



DESIGN LAB BRIEFING

Obesity medicines &
comprehensive solutions
pressure testing case study
September 2024

CONFIDENTIAL

Obesity medicines & comprehensive solutions pressure testing case study

The purpose of this Briefing Book is to clarify our systemic solution design and to prepare Design Lab participants to pressure test the solutions for providing adequate and equitable, perhaps even excellent, care for people with obesity. The class of medicines now available (i.e., GLP-1 Receptor Agonists) has dramatically advanced the opportunity to treat obesity as a persistent, chronic disease. However, revamped, systemic approaches are necessary if patients are to gain the full benefit of these medical advances.

Solution elements to pressure test in breakout groups

Each breakout group will pressure test one of the solution areas of the envisioned obesity health-care system in Table 1 below regarding:

- Is the solution area design sufficient to achieve the desired systems change for its area?
- How should the solution area elements be refined (modified, dropped, or new ones added)?
- Which of the seven themes critically impact the solution area and how might they be addressed?
- What are the challenges to reaching the ideal state? What execution challenges must be addressed?
- How should this solution module connect to those in the other areas?

At least one breakout group will address each solution area in Table 1.

Table 1: Solution areas of the envisioned obesity healthcare system

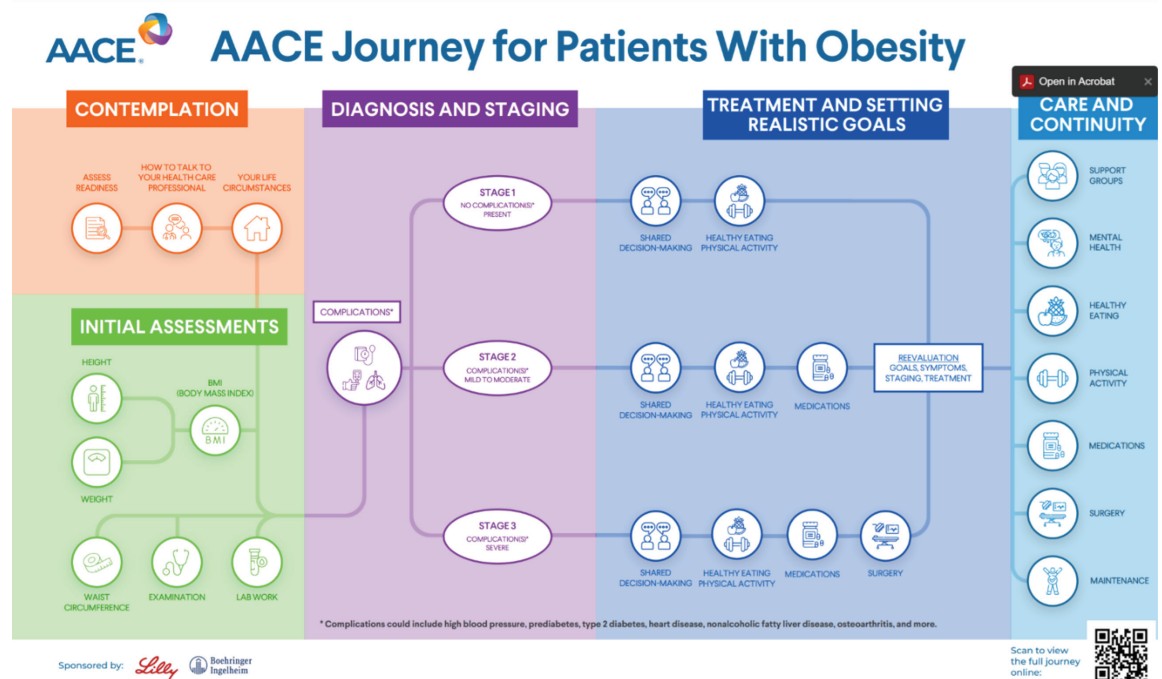
Solution area break out groups	Solution elements to pressure test
Patient Engagement/ID and Diagnosis	How to bring patients into the health support systems
Integrated Care	Targeted Intervention Elements
	Graduated Care
	Tailored Delivery
Shared Capability Building	Needed infrastructure, from coding systems to evidence generation for collaborative learning
Obesity Care Delivery Structures	Centers of Excellence (CoE) - centric delivery
	Primary Care Physician (PCP) - centric delivery
	Consumer - centric delivery

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Background

In the first Obesity Case Study at the April 2024 Design Lab, we launched an investigation into modern obesity medications and overall patient care for individuals with obesity. We endeavored to understand the health care and payment innovation challenges and opportunities for therapies targeting this chronic disease. Throughout those discussions, challenges and opportunities were identified by following the journey for patients with obesity. Utilizing the AACE Journey for patients with obesity (Figure 1 below), an idealized patient journey map, we identified access and outcome impediments and how they impacted key stakeholder groups. With this elucidation work complete, the team moved to investigate solutions to address the challenges identified.

Figure 1: Idealized, historic journey for patients with obesity



Clarity about the challenges led us to our next iteration. The design of a 3-5 year future-state, obesity healthcare system is now the focus of the September 2024 Design Lab, where we will pressure test whether this approach will create a learning system that provides comprehensive support for patients, trains health care providers, encourages adequate and standardized coverage for obesity care (i.e., not just weight loss), and is sustainable for all stakeholders involved. Further, we will assume that modern obesity medications will be covered at least to some extent by all payers including Medicare and Medicaid. We will also assume that product shortages will no longer be a concern due to expanded manufacturing capacity and additional market entrants.

Multi-faceted systems changes emerging from challenges

Through an iterative process, the Design Lab team has identified four solution areas where changes will, in combination, support a robust, effective health care response to obesity as a disease, by developing obesity healthcare systems that can be tailored to address the broad array of patient needs in four “Solution Areas” (Figure 2).

First, **how patients are identified, engaged, and diagnosed** requires change. This initial stage is particularly impacted by stigma and biased perceptions of people with obesity across society and our healthcare systems.

Second, patients and patient outcomes are best served by **integrated care**: based on the patient’s obesity and health status, integrated care would include what care elements are offered, at what intensity, at what time, and tailored to the patient’s preference across their obesity disease journey. Patients will engage more systematically as access to integrated care improves and patients have flexibility to tailor the care elements to their specific needs.

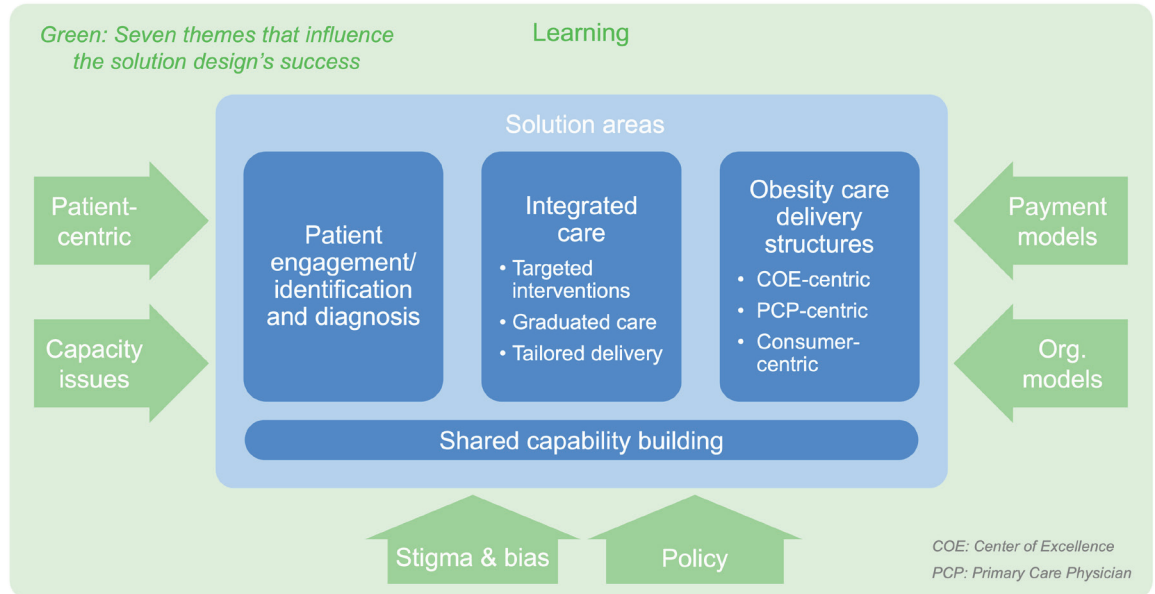
Third, new **shared capabilities** will need enhancement or creation, from care guidelines and outcome metrics to data generation and analysis that will continue to enhance our knowledge of what care pathways are most effective based on the patient’s obesity and health status.

Finally, we will explore **obesity care delivery structures**. A combination of different delivery structures will be needed to cover patients with varying levels of disease and to provide different opportunities for seeking care (e.g., time, cost, or other resource constraints). The key will be to develop systematic, high-quality care across all care delivery systems to treat this chronic disease.

These four solution areas do not operate separately but must be implemented in an integrative process to generate the most inclusive and appropriate care for patients with obesity. A patient’s engagement will improve as the care provided is more integrated. Integrated care that accommodates different patient needs will require shared capabilities that can build and monitor system changes to support flexible, or varied, care delivery structures. Such multi-faceted systems changes will spark an upward, positive cycle, where obesity care can be revised as new evidence shows what works best for patients with obesity.

Seven pervasive themes impact how obesity healthcare systems will develop and take hold. From bias and stigma to capacity issues to payment models, the breakout teams will each assess the mechanisms by, and degree to which, these themes influence the possible success of the solution areas and how to address them. These themes are represented by the six green arrows and the enveloping learning environment depicted in Figure 2 below.

Figure 2: Obesity Medication Management Framework: Four solution areas and seven system themes that influence the solution design's success



The themes above weave through all aspects of our solutions and must be considered as we pressure test the solution elements in the September Design Lab. Stigma and bias are listed first (above) for a reason: the stigma against people with obesity is pervasive in our society, affecting patients own identities as well as every person with whom they have contact. Bias starts when people assume there is fault associated with this disease and thus people with obesity are treated with disrespect. Bias finishes with limited health care, and certainly healthcare that is not patient-centered. With such high numbers of people living with obesity, care capacity and disease state management capabilities will influence how and who receives care, both in terms of how care can be integrated and how the organizational structures are built out. Today, the traditional organizational structures are unprepared for integrated care pathways that comprehensive obesity care will require. Payment models and policies to support a more robust obesity care environment are also underdeveloped. As a whole, these themes serve as drags on the people, programs, processes, and structures that we will be investigating in the Design Lab.

