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CURRENT OPINION

The Challenges and Opportunities Associated with Reimbursement for Obesity Pharmacotherapy in the USA

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Abstract Obesity has become a serious public health problem that has stimulated primordial and primary prevention efforts, and a triad of management options (lifestyle, pharmacotherapy, and surgical interventions). A growing body of evidence supports the need for a multi-pronged, clinic-based approach that leverages the synergy between pharmaceutical and lifestyle modification. Recent US policy changes—namely, the passage of the Patient Protection and Affordable Care Act coupled with recognition of obesity as a disease by the American Medical Association—suggest that financial incentives and attitudes towards obesity management are changing. This paradigm shift has implications for current and future obesity pharmacotherapy. However, barriers to pharmacotherapy utilization include patient and physician perceptions of modest efficacy, historical safety issues, regulatory obstacles, and lack of reimbursement. The shifting attitudes and challenges associated not only with a multi-payer system, but also the lack of clearly defined cross-payer reimbursement strategies, prompted a survey to determine coverage for obesity treatment. Participants indicated that federal/state mandates and growth of quality-driven healthcare initiatives will eventually drive wider pharmacotherapy reimbursement within 1–5 years. There are signs that federal/state programs are already moving towards reimbursement by improving quality measures to track obesity outcomes and reduce costs. Future research on clinical and economic outcomes of combination weight-management programs coupled with innovative approaches (e.g., eHealth) in the real-world setting that demonstrate value to patients, healthcare providers, payers, and employers will help reshape obesity management by reducing barriers and broadening reimbursement coverage for anti-obesity pharmacotherapy.

Key Points for Decision Makers

Obesity pharmaceuticals have historically suffered from drug-related tolerability/safety issues; however, heightened scrutiny during drug development and the mandatory inclusion of long-term cardiovascular safety studies has led to a growing number of safer treatment options.

There are multiple barriers to the widespread adoption of obesity pharmaceuticals in medical practice: patient perceptions and treatment expectations, lack of resources to address the full range of obesity lifestyle and environmental determinants, and limited health insurance coverage for treatment and medication.

1 Introduction

Obesity—defined by the US National Heart Lung Blood Institute (NHLBI) as a body mass index (BMI) $\geq$ 30.0 kg/m^2 [1]—has become a serious global public health problem disproportionately affecting developed countries [2, 3] and

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reaching epidemic proportions in the USA [4–6]. Efforts to limit the spread of obesity [7] have addressed both prevention and treatment. Preventive approaches have encompassed lifestyle modification interventions (e.g., diet and exercise) [8, 9], public education on nutrition [10], and efforts to increase access to nutritious food options [11, 12] and promote healthy eating (including regulation of the food industry [13, 14]). In addition, treatment efforts have included a triad of long-term therapeutic options: lifestyle modification such as behavioral therapy (BT), pharmacotherapy, and surgical treatment [15, 16].

Preventive efforts have seen some success [17–19], but not enough [20] to reverse the increasing obesity incidence in developed countries [3]. Clinical management efforts also face substantial difficulties, despite promising clinical trial results. Clinical trials of behavior and/or lifestyle modification have shown modest weight loss and beneficial effects on glycemic control, cardiovascular risk factors, and development of type 2 diabetes mellitus [21–26], but these findings have been difficult to translate into primary care settings for a number of reasons. First, these interventions are resource-intensive and require specially trained personnel such as behavioral psychologists, dietitians, and health coaches. Second, they often involve one-on-one or group sessions that require clinic space as well as repeat and frequent clinic visits, which, taken together, are financially unsustainable given the lack of commercial insurance reimbursement [27]. Third, physicians ably manage obesity-related co-morbid conditions, cardiovascular risk factors, and mechanical complications including obstructive sleep apnea [28, 29]. While aware of the need to address obesity, physicians lack adequate tools or support systems and, consequently, rarely assess the goals of treatment or provide motivational support or referral to weight-management counseling [30]. The US Patient Protection and Affordable Care Act (PPACA) [31] emphasizes the importance of prevention in primary care as a way to improve outcomes and reduce cost. However, without additional tools, and confronted with competing priorities, physician efforts against obesity remain modest. Recent data suggest that preventive health efforts have started to flatten the childhood obesity curves, though the opposite is true for rates of extreme obesity [32]. In addition, the modest degrees of weight loss observed with behavioral interventions have led to a rapidly growing specialization in surgical obesity treatment programs. An analysis by the Agency for Healthcare Research and Quality showed that the number of bariatric surgeries, which is generally reserved for highly motivated patients with a BMI cutpoint of $\geq$40 or $\geq$35 kg/m^2 with an obesity-related co-morbid condition [1], grew ninefold from 1998 to 2004 [33]; further, the use of lap-band surgery was recently expanded by the US Food and Drug Administration (FDA) to include patients with a BMI of $\geq$30.0 kg/m^2 with an existing condition related to their obesity [34]. A review of the different surgical treatment options is beyond the scope of this paper, but bariatric surgery has the demonstrated benefits of rapid and substantial weight loss and clinically important improvements in some biomarkers of co-morbid disease [35–37]. Unfortunately, recent studies of long-term outcomes with bariatric surgery show weight loss is sometimes not sustained; recidivism after surgery can be significant [38, 39]; and reoperation can be necessary with an attendant increase in operative and post-operative morbidity and mortality [40].

