

**Clinical study health outcomes for
Medicare beneficiaries with TRD**

and

**MEDCAC History with Chronic
Disease**

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Disclosure Information

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Health Outcomes Measures and Tools for Medicare Beneficiaries in Clinical Studies

- Validated outcomes measures and tools have been utilized in clinical studies focused on TRD populations
 - Specific measures and tools for Medicare population are not necessary
- For Stage II TRD, most utilized and relevant of the measures/tools include:
 - 24-item Hamilton Depression Rating Scale (HDRS-24)
 - Montgomery–Åsberg Depression Rating Scale (MADRS)
 - Clinical Global Impression of Improvement (CGI-I)
 - 30-Item Inventory of Depressive Symptomatology Self-Report (IDS-SR30)
 - Medical Outcomes Study 36-item Short Form (MOS SF-36)

MEDCAC Addressed Similar Issue in 2004

- MEDCAC commissioned to evaluate surgical treatments for morbid obesity
- Morbid obesity shares many commonalities with treatment resistant depression, including:
 - Difficulty in measuring disease state
 - Medicare population had limited representation in clinical studies
 - Significant levels of associated morbidity and mortality
 - Typical presence of comorbidities
 - Challenges measuring treatment success and outcomes
 - Staged approach to care
- MEDCAC determined that, despite these challenges, bariatric surgery for morbid obesity should be covered **with stipulations around when, where/by whom, and how patients could access treatment**
- Provides relevant model for surgical treatments for TRD

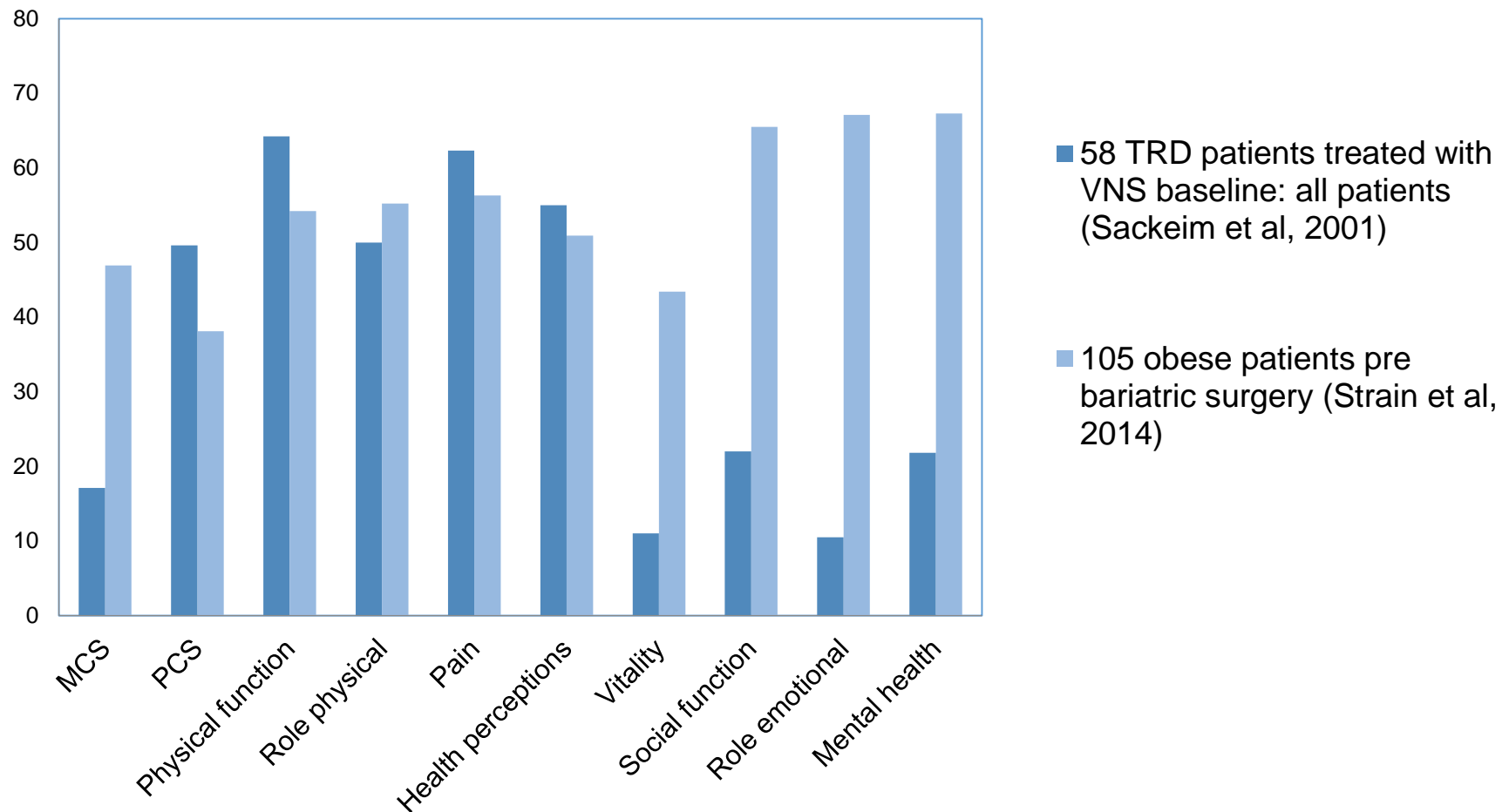
1. <http://www.ncbi.nlm.nih.gov/pubmed/18695655>