Patient engagement/identification and diagnosis

Weight stigma and biases profoundly impact the initiation of medical treatment of obesity as a chronic disease. A study in 2018 found that a total of 96% of adults with obesity are not seeking medical care¹. Potential patients and their family members usually assume that high weight is a character flaw; care providers are often not trained to address obesity as a disease and thus do not understand how to identify and engage new patients in an informed and collaborative manner. When providers do engage patients appropriately, they are often unable to ensure that evidence-based care can be provided once a diagnosis has been confirmed or provide a patient with an integrated care plan.

The current socio-cultural limitations to identifying, engaging, and diagnosing people living with obesity have begun to shift, thanks to medical science breakthroughs in the treatment of obesity as a disease. At the same time, healthcare providers are not trained in sufficient numbers to manage the increase in patients seeking care and diagnosis does not yet ensure that healthcare responses for treatment are triggered or managed. For medical science advances to benefit patients, significant changes are necessary.

First, a comprehensive “obesity is a disease” communication effort could not only build awareness and acceptance of obesity as a disease but also provide a foundation for reducing the impact of stigma on care. Second, more providers will require education or training to better understand treatment options and what successful patient pathways look like. As these circumstances unfold, patients will not start from the deficit of self- and system-biased assumptions but will confidently recognize that they require medical treatment. Finally, health systems must be more responsive to identification and diagnosis of patients with obesity, with more developed ICD-codes that trigger further health system support for patients.

Broadly communicate “Obesity is a disease”: To reframe obesity as a disease in society at large, targeted communication efforts could be an effective starting point. Government agencies, payers, providers, and developers could work collaboratively on campaigns tailored to build knowledge and understanding of obesity as a disease for specific stakeholder groups. Historically, such efforts have succeeded in transforming the general understanding of a disease (e.g., cardiovascular disease, osteoporosis, and others). Activities could include proven communication strategies, from cross-stakeholder awareness campaigns, public service announcements, educational pamphlets, and school-based education programs (both for K-12² students and incorporated into medical training curricula, etc.) and traditional news outlets (print, media). New communication technologies could also be employed, from social media influencers, targeted advertisements and various information-sharing platforms that can be monitored to understand their scope of influence. A relatively short-term effort to reconceptualize obesity from a “lifestyle choice” to a chronic disease could provide the impetus for patients to seek out medical treatment for obesity. In addition to this community outreach, solutions to include:

- Active patient outreach to normalize medical treatment for obesity care:
 - Provider and payer multi-modal outreach (e.g., email, phone calls, etc.) to encourage known patients/members with obesity to come in for care.
 - Explicit patient screening targets for PCPs to expand identification in currently underreported populations.

Educate, and train healthcare providers: Health Care Providers (HCPs) are the first point of contact for people with obesity seeking support to manage this disease. As society shifts away from a biased understanding of the disease, more certified HCPs with appropriate training will be required to meet the need. To date, the American Board of Obesity Medicines has certified approximately 8,500 physicians across multiple scientific disciplines³. Nurses are also trained in obesity care support but as more people with obesity seek care, more nurses with training in obesity will be required and they have the potential to play a much-needed broader role, coordinating care for obesity patients⁴. Specific training and certification solutions include:

- Increase obesity training courses within medical and nursing schools:
 - Metrics: increase available courses at number of schools/year; measure increase in educators capable of teaching these courses; measure number of students taking these courses.
- Double the number of trained doctors and nurses in obesity care & management every two years. In addition to medical doctors, track increases for physician assistants (PAs), nurse practitioners (NPs), Pharmacy Directors (PharmDs) and registered nurses (RNs).
- Build care coordination training programs in nursing schools
 - Metrics: Establish target number of new nursing courses for obesity care coordination and target/measure number of nursing candidates successfully completing these courses.

Build coding and quality measures that support a bias- and stigma-free patient induction

process: to redress how the health system currently progresses new patients, improved codes for obesity and quality measures are required. Providers must be able to utilize ICD-codes that trigger appropriate health insurance reimbursements, as well as progress patients to the next level of treatment after diagnosis (e.g., prompts for follow-up requirements)⁵. Providers will also be incentivized to work toward improved obesity care when care quality is measured. The further development and application of HEDIS and STAR metrics will provide these benchmarks for HCPs and payers⁶. Solutions to include:

- Develop a strategic set of peer-review articles that bring attention to the current state of coding & reimbursement rates for obesity⁷.
- Partner with National Committee for Quality Assurance (NCQA) to build across discipline approach to obesity quality measures.
 - Metrics: create NCQA behavioral health awards that recognize quality obesity care programs; partner to develop 2025 NCQA Innovation Summit focus on Obesity.
- Incorporate increased HCP outreach methods that succeed into HEDIS and Star metrics.

These early stages of patient engagement in care will shift dramatically as stigma and bias about obesity are attenuated if, at the same time, HCPs are trained, certified and ready to initiate care and the coding and quality metrics that signal and recognize appropriate care are further established and utilized. The induction phase of care for patients with obesity will remain complex, as the full panoply of support services must be balanced for any one patient and the coordination of these services must be established. As outlined in Figure 2 above, the range of services, the level of diagnosed obesity related diseases (formerly referred to as co-morbidities)⁸ and BMI range (at least for now) will all combine to build a picture of the initial patient journeys. As these patient journeys become established and patients seek to engage with healthcare systems, patients will have better access to treatment for this chronic disease.

Integrated care

To provide patients with obesity the comprehensive, integrated care options necessary to produce long-term positive results, we propose enhancing health systems in three ways:

- Offering **targeted intervention elements** that support the best health outcomes for each sub-population and that recognize patient preferences in a socio-economic context. The inter-

vention elements offered would cover the full set of services for obesity management: recognizing and shaping how care is provided. Elements to be actively engaged will include nutrition services, physical activity programs, food provision, comorbidity management, psychological support services, and medical treatment.

- **Graduated Care** that nuances sub-population best practices based on disease severity. In this heterogeneous disease, graduated care will be designed to support patients at different stages of their disease and recovery, recognizing that this chronic condition will not follow one, set path over time.
- **Tailored delivery** in a shared decision-making process, where patients' environment, culture and socio-economic conditions are considered as intervention elements are customized and coordinated for their care.

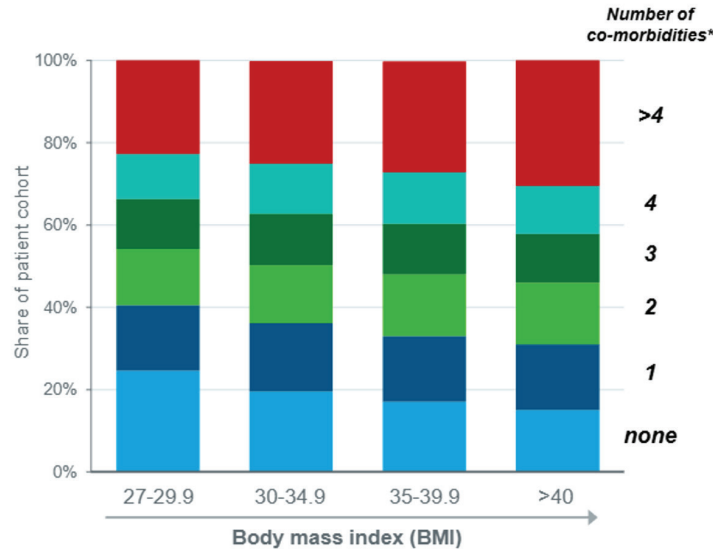
The first two (intervention elements and graduated care) would likely be encapsulated and disseminated in treatment guidelines. Still aligned with the treatment guidelines, the tailored delivery enhancements would be decided in a local, shared decision-making context among payers, providers, and patients. As telehealth and digital applications that create touch-points with patients are embraced, tailored delivery enhancements that save time and travel will support more equitable access to obesity care. Ideally, data from the local level would be developed and used to inform the treatment guidelines, establishing an ongoing learning process that will advance care over time.

Targeted intervention elements

With obesity firmly understood as “a serious, chronic, relapsing and treatable disease”⁹ with a complicated range of obesity related diseases, treatment is not complete with medicine or surgery alone. Currently, obesity medication labels awarded by the FDA identify medicines as “adjunct” to diet and exercise regimens.^{10,11} Complications of obesity, including obesity related diseases, are wide-ranging, and patients are often have more than one additional condition (see Figure 3 below). With such a heterogeneous disease, weight loss is one important aspect of the patient journey but does not address the disease comprehensively.

Figure 3: Obesity-related disease rate suffered by patients with obesity

taken from Gores, M., “When the dust settles: The future shape of the obesity market,” IQVIA Blog, May 13, 2024. *When the dust settles: The future shape of the obesity market - IQVIA* Accessed 7/16/2024.



To achieve comprehensive obesity care, the intervention elements will focus treatment based on a patient’s needs holistically, on required treatment intensity and patient engagement. In addition, patient needs will shift over the course of treatment, with more intense use of certain services early (or later) along the patient pathway. Targeted Intervention elements would include:

Table 2: Targeted intervention elements

Culture of Care	Active Engagement Programs	Psychological Support Services	Medical Treatment Elements
<ul style="list-style-type: none"> • Patient Encouragement (motivation & care planning) • Patient navigation (access) 	<ul style="list-style-type: none"> • Medical nutrition therapy • Dietary plans, consults • Food provision, food access • Physical Activity/ Fitness monitoring • Obesity related diseases management 	<ul style="list-style-type: none"> • Behavioral health access • Mental health programs • Peer mentoring 	<ul style="list-style-type: none"> • Intensive Behavioral Therapy (IBT) • Obesity medications • Metabolic surgery and devices

In addition to these targeted intervention elements, the overall integrated care must conform to reputable clinical practice guidelines or other evidence-based guidance that will provide a foundation for health outcome measures to develop. Over time, integrated care design will improve as clinicians and other obesity care specialists update the most effective patient care protocols. Coordinating these integrated care elements is a key design element for the Obesity Care Delivery Structures (below, see ‘Obesity Care Delivery Structures’ section) that we expect will require sig-

nificant development. Some level of clinician authority will be necessary to oversee the integrated use of intervention elements and to encourage appropriate transitions in care over time.

Graduated care

Targeted intervention elements provide the foundation for positive health outcomes for patients with obesity. At the same time, graduated care — the sequencing of targeted intervention elements based on disease severity – will best serve patient health equitably when the systems of care are organized to measure what works and improve care interventions over time. Payers and providers may best support patients by:

1. Basing programs on expert-designed clinical practice guidelines; and
2. Segmenting patient populations by disease severity.