The option of obesity pharmacotherapy, coupled with new and advanced minimal-contact behavioral modification and lifestyle change programs [41], represent another treatment option. Pharmacotherapy is recommended as an adjunct to lifestyle modification in obese individuals with a BMI of $\geq$30.0, or $\geq$27 kg/m^2 with an obesity-related co-morbid condition [1], and recent results support that combining pharmacotherapy with lifestyle intervention leads to greater weight loss than either therapy alone [42]. While pharmacotherapy-assisted weight loss is also subject to recidivism, evidence shows that weight regain may be slowed or prevented with continued medication use [1].

The economic consequences of obesity and its associated co-morbidities are staggering and 2008 US estimates suggest that annual aggregate medical spending may be as high as $US147 billion per year [43]. Efforts to curb healthcare spending in the USA have focused on obesity as an upstream driver of multiple chronic diseases and support the case for a comprehensive, multifaceted approach to the obesity epidemic. At an individual patient level, little data exist to support the effectiveness of non-surgical treatment on healthcare cost; however, a recent study from the University of Michigan reported promising data on a real-world treatment that reduced healthcare utilization and cost in as little as 1 year [44].

It is within the context of real-world observational analyses afforded by the vertical integration of the US healthcare system and the alignment of stakeholders on pay-for-performance for improved outcomes and cost savings that we believe the cost benefit of pharmacotherapy will be demonstrated. This review provides an update and perspective on the evolving healthcare determinants, which, when coupled with obesity pharmacotherapy cost benefit, may drive future insurance reimbursement and greater patient access to treatment.

2 Previous Anti-Obesity Drugs and Implications for Current Pharmacologic Treatment

Although the first anti-obesity drug desoxyephedrine (or methamphetamine) was approved by the FDA in 1947, and

the most commonly prescribed medication phentermine was approved in 1959, sales of drugs with this indication did not accelerate until the early 1990s [45]. During this period, obesity prevalence rapidly increased [46] and the contribution of obesity to the development or worsening of a large number of medical conditions was better recognized [47, 48]. Yet, the adverse effects associated with these early drugs were considered too dangerous or undesirable for long-term use, thus limiting physician treatment options [45]. The obesity drug combination of fenfluramine/phentermine (known as fen-phen) was serendipitously discovered through clinical trial and error. Fen-phen had potent anorectic effects and consequently gained popularity in the early 1990s, reaching a peak of 18 million prescriptions in 1996 [49] despite the absence of FDA approval [50]. Fenfluramine (with its derivative dexfenfluramine or Redux™) was withdrawn from use in the USA in 1997 amid a major safety signal from reports of increased rates of valvular heart damage, primary pulmonary hypertension, and other severe complications associated with long-term use [51]. After the fen-phen experience, sibutramine entered the anti-obesity field in 1997, orlistat in 1999, and rimonabant was approved for use in the European Union in 2006. While showing some initial success, concerns about the weak efficacy of some of these agents, disruptive adverse events in the case of orlistat (e.g., bloating, flatulence, and diarrhea), cardiovascular risks with sibutramine (leading to its subsequent withdrawal in 2010), and depressive/suicidal reactions with rimonabant (withdrawn in 2009) ultimately led to a steady decline in weight-loss drug sales. Consequently, global revenue of anti-obesity drugs went from an estimated $US870 million in 2000 [52] to $US677 million in 2009 [53], then to $US359 million in 2011 [54].

