Developing a Comprehensive Benefit for Outcomes-based Obesity Treatment in Adults

Obesity is a complex disease with detrimental impacts on the health, wealth, and longevity of Americans. There are evidence-based treatments for people with obesity that mitigate the impacts of the disease and improve health outcomes. The present landscape of obesity care coverage is piecemeal, and providers frequently cite inconsistent and/or inadequate reimbursement for obesity-related services as barriers to delivering appropriate care.

Without guidance on how to operationalize evidence-based behavioral, nutritional, pharmacological, and surgical obesity treatment modalities as health benefits, health insurance plans have taken vastly different approaches in determining what and how obesity treatment services are covered for their members. The lack of consistent coverage is a barrier to needed care for many U.S. adults with obesity. As a first step toward standardizing the provision of obesity care across plans, we have designed a comprehensive benefit for outcomes-based obesity treatment that provides guidance on minimum acceptable coverage for medically-necessary components of obesity care and conditions under which these services and/or items ought to be covered. Development of this comprehensive benefit was informed by input from key stakeholders, including representatives from large employers, health plan administrators, payers, patients, and providers. This document is intended to:

1. Identify evidence-based obesity treatment modalities that can support clinically-significant weight loss (≥5% reduction in body weight) among persons with obesity
2. Provide guidance on the appropriate amount, scope, duration, and delivery of obesity-related benefit offerings
3. Highlight real-world examples from plans that cover obesity treatment modalities
4. Support efforts to standardize the scope and availability of obesity treatment modalities that are covered across plans / systems.

Although we recognize that the design and successful administration of a health benefit is a complicated process, we hope that this tool will inspire employers, payers, and others involved in benefit design and administration to reassess the adequacy of coverage for obesity treatment services in current plan offerings. Where coverage for evidence-based obesity services is absent or limited, we hope that this comprehensive benefit will provide plans with useful guidance for how they can improve obesity care for their members. Where coverage for obesity care is available, we encourage plans to include detailed guidance on what constitutes appropriate provision of obesity-related services in their provider manuals and other relevant communications.

Insurers may choose to administer elements of this obesity benefit in different ways. Although we sought and incorporated feedback from industry experts regarding the feasibility of implementing each component of the comprehensive benefit, this tool does not address expected care costs or specific processes related to benefit administration that likely differ across geographies, systems, and plan types. We limited discussion of reimbursement to suggested cost-sharing arrangements (e.g. copayment), because there were insufficient data to

determine which reimbursement mechanisms (e.g. FFS, episodic, capitation) are most likely to optimize provider participation, enrollee engagement, overall benefit usage, and health outcomes in the context of obesity care.

Real-world examples of various reimbursement and care delivery strategies currently in use can be found in the *Examples* column of each section. The examples are selected from our research on the coverage of obesity treatment across state Medicaid and State Employee Health Insurance programs. (*Obesity* 2018;26:1834)

We have also not identified particular points at which care should be intensified, because as outlined in our proposed standards of care (*Obesity* 2019; 27: 1059), the decision to escalate care should be a product of joint decision-making by the provider and patient, informed by prudent clinical judgement and specific needs of the patient. Furthermore, the various provider types mentioned throughout the benefit illustrate current care practices but are not an exhaustive list of the providers who may deliver various components of care. We encourage payers to reimburse various types of providers who can reliably and safely deliver obesity care that achieves the desired treatment outcomes, regardless of their discipline and beyond those specifically mentioned herein.

In the pages that follow, we have outlined what we consider to be the **core components** of an obesity benefit package that are essential for effective and evidence-based treatment of obesity. We follow this with a section of **expanded components**. These provide an additional option for the delivery of the core benefits. The expanded components are recommendations based on anecdotal or emerging evidence.

KEY TERMS

Beneficiary. A person and his or her dependents for which a premium has been paid to a health insurer. Also called an enrollee, subscriber, or member.