2. <http://www.npr.org/templates/story/story.php?storyId=106268439>

3. <https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/chronic-conditions/downloads/2012chartbook.pdf>

MEDCAC Addressed Similar Issue in 2004 (cont.)

Pretreatment SF-36 Scores for Treatment Resistant Depression and Obesity



Bariatric Surgery for Obesity vs. TRD

	Bariatric Surgery for Obesity	Treatment Resistant Depression
Treatment Resistance	In the decision memo from CMS regarding the Bariatric Surgery NCD, it was noted that “extremely obese persons do not benefit from the non-surgical treatments for weight loss and weight maintenance”.	Similarly, evidence shows that some patients do not experience sustained benefit from multiple appropriate anti-depressant treatments.
Measurement	Obesity is generally measured by the Body Mass Index (BMI) scale, though there is a great deal of literature regarding its shortcomings for clinical evaluation ^{1,2} . As such, there are generally numerous criteria used for evaluating patients as obese.	There are numerous scales that have been validated for quantifying depression symptoms (for diagnosis) and for monitoring symptoms over time (for monitoring efficacy and effectiveness of treatments). Physician-administered scales, as well as patient self-report scales, have been validated and used.
Population Data	In the MEDCAC summary, it was noted that Bariatric Surgery lacked specific data relevant to the comorbidities and mortality for the Medicare age population, but that data could be “generalized to the older Medicare population”.	TRD may present in a younger population than what is typically age-eligible for Medicare; however, this population enters the Medicare system through disability, rather than age. TRD studies have included Medicare populations for age eligibility, as well as disability.
Morbidity/Mortality	Obesity is associated with significant, costly comorbidities, which was a primary driver of the MEDCAC discussion and ultimate coverage decision. Obesity is associated with nearly 1 in 5 US deaths, according the American Journal of Public Health ⁽⁴⁾ .	Depression, especially MDD, is associated with similar significant, costly comorbidities. TRD also carries high suicide attempt risk: 27% of patients reported at least 1 suicide attempt, compared to the 15% attempted suicide rate in non-TRD MDD Patients ⁽⁵⁾ .
Treatment	While treatment success is relatively easy to define for obesity, treatment and treatment adherence are not. CMS has noted that there is very little consistency in the measurement or duration of “attempted treatment” as a condition of coverage for bariatric surgery.	Treatment of depression, and TRD specifically, requires person-specific treatment. Access to all empirically proven treatment options in experienced centers is essential for the patients all along the continuum.
Approach to Care	There is often a stepped approach to the treatment of obesity, with first line treatments being the least invasive and least costly, moving onward through pharmaceutical interventions and eventually surgery.	The treatment of depression is similar, in that first line treatments typically involve pharmaceutical interventions and therapy; when these treatments do not achieve wellness, other treatment modalities, including neurostimulation, can be effective.

1. <http://www.ncbi.nlm.nih.gov/pubmed/18695655>
2. <http://www.npr.org/templates/story/story.php?storyId=106268439>
3. <https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/chronic-conditions/downloads/2012chartbook.pdf>
4. <http://www.medscape.com/viewarticle/809516>
5. Amital D, Fostick L, Silberman A, et al. Serious life events among resistant and non resistant MDD patients. *J Affect Discord*. 2008; 110(3):260-264

Pressing Need for Study of VNS in Medicare Stage II TRD Population

- Vagus Nerve Stimulation (VNS) approved by FDA in 2005 for adjunctive long-term treatment of chronic or recurrent depression for patients 18 years of age or older who are experiencing a major depressive episode and have not had an adequate response to four or more adequate antidepressant treatments
- VNS Therapy has been evaluated in randomized, controlled study, long-term comparison study, randomized dosing study, and registry (5-year follow up)
- No access to VNS Therapy for Medicare beneficiaries (non-coverage NCD)
- Based on this discussion, request that Medicare allow for Coverage with Evidence Development (CED) for indicated Medicare patients (disability and/or 65+) with following stipulations:
 - Study design based on feedback from MEDCAC and discussion with CMS
 - Stage II TRD - 4 or more failed therapies (validated through ATHF)
 - Investigators from experienced centers
 - Use of recommended outcomes measures and validated physician- and patient-completed assessment tools