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Evidence-Based Diabetes Management

THE OBESITY ISSUE

Research Report

Joslin's Hamdy: *Evidence Shows Diet, Exercise Effective Against Diabetes, Obesity Long-Term*

ANDREW SMITH

Osama Hamdy, MD, PhD, has spent much of the past few years presenting study data that dispute conventional wisdom about the futility of diet and exercise and suggest that lifestyle intervention may be the key to fighting type 2 diabetes mellitus (T2DM).

Each year, he reports another 12 months of follow-up information on 129 patients who spent 12 weeks in the Weight Achievement and Intensive Treatment (Why WAIT) program, based at the Joslin Diabetes Center. Each year, the information indicates that a majority of patients have maintained significant weight loss and enjoyed significant health benefits.[1,2] Each year, audiences tell Hamdy that the results are extremely promising but too preliminary to justify any major shift in treatment paradigm.

There are some indications that things may change this year, with the publication of a full 5 years of follow-up data. The study abstract that Hamdy and his colleagues prepared for the annual meeting of the American Diabetes Association (ADA) in June generated only moderate coverage in the specialty press, but it did win the Michaela Modan Memorial Award for its contribution to the understanding of T2DM,[3] and Hamdy hopes that many researchers and clinicians will come to appreciate the significance of its findings. (Medscape included the study among

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Commentary

Stumbling Toward Access to Evidence-Based Care for the Chronic Disease of Obesity

THEODORE K. KYLE, RPH, MBA; AND FATIMA CODY STANFORD, MD, MPH, MPA

One of the most substantial medical and financial threats to American healthcare is untreated obesity. Although options and guidelines for pharmacotherapy are growing, access to care is falling behind advances in treatment.

A COMPLEX, CHRONIC, AND COSTLY DISEASE

Obesity is a complex, chronic, and costly disease that has been shown to be the key driver behind 4 of the 10 most deadly and expensive diseases worldwide—ischemic heart disease, stroke, hypertension, and diabetes. More than one-fourth of total healthcare expenses in the United States are attributable to the rise in the prevalence of excess weight and obesity.[1] Obesity has been characterized as the greatest threat to American health for this century,[2] and it is rapidly becoming apparent that obesity will soon undermine the affordability of American healthcare, due to the epidemic of chronic diseases it is causing.[3]

In 2013, the American Medical Association (AMA) joined with the National Institutes of Health, the Obesity Society, the American Association of Clinical Endocrinologists, and the Endocrine Society in recognizing obesity as a complex chronic disease that requires a range of interventions for treatment and prevention.[4] Because of the symbolic significance of this decision,

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Pharmacy Management

For Now, PBMs Just Say No to High-Cost PCSK9 Inhibitors

MARY K. CAFFREY

When the FDA approved the first 2 PCSK9 inhibitors this summer, there was plenty of attention from health plans and cardiologists alike to scope of the labels, especially relative to what European regulators allowed for these breakthrough cholesterol drugs. But when the approvals came down for alirocumab (Praluent) on July 24, 2015, and for evolocumab (Repatha) on August 27, 2015, the next question was: what will they cost?[1-3]

First, Sanofi-Regeneron set the price of alirocumab at $14,600 a year for both the 75-mg and 150-mg injections—a eye-popping $40 a day.[4] Then, despite speculation that Amgen might price evolocumab well below its competitor, the second drug came in at $14,100 a year for its 140-mg injection.[5] Both drugs are given twice a month, although evolocumab plans to have a 420-mg monthly dose available next year.

The first entrants in this long-awaited class of monoclonal antibodies, which reduced low-density lipoprotein (LDL) cholesterol up to 60% in clinical trials, arrived well above the $7000 to $12,000 annual cost that analysts predicted.[6] ExpressScripts, the nation's largest pharmacy benefits manager (PBM), and CVS Health, the second-largest, had spent months before the FDA actions making it clear they intended to leverage the presence of 2 drugs to demand savings for their clients, and ultimately, consumers.[6-8]

As the prices were set reaction from

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PHASE 3 RESULTS

Intarcia Therapeutics Inc, announced topline results that say its ITCA 650 delivery system outperformed top-selling sitagliptlin in a clinical trial of patients with type 2 diabetes mellitus, (**SP445**).

Also in this issue...

(CONTINUED FROM COVER)

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Disclosures

Mr Kyle reports receiving fees for consulting services from Novo Nordisk and Eisai, Inc. Dr Stanford reports no relevant financial relationships.

it has been both hailed as a significant milestone to pave the way for more evidence-based obesity care and criticized by others as "medicalizing" a condition associated with unhealthy lifestyles.

ACCESS TO CARE HAS BEEN LIMITED AND EXTREMELY VARIABLE

Historically, access to evidence-based care for obesity has been limited by the small number of healthcare providers skilled in obesity treatment, by inadequate treatment options, and by poor coverage in health plans. Responding to the need for more skilled providers, the American Board of Obesity Medicine has now certified 1182 diplomates in the emerging specialty of obesity medicine. The number of diplomates continues to grow, with more than 400 physicians taking the exam in 2014.[5,6]

The primary tools for evidence-based obesity care are intensive behavioral therapy (IBT), pharmacotherapy, and surgery. Coverage for IBT is improving under the Affordable Care Act (ACA) because of the requirement that effective preventive services (as determined by the US Preventive Services Task Force) be covered by health plans without any cost to patients. IBT is one of these services.

