Health Outcomes After Bariatric Surgical Therapies in the Medicare Population

Medicare Evidence Development and Coverage Advisory Committee (MEDCAC)

August 30, 2017

Center for Clinical Standards and Quality
Coverage and Analysis Group
Division of Medical and Surgical Services

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Current Medicare Coverage

- National Coverage Determination 100.1: *Bariatric Surgery for Treatment of Morbid Obesity*
- Nationally Covered Indications
  - Open and laparoscopic Roux-en-Y gastric bypass (RYGBP)
  - Open and laparoscopic Biliopancreatic Diversion with Duodenal Switch (BPD/DS) or Gastric Reduction Duodenal Switch (BPD/GRDS)
  - Laparoscopic adjustable gastric banding (LAGB)
  - For beneficiaries who have:
    1. Body Mass Index (BMI) ≥ 35; and
    2. At least one co-morbidity related to obesity (Type 2 diabetes mellitus is a co-morbidity for purposes of this NCD); and
    3. Been previously unsuccessful with medical treatment for obesity.

Current Medicare Coverage

- Nationally Non-Covered Indications
  1. Treatments for obesity alone
  2. Supplemental fasting is not covered under the Medicare program as a general treatment for obesity
  3. Open adjustable gastric banding
  4. Open sleeve gastrectomy
  5. Open and laparascopic vertical banded gastroplasty
  6. Intestinal bypass surgery, and
  7. Gastric balloon for treatment of obesity

Current Medicare Coverage

- Medicare Administrative Contractor (MAC) Discretion
  - MACs acting within their respective jurisdictions may determine coverage of stand-alone laparoscopic sleeve gastrectomy (LSG) for the treatment of co-morbid conditions related to obesity in Medicare beneficiaries only when all of the following conditions a.-c. are satisfied.
    a. The beneficiary has a BMI ≥ 35 kg/m²
    b. The beneficiary has at least one co-morbidity related to obesity, and,
    c. The beneficiary has been previously unsuccessful with medical treatment for obesity.
  - Determination of coverage for any bariatric surgery procedures not specifically identified in an NCD as covered or non-covered, for beneficiaries who have a BMI ≥ 35, have at least one co-morbidity related to obesity, and have been previously unsuccessful with medical treatment for obesity, is left to the local MACs.

Current Medicare Coverage

- National Coverage Determination 210.12: *Intensive Behavioral Therapy for Obesity*
- Nationally Covered Indications
  - Effective November 29, 2011, CMS covers intensive behavioral therapy for obesity, defined as a BMI ≥ 30 kg/m², for the prevention or early detection of illness or disability. Intensive behavioral therapy for obesity consists of the following:
    - Screening for obesity in adults using measurement of BMI calculated by dividing weight in kilograms by the square of height in meters (expressed kg/m²);
    - Dietary (nutritional) assessment; and
    - Intensive behavioral counseling and behavioral therapy to promote sustained weight loss through high intensity interventions on diet and exercise.
  - For beneficiaries with obesity, who are competent and alert at the time counseling is provided and whose counseling is furnished by a qualified primary care physician or other primary care practitioner and in a primary care setting, CMS covers:
    - One face-to-face visit every week for the first month;
    - One face-to-face visit every other week for months 2-6;
    - One face-to-face visit every month for months 7-12, if the beneficiary achieves a reduction in weight of 3kg during the first six months.