Benefit design. Rules governing the terms under which medical care items or services obtained by beneficiaries are considered covered benefits. Benefit design sets out the parameters by which enrollees can obtain medical services (e.g. provider networks, prior authorization and PCP referral requirements) and their financial liability associated with receipt of this care (e.g. deductibles, copayments, coinsurance).

Covered benefits. The medical care items or services obtained by a subscriber that a health plan agrees to pay for, under certain terms and limitations. Covered benefits and excluded services, and the terms and limitations of coverage, are defined in the health plan's coverage documents or the subscriber contract.

Health plan. An individual or group plan that provides, or pays the cost of, medical care. The role of a health plan is distinct from the role of payer. Even though an entity can be in both roles, not all health plans are payers and not all payers are health plans.

Medical necessity. Refers to tests, procedures, and treatments which may be justified as reasonable, necessary, and/or appropriate for an individual patient's circumstances, based on evidence-based clinical standards of care. Health plans typically require medical necessity as a condition of benefit coverage, and receipt of a medical care item or service does not in and of itself indicate that the item or service was medically necessary.

Out-of-pocket costs. Expenses for medical care that are not reimbursed by insurance. These include deductibles, co-insurance, and co-payments for covered services in addition to all costs for non-covered services.

Payer. Any entity that is responsible for final processing of claims, member enrollment, premium payments, and/or inquiries related to eligibility and utilization review may be considered a payer. Private payers are typically insurance companies contracted by employers, but this is not always the case. Public payers are federal or state governments.

Utilization management. The process of evaluating and determining coverage for and appropriateness of medical care services to ensure appropriate use of pooled resources.

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STOP OBESITY ALLIANCE
STRATEGIES TO OVERCOME & PREVENT

OBESITY CARE BENEFIT DESIGN
Core Components

Treatment Type	Scope of Service [1]	Amount + Duration	Delivery	Examples
Prevention & Screening				
	All adults should be screened annually for obesity (document height, weight, waist circumference; calculate BMI), changes in weight status, and patient body weight concerns potentially indicative of an eating disorder. For adults with obesity (BMI ≥ 30 kg/m^2), waist circumference > 102 cm (> 40 in) for men / > 88 cm (> 35 in) for women, or BMI 25-29 with obesity-related risk factors: - offer or refer to intensive lifestyle intervention (see IBT section) - screen for obesity-related complications: impaired glucose tolerance (FPG and HbA_{1C}), dyslipidemia (lipid panel), depression (PHQ-9), and hypertension	1 screening / year 1+ follow-up visits (for overweight) **Labs / diagnostic tests** - FPG - HbA_{1C} - Lipid panel - PHQ-9 If suggested by history and/or physical exam: - sleep apnea - PCOS - liver function (ALT / AST)	Screening can be conducted: - by PCP during wellness visit - by other trained professional at worksite, pharmacy, or community clinic (results must be reported back to PCP) PCPs should provide anticipatory guidance on nutrition and physical activity for all adults, especially after weight loss.	**Mississippi Medicaid**: Covers annual adult health screenings/physical exam with separate reimbursement for cardiovascular (cholesterol, lipids, triglycerides) and diabetes (labs, urinalysis) screening tests if performed during the annual screening exam.

