well become an administrative burden. This is something that's going to evolve as we go along."

Ms. Carder-Thompson advised doctors to "stay tuned" on the details of Part D, since they seem to change every day. ■

VYTORIN® (ezetimibe/simvastatin)

VYTORIN: There are insufficient data for the safe and effective use of VYTORIN in pediatric patients. (See Ezetimibe and Simvastatin below.)

Ezetimibe: The pharmacokinetics of ezetimibe in adolescents (10 to 18 years) have been shown to be similar to that in adults. Treatment experience with ezetimibe in the pediatric population is limited to 4 patients (9 to 17 years) with homozygous sitosterolemia and 5 patients (11 to 17 years) with HoFH. Treatment with ezetimibe in children (<10 years) is not recommended.

Simvastatin: Safety and effectiveness of simvastatin in patients 10-17 years of age with heterozygous familial hypercholesterolemia have been evaluated in a controlled clinical trial in adolescent boys and in girls who were at least 1 year post-menarche. Patients treated with simvastatin had an adverse experience profile generally similar to that of patients treated with placebo. Doses >40 mg have not been studied in this population. In this limited controlled study, there was no detectable effect on growth or sexual maturation in the adolescent boys or girls, or any effect on menstrual cycle length in girls. Adolescent females should be counseled on appropriate contraceptive methods while on therapy with simvastatin (see CONTRAINDICATIONS and PRECAUTIONS, Pregnancy). Simvastatin has not been studied in patients younger than 10 years of age, nor in pre-menarchal girls.

Geriatric Use

Of the patients who received VYTORIN in clinical studies, 792 were 65 and older (this included 176 who were 75 and older). The safety of VYTORIN was similar between these patients and younger patients. Greater sensitivity of some older individuals cannot be ruled out. (See CLINICAL PHARMACOLOGY, Special Populations and ADVERSE REACTIONS.)

ADVERSE REACTIONS

VYTORIN has been evaluated for safety in more than 3800 patients in clinical trials. VYTORIN was generally well tolerated.

Table 1 summarizes the frequency of clinical adverse experiences reported in ≥2% of patients treated with VYTORIN (n=1236) and at an incidence greater than placebo regardless of causality assessment from 3 similarly designed, placebo-controlled trials.

Table 1*
Clinical Adverse Events Occurring in ≥2% of Patients Treated with VYTORIN and at an Incidence Greater than Placebo, Regardless of Causality

Body System/ Organ Class Adverse Event	Placebo (%) n=311	Ezetimibe 10 mg (%) n=302	Simvastatin** (%) n=1234	VYTORIN** (%) n=1236
Body as a whole – general disorders				
Headache	6.4	6.0	5.9	6.8
Infection and infestations				
Influenza	1.0	1.0	1.9	2.6
Upper respiratory tract infection	2.6	5.0	5.0	3.9
Musculoskeletal and connective tissue disorders				
Myalgia	2.9	2.3	2.6	3.5
Pain in extremity	1.3	3.0	2.0	2.3

* Includes 2 placebo-controlled combination studies in which the active ingredients equivalent to VYTORIN were coadministered and 1 placebo-controlled study in which VYTORIN was administered.

** All doses.

Post-marketing Experience: The adverse reactions reported for VYTORIN are consistent with those previously reported with ezetimibe and/or simvastatin.

Ezetimibe: Other adverse experiences reported with ezetimibe in placebo-controlled studies, regardless of causality assessment: *Body as a whole – general disorders:* fatigue; *Gastrointestinal system disorders:* abdominal pain, diarrhea; *Infection and infestations:* infection viral, pharyngitis, sinusitis; *Musculoskeletal system disorders:* arthralgia, back pain; *Respiratory system disorders:* coughing.

Post-marketing Experience: The following adverse reactions have been reported in post-marketing experience, regardless of causality assessment: Hypersensitivity reactions, including angioedema and rash; elevated creatine phosphokinase; elevations in liver transaminases; hepatitis; thrombocytopenia; pancreatitis; nausea; cholelithiasis; cholecystitis; and, very rarely, myopathy/rhabdomyolysis (see WARNINGS, Myopathy/Rhabdomyolysis).

Simvastatin: Other adverse experiences reported with simvastatin in placebo-controlled clinical studies, regardless of causality assessment: *Body as a whole – general disorders:* asthenia; *Eye disorders:* cataract; *Gastrointestinal system disorders:* abdominal pain, constipation, diarrhea, dyspepsia, flatulence, nausea; *Skin and subcutaneous tissue disorders:* eczema, pruritus, rash.

The following effects have been reported with other HMG-CoA reductase inhibitors. Not all the effects listed below have necessarily been associated with simvastatin therapy. *Musculoskeletal system disorders:* muscle cramps, myalgia, myopathy, rhabdomyolysis, arthralgias.

Nervous system disorders: dysfunction of certain cranial nerves (including alteration of taste, impairment of extra-ocular movement, facial paresis), tremor, dizziness, memory loss, paresthesia, peripheral neuropathy, peripheral nerve palsy, psychic disturbances. *Ear and labyrinth disorders:* vertigo.

Psychiatric disorders: anxiety, insomnia, depression, loss of libido.

Hypersensitivity Reactions: An apparent hypersensitivity syndrome has been reported rarely which has included 1 or more of the following features: anaphylaxis, angioedema, lupus erythematosus-like syndrome, polymyalgia rheumatica, dermatomyositis, vasculitis, purpura, thrombocytopenia, leukopenia, hemolytic anemia, positive ANA, ESR increase, eosinophilia, arthritis, arthralgia, urticaria, asthenia, photosensitivity, fever, chills, flushing, malaise, dyspnea, toxic epidermal necrolysis, erythema multiforme, including Stevens-Johnson syndrome.