To ensure systematic approaches to data generation and utilization, clinical guidelines must be well developed and updated regularly. With clinical practice guidelines clear and up-to-date, patients can be supported in their health journey by providers who adhere to known treatments to address the complexity of this disease: the targeted intervention elements outlined above will be combined differently in patient journeys considering the level of disease severity and other patient-centric considerations. Graduated care will necessarily respond to these changing patient conditions.

Graduated care might assess patient needs based on the severity of obesity, number of obesity related diseases, and the patient's level of engagement. At the diagnostic phase, care systems require clear strategies for identifying and supporting patients to seek care, with transparent methods for differentiating access to care once the patient's needs have been diagnosed. For example, using the Edmonton scale of severity or a simplified severity scale based on BMI and obesity related diseases such as:

- Overweight (BMI 27-<30)
- Overweight (BMI 27-<30) w/obesity related disease(s)
- Class I (BMI 30 - <35)
- Class I (BMI 30 - <35) w/obesity related disease(s)
- Class II (BMI 35 - <40)
- Class IIIa (BMI ≥ 40 - <55)
- Class IIIb (BMI ≥ 55)

If the Edmonton scale is to be consistently used, it will be important to note that there are clear racial differences in BMI assessments for obesity, including a lower cut-off point for Asians¹² and a higher cut-off for African Americans. More research in this area is required.

As more evidence accumulates, the most successful integrated care for each subpopulation of patients could be improved, with health outcomes that trigger changes in the aspects of care required as the disease reaches lower levels of severity (or with chronic resurgence of disease). In such “maintenance” phases of the patient journey, understanding what contributes to successful health outcomes will remain a complicated project, recognizing that measurement of BMI levels and more comprehensive diagnostics¹³, obesity related diseases and other indications of disease severity, as well as the nuanced use of integrated care services will all contribute to quantifiable obesity management.

Clinical guidelines, recommendations

With such a complicated chronic disease as obesity, many medical associations have weighed in with guidelines and recommendations for treatment since the American Medical Association designated obesity as a disease on 2013 (see below for a current list of organizations). Earlier guidelines established consistent steps for clinicians, and recent updates have included the new medical treatments available, the FDA labels granted, and weight-related complications to be considered in establishing comprehensive patient care.

Each guideline or recommendation considers diet, exercise, and behavioral modifications as a mainstay of all obesity management approaches. There remains agreement that BMI measurement is recommended to initiate evaluation and determine disease classification, but for a full diagnosis, a clinical assessment of weight-related complications and waist circumference measures are recommended.¹ Obesity medications and bariatric surgery can also be considered in combination with behavioral changes and increased physical activity. Evidence shows that when medicines (specifically GLP-1s) are used in tandem with behavioral modifications, greater and more sustained weight loss is achieved.²

Preventive care is also addressed in the guidelines. It is recommended that patients who are overweight stop gaining weight or lose weight to avoid progression to obesity and additional comorbid conditions. As identification of patients at risk for, or experiencing obesity, is very often first identified via a PCP office, the American Academy of Family Practitioners has also developed a comprehensive overview of clinical guidance and practical resources about obesity for PCPs.³

List of organizations providing guidelines and/or recommendations since 2013:

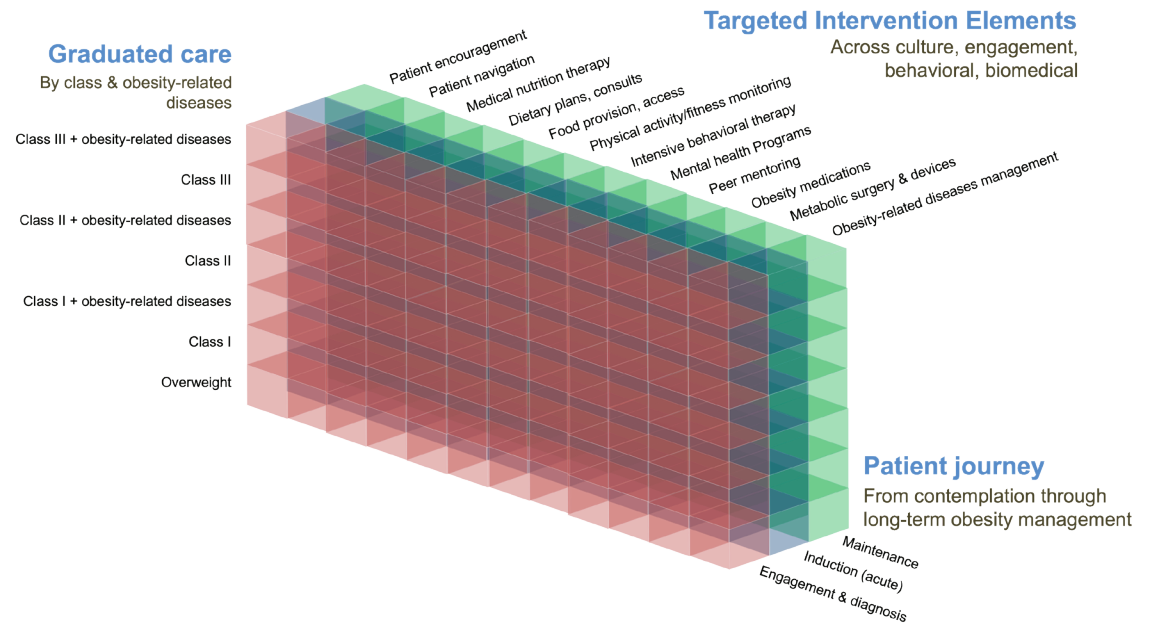
- 2014: The American College of Cardiology (ACC), the American Heart Association (AHA) and The Obesity Society (TOS) joint clinical practice guidelines.
- 2016: The American Association of Clinical Endocrinologists (AACE) and the American College of Endocrinology (ACE), jointly published evidence-based clinical practice guidelines.
- 2021: The American Heart Association.
- 2022: The American Gastroenterological Association (AGA) issues new clinical practice guideline on pharmacological interventions for adults with obesity, they identified the specific OM in their report.
- 2022: American Society for Metabolic and Bariatric Surgery (ASMBS) and the International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO) updated clinical guidelines to expand patient eligibility for weight-loss surgery, now to include surgery for individuals with BMI >35 and for a BMI of 30-34.9 with metabolic disease.⁴
- 2023: The American Academy of Pediatrics.
- 2023: Guidelines from the American Diabetes Association were updated.⁵
- 2024: The Obesity Medicine Association updated a tool for clinical practitioners, “the 2024 Obesity Algorithm[®]” that includes advice on starting an obesity medicine practice and how to use telehealth options.⁶

References

1. Cornier, M., “[A Review of Current Guidelines for the Treatment of Obesity](#),” 12/14/2022. Am J Manag Care. 2022;28(suppl 15):S288-S296. doi:10.37765/ajmc.2022.89292
2. Ibid. See also Cornier’s references 1,2.
3. [Obesity Clinical Guidance](#) | AAFP
4. Kissin, R. “After 30 Years- New Guidelines for Weight Loss Surgery,” news release from the American Society for Metabolic and Bariatric Surgery (ASMBS), 10/21/2022. After 30 Years — [New Guidelines For Weight-Loss Surgery](#) - American Society for Metabolic and Bariatric Surgery (asmbs.org). Accessed online 8/21/2024.
5. American Diabetes Association regularly updates recommendations on standards of care. See the 2023 Obesity Treatment and Weight Management Standards of Care for the Prevention and Treatment of Type 2 Diabetes - <https://pubmed.ncbi.nlm.nih.gov/36507637/>
6. [Obesity Algorithm](#) | Obesity Medicine Association

Figure 4 illustrates how the Targeted Intervention Elements, Graduated Care sub-populations, and patient journey phases (diagnosis, induction treatment, maintenance treatment) should interact to create differentiated 'ideal' care paths for each sub-population over time that vary in the number and intensity of interventions.

Figure 4: Integrated Care: Targeted Intervention elements create differentiated 'ideal' paths over time for each Graduated Care sub-population



Tailored delivery

A process to engage patients in tailored delivery of care that addresses underlying challenges. With effective medicines and treatment guidelines for this complicated disease available, how a patient engages with targeted intervention will require additional flexibility in service delivery. Any care delivery system must also be judged on its capacity to engage patients in shared decision-making, the flexibility in access to services (both in the range of services and the care delivery options), and the system's ability to reach a wide range of patients. We envision tailoring a patient's integrated care based upon:

A. The patient's current level of knowledge, readiness for treatment & personal preferences:

- Stigma & bias history
- Cultural differences, racial/ethnic preferences
- Readiness to change
- Peer and family support
- Learning style
- Time of life (work responsibilities, family responsibilities, availability for travel)
- Self-care advocacy capabilities/trauma-informed care options

B. The patient's accessibility constraints:

- Treatment and provider options available in their geographic area or virtually
- Internet access limitations (including due to work environment, remote location)
- Social Influencers of Health (including socio-economic circumstances, race/class biases, proximity to healthy food outlets)
- Obesity related disease burden (mobility limitations, complexity of care coordination)

Integrated care solution elements

Integrated Care will necessarily include targeted intervention elements, graduated care, and tailored delivery mechanisms. With a positive induction process and these integrated care elements in place, healthcare systems can embrace the opportunity to foster positive and equitable care for patients with obesity with consistent care quality. Taken together, these elements of Integrated Care will inform treatment guidelines and continue to refine how comprehensive care for patients with obesity develops.

Given the integrated care discussion above, solutions to test would build on the previous section, but also include:

- Build patient journeys over time for obesity sub-populations that are based on analysis of successful timing and utilization of targeted intervention elements as illustrations of best practices based upon the guidelines.
- Work with relevant medical societies and patient associations to create regular updates to clinical guidelines as new data about obesity treatment and outcomes develops (see breakout for currently active associations).¹⁴
 - Clinical guidelines will remain complex, with the ability to accommodate shared decision-making between patients and providers.
 - Clinical guidelines will necessarily incorporate measures of care quality and improvement in behavioral health, mental health, nutrition, and exercise.
- Publish a quality review of telehealth and digital technology (e.g., apps) that support tailored delivery of obesity care while maintaining care quality.
 - Identify and establish institutional networks between app developers and patient/ provider organizations.

Shared capability building

All stakeholders are in the early stages of understanding the breadth and scope of the potential health benefits of GLP-1 medicines and integrated care for patients with obesity. To capture these benefits, a “learning systems” approach could build capabilities across systems, and advance best practices for patients quickly, ensuring that the appropriate integrated care elements are initiated for each patient entering obesity care, as described in earlier sections, above. Yet, these improvements must be built on new data. Patients can find a more receptive healthcare system, and patient journeys, treatment guidelines and recommendations can be updated as evidence accumulates, clarifying which combination of interventions and medications are likely to improve

overall health outcomes for which patients (obesity severity, obesity related diseases, determinants of social influence, mental/behavioral health status) at which stage of treatment (engagement, induction, maintenance). While shared capability building approaches are ideal in any system, the current conditions for managing obesity as a chronic condition demand that a shared capability building approach develop to support rapid improvements that are now underway.