Treatment Type	Scope of Service [1]	Amount + Duration	Delivery	Examples
Intensive Behavioral Therapy (IBT)				
USPSTF-recommended intensive, multicomponent behavioral interventions for adults with obesity (BMI ≥ 30 kg/m^2)	Intensive behavioral therapy for obesity must include ALL <u>three</u> of the following: 1) **Cognitive component**: intervention using evidence-based educational and behavior-change techniques (e.g. CBT, MI, 5As) to facilitate behavioral change 2) **Physical activity component**: physical activity plan that includes personalized recommendations for aerobic (150 min/week goal adapted for patient's capacity) and muscle strengthening activity. 3) **Nutrition component**: program or dietary intervention that targets intrapersonal-level factors to assist with changing energy balance behaviors *NOTE: There should be low or no out-of-pocket costs to actively-engaged patients, regardless of weight loss*	26 sessions / year - additional visits PRN with prior authorization - allow unlimited lifetime attempts / repeats for structured programs [2] Initial assessment + up to 14 visits / year for weight loss - continue therapy for at least 6 months	Components of IBT must be delivered by qualified care providers / trained interventionists in outpatient clinics or commercial programs Individual or group sessions should be delivered in-person (clinical or community setting) or virtually[3] The physical activity plan should be developed based on clinical judgment, patient/client needs, and other components of the obesity care plan (e.g. diet, medication, comorbidities) The nutrition component should be delivered by a registered dietitian, nutritionist, or PCP with expertise in nutrition. It must include a nutrition assessment; development of a dietary plan acceptable to the patient; and monitoring, evaluation, and revision of dietary strategy as needed.. Very low-calorie diets (VLCD; ≤ 800 calories/day) may be prescribed if appropriate, under supervision of PCP or another trained clinician.	**California Medicaid**: IBT (G0447, G0473) is a benefit for recipients with BMI ≥ 30 in accordance with USPSTF guidelines; treatment authorization request required only if >22 units/yr **Exercise is Medicine Greenville® Program**: Comprehensive 12-week <u>clinical exercise program</u> that provides exercise and health education led by qualified, credentialed EIMG® Professionals; lifestyle medicine interventions delivered in both clinical and community settings **Wyoming Medicaid**: Covers medical nutrition therapy provided by a registered dietician (up to 12 visits per year for adults); services must be ordered by PCP, but dietician can bill Medicaid directly

Treatment Type	Scope of Service [1]	Amount + Duration	Delivery	Examples
Pharmacotherapy [4]	NOTE: Because a generalizable hierarchical algorithm for medication preferences that would be applicable to all beneficiaries cannot currently be scientifically justified, clinicians and beneficiaries with obesity should have access to all approved medications to allow for the safe and effective individualization of appropriate pharmacotherapy.			
FDA-approved medications, prescribed in conjunction with behavioral interventions when acceptable to the beneficiary	**Short-term medications**: diethylpropion HCl ER, phentermine HCl	3 months; use beyond 3 months consecutively constitutes off-label use [dosing varies by medication]	Prescribed as short-term adjunct to obesity management care plan. Combinations acceptable when informed by sound clinical judgement Prescribed as part of chronic obesity management plan; continued renewal of prescription at quarterly check-in with PCP if therapeutic benefit persists (maintenance of weight loss may constitute sufficient benefit)	**Wisconsin Medicaid**: Coverage available for all agents with BMI ≥ 30 (or BMI ≥ 27 w/ two risk factors) and prior approval; must continue participation in obesity treatment plan and meet weight loss targets for continued coverage
	Long-term medications: bupropion HCl/naltrexone HCl (Contrave), liraglutide (Saxenda), semaglutide (Wegovy), orlistat (Xenical), phentermine HCl/topiramate ER (Qsymia)	3-months initial trial; quarterly renewals if therapeutic benefit persists (indefinitely) [dosing varies by medication]		
	Weight-centric prescribing For beneficiaries with obesity, the plan should authorize coverage for an alternative medication that is not associated with weight gain when the standard formulary agent(s) used to treat a covered comorbid condition (e.g. depression, allergies) is/are weight-positive.	(see Appendix A for suggested alternatives to commonly prescribed medications by condition type)	Prescribers should be knowledgeable about the indications and relative efficacies of weight-neutral and/or weight-negative medications that can be used to treat common conditions. - Care providers should recognize when a beneficiary with obesity has been prescribed a weight-positive medication and consult with the prescribing provider to identify an acceptable weight-neutral or weight-negative alternative. - The risks of stopping or changing medication should be balanced against the risks of obesity and related co-morbidities.	

