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Closing the Gap in Obesity Management Solutions

Integrating New Prescription Medications into
Employer Strategies to Help Reduce Obesity
in their Employee and Dependent Populations



** The quotes in this report are paraphrased statements made by Advisory Board members during the July 2012 meeting.*

“ Obesity is a serious issue for employers, and time is not on our side. We can’t afford to wait. We need to make progress now in providing efficient and effective interventions to our employees.”

— Advisory Board Member

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Most large employers in the U.S.
face a major challenge in managing
their employee health benefit.

Obesity

has become an important issue for their employee populations. It is impacting the health and productivity of their employees, and it is driving up their benefit costs.

As employers, they have been making significant investments in a broad array of anti-obesity programs and initiatives for several years.

These investments have not made an impact that is large enough to reverse the underlying trend toward increasing obesity in their employee populations.

These findings were confirmed by research that The Benfield Group conducted on behalf of Eisai Inc. in May 2012. (See Figure 1 on page 4 for selected employer survey results.) The research also found that many employers are grappling with a critical question:

“What can we do to achieve better results from our obesity management strategy?”

One potential answer could lie in important recent developments in the field of drug therapy. As new prescription weight management medi-

cations receive approval from the FDA, these drugs may provide an additional therapy option for individuals that are not making enough progress through diet and exercise alone.

So employers now face two related questions as well: **“Should we include these new prescription medications in our pharmacy benefit?”** and **“What steps can we take to ensure that these drugs, when used as prescribed, contribute effectively to our overall health/well-being strategy?”**

To help answer these questions, Benfield convened an Advisory Board of leading employer health benefit decision-makers in July 2012. (See page 7 for more information.) Their assignment was to develop recommendations for employers to follow in making coverage decisions for the new weight management medications. These Advisors agreed on two overarching objectives and developed recommended plan designs to achieve them:

- **Ensure that employees and dependents who meet explicit treatment indications criteria have affordable access to weight management medication; and**
- **Structure the benefit design to promote long-term treatment success, based on behavior change.**

A summary of their recommendations is presented on pages 8-13, following a brief description of the obesity management challenge, the gap that exists with available interventions, and the role that medications can play in addressing the gap. Then on page 14, there is a suggested Action Plan for those employers who prefer to take a proactive approach to coverage decisions.



For the past several years,
U.S. employers have been struggling
with some frustrating realities.

The Obesity Management Challenge

Workforce obesity has become a leading driver of increasing healthcare costs, while impacting the health and productivity of affected individuals. Employer survey data¹ shows that:

- The percentage of overweight and obese individuals has been increasing in their employee populations.
- Obesity is associated with greater prevalence of high-cost conditions, including diabetes, cardiovascular disease and musculoskeletal conditions.²

Despite investing in a broad range of obesity management programs and incentives, most employers have seen few results in terms of reversing the trend toward weight gain in their employee and dependent populations.

While these realities are alarming, they should come as no surprise given the latest obesity trends. Obesity has become a national epidemic—35.7% of U.S. adults were obese in 2009–2010³—and it is especially prevalent in certain regions like the southeast, as shown in Figure 3. There are multiple explanations for this trend. But the reality is that weight gain appears to be embedded in the cultural environment, and as a result, fighting the trend is an uphill battle. The challenge is multiplied by the difficulties many obese individuals face as they attempt to lose weight.

Why is Losing Weight So Difficult?

Why have these obesity trends persisted, when most people do not want to be overweight, and when the fundamental solutions—eat less and move more—are so simple and so well known?

Experts have come to recognize that sustained weight loss is inherently very difficult for many people to achieve, due to the complex mix of physiological, psychological and social factors that are often involved.⁴ Here are just a few of them:

Factors Impacting Obesity	Implications for Obesity Management
When we reduce calorie intake, our bodies naturally adjust metabolism levels.	Many people pursuing weight loss goals reach a plateau and then get frustrated.
Obesity tends to be more prevalent in certain families and communities than in others.	It is difficult to enable success at the individual level without changing the social environment.

Losing weight is not just a matter of discipline and willpower. Many individuals need additional help.

¹ See Figure 1 on page 4 for employer survey results.