Gastrointestinal system disorders: pancreatitis, vomiting. *Hepatobiliary disorders:* hepatitis, including chronic active hepatitis, cholestatic jaundice, fatty change in liver, and, rarely, cirrhosis, fulminant hepatic necrosis, and hepatoma. *Metabolism and nutrition disorders:* anorexia.

Skin and subcutaneous tissue disorders: alopecia, pruritus. A variety of skin changes (eg, nodules, discoloration, dryness of skin/mucous membranes, changes to hair/nails) have been reported.

Reproductive system and breast disorders: gynecomastia, erectile dysfunction.

Eye disorders: progression of cataracts (lens opacities), ophthalmoplegia. *Laboratory Abnormalities:* elevated transaminases, alkaline phosphatase, γ-glutamyl transpeptidase, and bilirubin; thyroid function abnormalities.

Laboratory Tests

Marked persistent increases of serum transaminases have been noted (see WARNINGS, Liver Enzymes). About 5% of patients taking simvastatin had elevations of CK levels of 3 or more times the normal value on 1 or more occasions. This was attributable to the noncardiac fraction of CK. Muscle pain or dysfunction usually was not reported (see WARNINGS, Myopathy/Rhabdomyolysis).

Concomitant Lipid-Lowering Therapy

In controlled clinical studies in which simvastatin was administered concomitantly with cholestyramine, no adverse reactions peculiar to this concomitant treatment were observed. The adverse reactions that occurred were limited to those reported previously with simvastatin or cholestyramine.

Adolescent Patients (ages 10-17 years)

In a 48-week controlled study in adolescent boys and girls who were at least 1 year post-menarche, 10-17 years of age with heterozygous familial hypercholesterolemia (n=175), the safety and tolerability profile of the group treated with simvastatin (10-40 mg daily) was generally similar to that of the group treated with placebo, with the most common adverse experiences observed in both groups being upper respiratory infection, headache, abdominal pain, and nausea (see CLINICAL PHARMACOLOGY, Special Populations and PRECAUTIONS, Pediatric Use).

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Survey Examines Disclosure of Medical Errors

BY KATHLEEN LOUDEN
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CHICAGO — Four percent of primary care physicians and third-year medical students surveyed in a regional study reported that they made errors resulting in a patient's death but did not disclose them to their institution, Lauris C. Kaldjian, M.D., said at the combined annual meeting of the Central Society for Clinical Research and the Midwestern section of the American Federation for Medical Research.

Dr. Kaldjian surveyed faculty, residents, and third-year medical students in the departments of internal medicine, family medicine, and pediatrics at two medical schools and three hospitals in the Midwest and Northeast. The 538 responses were weighted more heavily toward residents and students than faculty members.

Of respondents, 17% did not disclose to their institution medical errors that prolonged the course of treatment or caused discomfort, and 12% did not disclose to the patient.

Still, more primary care physicians and students volun-

tarily disclosed medical errors than those who did not, said Dr. Kaldjian, a bioethicist at the University of Iowa.

Of the respondents, 27% revealed to the patient a medical error that prolonged therapy, and 18% disclosed such a mistake to their institutions.

The study was designed to develop a comprehensive taxonomy of the factors that influence voluntary disclosure of errors by physicians and to use the taxonomy in a cross-sectional survey of primary care physicians. The survey

asked about factors that facilitate the voluntary disclosure of medical errors in four domains: a sense of responsibility to the patient, oneself, the medical profession, and the community. It also solicited reasons that impede disclosure of errors in four domains: attitudinal barriers, uncertainties, helplessness, and fears and anxiety.

These eight domains included 59 factors that either facilitate disclosure, such as the belief that telling patients about mis-

takes increases their trust in the physician, or hinder disclosure—for example, fear of legal liability.

"This study is trying to get at the deepest motivations and barriers that come into our minds and even our hearts when it comes to talking to patients about medical errors," said Dr. Kaldjian, whose work was funded by the Robert Wood Johnson Foundation. "The issue of disclosure of errors has come to the fore in recent years because of the patient safety movement."

Among fears, the most common reason survey respondents did not disclose an error was fear of the patient's or

family's reaction (88%).

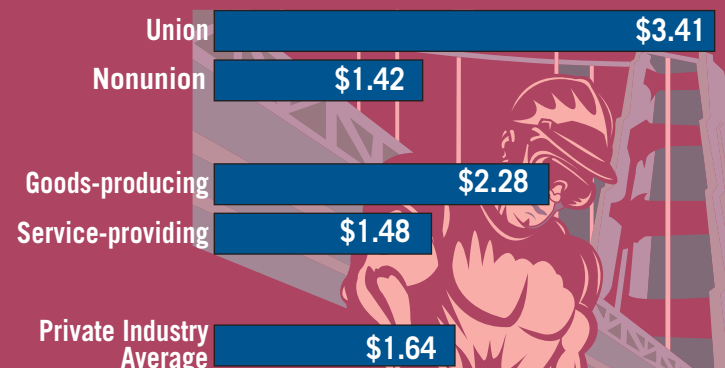
Women in the study were more inclined than men to disclose their errors to patients. Faculty members appeared more willing than trainees to disclose errors to their patients but not as willing to disclose to their colleagues.

Dr. Kaldjian did not break down medical errors other than those that prolonged therapy or caused discomfort and those that caused death, he told FAMILY PRACTICE NEWS.

The taxonomy he developed may assist in the design of systems for reporting medical errors and might be helpful for educational interventions, Dr. Kaldjian said. ■

DATA WATCH

Employer Costs for Health Benefits Highest for Union Workers



Note: Based on average employer cost data for health benefits per hour worked in private industry, March 2005.

Source: Bureau of Labor Statistics