



CALIFORNIA TECHNOLOGY ASSESSMENT FORUM<sup>SM</sup>

## Obesity Management

### Questions for Deliberation: July 14, 2015 Public Meeting

#### Clinical Effectiveness

##### Surgical procedures and devices

1. For adult patients with a BMI  $\geq 35$ , with or without clinical comorbidities, is the evidence adequate to demonstrate that the net health benefit of **bariatric surgery** is greater than that of **conventional weight-loss management** (i.e., combinations of diet, exercise, and/or behavioral and lifestyle interventions)?  
Yes                  No
2. For adult patients with a BMI of 30.0-34.9 and Type 2 diabetes, is the evidence adequate to demonstrate that the net health benefit of **bariatric surgery** is greater than that of **conventional weight-loss management**?  
Yes                  No
3. For adult patients with a BMI 30.0-34.9 who do not have Type 2 diabetes, is the evidence adequate to demonstrate that the net health benefit of **bariatric surgery** is greater than that of **conventional weight-loss management**?  
Yes                  No
4. For adult patients with a BMI  $\geq 35$ , is the evidence adequate to demonstrate that **RYGB** and **VSG** have a comparable net health benefit?  
Yes                  No
5. For adult patients with a BMI  $\geq 35$ , is the evidence adequate to demonstrate that the net health benefit of **the Maestro vBloc system** is greater than no treatment?  
Yes                  No

##### Drugs

6. For adult patients with a BMI  $\geq 30$  or BMI  $\geq 27$  with an obesity-related comorbidity, is the evidence adequate to distinguish the net health benefit among the four drugs reviewed?  
Yes                  No

## Value

### Surgical procedures and devices

7. [If yes to question 1 – adult patients with a BMI  $\geq 35$ , with or without clinical comorbidities] Given the available evidence, what is the care value\* of bariatric surgery vs. conventional weight-loss management?  
a. Low      b. Intermediate      c. High
8. [If yes to question 1] Given the available evidence, what is the overall health system value\*\* of bariatric surgery for a state Medicaid program?  
a. Low      b. Intermediate      c. High
9. [If yes to question 2 – adult patients with a BMI of 30.0-34.9 and Type 2 diabetes] Given the available evidence, what is the care value of bariatric surgery vs. conventional weight-loss management?  
a. Low      b. Intermediate      c. High
10. [If yes to question 2] Given the available evidence, what is the overall health system value of bariatric surgery for a state Medicaid program?  
a. Low      b. Intermediate      c. High
11. [If yes to question 3 – adult patients with a BMI 30.0-34.9 who do not have Type 2 diabetes] Given the available evidence, what is the care value of bariatric surgery vs. conventional weight-loss management?  
a. Low      b. Intermediate      c. High
12. [If yes to question 3] Given the available evidence, what is the overall health system value of bariatric surgery for a state Medicaid program?  
a. Low      b. Intermediate      c. High
13. [If yes to question 5 – adult patients with a BMI  $\geq 35$ ] Given the available evidence, what is the care value of the Maestro vBloc system vs. no treatment?  
a. Low      b. Intermediate      c. High
14. [If yes to question 5] Given the available evidence, what is the overall health system value of the Maestro vBloc system for a state Medicaid program?  
a. Low      b. Intermediate      c. High

**\* *Care value* is a judgment comparing the average per-patient costs, clinical outcomes, and broader health effects of two alternative interventions or approaches to care.**

There are four elements to consider when deliberating on care value:

1. ***Comparative clinical effectiveness*** is a judgment of the overall difference in clinical outcomes between two interventions (or between an intervention and placebo), tempered by the level of certainty possible given the strengths and weaknesses of the body of evidence. CTAF now uses the ICER Evidence Rating Matrix as its conceptual framework for considering comparative clinical effectiveness.
2. ***Incremental cost per outcomes achieved*** is the average per-patient incremental cost of one intervention compared to another to achieve a desired “health gain,” such as an additional stroke prevented, case of cancer diagnosed, or gain of a year of life. Alternative interventions are compared in terms of cost per unit of effectiveness, and the resulting comparison is presented as a ratio: a “cost per outcome achieved.” Relative certainty in the cost and outcome estimates continues to be a consideration.
3. ***Additional benefits*** refers to any significant benefits offered by the intervention to caregivers, the delivery system, or other patients in the health care system that would not have been captured in the available “clinical” evidence. Examples of potential additional benefits include mechanisms of treatment delivery that require many fewer visits to the clinician’s office, treatment outcomes that reduce disparities across various patient groups, and new mechanisms of action for treatments of clinical conditions (e.g., mental illness) that have demonstrated low rates of response to currently available treatments. For each intervention evaluated, it will be open to discussion whether additional benefits such as these are important enough to factor into the overall judgment of care value. There is no quantitative measure for additional benefits.
4. ***Contextual considerations*** can include ethical, legal, or other issues (but not cost) that influence the relative priority of illnesses and interventions. Examples of contextual considerations include whether there are currently any existing treatments for the condition, whether the condition severely affects quality of life or not, and whether the condition affects priority populations. There is no quantitative measure for the role of contextual considerations in an overall judgment of care value.

CTAF will use this conceptual description of the elements of care value when deliberating on the evidence and voting. The CTAF Panel will be asked to vote whether interventions represent a “high,” “intermediate,” or “low” care value.

**\*\* *Health system value* is a judgment of the affordability of the short-term budget impact that would occur with a change to a new care option for all eligible patients, assuming the current price and payment structure.**

Usually, the care value and the health care system value of an intervention or approach to care will align, whether it is “high,” “intermediate,” or “low.” For example, a treatment that is judged to represent high care value from the perspective of per-patient costs and benefits will almost always represent a high health system value as well. But health system value also takes into consideration the short-term effects of the potential budget impact of a change in care across the entire population of patients. Rarely, when the additional per-patient costs for a new care option are multiplied by the number of potential patients treated, the short-term budget impact of a new intervention of intermediate or even high care value could be so substantial that the intervention would be “unaffordable” unless the health system severely restricts its use, delays or cancels other valuable care programs, or undermines access to affordable health insurance for all patients by sharply increasing health care premiums. Under these circumstances, unmanaged change to a new care option could cause significant harm across the entire health system, in the short-term possibly even outweighing the good provided by use of the new care option itself.

To consider this possibility, CTAF reviews estimates of the potential budget impact for a change in care as measured by the estimated increase in “per-member-per-month” health care premiums that would be needed to fund a new care option in its first year of use were all eligible patients to be treated. It should be noted that if, after considering potential budget impact, a health intervention judged to have high care value receives a judgment of “low” health system value from the CTAF Panel, this does not imply that the health system should not adopt the intervention; rather, the vote indicates that policy makers should consider implementing mechanisms related to patient selection, step therapy, pricing, and/or financing to ensure that the short-term budget impact of a high care value intervention does not lead to more harm than good. CTAF votes on health system value will therefore serve an important function by highlighting situations when policymakers need to take action and work together to align care value with health system value.