² NIH/NHLBI. Clinical Guidelines on the Identification, Evaluation and Treatment of Overweight and Obesity in Adults. Sept. 1998. Available at <http://www.nhlbi.nih.gov/guidelines/obesity/index.htm>. Accessed Nov. 12, 2012.

³ CDC/NCHS, National Health and Nutrition Examination Survey, 2009–2010. Available at: <http://www.cdc.gov/nchs/data/databriefs/db82.pdf>. Accessed October 11, 2012.

⁴ Redman L, et al. Regulation of Body Weight in Humans. Chapter 7.2. www.endotext.org. 2012. Chaput JP and Tremblay A. Adaptive Reduction in Thermogenesis and Resistance to Lose Fat in Obese Men. *The British Journal of Nutrition*. 102:488, 2009. Hernandez L and Blazer D. Genes, Behavior, and the Social Environment: Moving Beyond the Nature/Nurture Debate. 2006.

Fig. 1 The Experience of Jumbo Employers in Managing Obesity

The responses to the right are from the results of a survey of 75 employers with at least 5,000 U.S. employees that The Benfield Group conducted in May 2012. As suggested in the Employer Action Plan on page 14, employers can use the right hand column to provide responses to each of these survey questions as part of a self-evaluation of their own organization's obesity management strategy.

* Responses to these questions total 100% when "Don't Know" is also included.

Percentage of employees that are obese (BMI ≥ 30)*

Less than 10%	12%	<div></div>
Between 10% and 20%	39%	<div></div>
Between 20% and 30%	20%	<div></div>
More than 30%	14%	<div></div>

Impact of obesity on total health benefit costs*

Less than 10%	8%	<div></div>
Between 10% and 20%	41%	<div></div>
Between 20% and 30%	23%	<div></div>
More than 30%	12%	<div></div>

Obesity management tactics currently in use

■ Environmental ■ Behavioral ■ Medical

Change the work environment to support healthy behaviors	71%	<div></div>
Wellness programs that promote healthier behaviors	88%	<div></div>
Provide weight loss programs at the worksite	75%	<div></div>
Biometric screening	64%	<div></div>
Telephonic health coaching	75%	<div></div>
Live health coaching	35%	<div></div>
Subsidize participation in commercial weight loss programs	40%	<div></div>
Psychological counseling	47%	<div></div>
Cover bariatric surgery	81%	<div></div>
Cover prescription weight loss medications	59%	<div></div>
Cover medically-supervised weight loss programs	44%	<div></div>

Overall effectiveness of the employer's obesity management strategy*

Not effective	11%	<div></div>
Somewhat effective	73%	<div></div>
Very effective	0%	<div></div>

Agreement with the statement: "The trend among our employee population is toward increasing levels of obesity."

Strongly agree	67%	<div></div>
Agree somewhat	28%	<div></div>
Disagree	5%	<div></div>

Surveyed
Employers

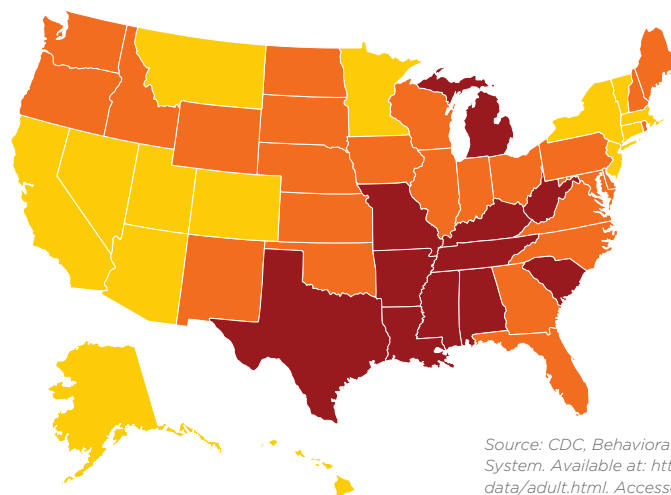
Your
Organization?

Fig. 2 Prevalence of Adult Obesity in the U.S., 2010

20-24%

25-29%

30%+



Source: CDC, Behavioral Risk Factor Surveillance System. Available at: <http://www.cdc.gov/obesity/data/adult.html>. Accessed October 11, 2012.