To build out a learning system environment that shares capabilities, key structures will have to be created or supported to ensure cross-functional collaboration. Four shared capability solution elements have been identified:

1. Clinical practice support
2. Data generation infrastructure
3. Data analytics and analysis
4. Aligning incentives for integrated care

Clinical practice support

- **Care guideline development, dissemination, and adoption processes** that rapidly incorporate new evidence and clinical best practices, updated frequently as is done in cancer where rapid learning also occurs.
- **Metric standards creation:** A cross-industry effort to update how obesity is measured and coded, and how care quality is assessed and compared across care delivery systems.
- **Health system accessibility and capacity building** – educate health systems on federal accessibility and equipment requirements to provide care for people living with obesity (Rehabilitation Act, Section 504 final rule recognizes obesity as a disability).

Data generation infrastructure

- **One or more data collection systems for outcomes tracking and evidence generation.**
Currently, we have:
 - Developer trials (RCTs and RWE)
 - Registries to be developed
 - NIH or PCORI clinical trial/RWE networks
- The objectives of these data collection and dissemination systems would include:
 - Tracking and sharing of obesity medication evidence.
 - Meta-analysis of long-term effectiveness of integrated care studies (e.g., self-reported Quality of Life (QoL) measures, patient outcomes, etc.)
 - Analysis of studies that compare outcomes of care elements for sub-populations (e.g., is mental health a larger challenge for patients with more obesity related diseases?)
 - Review of RWE studies that examine how intervention elements are provided and at what time in the patient journey.

Data analytics & research

- **A national obesity collaboration network that can synthesize new data from both ongoing scientific research and from real world evidence.** Such a network would be responsible for translating the evidence into concrete recommendations to support patient health and disseminating their findings across payer and provider organizations, especially via incorporation into the care guidelines.
 - A national obesity collaboration network would include groups such as the Obesity Action Coalition, the Obesity Society, the STOP Obesity Alliance, as well as other relevant medical and patient associations.
- **Reliable long-term funding sources for these shared capability-building efforts:** Options range from current ad hoc private company/charity/government sources to long-term federal government funding, to a fee imposed on drugs (as is done for vaccines), payers (as is done for PCORI), or some other regular source of funding.

Aligning incentives for integrated care

As this new era takes hold, payers and providers can develop contracts which incentivize appropriate treatment and a willingness to treat obesity as a disease. These contracts may take different forms but would be grounded in clinical practice guidelines and set up to collect data to further our understanding of the combinations of treatments that are most successful. Moreover, these contracts would serve to link payments to disease management practices, incentivizing continuous learning and improvement in patient care over the long-term. Some viable contract options might include:

- A. Tiered Care Volume contracts:** Because we are still in an era where obesity bias and stigma are strong, providers and payers could negotiate based on “willingness to treat” whereby care providers would receive incentive payments based on the % of their total obesity population that they are actively treating. As providers reach higher percentages of patients with obesity in treatment, they would receive a higher reimbursement per patient. Other triggers for larger payments might include outcome measures, where patients achieve cholesterol or glucose level changes, improvements in mental health and/or agility function improvements, or patient-reported quality of life improvements. Tiered contracts would encourage treatment to guidelines while reducing the stigma and bias now associated with this chronic disease. Such contracts would also require clear identification of the patient population to be treated, supporting a more systematic approach to identifying and retaining patients, as well as developing systems to monitor disease management.
- B. Subscription models:** Payers and providers would negotiate more proscribed patient journey, with a limited range of older medications and GLP-1 based medicines provided for a defined population and with the requisite intervention elements included. In this case, the stakeholders would contract based on expected population size and target health outcomes. Subscription models would support evidence generation to understand how a GLP-1based medication works with what combination of intervention elements for specific subpopulations. This model would also require clear identification of the patient population to be treated in advance, supporting a more systematic approach to identifying and retaining patients, as well as developing systems to monitor patient outcomes.

- C. **Bundled Programs:** Payers and providers would contract with a third party to provide access to the range of targeted interventions, with patients paying a fee-for-services utilized across the range of intervention elements. Such programs would increase the opportunities for obesity care and support to develop, especially now as patient surges are expected. Third parties could also contribute to the knowledge of what combination of services are most requested and how they are utilized by patients to best effect. Bundled programs would have to remain tied to healthcare providers to oversee progress toward their goals (e.g., weight loss, reduction in obesity related diseases, improvements in sleep, or improved mental health). Such programs might also then enable providers to go at risk for their patient population outcomes.

Quality measures & coding for reimbursement

To date, obesity quality measures, either process or performance-related, are underrepresented across the various quality development and utilization programs and processes. Body Mass Index (BMI) screening quality measures do exist, collecting information on patients since 2009. Yet apart from such process measures, quality performance measures of obesity treatment have not caught up with current care and are absent from clinical care decision-making.¹ Moreover, as a process measure, BMI can trigger false positive/negative results in patients who have higher muscle mass, or patients who differ by social determinants, race, ethnicity or age. Quality measures that assess the care of obesity are not yet formulated, which limits even the best attempts to apply clinical guidelines and understand what works. Without a robust set of quality measures, healthcare systems will have limited success in tracking the disease and identifying effective treatments and health outcomes.

Overall, quality measures are meant to monitor changes in health outcomes, inform consumers and influence payments in US healthcare systems.² Medical billing codes (ICD and CPT codes) are used specifically to gain reimbursement for specific treatment interventions.³ At this time, the billing codes for obesity also remain limited, but new ICD-10 codes for obesity will be released by the National Center for Health Statistics in October 2024. The 2025 ICD-10-CM codes allow providers to identify obesity severity accurately, by providing codes for the obesity classifications as outlined by the Centers for Disease Control and Prevention (CDC):⁴

- Class 1: BMI \geq 30.0-34.9 kg/m²,
- Class 2: BMI \geq 35.0-39.9 kg/m², and
- Class 3: BMI \geq 40 kg/m².

In addition, the new codes use the appropriate terms “severe obesity” and include the use of people first language. It’s important for providers to use these new codes so the electronic health records can track trends in the prevalence of obesity and its obesity related diseases to determine the best public health approaches to obesity management. Obesity diagnosis, treatment and access to care will improve substantially when quality measures and coding processes are updated and utilized across healthcare providers and payer institutions.

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As the system as a whole shares the work of building capabilities, invigorated induction and diagnostic capabilities, and integrated care solutions will take hold. Shared capability processes will help to standardize patient care and quantifiable obesity management. As these attitudinal and institutional shifts progress, patients with obesity, care providers, payers and developers will interact with the assumption that obesity is a disease that can be treated. In a learning system, where shared capability-building has been established, progressively improving obesity care will be expected and contracting options that include data generation will reward obesity management that can measure patient health outcomes.

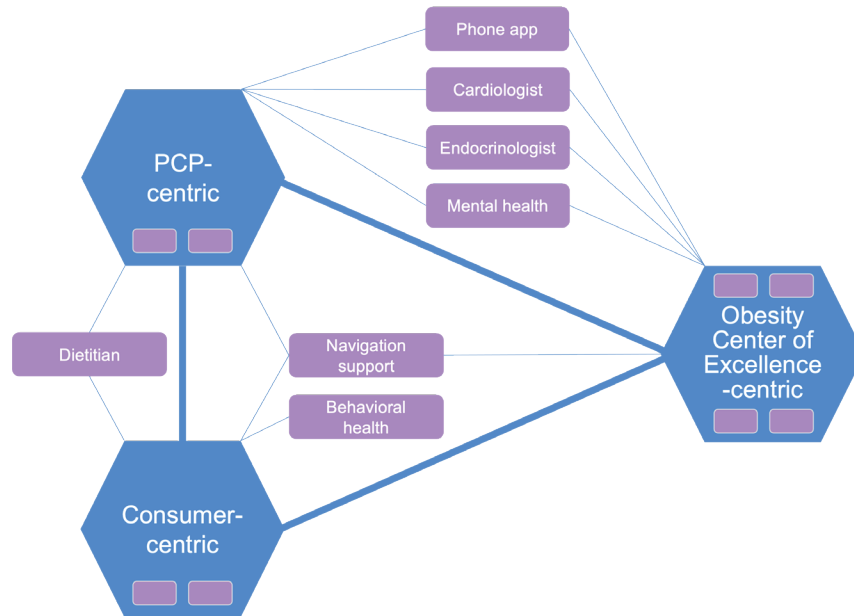
Obesity care delivery structures

Medical science research is bringing staggering advances to the treatment and care of people with obesity and its complications. With rates of adult obesity at about 42% of the US adult population, obesity medications such as GLP-1s, in combination with comprehensive graduated care pathways, present significant opportunities to improve the health and well-being of many people. Yet, we cannot assume that our many healthcare systems are prepared to reach all patients at all levels of severity, across the many insurance systems (public and private) or across socio-economic divides that leave people without the time or the financial resources to take full advantage of these medical advances. With the current healthcare delivery systems unchanged, it will take a long time for people with obesity to receive the care they need in a timely, equitable, and efficient manner.

The following three obesity care delivery structures (Figure 5 below) appear to be the main anchor model options to provide the needed integrated care for the diverse populations with obesity in the United States.¹⁵ In this Design Lab, we will pressure test each of these systems, recognizing that no one anchor model can supply all the necessary integrated care elements on its own. Moreover, these anchor models must align with a patient's general healthcare system touchpoints to fully satisfy a comprehensive care approach, recognizing that the care of obesity requires a care management role that is not yet fully developed in any of these anchor models. Ultimately, each system will be assessed by the same criteria to understand the delivery structure's strengths in treating obesity.

Common gaps that need to be addressed across all three obesity care delivery structures follow the Design Lab deliberations outlined in this document, from patient engagement and diagnosis, and integrated care, to the infrastructure for shared capability-building. To ensure consistent quality, how each healthcare system manages across these criteria must be assessed.

Figure 5: Anchor Healthcare Delivery Models will co-exist to provide patient options, refer patients to each other and likely supplement their internal capabilities with alliances with other services and specialists.



A. Patient Engagement, Identification and Diagnosis:

- How would these systems shift away from stigma and bias-driven induction, diagnosis, and care?
- How would each system improve communication skills to attract and retain patients?
- How would each system contribute to improved diagnostic tools for patients with obesity?