Treatment Type	Scope of Service [1]	Amount + Duration	Delivery	Examples
Surgery [5]				
	Primary bariatric procedures: Laparoscopic sleeve gastrectomy Roux-en-Y gastric bypass Biliopancreatic diversion w/ DS	1 primary procedure	Procedure should be performed by an experienced surgeon who works as part of a multidisciplinary care team, in a designated bariatric Center of Excellence (COE) when feasible. - If health plan contracts with clinic outside of beneficiary's locality, costs of travel and/or remote follow-up care should be reimbursed.	**California Medicaid**: Covered when BMI ≥ 40 (≥ 35 with comorbidity), documented failure of conservative treatments, a comprehensive pre/post-operative treatment plan established, and no medical or psychiatric contraindications to the procedure.
	Revisional procedures to correct complications or when inadequate weight loss achieved despite adherence to prescribed post-op treatment regimen.	1+ revisional procedures		

Treatment Type	Scope of Service [1]	Amount + Duration	Delivery	Examples
Weight Maintenance				
Strategies to prevent and mitigate weight regain are integral to the obesity care plan.	**Monitoring & Prevention:** Continued tracking and documentation of weight status (waist circumference; BMI), changes in weight status (% change in body weight), and body weight concerns.	2 visits / year (minimum) - 1 with dietitian - 1 with PCP	Patients should take measures to prevent weight regain, including:[6] - 60-80 minutes of moderate-intensity physical activity per day - measure weight each week - ongoing external support via peer network, structured program, or other method	
	Maintenance of clinically-significant weight loss constitutes sufficient medical benefit to warrant coverage for ongoing services / supports. - may include continued access to pharmacological and/or behavioral therapies as appropriate	PRN on case-by-case basis; appropriate services will vary but may include: - behavioral intervention - nutritional therapy - pharmacotherapy - surgery / revision of prior surgery	The plan should adopt and promote monitoring systems / practices that prompt intervention when regain occurs.	
	Follow-Up & Intervention: Re-initiation or intensification of obesity treatment plan when patient: - begins to regain weight; - presents with a new or worsening obesity complication; or - requests intensification of treatment (as medically appropriate)		In consultation with the patient, adjust obesity care plan as necessary to halt and reverse weight regain and/or to resolve an emergent obesity complication.	

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OBESITY CARE BENEFIT DESIGN
Expanded Components

Treatment Type	Scope of Service[1]	Amount + Duration	Delivery	Examples
Intensive Behavioral Therapy (IBT)				
Cognitive Component	Benefit may also include: - additional services and/or resources to meet the psychosocial needs of patients with weight management challenges	PRN on case-by-case basis as part of an obesity care plan	Offerings and delivery vary by health system, community assets, other benefit offerings, and composition of plan	
Physical Activity Component	Benefit may also include: - clinical or community-based program that includes exercise, health education, counseling and support for patient/client, - specialty care needed to address functional impairments that inhibit or substantially limit a beneficiary's ability to engage in physical activity as prescribed - facility fees / gym membership	2-3 sessions / week for at least 12 weeks - multiple lifetime attempts allowed PRN on case-by-case basis as part of an obesity care plan Continued reimbursement contingent upon engagement[8]	Reimburse with PCP referral to program; may include medical exercise classes (small-group) and/or individual personal training sessions[9] - PCPs and beneficiaries should have access to current list of plan-approved facilities, programs, and resources - plan should provide clear instructions for accessing services and requirements to obtain / maintain coverage	**Fallon Health *It Fits!* Fitness Reimbursement Program** Reimburses beneficiaries for gym memberships, pilates and yoga classes, WW (Weight Watchers®) programs, town sports programs, ski passes, road race fees, and some types of cardiovascular home fitness equipment
Nutrition Component	Benefit may also include: - Medically-tailored meals: consider use of home-delivered meals[7] and/or commercial meal replacements to optimize nutrition outcomes for certain patients with obesity	15 meals/week - initial 3-month trial; continue if therapeutic benefit persists - 4-week package ancillary to bariatric surgery	PCP or RD prescribes as component of care plan for adults with obesity and impaired glucose tolerance and/or evidence of food insecurity	**Nevada State Employee Health Plan**: Covers up to 50% of monthly member OOP costs for meal replacements (if enrolled in CDHP Overweight Care Management Program)