Weight Management Medications: An Opportunity to Close the Gap

Prevention & Management

For employers to be successful at preventing and managing obesity, they need an effective array of programs and policies that they may deploy.

Until recently, employers have had only a limited number of interventions at their disposal. Essentially, these interventions have been limited to:

- **Changes to the workplace environment** such as redesigned cafeterias, on-site exercise facilities and programs, walking paths, signage to encourage use of stairs, etc.—that can reinforce healthy lifestyle habits.
- **Behavioral programs and incentives** that encourage individuals to adopt healthier habits for nutrition and exercise.
- **Bariatric surgery** for the most seriously obese individuals.

The critical intervention that has been missing up to this point in time is a new set of safe and effective medical therapies that can help overweight and obese individuals who have difficulty achieving sustained weight loss through behavioral programs alone—and who are not candidates for (or do not want) bariatric surgery. Figure 3 provides a conceptual representation of how important the gap has been in addressing the needs of a large class of patients.

This gap has persisted because some weight loss products have been withdrawn from the market due to safety issues, and no new drugs were approved between 2000 and 2012.

Recognizing the need for safe and effective prescription medications for obesity, in 2007 the FDA drafted specific guidelines to encourage drug development by providing greater clarity regarding the specific efficacy and safety criteria that new products would need to meet in order to gain approval. These draft guidelines detailed the clinical study designs that manufacturers have since pursued.

As the FDA approves new prescription medications, employers need to determine how these medications will fit into their obesity management strategies.

“ Obesity is one of our greatest concerns, and we have a high level of frustration, since we’re already spending a lot of money trying to address it. If adding the medications to our weight management programs can help shift them from something that’s not working to something that does work, that will be really valuable.”

— Advisory Board Member

Fig. 3

Closing the Gap in Obesity Interventions

New safe and effective medical therapies can help overweight and obese individuals who have difficulty achieving sustained weight loss through behavioral programs alone—and who are not candidates for (or do not want) bariatric surgery.



Advisory Board Recommendations for Employers

An Advisory Board of leading employer health benefit decision-makers met for one and one-half days in July 2012.

The objective of the meeting was to develop recommendations for benefit plan designs that self-funded employers may adopt in order to make effective use of new weight management medications.

The Advisory Board Members

The employer representatives that participated in the Advisory Board are all well-respected leaders in the management of employee health. They include corporate medical directors, benefits decision-makers, wellness program directors and human resources leaders for nine Fortune 1000 corporations representing a wide range

of industries, along with two major universities/academic medical centers. Each Advisor is responsible for making decisions that impact at least 25,000 covered lives.

The two coalition representatives are CEOs of leading regional business health coalitions. Both of them are well-respected for their innovative services and programs to deliver value to their employer members.

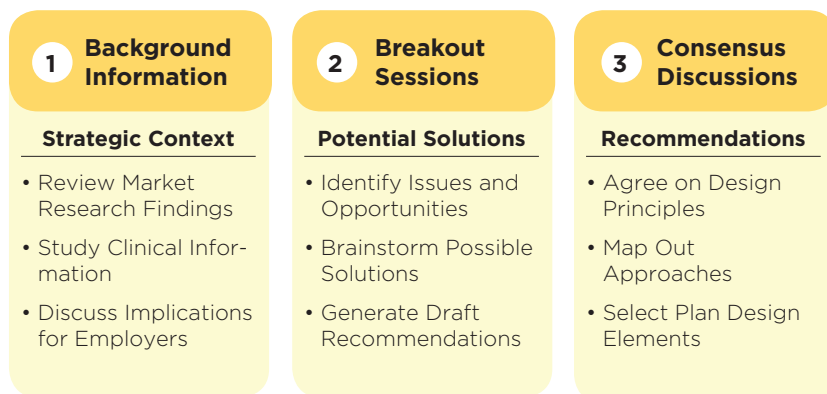
Meeting Structure

The meeting took place just one day after the FDA had approved the second of the two recently approved weight management drugs. The Advisors were aware of the news, but they had not yet had any internal discussions about these drugs.

As Figure 4 depicts, the meeting was comprised of three parts. The first session featured presentations to set the context for discussions. As background information, the Advisors were given an opportunity to review market research that Benfield had conducted, along with some clinical information about one of the drugs. Following the presentations, the Advisors discussed the implications for employers.