Since 2012, three anti-obesity drugs have received regulatory approval in the USA (lorcaserin [55], phentermine/topiramate combination [56], and bupropion SR [-sustained-release formulation]/naltrexone SR combination [57]) after additional regulatory demands and delays [58]. These anti-obesity pharmacotherapy options along with orlistat remain available for long-term treatment; however, phentermine is currently the most commonly prescribed anorectic agent despite FDA labeling that limits use to 3 months or less.

The recent successful approval of three new anti-obesity agents belies a number of barriers. First, drug development is both costly and risky. Between 1993 and 1994, only 7.9 % of all compounds first tested in humans received regulatory approval [59], and $US0.8–1.2 billion was spent on average for each new drug development [60–63]. While the probability of regulatory approval is estimated to be 19 % for applications across drug classes [59], the historical success rate (1993–2004) for medications affecting metabolism/the gastrointestinal system and the central nervous system has been much lower—3.3–3.8 % [59]—and reflects the difficulty in finding targets that are free from metabolic redundancy and safety issues. Nonetheless, regulatory approval is particularly difficult to obtain for anti-obesity drugs [64, 65], and the FDA now requires the results of a long-term cardiovascular outcomes trial in the applications.

On top of drug development and approval barriers, pharmaceutical companies have largely relied on patient and physician acceptance of out-of-pocket reimbursement. Low rates of insurance reimbursement remain a major barrier, despite clinical guidelines recommending the use of anti-obesity drugs [15, 66]. Insurance coverage has generally been confined to employer-sponsored insurance plans with no government reimbursement [67, 68]. Finally, the lack of insurance has precluded long-term treatment and led to reluctance to prescribe due to the belief that weight regain post short-term treatment is likely. These treatment barriers taken together with historical safety issues have led providers to resist prescribing anti-obesity medications [68, 69]. However, the multiple factors affecting anti-obesity medication use have not seemed to slow the influence from pharmaceutical companies, and pipelines remain robust.

3 Recent Policy Developments May Presage Change

Since the withdrawal of sibutramine from the list of approved drugs for the treatment of obesity in 2010 [70], two significant developments in US healthcare policy have occurred, with important implications for the treatment of obesity. First, the PPACA, adopted into law in 2010 [31], strengthened the trend toward financial incentives for improved care and preventive health measures, including the prevention of obesity [71]. Two federal initiatives within PPACA created Accountable Care Organizations (ACOs), particularly the Medicare Shared Savings Program (MSSP) in which individual and organizational healthcare providers assume financial risk for a defined population of elderly and disabled Americans. MSSP ACOs expect to benefit from the shared savings that result from improved quality performance measures [72]. Among the MSSP ACO quality measures are BMI screening and follow-up, which are expected to affect more than 4 million Medicare beneficiaries. The same BMI quality measures are reported to the National Committee on Quality Assurance (NCQA) as part of their ACO accreditation program. As opposed to self-insured providers, MSSP ACOs have required integration and employment of providers within coordinated hospital systems (i.e., vertical healthcare) to achieve improvements in healthcare quality and secondarily reduce costs. In parallel with government-sponsored ACOs,

commercially insured ACOs have arisen within these systems, which now number close to 1,000.

In addition to quality measures, incentive programs were provided by the Health Information Technology for Economic and Clinical Health Act (HITECH Act) of 2009 [73] to help integrate patient information from acute care visits, ambulatory encounters, pharmacy, laboratory, imaging, and even genetic and other relevant data through the implementation of efficient Electronic Health Records (EHR) systems. These measures are intended to improve patient safety and outcomes and reduce the costs associated with uncoordinated, unnecessary, or duplicative care. By 2015, incentives for EHR will require meaningful use of data to improve population health [74], creating an ideal environment for the care integration required for effective obesity treatment.

