

Slimmer Boomers Could Save Medicare Billions

VITALS

Major Finding: Community-based weight loss programs for individuals ages 60 years or older who are at risk for diabetes or heart disease could save Medicare between \$7 billion and \$15 billion over the lifetimes of one cohort of baby boomers.

Data Source: Estimates of net savings to Medicare over 10 years and participants' lifetimes.

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FROM HEALTH AFFAIRS

ATLANTA — Community-based weight loss programs for individuals ages 60 years or older who are at risk for diabetes or heart disease could save Medicare between \$7 billion and \$15 billion over the lifetimes of

one cohort of baby boomers, according to a recent study.

Obesity, defined as body mass index (BMI) of 30 kg/m², more than doubled from 18% to 37% of adults ages 65 years and older between 1980 and 2008, according to data from the Centers for Disease Control and Prevention. At the same time, obese adults spent about 40% more

on health care than adults whose weight was normal, due to higher rates of diabetes and other chronic illnesses.

"It seems to me that Medicare has an incentive to reach out earlier and improve the health of people who will be coming into the program," study author, Kenneth E. Thorpe, Ph.D., of Emory University, Atlanta, said in a statement.

Dr. Thorpe and his colleague, Zhou Yang, Ph.D., proposed an evidence-based weight loss program for individuals aged 60-64 who are not yet eligible for Medicare but are overweight (BMI higher than 24) or obese and at risk for diabetes, cardiovascular disease, or both (Health Affairs 2011 [doi:10.1377/hlthaff.2010.0944]).

Specifically, they suggested expanding an existing community-based weight loss program developed by the CDC, the YMCA of the USA, and UnitedHealth Group, in which trained lifestyle coaches help overweight individuals select healthier foods and increase physical activity. Studies of this and similar programs show that participants ages 60 years and older lose weight and reduce their risk of developing diabetes by up to 71%.

For the current study, the investigators used 2009 census data to estimate net savings to Medicare over a 10-year period over the lifetime of a single cohort of eligible individuals. Their findings were based on the assumption of participation rates of 70% and 55% of eligible individuals using two enrollment scenarios.

The first scenario would limit enrollment to individuals aged 60-64 who have prediabetes and whose BMI is higher than 24. The cost to enroll 70% of that target group would be about \$590 million (\$240 per person for 2.6 million participants) but would result in a net savings of \$2.3 billion over 10 years and \$9.3 billion in net lifetime savings. If 55% of those eligible participated, estimated savings would exceed \$1.8 billion over 10 years and \$7.3 billion in net lifetime savings.

The second scenario would broaden eligibility to individuals with the same BMI who were at risk for cardiovascular complications (high blood pressure or elevated cholesterol) regardless of whether they had prediabetes. If 70% of eligible patients participate, Medicare would achieve an estimated net savings of \$1.4 billion over 10 years and \$5.8 billion in net lifetime savings. If 55% of eligible patients participate, the estimated additional net savings to Medicare would be \$1.2 billion over 10 years and \$4.6 billion over participants' lifetimes.

By extending eligibility to both at-risk groups, the authors estimate that Medicare would see net savings of \$3 billion to \$3.7 billion over the next 10 years and \$11.9 to \$15.1 billion over participants' lifetimes, depending on the participation rate.

Estimated lifetime savings of \$7 billion to \$15 billion depend on several factors, such as how broad eligibility and participation are, the researchers said. They used a 4.2% weight loss impact to avoid overestimation, so the program might have larger effects than expected. ■

concomitant use of WELCHOL and warfarin has been associated with reduced INR. Therefore, in patients on warfarin therapy, the INR should be monitored before initiating WELCHOL and frequently enough during early WELCHOL therapy to ensure that no significant alteration in INR occurs. Once the INR is stable, continue to monitor the INR at intervals usually recommended for patients on warfarin. [See Post-marketing Experience (6.2)]

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Category B. There are no adequate and well-controlled studies of colesevelam use in pregnant women. Animal reproduction studies in rats and rabbits revealed no evidence of fetal harm. Requirements for vitamins and other nutrients are increased in pregnancy. However, the effect of colesevelam on the absorption of fat-soluble vitamins has not been studied in pregnant women. This drug should be used during pregnancy only if clearly needed.

In animal reproduction studies, colesevelam revealed no evidence of fetal harm when administered to rats and rabbits at doses 50 and 17 times the maximum human dose, respectively. Because animal reproduction studies are not always predictive of human response, this drug should be used in pregnancy only if clearly needed.

8.3 Nursing Mothers

Colesevelam hydrochloride is not expected to be excreted in human milk because colesevelam hydrochloride is not absorbed systemically from the gastrointestinal tract.

8.4 Pediatric Use

The safety and effectiveness of WELCHOL as monotherapy or in combination with a statin were evaluated in children, 10 to 17 years of age with heFH [See Clinical Studies (14.1) in the full prescribing information]. The adverse reaction profile was similar to that of patients treated with placebo. In this limited controlled study, there were no significant effects on growth, sexual maturation, fat-soluble vitamin levels or clotting factors in the adolescent boys or girls relative to placebo [See Adverse Reactions (6.1)].