During the next session, the Advisors were divided into two breakout groups to discuss plan design issues and develop potential solutions. After break-out group presentations, the Advisors engaged in a facilitated discussion leading to consensus on recommendations for benefit plan design principles, approaches and key elements.

Fig. 4
Advisory Board Meeting Structure



Consensus

In the July 2012 meeting, the Advisory Board achieved consensus around a key set of recommendations for employers.

Their recommendations encompassed overarching principles that should guide coverage decisions for weight management medications, along with a specific set of approaches that employers can adopt in their respective plan designs. The Advisors recognized the potential benefits of applying Value Based Benefit Design (VBBD) concepts to these drugs. However, they also presented a pathway of alternative approaches that employers can adopt, depending on the level of clinical and economic evidence available to support each of the alternatives.

“ I see these medications as tools to enhance existing programs....Given the prevalence of obesity and the impact on employee health, this could be a huge opportunity.”

— Advisory Board Member

Overarching Design Principles

As overarching principles, Advisors recommended that employers should take steps to ensure that new prescription weight management medications are:

- 1. Covered under the employer's pharmacy benefit plan.** As long as the approved drugs are affordable, the Advisors see them as an important therapy for employers to make available to their employees and dependents.
- 2. Prescribed for patients in accordance with FDA-approved labeling.** With any weight management medication, there is a risk that otherwise healthy individuals will demand prescriptions for aesthetic reasons alone. Advisors emphasize that the drugs should be prescribed only to patients according to approved labeling.
- 3. Used to supplement behavioral interventions, not substitute for them.** Advisors understand new weight management medicines are not magic bullet solutions. They work to the degree that they support behavior change, and as such, should be prescribed in conjunction with a reduced calorie diet and increased physical activity—as they were in the clinical trials. Benefit designs are likely to be more effective if they reinforce the objective of integrating drug therapy with behavioral interventions.
- 4. Prescribed only as long as the therapy provides a benefit.** Advisors believe that weight management medicines should be prescribed to help people lose weight, and that they should be taken only as long as needed to achieve sustainable weight loss, consistent with FDA labeling.

With these principles in mind, the Advisors developed a set of recommendations for plan benefit design.



The Vision of a Comprehensive, Value-Based Solution

Vision

The principle that medications should “supplement behavioral interventions, not substitute for them” was especially important to the Advisors. They stressed the following point:

The key to an effective benefit design is to integrate the weight management medications into a comprehensive weight reduction program.

In taking this position, the Advisors explicitly noted the analogy of smoking cessation programs as relevant to their approach to obesity management. They could see that many of the same issues and opportunities were at play. (See sidebar on “A Helpful Analog: Smoking Cessation”.)

As Benfield’s survey results showed, most large employers already offer employer-sponsored weight loss programs for their employees through a number of vendors. So the need is not to create these programs. Instead, it is to ensure that the various components of the solution work together in a way that is mutually reinforcing.

Fig. 5
Promoting Integrated Solutions Through Value-Based Benefit Design

Employee commits to participate in employer-sponsored behavioral programs.

Employer reduces out-of-pocket costs for the medication.



Lowers financial barriers to therapy access for the employee.

Encourages employee engagement and accountability.

Reinforces a more comprehensive approach to weight loss, combining medical therapy with behavioral programs.

The consensus of the Advisory Board was:

The most effective approach to integration is a Value-Based Benefit Design (VBBD).



In this approach, the employer combines patient incentives with patient accountability in a clear and transparent way. That is, the employer reduces the out-of-pocket costs of the drugs to employees and dependents that are willing to assume related obligations such as participation in employer-sponsored behavioral programs.



In effect, the drug subsidy provides a financial incentive to encourage other desirable actions on the part of the patient, as shown on Figure 5. Many employers have adopted a similar tactic for diabetes management—offering drugs, devices and supplies to their plan members at very low cost, provided that the members also participate in a disease management program for diabetes.



At the same time, the Advisors recognized that the subsidy embedded in a VBBD approach involves greater pharmacy costs to the employer. They were hopeful that the approach will generate an attractive return on investment (ROI) to employers through future cost savings as the obese individuals lose weight and enjoy other health improvements. Nevertheless, they did not yet have the drug pricing information or the economic evidence



available to confirm that expectation for the recently approved drugs.