Treatment Type	Scope of Service[1]	Amount + Duration	Delivery	Examples
Bariatric Surgery				
	Benefit may also include the following ancillary services:[10]			
	- Pre-op psychological evaluation - Pre-op surgical consultation - Pre-op preparatory regimen - Post-op medical / nutrition services - Post-op supervised WMP	1 consultation 1+ consultation PRN PRN for ≥ 24 mos 6+ sessions / 6 mos	Pre- and post-operative services should be delivered by the surgical care team, member's PCP, and/or qualified providers in designated outpatient program	
	Travel expenses	Up to $3,000	Beneficiary may submit for reimbursement of transportation, lodging, food for self + one companion if 50+ miles from facility	
	Nutritional supplements	Lifelong coverage for vitamins; other medications PRN	Bariatric vitamins, prescription medications for post-operative care	
	Panniculectomy	Up to $5,000 12 months post-op	Offered if member has achieved and maintained adequate weight loss and presents with functional impairment due to excess skin, cellulitis, skin necrosis, or ulcerations	

Weight Maintenance

	Benefit may also include additional products and/or services to prevent weight regain and support continued monitoring of weight-related health, such as: - Self-monitoring devices (digital scales, fitness trackers) - Access to gym / fitness facility (see above) - Community programs that provide ongoing external support	PRN on case-by-case basis; appropriate services will vary by member experience	The plan should adopt and promote monitoring systems / practices that prompt intervention when regain occurs. Plan may cover services related to weight maintenance through normal claims process as preventive service, as global benefit contract directly with vendor / provider, or request that beneficiary pay out-of-pocket and submit for reimbursement

[1] Indications for these procedures / medical treatments are detailed in the following clinical practice guidelines:
- *2013 AHA/ACC/TOS Guideline for the Management of Overweight and Obesity in Adults*
- *Managing Overweight and Obesity in Adults: Systematic Evidence Review from the Obesity Expert Panel, 2013*
- *AACE/ACE Comprehensive Clinical Practice Guidelines for Medical Care of Patients with Obesity*
- *Pharmacological Management of Obesity: An Endocrine Society Clinical Practice Guideline*
- *Clinical Practice Guidelines for the Perioperative Nutritional, Metabolic, and Nonsurgical Support of the Bariatric Surgery Patient*

[2] Plan may impose reasonable limits on multiple program attempts within a single calendar year

[3] Virtual or telephonic components can be used to supplement in-person contacts (multi-modal).

Electronically-delivered components must include personalized feedback. Tauro SJ, Gold EC.

The Feasibility of Using Internet Support for the Maintenance of Weight Loss. *Behav Mod* 2002;26(1):103-116.

[4] Minimum prescribing threshold is BMI ≥ 30 or BMI ≥ 27 with obesity-related complication(s)

[5] Minimum threshold to refer is BMI ≥ 40 or BMI ≥ 35 with obesity-related complication(s)

[6] Klem ML, Wing RR, McGuire MT, Seagle HM, Hill JO.

A descriptive study of individuals successful at long-term maintenance of substantial weight loss.

American Journal of Clinical Nutrition. 1997;66(2):239-46.

[7] Medically-tailored meals reimbursable under Medicare (CHRONIC Act);
pilots in Commonwealth Care Alliance (MA), Medi-Cal (CA), Health Partners (PA) add more detail on Medi-Cal pilot program

[8] The plan should consider supporting ≥ 50% the costs of ancillary services / resources needed to enable adherence to prescribed physical activity regimen for certain populations (e.g. beneficiaries with most severe disease, lack of access to safe spaces for physical activity, income within 100% FPL, and/or limited local access to needed specialty care)

[9] Plan may cover through normal claims process, contract directly with vendor / provider, or request that beneficiary pay out-of-pocket and submit for reimbursement

[10] Kaiser Permanente Bariatric Surgery Program provides useful reference points for acceptable OOP costs / patient engagement requirements.