B. Integrated Care:

- What kind of “care tailoring” could each system manage at what levels of disease severity?
 - **Targeted intervention elements:** How robust a selection of interventions could be made available? What stakeholder group will be responsible for care coordination?
 - **Graduated care:** How effective would this system be to identify sub-populations and provide appropriate care to each?
 - **Tailored delivery:** How would this system address a patient’s readiness for treatment and personal preferences? How flexible would this system be to address accessibility constraints or to apply technological innovations during care?

Would this system have the capacity to serve diverse and/or vulnerable patient populations?

C. Shared Capability Building:

- How would this system manage data development and sharing of research?
- How would this system respond to new evidence?
- What metrics can be applied to identify successful disease management?
- How well-aligned/receptive to external authorities/expert advice would this system be?
- What incentive structures and contracts could each system effectively employ and how would it support continued evidence generation?

Center of Excellence-centric obesity care delivery

Traditional Centers of Excellence (CoEs) are centrally located to provide many patients access across a large geographic area. Primary care and subspecialty providers refer patients to such centers which include specialists that concentrate on patient care with the targeted conditions. Given the range of obesity patient sub-populations, these CoEs may best serve more severe subpopulations, who would be eligible for surgical interventions and follow-up. For example, academic medical centers are superb locations for transplant Centers of Excellence, as specialists can be available to patients via the CoE, as well as serve broader populations in their regions, and even internationally, from within the same institution. If patients can, and choose to, access a Center that offers a centralized array of services, then the Center of Excellence can be a viable health care structure to support obesity treatment. In addition, patients may feel more comfortable, confident, and secure to engage in diagnosis and treatment in an obesity Center of Excellence setting.

At the same time, a CoE may or may not provide all the integrated care elements required within the one setting and coordination services would have to be developed or designated. This anchor healthcare model would need coordination across PCPs, providers of other integrated care elements, and/or additional specialists who would engage patients with obesity to address obesity related diseases.

Patient Engagement: The CoE care delivery option would be well situated to support provider education and build strong communications for patients rid of stigma or bias. With experts at the helm, these CoEs would have a head start in building confidence with patients, but patients may not have early access to these Centers until after engagement, diagnosis and induction of a patient has been established in a PCP setting. The CoE Model may or may not manage ongoing service support effectively. Yet with experts on hand, this model may best serve more severe patients.

Integrated Care: Starting from a base of expertise, the CoEs would be cognizant of what services have supported positive health outcomes, particularly for more severe patients (e.g., understanding after care for bariatric surgery patients and supporting patients with high numbers of obesity related diseases). As stable institutions, the CoE approach may not be popular with remote patients who require different tailored delivery mechanisms.

Shared Capability Building: As part of larger institutions, CoEs are likely to have the administrative support to engage in a learning systems approach, with capabilities to generate data from their own patient populations and react to new evidence, improving care delivery as a result. The size and scope of CoE-centric care could prompt a range of incentives to develop with payers that will differentiate sub-population patient journeys.

Primary Care Physician-centric obesity care delivery

A second obesity treatment anchor model could be centered around the Primary Care Provider (PCP), or more broadly, a patient's main medical provider (e.g., a specialist, but not one associated within a comprehensive obesity CoE). In this case, the PCP would be a point of entry for patients who want to work with trusted clinicians and ancillary services providers with whom the patient has ongoing interactions. PCPs (and their staff) would coordinate care services for each patient's

needs, most likely working with external health insurance structures, and negotiating and assessing the quality of services that their patients receive. In this system, PCPs would need the infrastructure (e.g., training, stable resources for intervention element supply, robust reimbursement coding) available to work successfully with patients with obesity and coordinate with other care providers. The PCP in this anchor delivery model would manage and measure the care delivered by other clinicians and ancillary service providers.

Patient Engagement: To date, PCP support for people with obesity has not been robust. Providers of this delivery model would require quality external training programs to ensure consistent, unbiased care for patients newly seeking medical support. The PCP model as a coordinator of care resources would require communication outreach skills to reach currently untreated populations and to work effectively across other care delivery institutions and experts. Physicians, physician assistants, or nurse practitioners could be trained to fill this care coordination role.

Integrated Care: The PCP model would benefit from external collaborations to identify and build networks with third parties that could supply targeted intervention elements. To engage the appropriate patient sub-populations, PCP delivery models might best manage mid- to low-level severity patients and patients who have reached a relatively “steady state” of managed disease. Depending on the size of the PCP delivery system, PCPs could do well with tailored delivery options, including text and telehealth follow up options.

Shared Capability Building: Depending on the size of a PCP program (i.e., is it connected to a larger network or solo), the PCP model could engage in a shared capability-building infrastructure. For small PCPs, they might have delayed responses to new evidence, while larger/connected PCPs might support data generation and be involved directly in shared capability-building. PCP size and level of connectedness would also impact what incentive contracts would be available for their patient populations.

Consumer-centric obesity care delivery

At the cusp of quite radical change in care for patients with obesity, a consumer-centered care delivery anchor model could provide more scale, access to care, and flexibility, with aspects of treatment provided remotely to people who are not able to access care in person on a regular basis. In a consumer-centric care system, we will consider only programs that are connected to healthcare professionals. While this anchor model may prioritize patient convenience for care (e.g., using apps, telehealth appointments or other digitally-based services), the model will be held to the same quality standards as other anchor models. Currently, consumer-centered programs have aligned across needed services, from nutrition and exercise plans to patient support groups. The coordination of these services could serve as an early strength of this anchor model. Consumer-centric programs have also been working to incorporate telehealth structures so that medical standards are upheld across their systems. Ideally, this delivery system model would also be integrated across other systems, adhering to, and perhaps supporting the development of, health quality standards and medical guidelines.

There are a wide range of consumer-centric care options, from those that are fully independent of health care to those that are aligned and engaged with health care systems. In this analysis, we

will focus on the latter cases, where quality metrics, health outcomes and evidence-based decision-making strategies are employed and supported. We will consider those direct-to-consumer programs that have no touch points with the healthcare professionals as out of scope (and in fact a threat to quality care for patients with obesity). Consumer-centric programs that are aligned with health care systems and engage board-certified specialists in their physician consultation programs are in scope and would be assessed by the same quality standards as the other systems.

Patient Engagement: Driving from a consumer-centered position, these care delivery systems would likely excel in appropriate engagement of new patients, quickly overcoming the bias and stigma approach to people with obesity. The time from patient engagement to treatment would require a medical diagnosis, so patients might see a delay, depending on how developed the telehealth or other board-certified physician consultation process is within the consumer-centric system.

Integrated Care: The consumer-centered models would have an early jump on the targeted intervention elements needed for people with obesity. These delivery systems would have formed to identify and differentiate patient subpopulations, with flexible delivery options to capture a wide array of patient preferences/needs. Targeted delivery options, from the use of apps to track behavioral health or telehealth interventions would likely be well developed with consumer-centric models, but would likely not be adept at managing tailored delivery for patients with geographic or socio-economic hardships. These delivery systems would also be best situated to refer more severe patients to PCP- or CoE -centric models of care.

Shared Capability Building: Consumer-centric care delivery models may not be well organized to contribute to a learning systems approach, as their coordination-focused role might not develop data generation capabilities. However, these systems are likely to pivot quickly to address new evidence that would impact patient needs and might, over time, create new data-generation systems if it developed as part of payment contracts with payer organizations.

Table 3 below summarizes the three ideal-type care delivery structures, assuming that the infrastructure for each anchor system can be built based on the recommendations outlined in this Briefing Book. At this point in the development of obesity care management, it is not expected that any one anchor healthcare delivery structure would be capable of providing the full range of integrated care elements. Rather, progress in obesity care overall will require continuous learning that is able to be effectively integrated into care delivery options. For example, the continued improvement in treatment guidelines will serve as an excellent trigger for improved care in each of these delivery structures. Even more broadly, each care delivery structure will be transformed as patients, providers, payers, and developers overcome the socio-cultural bias and stigma that have kept so many patients out of treatment altogether and the policies that serve these multiple patient sub-populations become firmly established.

Table 3: Three types of care delivery structures

Note: TIE – Targeted Intervention Elements, GC – Graduated Care, TD – Tailored Delivery; “√” denotes strong and “—” denotes weak /underdeveloped

	Patient engagement	Integrated Care			Shared capability building
		TIE	GC	TD	
CoE-centric care	Best for patients with more severe obesity	√	√	—	√
PCP-centric care	Best for induction of new patients, where initial guidance required to understand care options	√	√	√	—
Consumer-centric care	Will attune well with patient needs, esp. when patients self-advocate	√	—	√	√

Conclusion

In the USA, it is just over a decade since the American Medical Association defined obesity as a chronic disease, and the first GLP-1 agonist was approved by the FDA for obesity care. Since that time, accumulating data and new medications suggest a transformation of obesity care is possible.

The NEWDIGS process has fostered a cross-functional team, integrating a broad array of stakeholders to envision obesity care that will be capable of improving patient health in the short-term, and providing long-term maintenance care through the complicated patient journey that inevitably accompanies this “serious, chronic, relapsing and treatable disease.”¹⁶ For the September Design Lab, this Briefing Book lays out four key, interlocking solution areas that the team has identified as crucial elements of a comprehensive, efficient, effective, and equitable obesity health-care system.

To clarify each solution area, they are necessarily organized in four sections, but in ideal terms no one solution area should develop in a silo, but in lock-step with the other solution areas. It is only this unified and integrated approach that will produce a learning system, able to incorporate new medical science research and further develop obesity care seamlessly.

Patient engagement/identification and diagnosis

Our first solution area investigates the early stages of a person with obesity’s engagement with healthcare. In order to progress patients to disease identification and diagnosis, communication, training and education programs for the public, the patient, providers and payers will be required. Once diagnosis is established, providers and payers must be supported by systems that smoothly support a patient’s need to be treated. Identified solutions include:

- A comprehensive communication plan to establish societal recognition of obesity as a disease.
- Active patient outreach to normalize medical treatment for obesity care:
 - Provider and payer multi-modal outreach (e.g., email, phone calls, etc.) to encourage known patients/members with obesity to come in for care.
- Explicit patient screening targets for PCPs to expand identification in currently underreported populations.
- Increase obesity training courses within medical and nursing schools:
 - Metrics: increase available courses at number of schools/year; measure increase in educators capable of teaching these courses; measure number of students taking these courses
- Double the number of trained doctors and nurses in obesity care & management every two years. In addition to medical doctors, track increases for physician assistants (PAs), nurse practitioners (NPs), Pharmacy Directors (PharmDs) and registered nurses (RNs).
- Build care coordination training programs in nursing schools:
 - Metrics: Establish target number of new nursing courses for obesity care coordination and target/measure number of nursing candidates successfully completing these courses.
- Develop a strategic set of peer-review articles that bring attention to the current state of Coding & reimbursement rates for obesity.
- Partner with National Committee for Quality Assurance (NCQA) to build across discipline approach to obesity quality measures.
 - Metrics: create NCQA behavioral health awards that recognize quality obesity care programs; partner to develop 2025 NCQA Innovation Summit focus on Obesity.
- Incorporate increased HCP outreach methods that succeed into HEDIS and Star metrics.