A Helpful Analog: Smoking Cessation

The Advisors identified smoking cessation as a helpful analog in determining what coverage policies will be most effective for weight management therapies.

As the Advisors observed, both smoking cessation and weight loss involve:

- Health risks that are critical and controllable.
- Behavioral changes that are difficult for individuals to sustain due to physiological, psychological and social factors.
- Patient histories that often include multiple unsuccessful efforts.
- Medical therapies that can assist individuals in achieving their objectives—particularly if they are embedded in an integrated solution that provides other forms of patient support.

As a result, the Advisors' recommendations reflected in part the successful results that many employers have experienced with smoking cessation programs over the past several years.

In particular, they emphasized the need for both medications and proactive patient support, plus the need to be flexible in providing on-going support if initial efforts are unsuccessful. They also acknowledged the importance of offering their employees an effective solution to help them achieve an important health improvement objective – like smoking cessation or weight loss – if the employer is going to hold the employee accountable for achieving the objective.

Pathway to a Value-Based Benefit Design

To address potential uncertainty around the economics, the Advisors developed a pathway of approaches—with increasing employer costs and also potentially greater employer value—that employers can adopt depending on the strength of the clinical and economic evidence for a particular medication.

“If we can add the medications to our disease management and health & wellness programs in an integrated approach, the synergy with these programs will have a multiplier impact..... And we know from experience that employees will trust employers that do it right.”

— Advisory Board Member

As shown in Figure 6, the pathway that they developed consists of three alternative benefit designs for employers to consider. These designs involve progressively more supportive approaches to coverage of prescription weight management medications:

- 1 Basic Coverage** at the standard pharmacy benefit tier for non-preferred brands, with no patient requirements.
- 2 Intermediate Incentives** that provides a moderate financial incentive for using the drug, along with a moderate level of accountability for employees and dependents.
- 3 Value-Based Benefit Design**, in which the employer sets a low/zero co-payment/co-insurance rate in exchange for requirements such as participation in an employer-sponsored behavioral program.

The Link Between Design Approaches and the Supporting Evidence

Finally, the Advisors identified the level of evidence they would want to see in order to institute each of these approaches. For Basic Coverage, they considered the level of clinical evidence evaluated by the FDA as adequate, as long as the drug is priced in line with other widely prescribed, branded oral prescription medications. However, in order to invest in lowering patient out-of-pocket costs for the Intermediate Incentives or Value-Based Benefit Design approaches, the Advisors expect to see some economic evidence as well.

Fig. 6

Pursuing Progressively More Supportive Benefit Designs for Coverage of Weight Management Medications



As the Advisors noted, they are already investing in a range of obesity management programs, so the key is to see evidence of improved outcomes and related future health benefit cost savings that justify the additional costs of drug coverage at the lower out-of-pocket benefit tiers. For Intermediate Incentives, Advisors were comfortable accepting economic models that combine clinical study results for weight loss with data showing medical and pharmacy cost savings associated with lower weight for relevant patient populations.

In order to move to the Value-Based Benefit Design approach, most Advisors would prefer to see evidence of actual savings that result from applying the VBBD approach with the drug in an employer setting.

However, until that evidence becomes available, several Advisors were willing to conduct pilot initiatives to test the value proposition in their own organizations.

One Advisor noted that in a well-managed employer setting the weight loss results may outperform clinical trials because of other employer initiatives, including robust behavioral change programs, incentives to lose weight and environmental support, such as exercise facilities and healthy cafeterias.

Integrating Medications into Bariatric Surgery Policies and Disease Management Programs




The Advisory Board noted the potential value of integrating weight management medications into the plan design for bariatric surgery and into disease management programs for obesity-related conditions like diabetes and cardiovascular disease. For example, the Advisors said they would consider requiring prior use of the medications in order to qualify for bariatric surgery.



Recommended Plan Design Elements

Table 1 provides a summary of the Advisors' benefit design recommendations.