APPENDIX A: Possible Alternatives to Medications Associated with Weight Gain

The following table of medications is neither exhaustive nor authoritative. The mechanisms by which weight-positive medications contribute to weight gain vary and may include:

- stimulation of appetite
- stimulation of fat storage (lipogenesis)
- reduced energy expenditure via [a] slowed metabolism and/or [b] impaired exercise tolerance
- fluid retention

Therapeutic Class	Condition(s) Treated	Weight-Positive Medications	Preferred Alternatives * = weight-negative
Anticonvulsants			
[a] GABA augmenting agents [b] Other	Epilepsy Migraines Neuropathy Bipolar disorder BPD	[a] gabapentin, pregabalin [b] divalproex, valproic acid	✓ topiramate * ✓ Sodium channel blockers (zonisamide *, lamotrigine, carbamazepine) ✓ felbamate *
Antidepressants			
[a] tricyclic [b] MAOIs [c] SSRIs [d] Other	Depression Bipolar disorder OCD PTSD Dysthymia Panic disorder	[a] amitriptyline HCl, doxepin, imipramine HCl, mirtazapine, nortriptyline, trimipramine [b] phenelzine sulfate, tranylcypromine sulfate [c] paroxetine HCl, citalopram [d] lithium	✓ bupropion HCl* ✓ SSRIs (fluoxetine, sertraline) ✓ nefazodone HCl
Antihyperglycemics			
[a] Insulins [b] Sulfonylureas [c] Thiazolidinediones [d] Meglitinides	Diabetes	[a] ALL insulins [b] glimepiride, glipizide, glyburide [c] pioglitazone HCl, rosiglitazone maleate [d] nateglinide, repaglinide	✓ insulin + pramlintide ✓ Biguanides (metformin HCl) * ✓ GLP-1 agonists (exenatide, albiglutide, dulaglutide, liraglutide, semaglutide) * ✓ SGLT-2 inhibitors (canagliflozin, dapagliflozin, empagliflozin) * ✓ AGIs (miglitol, acarbose) *
Antihistamines			
[a] H1-receptor antagonists [b] H2-receptor antagonists	Allergies GERD	[a] azelastine HCl, cetirizine HCl, cyproheptadine HCl, diphenhydramine HCl, fexofenadine [b] ranitidine HCl	✓ H2-receptor antagonists (loratadine) ✓ non-pharmacological methods (e.g. nasal irrigation)
Antihypertensives			
[a] β-blockers [b] α-blockers	Hypertension	[a] atenolol, metoprolol, propranolol, acebutolol [b] clonidine	✓ ACE inhibitors (enalapril, lisinopril, captopril) * ✓ ARBs (losartan, telmisartan) *
Antipsychotics			
[a] Typical, 1st gen. [b] Atypical, 2nd gen. [c] Treatment-resistant	Schizophrenia Psychosis Nausea	[a] haloperidol, perphenazine	✓ ziprasidone ✓ aripiprazole

			[b] clozaril, olanzapine, risperidone, quetiapine fumarate [c] clozapine HCl	
Corticosteroids				
[a] Glucocorticoids [b] Mineralocorticoid		Asthma Allergies Arthritis Dermatological disorders Autoimmune diseases	[a] prednisone, prednisolone, methylprednisolone [b] fludrocortisone	✓ NSAIDs (celecoxib, diclofenac, ibuprofen, naproxen) ✓ DMARDs (leflunomide) ✓ PDE4 inhibitors (apremilast)
Contraceptives				
[a] Synthetic progestins		Unwanted pregnancy PCOS Endometriosis	[a] progestin-only contraceptives; medroxyprogesterone, norethindrone, levonorgestrel	✓ IUDs ✓ physical barriers ✓ oral preferred to injectable

Sources:

Apovian CM, Aronne LJ, Bessesen DH et al. Pharmacologic Management of Obesity: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab* 2015; 100(2):342-62

Wharton S, Raiber L, Serodio KJ, Lee J, Christensen RA. Medications that cause weight gain and alternatives in Canada: a narrative review. *Diabetes Metab Syndr Obes* 2018;11:427.