As evidence for the effectiveness of bariatric surgery has grown, coverage for bariatric surgery by health plans for people with severe obesity has also increased, though both patients and surgeons report that problems remain.[7]

Coverage for pharmacotherapy has been the most restricted of the options for obesity treatment. Drugs used for obesity treatment often have been considered "lifestyle" drugs and have been routinely excluded from prescription benefit programs, as is notably the case for Medicare Part D. In 2010, most health plans reported that 20% or fewer employers were including coverage for obesity medications in their benefits. Under the ACA, while 23 states classify bariatric surgery as an essential health benefit, only 5 states classify medical obesity treatment as an essential benefit.[8] Poor coverage for obesity medications has been identified as a key barrier to the development and introduction of improved therapies.[9]

Limited coverage of pharmacotherapy for obesity leaves both clinicians and patients with a substantial gap in options. Between low success rates with diet and exercise and much higher efficacy at a much higher cost with bariatric surgery, new and effective obesity drugs are often unaffordable.

EVIDENCE-BASED OPTIONS ARE GROWING AND GUIDELINES ARE EVOLVING

In 2013, the American Heart Association, American College of Cardiology, and the Obesity Society jointly issued new evidence-based guidelines for the management of overweight and obesity in adults.[10] These guidelines affirmed that clinical care to reduce weight by as little as 3% and prevent further weight gain can yield significant health benefits.

Those guidelines were followed in 2014 by new evidence-based guidelines of the Endocrine Society, the European Society of Endocrinology, and the Obesity Society for the pharmacological management of obesity.[11] These drug treatment guidelines affirm the value of medications approved for chronic weight management as an adjunct to behavioral therapy for diet and exercise. They also emphasize the importance of considering the weight effects of other drugs that patients with obesity may be receiving.

Responding to the medical need for better treatment options in obesity, the FDA has approved 4 new obesity medications since 2010: phentermine/topiramate, lorcaserin, bupropion/naltrexone, and liraglutide. Each of these drugs met FDA criteria for efficacy, namely providing sustainable weight loss of 5% or more—either on average or in more than 50% of patients treated. Consistent with guidelines for obesity care, this level of efficacy was shown for each of these new drugs to provide significant improvements in diabetes, cardiovascular disease, and quality of life.

However, incorporation of these new drugs into clinical care of people with obesity has been slow, in large part due to poor coverage under drug benefit plans.[12]

EVIDENCE-BASED OBESITY CARE CAN DELIVER GOOD VALUE

Exclusive reliance upon changes in diet and exercise to reduce the health impact of obesity is often unsuccessful. Metabolic adaptation triggers potent biological responses that act to protect an individual's highest lifetime weight indefinitely.

Economic analysis shows that 5% weight loss can deliver substantial financial benefits, even in a person with a high body mass index (BMI). Cawley et al documented the potential for savings of $2000 per year in medical costs with a 5% weight reduction in persons with a BMI above 40.[13] And because the cost curve is even steeper for people with diabetes, they found further value in preventing progression to diabetes in people with obesity.

In this analysis, the greatest economic benefit comes from the first 5% of weight loss, which is the efficacy standard for FDA approval of new obesity medicines.

Thorpe et al recently analyzed the impact of weight loss on health costs for seniors and concluded that "Medicare can realize significant cost savings through anti-obesity medications that produce substantial weight loss."[14]

SIGNS OF CHANGE ARE EMERGING

On several fronts, tentative signs of change in coverage for obesity pharmacotherapy are visible. The AMA resolved in 2014 to press for patient access to the full spectrum of evidence-based obesity treatment, including pharmacotherapy.[15]

Also in 2014, the federal Office of Personnel Management ruled that health plans for federal employees could no longer exclude obesity medicines by characterizing them as "lifestyle" drugs.[16] The guidance further encouraged coverage of both behavioral therapy and pharmacotherapy for obesity. The National Conference of Insurance Legislators resolved in July 2015 that state legislatures should provide for "coverage of the full range of obesity treatment."[17] The growing support for access to evidence-based obesity care is beginning to show up in drug benefit plans. In 2012, Reuters reported that Express Scripts and Aetna had begun to cover new obesity drugs, phentermine/topiramate and lorcaserin.[18] More recently, CVS Caremark has been reported to have included liraglutide, the newest obesity treatment, on its 2016 formulary.[19]

Finally, legislation to open the door for obesity drugs in Medicare Part D is gaining support. The Treat and Reduce Obesity Act has been introduced in both the Senate and the House, with more than 100 bipartisan supporters.[20] It would remove the now archaic prohibition on coverage for obesity drugs by CMS.

WITHOUT ACCESS TO EVIDENCE-BASED CARE, COSTS CONTINUE TO MOUNT

Recent suggestions that growth in the prevalence of obesity might be ending are misleading. Alhough the overall prevalence of obesity may be reaching equilibrium at an unacceptably high rate, the rate of severe obesity is continuing to grow and is driving tremendous growth in the burden of chronic diseases.[3] Obesity is a key driver, for example, of chronic liver disease, and is becoming a key factor in the growing need for liver transplantation.[21] Obesity is increasingly recognized for contributing to growth in the prevalence of many forms of cancer. All this is in addition to the long-recognized relationship with cardiovascular disease and diabetes.

So health plans are indeed paying a high price for treating the consequences of untreated obesity. Without evidence-based treatment, obesity persists, progresses, and causes chronic diseases that affect virtually every organ system.

Advising people with obesity to eat less and move more is sound advice, but it is a strategy that most people with obesity have already pursued, finding limited success. A growing body of scientific knowledge explains how the body adapts to keep people from losing their excess body weight.[22] It is now apparent that obesity will typically progress without biologically potent treatment.

As those treatments are emerging, health plan coverage will need to keep up. Without routine, evidence-based treatment, medical costs for obesity—especially severe obesity—are becoming unsustainable. **EBDM**