Integrated care

How patients are treated requires integrated care programs that not only embrace a stigma and bias-free patient engagement, but also recognize that 1) targeted interventions must be multi-faceted; 2) graduated care will align treatment intensity with level of disease; and 3) patients will require targeted delivery of care that works within their available resources and capabilities. Solutions include:

- Build patient journeys for obesity sub-populations that are based on analysis of successful timing and utilization of targeted intervention elements.
- Work with relevant medical associations to create regular updates to clinical guidelines as new data about obesity treatment and outcomes develops (see breakout for currently active associations).
 - Clinical guidelines will remain complex, with the ability to accommodate shared decision-making between patients and providers.
 - Clinical guidelines will necessarily incorporate measures of care quality and improvement in behavioral health, mental health, nutrition, and exercise.
- Publish a quality review of telehealth and technology (i.e., apps) that support tailored delivery of obesity care while maintaining care quality.
 - Identify and establish institutional networks between app developers and patient/ provider organizations.

Shared capability building

These integrated care elements are to be provided in settings that generate data to show what combination of care services work best. In this way, integrated care will support a system where shared capability building is possible. As a solution area, shared capability building requires:

- **Clinical Practice Support:** Care guideline development, dissemination, and adoption processes that rapidly incorporate new evidence and clinical best practices into guideline updates, obesity coding improvements, quality metrics creation, and health systems equity of access.
- **Data Generation Infrastructure:** One or more data collection systems for outcomes tracking and evidence generation. Once established, this infrastructure would be utilized to generate and disseminate evidence to improve obesity care across obesity related disease conditions.
- **Data Analytics and Research:** A broad, national obesity collaboration network that is well funded and can synthesize new data from both ongoing scientific research and from real world evidence.
- **Aligned Incentives for Integrated Care:** By sharing capabilities across stakeholder groups, collaborative, systemic learning programs will enable providers and payers to contract based on health outcomes.

Obesity care delivery structures

The fourth solution area focuses on obesity care delivery structures. Here, we've outlined three potential anchor healthcare delivery systems and investigated how each might further patient engagement, identification, and treatment; how well they might manage integrated care needs; and how each anchor delivery system might contribute to a collaborative learning system agenda.

On the cusp of significant change for a growing patient population, this Design Lab will pressure test the solution areas presented in this Briefing Book. The solutions will require changes across many aspects of healthcare as it is organized today. With the right programs, our culture can change to recognize obesity as a disease and shift care as a result. With the right knowledge of successful care practices, the systems learning and organizational capabilities are available to provide adequate and equitable, perhaps even excellent, care for people with obesity.

Appendix A: April 2024 Design Lab Summary

Case study discussion

Payment innovation opportunities for anti-obesity medications as an archetype for other emerging large-population therapies

Early Payment Innovation experiences for large population therapies panel

To kick off the conversation about payment innovation opportunities for large-population therapies, the Design Lab presented a panel discussing lessons from past therapies in this category. The discussion, which ranged from hepatitis C treatments and PCSK9 inhibitors to patient engagement and data collection challenges, challenged the audience to consider how payments for new treatments may be better aligned with their value and prepared the group to participate in a case study about anti-obesity medications later that day.

The panel provided a diverse range of experiences with large-population therapies. One participant discussed lessons from healthcare research, including how evidence is generated about new therapies and how different stakeholders make decisions. Another panelist also focused on data collection, describing the challenge of evaluating whether new therapies are successful. A different panelist shared experience with designing and implementing value-based contracts for small-population therapies, while the final participant brought a valuable health equity perspective.

NEWDIGS has previously focused on value-based contracts and other payment innovation strategies for cell and gene therapies, which tend to serve people with rare diseases and other smaller populations. Learnings from this prior work can also apply to therapies for large populations, as payment innovation strategies can be used to improve access for these products. As examples, panelists pointed to therapies for hepatitis C, PCSK9s, and diabetes, as well as vaccines.

An overarching theme across the panel was the challenge of measuring a drug's value, or its material benefit, at both individual and population levels. This measurement is particularly difficult at the population level when many patients may be eligible for a novel therapy. If value is better understood, stakeholders may be better equipped to negotiate innovative payment strategies that match the opportunities posed by a new therapy.

One challenge in measuring value is understanding a disease's epidemiological burden and identifying the patient population that will be eligible for a novel therapy, as well as estimating the population that will seek out that therapy. Healthcare data in the U.S. are fragmented, leaving stakeholders with limited understanding of broad patterns outside of their specific jurisdictions. Disparities in healthcare access may exacerbate the challenge, as people who meet certain diagnostic criteria — but have not received care — are not included in healthcare records.

For example, with hepatitis C, high demand for new treatments indicated that some stakeholders may have underestimated the population served by these therapies, one panelist observed. PCSK9 drugs, meanwhile, offered a lesson in better engagement between developers, payers, providers, and patient groups about the opportunities offered by new therapies, as some panelists and audience members suggested that the utilization of these drugs may have initially been overestimated.

Developers that understand and respond to patient needs may be better positioned for success, panelists suggested. As an example, one panelist described the case study of a developer launching a new prostate cancer medicine that identified Black men as an underserved group within this disease population. The developer marketed their drug specifically to this group, and found success in uptake for this therapy.

In addition to understanding patient needs, stakeholders must understand patients' journeys to treatment, panelists said. Patients have vastly different journeys depending on their disease state awareness, ability to manage engagement with a health system, insurance coverage, demographics, and socioeconomic factors; these factors can all complicate their ability to access a new therapy. With anti-obesity medications, for example, some employer insurance benefit designs consider these treatments to be “cosmetic” and fail to opt into coverage options, leaving their employees with higher barriers to receiving treatment. Similarly, there is limited coverage in state Medicaid programs and an outright exclusion for coverage in Medicare Part D.

Demographic and socioeconomic factors also complicate the process of interpreting clinical trial results for new therapies. The populations included in clinical trials often do not represent the real-world populations served by new therapies, which presents a data challenge for different stakeholders. For example, Black women are at high risk of Alzheimer's yet are underrepresented in clinical trials, one panelist pointed out.

Developers and regulators have long recognized the need to improve diversity in clinical trials, but panelists observed more movement on this issue in recent years, inspired by opportunities posed by new technology such as platforms that enable decentralized trials. The FDA has started to require some diversity metrics in trials, though there is more room for improvement in incorporating real-world evidence into regulatory decisions.

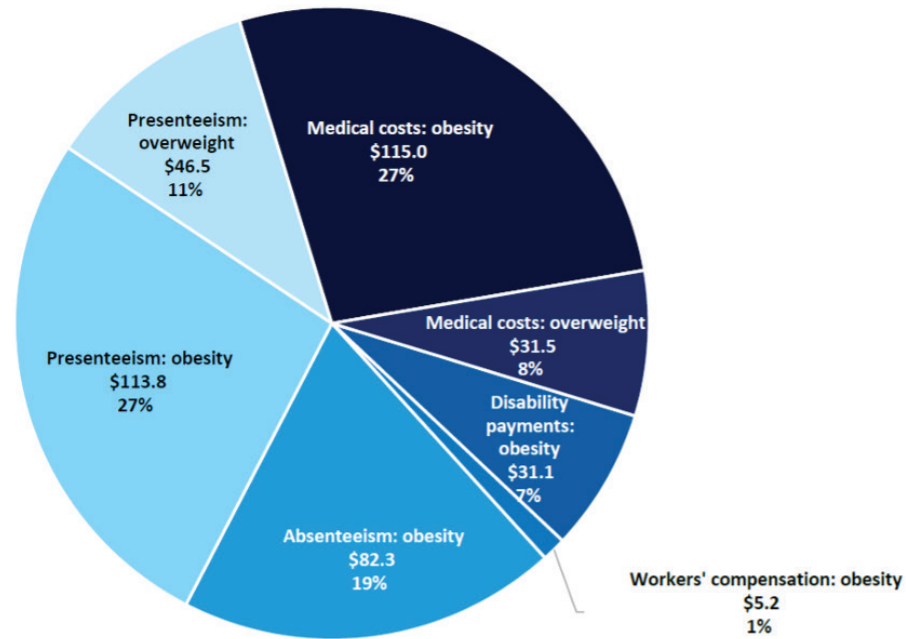
With new therapies for large populations, determining the potential value at the population level is crucial, the panelists and audience members agreed. Such analysis is especially important for payers for which many people in their covered populations will be eligible for a therapy, as well as for drugs that could face government regulation through the Inflation Reduction Act. While a conversation full of challenges, the panel prepared the Design Lab participants to engage further in these issues through the case study.

Elucidation case study: Obesity and the latest generation of anti-obesity medications

The case study

More than 40% of adults in the U.S. currently live with obesity, a figure that is projected to increase to 50% by 2030. The disease costs the U.S. employers and workforce hundreds of billions of dollars every year, with Medicaid and Medicare shouldering similarly high medical costs. Medical authorities such as the American Medical Association recognize obesity as a chronic disease, and promising new anti-obesity medications, such as GLP-1 drugs, are available to treat it.

Figure 1: Cost implications of obesity and overweight: All nonfarm civilian workforce, 2023 (\$Billions)⁸



Yet many people with obesity do not receive the treatments that would improve their health. Patients face a wide variety of barriers to access, ranging from stigma at the doctor’s office, to lack of insurance coverage for anti-obesity treatments, to the high cost of these new therapies. In the April Design Lab’s elucidation case study, the NEWDIGS consortium sought to better understand these barriers and aspects of the patient journey, then discuss potential solutions to improve access. The discussion encompassed payment innovation opportunities as well as improving provider capacity, public outreach and education about obesity, and other potential system-wide solutions.

To understand the patient journey, participants heard from a patient-advocate who has lived with obesity her entire life, yet has been unable to access the latest anti-obesity medications. The advocate had never been formally diagnosed with obesity, she said; rather, doctors gave her behavioral recommendations to eat less and exercise more, even as she developed obesity related diseases from obesity, including high blood pressure and sleep apnea. She didn’t learn about the complex biological basis for obesity until her late 30s and has since taken on the role of educating her doctors about the latest research.

In addition to bias from healthcare providers, the patient-advocate described challenges with insurance coverage. She has generally worked at small nonprofits, leading her health insurance to primarily come from small employers and marketplace plans; these plans generally treat anti-obesity medications as “cosmetic” and do not cover them, she said. While she has received a prescription from her doctor for one of the latest anti-obesity medications, she is unable to fill the prescription because her insurance does not cover this product and she would not be able to afford it out-of-pocket, she said.