The second significant development came in June of 2013, when the American Medical Association (AMA) recognized obesity as a complex disease [75, 76] requiring a range of interventions for effective treatment. Other organizations were more tentative in their approach: new cholesterol and obesity guidelines issued by the American Heart Association, the American College of Cardiology, and The Obesity Society [1] were not endorsed by the American Association of Clinical Endocrinologists (AACE) because the guidelines "fail to classify obesity as a disease and continue the paradigm of BMI-centric risk stratification, both of which are contrary to recently stated AACE positions. Moreover, the guidelines do not include any of the new FDA-approved pharmacologic agents to assist with weight loss" [77]. Regardless, recognition of the complexity of obesity, its multifactorial etiology, and its contribution to increased morbidity and mortality [78] should encourage prevention programs and treatment, and increase access to a range of treatment options [79]. The goal will be a concerted effort by patients, physicians, and payers to address and manage the current obesity epidemic [80, 81].

Together, these policy developments increase incentives for stakeholders to manage obesity more proactively, including through pharmacotherapy, if incremental anti-obesity benefit can be provided with appropriate levels of safety. This assumption may not be unlike past health policies focused on chronic health conditions (e.g., excise taxes that raised the price of cigarettes, pharmacological treatment/behavioral support for smoking cessation, indoor smoking bans) that presaged a significant decline in smoking in the USA [82].

4 Patient and Physician Perspectives: Challenge of Market Demand

Patient and physician views on obesity present a potential barrier to more systematic use and reimbursement of pharmacotherapy. Patients have historically pursued a number of self-management options for weight loss, including popular diets and commercial programs [83], or other over-the-counter options such as dietary/herbal supplements [84]. Past treatment patterns also indicate that patients take drugs seasonally [85], and do not recognize a role for pharmacologic therapy in maintenance of weight loss. While behavioral and pharmacologic treatments have typically yielded a clinically beneficial [86–89] 5–10 % weight loss, patients frequently expect much greater weight loss [90]. In part, their expectations are conditioned by their desire to return to a prior baseline weight, reflecting an under-appreciation of the social, environmental, and metabolic barriers that make weight loss difficult [90]. Hence, when coupled with lack of insurance reimbursement, there is little long-term adherence to current anti-obesity pharmaceuticals [91].

Physicians' perceptions and views of obesity also have affected treatment patterns for obesity. While there are limited data on physician treatment choices in the primary care setting, surveys have found that physicians recommend counseling for weight loss, including generalized advice on physical activity and diet [92, 93]. Although 92 % of respondents in a 2003 study of primary care physicians viewed obesity as a chronic condition, a much smaller percentage (26 %) felt that anti-obesity medicines should be used long-term [94]. In a 2007 survey of family physicians in Central New York, respondents typically viewed obesity as a chronic disease [95] and were relatively well aware that a 10 % decrease in total body weight may have significant impact on obesity-related co-morbidities, such as hypertension, diabetes, and heart disease [96]. Physicians have traditionally been more comfortable addressing obesity-related co-morbidities [93, 97–99], rather than addressing obesity treatment options, largely because of lack of training in prescribing specific nutrition and physical activity regimens [100]. Given the recent US approval of long-term anti-obesity pharmacotherapies, eHealth options [101], and advances in self-monitoring technologies [102], it will soon be possible to relieve physicians of some of the barriers of treatment. In addition, there is a need for better treatment guidelines, tools for screening, and better coordination of care, including alignment with public health efforts [95]. These are the very issues that the PPACA and the AMA declaration of the obesity disease model are currently attempting to address through policy changes focused on obesity.

5 Payer and Employer Perspectives: Challenges of Reimbursement

Provider reimbursement for surgical management of extreme obesity (BMI $\geq$40 kg/m^2) has not only evolved but