Due to tablet size, WELCHOL for Oral Suspension is recommended for use in the pediatric population. Dose adjustments are not required when WELCHOL is administered to children 10 to 17 years of age.

WELCHOL has not been studied in children younger than 10 years of age or in pre-menarchal girls.

8.5 Geriatric Use

Primary Hyperlipidemia: Of the 1350 patients enrolled in the hyperlipidemia clinical studies, 349 (26%) were ≥65 years old, and 58 (4%) were ≥75 years old. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

Type 2 Diabetes Mellitus: Of the 1128 patients enrolled in the four diabetes studies, 249 (22%) were ≥65 years old, and 12 (1%) were ≥75 years old. In these trials, WELCHOL 3.8 g/day or placebo was added onto background anti-diabetic therapy. No overall differences in safety or effectiveness were observed between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

8.6 Hepatic Impairment

No special considerations or dosage adjustments are recommended when WELCHOL is administered to patients with hepatic impairment.

8.7 Renal Impairment

Type 2 Diabetes Mellitus: Of the 1128 patients enrolled in the four diabetes studies, 696 (62%) had mild renal insufficiency (creatinine clearance [CrCl] 50-80 mL/min), 53 (5%) had moderate renal insufficiency (CrCl 30-50 mL/min), and none had severe renal insufficiency (CrCl <30 mL/min), as estimated from baseline serum creatinine using the Modification of Diet in Renal Disease (MDRD) equation. No overall differences in safety or effectiveness were observed between patients with CrCl <50 mL/min (n=53) and those with a CrCl ≥50 mL/min (n=1075).

10 OVERDOSAGE

Doses of WELCHOL in excess of 4.5 g/day have not been tested. Because WELCHOL is not absorbed, the risk of systemic toxicity is low. However, excessive doses of WELCHOL may cause more severe local gastrointestinal effects (e.g., constipation) than recommended doses.

17 PATIENT COUNSELING INFORMATION

Dosing: Patients should be advised to take WELCHOL Tablets with a meal and liquid. WELCHOL can be taken as 6 tablets once daily or 3 tablets twice daily. Patients should be advised to take WELCHOL for Oral Suspension as one 3.75 gram packet once daily or one 1.875 gram packet twice daily. To prepare, empty the entire contents of one packet into a glass or cup. Add ½ to 1 cup (4 to 8 ounces) of water, fruit juice, or diet soft drinks. Stir well and drink. WELCHOL for Oral Suspension should be taken with meals. To avoid esophageal distress, WELCHOL for Oral Suspension should not be taken in its dry form. Always mix WELCHOL for Oral Suspension with water, fruit juice, or diet soft drinks before ingesting. [See Dosage and Administration (2) in the full prescribing information]

Drug interactions: Drugs with a known interaction with colesevelam (e.g., cyclosporine, glyburide, levothyroxine, oral contraceptives) should be administered at least 4 hours prior to WELCHOL. Drugs that have not been tested for interaction with colesevelam, especially those with a narrow therapeutic index (e.g., phenytoin), should also be administered at least 4 hours prior to WELCHOL. Alternatively the physician should monitor blood levels of the coadministered drug. [See Drug Interactions (7)]

Gastrointestinal: WELCHOL can cause constipation. WELCHOL is contraindicated in patients with a history of bowel obstruction. WELCHOL is not recommended in patients who may be at risk of bowel obstruction, including patients with gastroparesis, other gastrointestinal motility disorders, or a history of major gastrointestinal surgery. Patients should be instructed to consume a diet that promotes bowel regularity. Patients should be instructed to promptly discontinue WELCHOL and seek medical attention if severe abdominal pain or severe constipation occurs. Because of the tablet size, WELCHOL Tablets can cause dysphagia or esophageal obstruction and should be used with caution in patients with dysphagia or swallowing disorders. To avoid esophageal distress, WELCHOL for Oral Suspension should not be taken in its dry form. Always mix WELCHOL for Oral Suspension with water, fruit juice, or diet soft drinks before ingesting. [See Warnings and Precautions (5.4)]

Hypertriglyceridemia and pancreatitis: Patients should be instructed to discontinue WELCHOL and seek prompt medical attention if the hallmark symptoms of acute pancreatitis occur (e.g., severe abdominal pain with or without nausea and vomiting). [See Warnings and Precautions (5.2)]

17.1 Primary Hyperlipidemia

Patients should be advised to adhere to their National Cholesterol Education Program (NCEP)-recommended diet.

17.2 Type 2 Diabetes Mellitus

General: Patients should be advised that it is important to adhere to dietary instructions, a regular exercise program, and regular testing of blood glucose.

Hypertriglyceridemia and cardiovascular disease: Patients receiving a sulfonyleurea or insulin should be informed that WELCHOL may increase serum triglyceride concentrations and that the long-term effect of hypertriglyceridemia on the risk of coronary artery disease is uncertain. [See Warnings and Precautions (5.2)]

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