“I want to improve my health as a patient,” the advocate said. “And I run into roadblocks that prevent me from furthering my health.” Many other people with obesity face similar roadblocks, she

said. She encouraged Design Lab participants to remember these patients as crucial stakeholders during the elucidation process.

Following the patient-advocate's testimony, members of the case study team presented other key background information about obesity. The presentation emphasized that obesity is a disease, not a lifestyle choice, driven by brain pathways that manage energy and appetite. Medical research has identified a variety of factors — many of them outside an individual's control — that make patients susceptible to this disease, including genetic and epigenetic factors, physiological and behavioral factors, and environmental and sociocultural factors.

As a disease, obesity can damage different organ systems and lead to obesity related diseases and complications, such as diabetes, asthma, and cardiovascular disease. Providers often use these obesity related diseases to measure obesity's burden on a patient, along with quality-of-life-metrics. Body mass index (BMI), historically considered the primary metric for identifying obesity, should not be used in isolation as other diagnostic tools and assessments provide valuable information, the presenters explained.

From a physician's perspective, provider capacity is incredibly limited when compared to the number of people with obesity in the U.S. As of late 2023, there are only about 8,250 providers certified by the American Board of Obesity Medicine (ABOM). Other, non-certified providers are not trained to recognize obesity as a disease or to use anti-obesity medications. Training is needed for more obesity specialist providers, as well as more collaboration with nutrition and behavioral specialists.

Adding to the challenge, providers do not currently have established processes for payer reimbursement of the full spectrum of obesity care. Anti-obesity medications, and even procedures like bariatric surgery, often are not covered by insurance benefit designs. If they are covered, providers and patients often face barriers and restrictions to reimbursement.

Historically, providers have treated obesity with lifestyle interventions, namely dieting and exercise. These interventions often fail in the long term because the biology of the reduced weight state leads to reduced adherence to these interventions, resulting in patients regaining weight. New medications, on the other hand, lead to lasting weight loss by leveraging naturally occurring hormones to suppress appetite centers in the brain, consequently reducing hunger and calorie intake.

These medications are commonly referred to as modern AOMs or Anti-Obesity Medications, or simply obesity medications. Some also use the shorthand "GLP-1s," which stands for glucagon-like peptide-1, one of the hormones targeted by these medications, or the term "receptor agonists" for medications that target GLP-1 and another hormone. Patients self-administer these medications once a week via injection and consult with their providers to adjust dosages over time for maximum efficacy.

GLP-1 drugs on the market so far, such as Wegovy and Zepbound, have promising safety and effectiveness profiles — and many more drugs are in the pipeline. Developers are devoting resources to innovation in this space; for example, there's a growing interest in oral medications, reflecting a shift towards a range of care and medication delivery options. As new drugs are developed

and go through clinical trials, developers are considering different potential clinical endpoints beyond BMI, such as comorbidity outcomes and measures of adiposity.

New anti-obesity medications also pose challenges and opportunities for payers, many of which still prioritize only behavioral and lifestyle interventions or bariatric surgery, leaving a gap in the treatment option continuum. Payers must consider how to make these medications available to their members while mitigating risks for high-budget impacts, low-value utilization, and patients lacking provider support. The budget impacts are particularly pertinent for large and public payers. In this case study, the team assumed that Medicaid and Medicare will cover anti-obesity medications in the next several years.

The case study team presented one example of an employer tackling this challenge: one large, national company recently launched an anti-obesity medication program for its employees, dependents, and retirees. The program includes a plan to prioritize patients who would benefit most from anti-obesity medications, coverage of a variety of therapies beyond the GLP-1 drugs, and digital tools that support provider capacity.

Throughout the presentation, the case study team emphasized the challenges of bias and stigma that patients face. Payment innovation and healthcare system solutions for anti-obesity medications must be paired with education and outreach that helps to break down this barrier across different stakeholders and for society at large.

In five breakout groups, the Design Lab participants described the impediments that people with obesity face in receiving healthcare and identified potential solutions that would remove impediments while also meeting the needs of other stakeholders. They evaluated the following questions:

- What are both the usual and unique patient journey impediments to appropriate access and successful outcomes?
- What are the challenges that impede payers (by type) from providing appropriate patient access beyond price?
- What challenges do providers face in treating obesity?
- What are the near-term versus medium-term impediments to appropriate patient access and outcomes?
- What are the opportunities for learning to improve appropriate access and outcomes?

Patient journey challenges

The first breakout group, which focused on impediments in the patient journey, identified a lack of informed providers and social stigma around obesity as the two most pressing issues. Providers who specialize in treating obesity are limited in the U.S., and these limitations may be exacerbated based on where a patient is located, their insurance coverage, demographics, and other factors. When they are unable to access one of these specialist providers, patients face stigma from providers who do not consider obesity as a disease and may be unwilling to prescribe medications.

To address these challenges, the group discussed several solutions around provider training, guidance, and education. For example, a hub and spoke model may enable specialist providers at one facility to train and support others in their region; this model has proven successful for other diseases, particularly in rural areas. Consensus-based guidelines on treating obesity would also be

helpful for non-specialist providers to gain familiarity with this disease and to reduce stigma, the group suggested.

Along with educating providers, the breakout group suggested education for the broader public as a strategy to reduce stigma. Some people with obesity may not themselves recognize that they have a disease and can seek treatment, as discussed in the patient testimony. Such education may also help motivate employers to include obesity care in their health plans, and motivate developers to scale up their supply of these drugs.

In addition to physicians, psychologists, nurses, dietitians, and other types of providers could support patients in the obesity care journey. However, these providers similarly may be unavailable to some patients, particularly those with limited insurance plans and those living in rural areas. Patients may also struggle to coordinate care between different providers, leading the breakout group to suggest that patients need a “medical home” for obesity care.

Payer challenges

The breakout group focused on payers discussed a long list of challenges that this stakeholder faces in covering anti-obesity medications. These challenges include a surge of patients seeking the medications, a limited provider network, uncertainties about long-term outcomes for different patient subgroups, challenges for care coordination across different providers, equity issues, and identifying the “right” patients who would be most served by the new medications.

In brainstorming potential solutions, the payer group focused on three higher-impact challenges. One of these was the potential patient surge. To address the high number of patients interested in treatment, the group suggested that, as supplies are limited in the current, early-adoption stage of anti-obesity medications, this supply limitation provides an opportunity to identify the highest-risk patients who would benefit most from these drugs and put them at the front of the line. The group also recommended removing barriers, such as prior authorizations, for less expensive treatment options (i.e. behavioral and lifestyle changes and older anti-obesity medications) so that patients may try these before seeking medications. Innovative payment models with budget caps at population levels may additionally help address this challenge.

The group then discussed solutions for provider shortages and limited coordination between different types of providers. To address these challenges, the group proposed several options for building a larger network of specialists: a hub and spoke model (similar to the patient group’s proposal), building Centers of Excellence for anti-obesity medications, developing training for primary care providers so that they can prescribe these medications, advancing claims metrics and integrated health record data for obesity care, and training “obesity care navigators” who could help patients through their care and insurance processes.

Finally, the group discussed how to improve access to anti-obesity medications for minority populations. The “obesity care navigators” recommendation would also address this challenge, by helping level the playing field for patients of different backgrounds. Payers could also encourage flexibility in treatment options through options such as telehealth appointments, evening and weekend hours, and navigators who speak different languages. In addition, developers could help with this challenge by creating copay assistance programs for obesity drugs, like the options for other diseases.

Provider challenges

Providers also face a range of challenges in treating obesity, whether they are specialists in this disease or serve a primary care role. The breakout group focused on providers discussed several of these challenges: bias and stigma among providers, provider availability to see patients, knowledge and training about this disease and its different treatment options, coordinating with ancillary services, understanding the variability in coverage and reimbursement policies, and fragmentation in the medical system.

To address the challenges with providers' internal resources to care for patients, the group proposed a hub and spoke model, echoing the prior two breakout groups. Innovative payment models could also help incentivize providers to build in more capacity for obesity care, through longer follow-up appointments, continued management, and improved data collection. In addition to the capacity challenges, a hub and spoke model would provide education to providers in the "spokes" and could serve as a resource for reimbursement challenges, the group suggested.

Education and outreach about obesity is critical for providers, the group agreed. Provider institutions could require continuing education modules about obesity for their staff, while medical schools could add more information on obesity as a disease to their curricula. Such education is especially important for primary care providers, who are typically patients' entry point into obesity care; these providers must be connected to resources and support, particularly to ensure they are appropriately reimbursed, the group said.

Along with education, providers would be served through better coordination with nutrition and lifestyle services for people with obesity. A "medical home" model, also proposed by the patient group, would offer a one-stop-shop for patients to access all of the services they need and improve coordination, rather than having patients see several different providers for different services. Public education for patients and the broader public would also help address access challenges, by empowering patients to seek medical care.

Near-term versus medium-term

Another breakout group discussed the comparisons between near-term and medium-term impediments to accessing anti-obesity medications. The group interpreted this question as a comparison between challenges as payers start to cover these medications and challenges after coverage becomes more widely available.

In the near-term coverage category, the group discussed challenges stemming from the historical standards of both providers and payers that have not considered obesity as a disease. For example, many providers lack understanding of the new anti-obesity medications and may default to recommending that patients engage in diet and exercise programs even when the medications may be more effective. Payers that similarly lack understanding may hesitate to cover the drugs, especially given the high price tag at a population level.

To address these near-term challenges for payers, the group recommended pricing strategies such as copay caps for patients similar to insulin caps at \$35. For providers, treatment guidelines and training would help educate physicians on how to prescribe the new medications. Employers are also an important stakeholder in these discussions, the group suggested, as obesity coverage (in-

cluding the new medications and nutrition and lifestyle services) currently represents a new benefit that must be added to employment packages — potentially adding to the cost of each employee.

In the medium term, challenges would shift to tracking outcomes, identifying value, and shifting societal views of obesity through education and outreach. For example, payers would seek to track how patients are faring on the new drugs over time and potentially expand coverage if the data are promising. Payers may also move to require training for providers to support reimbursement, passing on medium-term challenges to providers and patients. Standardizing outcomes measures and standards of care across different payers and providers would become an important goal in the long term, the group suggested.

Opportunities for learning

The final breakout group discussed opportunities for learning about anti-obesity medications to improve appropriate patient access and outcomes. The group interpreted its question as: “If we were able to know more to help improve access and outcomes, what would we want to know more about?”