also dramatically increased over the last 10–15 years. This growth has been fueled by multiple factors, including improved procedures, weight loss, outcomes, and the recognition of extreme obesity as the fastest growing segment of the obese population [103]. While bariatric surgery can significantly improve weight-related co-morbid disease and consequently be life-saving, concerns about the financial burden remain, with average cost estimates approximating $US20,000 among an eligible US population of 14.5 million adults [103]. In the fragmented US payer environment, with private, government, and employer-based reimbursement systems, and patient movement between these systems (average turnover of 2–3 years), there has been reluctance to pay for bariatric surgery and obesity pharmacotherapy, despite evidence suggesting long-term health benefits and cost effectiveness [103, 104]. The passage of the PPACA and government mandates, such as increased reimbursement for lifestyle/behavioral approaches to obesity treatment, attempt to bypass barriers and may help drive the liberalization of physician treatment reimbursement as well as increased willingness to prescribe anti-obesity medication [68, 69]. Additionally, with adequate medication reimbursement, patients stay on anti-obesity drugs longer, see their doctor more often, and lose more weight [105]. The recent AMA declaration of obesity as a disease has also led to prominent policy changes. Recently, the US Office of Personnel Management indicated that federal employees' health benefit plans are not permitted to exclude coverage of newly approved obesity medications on the basis that obesity is a "cosmetic" or "lifestyle" issue; this policy goes into effect in 2015 and will impact 2.7 million federal employees and their beneficiaries [106, 107].

Based on the paucity of data on obesity pharmacotherapy reimbursement across non-governmental payers and the rapidly changing US attitudes toward obesity treatment reimbursement, a survey was undertaken in November 2013, which was funded by Takeda Pharmaceuticals USA, and executed by Strategic Healthcare Alliance (SHA). The goal of the survey was to determine the current and future plans of healthcare funding entities (employers and private insurance payers) with regard to coverage for obesity treatment. The findings of the study described here provide general direction on this topic, but are based on qualitative research and may not be generalizable to the broader population of payers and healthcare systems. Three 90-min group discussions were held with senior-level representatives from different stakeholder audiences: commercial Managed Care insurance Organizations (MCOs; $n = 9$), Pharmacy Benefit Managers (PBMs; $n = 9$), and healthcare providers from Integrated Healthcare Systems (IHSs; $n = 10$)—all of whom share risk around cost and healthcare outcomes with government and/or commercial payers. SHA provided a list of six levers for respondents to rank by importance (Fig. 1). Overall, respondents agreed that federal/state coverage mandates and the growth of quality-driven healthcare initiatives (that include obesity-related chronic diseases) would be the most significant contributors to broader coverage (Fig. 1). The perception that obesity medication coverage will eventually be mandated by state/federal governments (and adopted by all payers) emerged as an overall theme. MCOs and IHSs cited competitor coverage by other payers and real-world evidence (RWE) pilot programs as intermediary factors encouraging future reimbursement. Not surprisingly, PBMs ranked their support fourth with physician/patient demand as the lowest lever, largely because of their mandate to control pharmaceutical costs. Emergence of the importance surrounding an RWE requirement for future coverage reflects the growing ability to easily collect health outcomes and cost data at the level of the individual providers. Finally, a number of participants indicated an interest in non-traditional coverage options such as risk-share contracts with pharmaceutical manufacturers.

Overall, participants predicted forthcoming access to anti-obesity medication within a 1- to 5-year time horizon (Fig. 2).

	MCO	IHS	PBM
1	Federal/State Coverage Mandate	Federal/State Coverage Mandate	Federal/State Coverage Mandate
2	NCQA/HEDIS/STAR Measures	NCQA/HEDIS/STAR Measures	NCQA/HEDIS/STAR Measures
3	Competitor Coverage	Pilot Programs for RWE	Pilot Programs for RWE
4	Pilot Programs for RWE	Competitor Coverage	PBM Support
5	Physician/Patient Demand	Demand – of employers vs. physicians/patients	Competitor Coverage
6	PBM Support	PBM Support	Physician/Patient Demand

Fig. 1 Payer incentives to provide obesity coverage. *HEDIS* Healthcare Effectiveness Data and Information Set, *IHS* Integrated Healthcare Systems, *MCO* Managed Care Organization, *NCQA* National Committee for Quality Assurance, *PBM* Pharmacy Benefits Managers, *RWE* real-world evidence, *STAR* Medicare star rating