Moving from top to bottom in the table, the trade-off for employees is a lower drug cost in exchange for greater commitment to behavioral programs. The Advisors devoted the most time to developing the Value-Based Benefit Design approach, which they saw as the most robust, and to a lesser extent the Basic Coverage approach, which is the simplest one. They identified a number of potential trade-offs that employers could offer for the Intermediate Incentives approach, but they did not settle on a single specific design. In their view, employers should look to combine a reasonable mix of employee incentives and obligations to encourage both appropriate use of the medication and participation in behavioral programs at a reasonable cost.

Benefit Designs	Pharmacy Benefit Tier	Patient Accountability	Controls		Desired Level of Evidence
 Basic Coverage	Tier for non-preferred brands	Recommend participation in a behavioral program	Prior authorization to ensure patient meets appropriate requirements (e.g., minimum BMI that varies depending on comorbid conditions)	Allow 1-2 attempts per year to reach the dose limit/renewal threshold	Evidence the drug is safe and effective for sustained weight loss in qualifying patients
 Intermediate Incentives	Tier for preferred brands	Require some level of commitment to participate in a behavioral program	Step therapy: Patient must have previously tried a behavioral program unsuccessfully	Provide greater flexibility on the number of attempts, depending on the level of accountability	Model-based evidence showing a positive ROI for coverage with limited incentives
 Value-Based Benefit Design	Tier for generics or preventative medications (low or zero out-of-pocket)	Require full participation in an employer-sponsored behavioral program	Dose limit/renewal: Require demonstrated success to continue coverage at periodic intervals (e.g., ≥ X% weight loss at Y weeks)	Allow multiple attempts, as long as other accountabilities are met	Study-based evidence showing a positive ROI for coverage using VBBD

**Table 1
Recommended Plan Design Elements**

The Advisory Board recommended the plan designs outlined in this table to implement the three approaches in their pathway

“Although there are still some unknowns, it is exciting to have new medications as part of our arsenal. We need to think through carefully how we'll fit them into our health plan and our health & wellness plan so we can be ready to really support the implementation.”

— Advisory Board Member

Employer Action Plan

Based on the Employer Advisory Board's recommendations, there are several steps employers should take to ensure they have an effective benefit design in place for weight management medications.

1. Gather Information About Your Situation

- a. Estimate the current impact of obesity on employee health and productivity as well as benefit costs for your organization.
- b. Complete the table in Figure 1 on page 4 for your organization, and use it as a guide to evaluate your current obesity management strategy and tactics.

2. Update Your Obesity Management Strategy and Tactics

In particular, determine what coverage approach for prescription weight management medications and related benefit design changes will deliver the greatest overall value to your organization. As part of this evaluation, consider establishing the use of weight management medications as a prerequisite for approving bariatric surgery procedures.

- a. Review the Employer Advisory Board's recommendations on pages 8 through 13. Consider what approach best fits your obesity management strategy and your organization's overall health benefit philosophy.
- b. Implement your preferred formulary and benefit design. Communicate the changes to your health plan members and your health benefit supply chain.

3. Monitor the Progress of Your Strategy and Benchmark It Against Best Practices

- a. Evaluate the impact of weight management drugs on your obesity and health benefit cost trends using Health Risk Assessment and medical/pharmacy claims data.
- b. Look for opportunities to enhance your strategy—such as implementing a more supportive benefit design—as new clinical and economic evidence becomes available.
- c. Periodically identify employer best practices for obesity management strategy and tactics, and adopt the ones that are promising for your situation.





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About Eisai

Eisai Inc. was established in 1995 and began marketing its first product in the United States in 1997. Since that time, Eisai Inc. has rapidly grown to become a fully integrated pharmaceutical business. Eisai's key areas of commercial focus are neurology, oncology, and metabolic disorders. The company serves as the U.S. pharmaceutical operation of Eisai Co., Ltd., a research-based human health care (hhc) company that discovers, develops and markets products throughout the world.

Eisai has a global product creation organization that includes U.S.-based R&D facilities in Massachusetts, New Jersey, North Carolina and Pennsylvania, as well as manufacturing facilities in Maryland and North Carolina. The company's areas of R&D focus include neuroscience; oncology; vascular, inflammatory and immunological reaction; and antibody-based programs. For more information about Eisai, please visit www.eisai.com/US.



Eisai Inc.
100 Tice Blvd.
Woodcliff Lake, NJ 07677

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