As one answer to this question, the group suggested that this field would be well-served by transparency about how current pilot programs to improve access to anti-obesity medications are going. For example, the group and other participants were excited to see results from the large employer program described during the case study’s introduction. Coalitions and industry groups like the Self-Insured Employers of America and Employee Benefit Research Institute could also compile and share results.

In another opportunity for learning, the group suggested that patient groups and researchers could compile and share information about the patient journey. This information would help payers better align benefits and reimbursement policies with patient outcomes, while it would help providers develop training materials and inform clinical guidelines (a common theme across the breakout groups). Improving provider reimbursement for treating obesity may be one high-impact change, the group suggested.

Related to the patient journey, the group also identified addressing health disparities and improving equitable access as a key area for learning. Different stakeholders in the obesity field tend to agree that there are significant disparities in access to anti-obesity medications, but these disparities are not well understood in detail. More research and data collection could help identify gaps in the current care system that could be addressed through new supports for specific disadvantaged patient groups.

As an overarching theme, this group, like the other breakout groups, discussed how to reduce the stigma around obesity. All stakeholders need to be improved with this effort, the group suggested. Potential solutions suggested by this group and others include provider education, support for patient advocacy, and public awareness campaigns. The group also discussed a potential research challenge: what outcomes metrics would measure success in reducing stigma around obesity?

Overarching conclusions

Overall, the NEWDIGS case study model proved informative for elucidating challenges around

anti-obesity medications, even though the topic was newer to many participants. Breakout group discussions were engaging, identifying both challenges specific to the obesity space (such as stigma) and parallels between anti-obesity medications and cell and gene therapies, such as provider capacity challenges, issues with reimbursement, and uncertainty about long-term outcomes.

The case study discussion highlighted several solutions from other therapeutic areas (particularly CGT) that could be helpful for addressing challenges with anti-obesity medications. More research and creative discussion will be needed to identify novel solutions that may be more catered to obesity. In particular, the case study demonstrated that significant investment and infrastructure is needed for the healthcare system as a whole to address obesity, going beyond payment for anti-obesity medications themselves.

The discussion also highlighted the expansive scope of the obesity space. One participant referenced a [recent opinion piece in STAT News](#) that argues, if Medicare covered anti-obesity medications, this policy would save the U.S. billions of dollars by reducing healthcare costs related to obesity related diseases. As different stakeholders consider how to calculate value of large-population therapies, the costs associated with not supporting such populations with treatment become clear.

Future directions

Following the April Design Lab, the case study team will develop one or a select few solutions that emphasize — but are not limited to — payment innovation, for improving access to anti-obesity medications. The consortium will then pressure-test these solutions through a follow-up case study at the September Design Lab. Save the date for September 24 to 25.

[Access the April 2024 Design Lab Obesity Case Study Briefing Book here.](#)

Appendix B: AT&T Anti-Obesity Medication (AOM) Program



Anti-Obesity Medication (AOM) Program
DRAFT 2/3/2024

Anti-Obesity Medication (AOM) Program

Overview of AT&T and the Anti-Obesity Medication (AOM) program co-developed by AT&T and FORM Health

AT&T Demographics/Enrollment

AT&T has 135,000 active U.S. employees across all 50 states and territories. The average employment tenure is 14 years, with an average employee age of 46. There are 260,000 members, including employees (44%) and their dependents (56%), who are enrolled in AT&T self-insured medical plans. Among this population, 7% of adults aged 18 or older have a known BMI of 40+ based on diagnosis codes, and there are an estimated 58,000 members (34% of members) with a BMI of 30 or above based on national prevalence estimates from the Behavioral Risk Factor Surveillance System¹. Our employee tenure gives us a unique perspective as an employer – we consider long time horizons when designing health programs that can aim to provide long-term benefits with significant financial investments today.

AOM Program Goals

The goal of the program is to responsibly make high-cost Anti-Obesity Medications (hcAOMs) available to our members while mitigating the following risks:

Risk	Description	Program Approach
Budgetary Impact	Near-term costs could cause the health plan to be unsustainable if utilization of hcAOMs is sufficiently high.	Prioritize hcAOMs for patients whose health is most impacted by obesity, as determined using an obesity staging model, by requiring a patient-specific determination by a specialist
Low-Value Utilization	hcAOMs are not appropriate for every patient and may not be the most efficient treatment option for delivering the desired obesity reduction outcomes.	Offer the full range of AOM therapies and educate patients on their full set of options in addition to the specialist determination outlined above for hcAOMs.

¹ Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Division of Population Health. BRFSS Prevalence & Trends Data [online]. 2015. [accessed Feb 03, 2024]. URL: <https://www.cdc.gov/brfss/brfssprevalence/>.



<p>Unsupported Prescribing</p>	<p>Long-term success with hcAOMs is predicated on companion diet and lifestyle changes.</p>	<p>Integrate tools and expert support for behavioral and lifestyle changes that are connected to the patient’s primary care team.</p>
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Program Design

The program will launch in March 2024 with only reactive communication. In the first phase of the program, FORM will provide prior authorization and utilization management for hcAOM limited to patients who meet the FDA criteria for hcAOM. Each patient will be supported by an Obesity board-certified MD and an Obesity and Weight Management Certified Registered Dietitian. The program includes a mobile app with digitally-supported interventions regarding diet and lifestyle and asynchronous care team communication beyond provider visits. Depending on their obesity staging, patients may first be offered care options through FORM that do not include hcAOM including lifestyle only or including lower cost medication options. FORM is paid using milestone-based payments per patient based on reducing the patient’s weight by 5, 10, and 15% and additional payments for 12-month maintenance of each of those milestones.

Data Sources

Data available to AT&T includes medical/pharmacy claims data, detailed demographics, and most lab values/results for our members. Specifically for this program, AT&T’s data enablement platform, Abett, will capture interactions with the mobile app (e.g. food tracking, asynchronous communications, etc.), readings from the connected scale and blood pressure cuff, and clinical notes by the providers. Through the mobile app, a net promotor score will be captured to measure user experience. The Work Limitations Questionnaire (WLQ) will also be captured through the mobile app at baseline and regular intervals to assess impact on productivity.

Outcomes Measures

Phase One

- 80% of engaged patients reduce 10% of weight at 6 months from baseline
- hcAOM utilization <60% of engaged patients
- WLQ scores of engaged patients improve at 6 months from baseline

Overall

- 10% weight reduction maintained for 12 months
- Net Promoter Score of 50+ among engaged members
- Program enrollment is comparable or higher to the general enrollment for non-white members, female members, and members living in locations with a high area deprivation index – subpopulations selected given their high obesity rates compared to the national average.

Appendix C: Medical science advances in obesity care

The new science of obesity medications has the potential to transform obesity care in the United States and around the world. In the US, GLP-1 agonists on their own can currently support up to 25% body mass decrease over 48 weeks. Soon to be introduced are amylin/dual agonists and triple agonists that will increase that level to 30% body mass decrease over a year of treatment. Moreover, whereas today approximately 30% of GLP-1 agonist users drop off within one month due to tolerability issues, the amylin agonists appear to have a higher tolerability ratio.^{17,18} With over 1,000 studies ongoing today related to this new class of medicines, the next ten years are likely to transform the average American's health profile and reinstate increases in longevity, with more years of health and well-being.

The evidence supporting these new medications is game-changing but is not to be provided in a vacuum. The U.S. Food and Drug Administration (FDA) approved semaglutide and liraglutide to be used as an adjunct to diet and physical activity.^{19,20} Providing behavioral guidance to individuals on GLP-1 medications is essential for optimizing people with obesity's overall health, including nutritional status, muscle maintenance, and mitigation of side effects. Because GLP-1s prompt individuals to decrease their food intake, it is important that the foods that are consumed are of high dietary quality in order to prevent nutrient deficiencies that commonly accompany energy-restricted diets.²¹

As medical science research continues to develop, obesity research into obesity related diseases continue to develop. There are second and third-round investigations already underway to understand and address other diseases from diabetes to heart disease, to sleep apnea and mental health conditions and chronic inflammation.²² In response to this global enthusiasm and interest in the benefits of GLP-1 agonists and beyond, the pharmaceutical industry is investing heavily in manufacturing capabilities. These bricks-and-mortar sites are expensive to build and maintain and represent a concerted long-term commitment to this class of medicines and an expectation of continued growth in this market.

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2. Please note that training and education programs for different specialties and for children at different ages will have to be developed and tested before they are deployed. There is a substantial amount of work to be done to build such programs.
3. [Stats and Data](https://abom.org) - American Board of Obesity Medicine (abom.org)
4. Barrea L, Framondi L, Di Matteo R, Verde L, Vetrani C, Graziadio C, Pugliese G, Laudisio D, Vitale G, Iannicelli AM, Savastano S, Colao A, Muscogiuri G. The role of the nurse in the Obesity Clinic: a practical guideline. *Panminerva Med*. 2021 Dec;63(4):539-546. doi: 10.23736/S0031-0808.21.04540-7. Epub 2021 Sep 21. PMID: 34544231.
5. New ICD-10 codes for obesity will be released by the National Center for Health Statistics in October 2024. See Box: Quality Measures & Coding for Reimbursement.
6. To date, Medicare does not reimburse GLP-1 medications. However, we are assuming that CMS will reimburse for the purposes of this Design Lab.
7. Avalere put together an overview of coding, billing and reimbursement barriers that provides a good start to a comprehensive, multi-avenue review and education of the current circumstances for obesity care. See: [obesity_care_barriers_white_paper.pdf](https://avalere.com) (avalere.com)
8. Please note that the appropriate terminology in obesity care is evolving. In this brief, we endeavor to use the most up-to-date terms, including “obesity related diseases,” replacing “co-morbidities.” Where “co-morbidities” remains, we have used this term to be consistent with borrowed/quoted resources (e.g., in Figure 3).
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12. Liu, Buyun et al., “Trends in obesity and adiposity measures by race or ethnicity among adults in the United States 2011-18: population based study.” *BMJ* 2021;372:n365 <http://dx.doi.org/10.1136/bmj.n365>
13. Please note that currently, FDA guidance stipulates BMI as the main diagnostic tool for obesity disease classification. However, guidelines and recommendations are encouraging more robust analysis of the patient condition, with the use of body composition, waist-to-hip/height ratio measure, etc. Please see the breakout section on guidelines.
14. Please note that The Obesity Society (TOS) is currently working on Standards of Care for Obesity. It will be important that a process of regular updates is institutionalized. [The Obesity Society - Research, Education, Action](https://www.obesitysociety.com).
15. A Milliman White Paper explores an obesity center of excellence care delivery model. See: [Employers and targeted obesity care: Exploring the concept of an obesity center of excellence](https://www.milliman.com) (milliman.com)
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