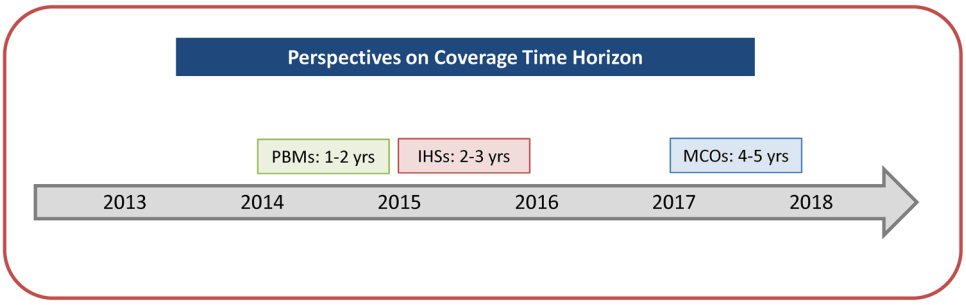

Fig. 2 Perspectives on coverage time horizon. *IHSs* Integrated Healthcare Systems, *MCOs* Managed Care Organizations, *PBMs* Pharmacy Benefits Managers, *yrs* years

5.1 Opportunities: Moving Towards Reimbursement

5.1.1 Federal/State Coverage Mandates

In addition to private insurers, there are government programs that provide medical and health-related services at the state and federal levels. Medicare is a nationwide social program that serves 44 million elderly and disabled people, whereas Medicaid serves about 40 million low-income people at the state level [102, 103]. Of note, the most important lever identified by the stakeholder survey included state and federal coverage mandates. At the federal level, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) [108] created the federal prescription drug benefit program Medicare Part D (effective 1 January 2006), which excluded anti-obesity drugs from coverage. The MMA did not recite a list of excluded drugs or classes of drugs; instead, the MMA identified the exclusions by reference to the Medicaid drug rebate provisions in the Omnibus Budget Reconciliation Act of 1990 (OBRA) [109]. Among the drugs "subject to restriction" were "Agents when used for anorexia, weight loss, or weight gain". The Centers for Medicare and Medicaid Services (CMS) further defined this section in guidance [110] issued on 18 July 2008, which clarified there was no Part D coverage for "agents when used for…weight loss…(even if used for a non-cosmetic purpose, i.e. morbid obesity)". However, some private insurance companies with federal contracts to provide Medicare benefits (known as Medicare Advantage plans) are allowed to exceed the scope of the Part D-defined benefit; thus, some Medicare beneficiaries can have covered access to these drugs, although few have implemented coverage. In 2013, legislative efforts were made to amend the MMA to include anti-obesity medication: legislation co-sponsored by a substantial number of members of Congress was introduced in both chambers to allow coverage of weight-loss medications under Medicare Part D. The Treat and Reduce Obesity Act of 2013 (H.R. 2415 and S. 1184) [111, 112] amends the MMA to allow coverage of FDA-approved weight-loss drugs. The bill also attempts to address the need to expand covered providers' (i.e., nurse practitioners, behavioral therapists, others) reimbursement for intensive BT. Currently, only primary care providers are eligible for reimbursement, which raises practical concerns about training and the ability to carve out adequate time within a busy primary care practice. The CMS considered the impact of BT on practice time and through coverage constraints created time limits (i.e., 10–15 min). Unfortunately, experts in BT have raised concerns about the efficacy of short-term BT interventions [113]. Although the bills died in December 2014 when the 113th Congress adjourned, the legislation will be reintroduced in the 114th Congress. However, as reported by GovTrack (https://www.govtrack.us/), a government transparency website, any bill has a very low chance of being enacted in the near future given the large number of bills introduced each year.

At the state level, programs may elect to cover (either through state directives or statute) [114] obesity treatments for Medicaid patients, but they are not required to do so per OBRA 1990. In addition, state governments legislate, regulate, and purchase/pay for healthcare for their employees and retirees. State fiscal pressures and the rising cost of total healthcare for their citizens has prompted states to more closely consider the benefits of implementing wellness programs that include coverage of smoking cessation, stress management, and weight-loss management (e.g., New York [115]). In addition, the implementation of federal healthcare recommendations at the state level has also affected the coverage offered by commercial health plans, though not in a uniform manner [116]. Most states do have health promotion initiatives in place for non-Medicaid citizens, but no standards of care mandate that insurance offerings in the private marketplace must cover weight-loss medicines. Yet, some states have elected to provide insurance coverage for weight-loss treatments for their employees and retirees [114]. Whereas at least 23 states, as of 2012, provided wellness programs for their employees (such as screening for cholesterol, glucose, blood pressure, and BMI), only a few currently provide incentives for weight loss and/or coverage of weight-loss therapies. These states also may provide health coaching for weight management (e.g., the Kansas HealthQuest Health and Wellness program).