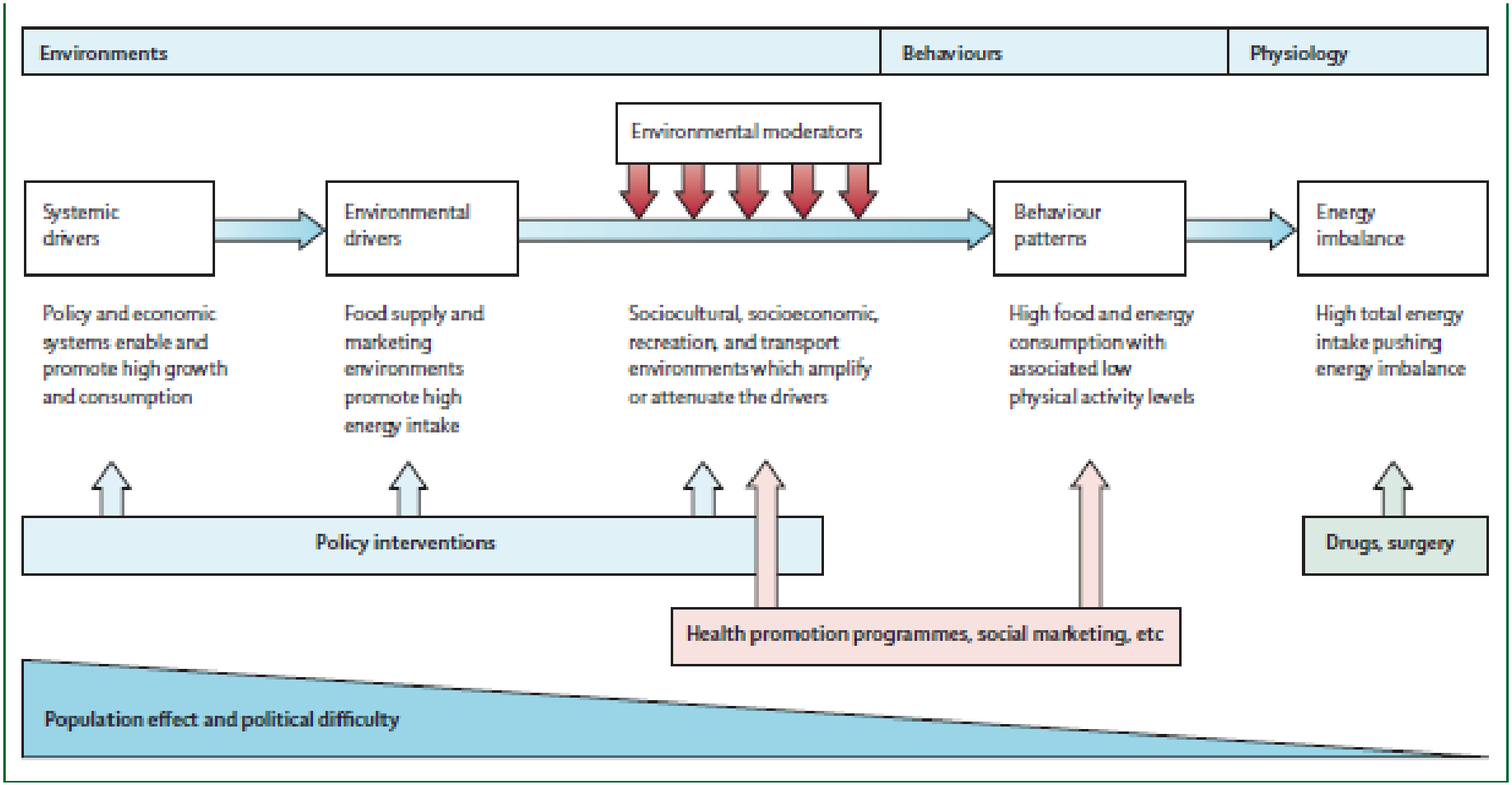
State of Evidence

- Current evidence assesses surgical bariatric therapies, however evidentiary questions remain for CMS with respect to the clinically meaningful health outcomes for Medicare beneficiaries and, importantly, informed decision making for patients.

- Identification of information needed for beneficiaries to make informed treatment decisions with their provider(s) is critical.

- Facilitation of meaningful health outcomes is important for Medicare coverage policies and essential for beneficiaries to make informed treatment decisions.

A framework to categorize obesity determinants and solutions



Swinburn B, Sacks G, Hall K, et al. *The Lancet.* 2011: 378; 804 – 814.

Meeting Purpose

Obtain MEDCAC recommendations regarding the appraisal of the state of evidence for health outcomes in the Medicare population for surgical and endoscopic procedures based on:

- Scientific evidence for health outcomes after bariatric therapies, including open and laparoscopic surgeries and endoscopic procedures

Identify evidence gaps related to treatment of obesity and related co-morbidities and discuss efforts aimed at patient-centered care.

Meeting Purpose

Today we will discuss:

- Clinical study endpoints and patient outcomes, both weight loss and non-weight loss related
- Duration of intervention effects
- Evidence gaps
- How these elements impact patient decision making
- How to provide support for patient decision making

Voting Question #1

- How confident are you that the following are meaningful primary health outcomes in research studies of bariatric surgery:
  a. Weight loss;
  b. Postoperative complications;
  c. Diabetes and metabolic outcomes;
  d. Cardiovascular outcomes;
  e. Respiratory outcomes;
  f. Musculoskeletal outcomes; and
  g. Quality of life.

Use the following scale identifying your level of confidence - with a score of 1 being low or no confidence and 5 representing high confidence.

1 — 2 — 3 — 4 — 5
Low Confidence ***Intermediate*** ***High Confidence***

Voting Question #2

- How confident are you that there is sufficient evidence for an intervention (to include open and laparoscopic surgeries and endoscopic procedures) where the benefit outweighs the harm for:

  a. Short term (2 years or less from surgery) weight loss?
  b. Mid-term (more than 2 but 5 or less from surgery) weight loss?
  c. Long-term (more than 5 years after surgery) weight loss?

Use the following scale identifying your level of confidence - with a score of 1 being low or no confidence and 5 representing high confidence.

1 — 2 — 3 — 4 — 5

Low Confidence ***Intermediate*** ***High Confidence***

Voting Question #3

- For outcomes listed in Question 1 with a voting score >2.5, how confident are you that there is sufficient evidence for an intervention (to include open and laparoscopic surgeries and endoscopic procedures) where the benefit outweighs the harm for:

  a. Short term (2 years or less from surgery) outcomes?
  b. Mid-term (more than 2 but 5 or less from surgery) outcomes?
  c. Long-term (more than 5 years after surgery) outcomes?

Use the following scale identifying your level of confidence - with a score of 1 being low or no confidence and 5 representing high confidence.

1 — 2 — 3 — 4 — 5
Low Confidence ***Intermediate*** ***High Confidence***

Voting Question #4

- How confident are you that the predictors of success in the Medicare population (such as patient characteristics and pre and post procedure standards of care) for any bariatric therapy is known?

Use the following scale identifying your level of confidence - with a score of 1 being low or no confidence and 5 representing high confidence.

1 — 2 — 3 — 4 — 5
Low Confidence ***Intermediate*** ***High Confidence***

Discussion: List the predictors of success and the correspondent strength of evidence.

Discussion Questions

1. Discuss important evidence gaps that have not been previously or sufficiently addressed.

2. Discuss any known treatment disparities.

3. Considering both existing and new procedures and devices as well as potential barriers to care, discuss any mechanisms that might be supported by CMS that would more quickly generate an improved evidence base that would underpin improved care and decision-making for the Medicare population affected by obesity.

References

Swinburn B, Sacks G, Hall K., et al. *The global obesity pandemic: shaped by global drivers and local environments*. The Lancet 2011: 378; 804 – 814.