5.1.2 Measures of Treatment Performance

The next important factor in obesity reimbursement is the availability of quality measures, which can track obesity treatment outcomes. There are obesity performance measures within the Federal ACO MSSP and the Medicare Star Ratings System for the percentage of patients with a recorded BMI and the documentation of a follow-up plan in patients 18 years and older with a BMI outside the normal range. Also included are additional performance standards for obesity-associated co-morbidities, such as diabetes (e.g., glycated hemoglobin control and low density lipoprotein control), hypertension (e.g., controlling high blood pressure), and coronary artery disease (e.g., lipid control). There are financial incentives provided to physicians when a desired performance level is met [117, 118]. Finally, the Healthcare Effectiveness Data and Information Set (HEDIS), sponsored by the NCQA, is used by various payers to measure performance on care and service; HEDIS includes in its measures an adult BMI assessment and a child/adolescent measure focused on weight assessment and counseling for nutrition and physical activity [119]. Reporting the results of HEDIS measures allows the purchasers of healthcare to compare the relative quality of commercial, Medicaid, and Medicare plans. As new and evolving obesity treatment approaches gain traction in clinical practice, additional outcomes and quality measures related to weight-loss treatment will likely be added to these quality performance panels. For now, the focus on BMI and obesity-related co-morbidities is an important first step in encouraging disease prevention.

5.1.3 Employer Initiatives

Anti-obesity coverage for employees of private companies is more variable. According to the US Census, in 2013 more than half (i.e., 54 %) of Americans had employment-based health insurance [120]. Consequently, employers have enormous influence over insurance coverage. Payer research indicates that only larger employers who fully subsidize employees' healthcare (self-insured employers) with co-pay offsets borne by the subscriber purchase additional coverage outside standard benefits (insurance riders). Thus, obesity coverage for many Americans is limited. Payers have indicated that generally an obesity rider is not directly requested; rather, employers specify that they believe obesity is a problem in their population and that they would like information on management options. Approximately 60 % of current plans ($n = 99$, based on large regional and national plans and PBMs) do not cover anti-obesity medications [68]. Yet, over 50 % of employers offer wellness programs, largely as a way to foster employee loyalty, but with little evidence of health improvements or reduced cost [121]. For pharmaceutical manufacturers, shifting the employer focus from wellness offerings to clinical interventions targeting overweight and obese employees will require real-world studies that examine the role of structured weight-loss interventions on cost savings (similar to recent studies, but within employer groups).

6 Future Directions

The recognition of obesity as a complex disease with multiple co-morbidities and expensive consequences is driving research into the development of effective treatment options. Emerging evidence suggests that the best outcomes derive from multidisciplinary approaches that utilize a broad range of expertise and varied interventions with proven synergy [42]. Combination weight-management programs coupled with innovative, promising eHealth programs [122], behavioral incentives [44, 123], and health-promoting policy decisions [31, 72, 76, 77] should continue to undergo real-world clinical and economic evaluation. Historically, the perception of obesity as a lifestyle concern led payers to limit coverage and physicians to limit prescribing. The scarcity of information about effective treatment options and clinical outcome benchmarks resulted in patient-driven demand (or lack of demand) for certain treatments and unrealistic expectations of therapy success. Today, however, the consequences of obesity are understood as both clinically and economically relevant, and obesity itself is no longer considered merely a lifestyle issue. As data emerge on the cost benefit of medical weight management, barriers to managed care coverage will likely decline.

Further research, particularly focusing on outcomes and economic benefits in real-world settings, needs to be conducted on all proposed approaches, whether primary prevention, lifestyle- or behavior-focused clinical interventions, surgical or pharmacologic interventions, or a combination. The creation of quality metrics and data-driven healthcare community practice will formulate this effort. Other innovative approaches that demonstrate value, such as risk- or outcomes-based contracting between insurers and manufacturers, may help drive innovation and hasten the evolution of the value proposition needed to persuade payers, employers, providers, and patients of the benefits of pharmacotherapy.

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