Treatment Resistant Depression

Medicare Evidence Development and Coverage Advisory Committee (MEDCAC)

April 27, 2016

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Purpose of Meeting

- **Obtain MEDCAC recommendations regarding**

1. Definition of TRD

2. Advise CMS on the use of the definition of TRD in the context of clinical studies, coverage with evidence development, and treatment outcomes

Voting Question # 1

- **How confident are you that there is a standard definition of TRD that can be applied to Medicare beneficiaries in clinical studies of therapies for this disease?**

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

$$1 \quad — \quad 2 \quad — \quad 3 \quad — \quad 4 \quad — \quad 5$$

Low Confidence *Intermediate* *High Confidence*

Voting Question # 2

- **If intermediate confidence (≥ 2.5) is noted for Question #1, please vote by "yes or no" as to whether the following are important defining characteristics of TRD that are to be considered in clinical research:**

  a) The number, duration, dosage, and/or classes of antidepressants attempted

  b) The use of augmentation/combination pharmacological therapies

  c) Type of depressive episode (unipolar, bipolar, psychotic, atypical, other)

  d) The use of nonpharmacological treatments such as electroconvulsive therapy

  e) The use of psychotherapy

  f) Score changes on standardized and validated depression rating instruments (e.g. Hamilton Depression Rating Scale)

  g) Suicidal ideation and suicide attempts

  h) Other

Voting Question # 3

- **If intermediate confidence (≥ 2.5) is noted in Question #1, how confident are you that this definition can be applied to Medicare beneficiaries:**
    a) In primary care settings?
    b) In general psychiatric settings?
    c) In specialty psychiatric settings?

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 each of the below is a reliable, valid, and meaningful health outcome for Medicare beneficiaries in a clinical study on TRD?**
  - a) Improvement or decline in function
  - b) Improvement or decline in quality of life
  - c) Decrease in suicide ideation
  - d) Decrease in suicidal attempts
  - e) Other

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   Intermediate   High
Confidence   Confidence

Question # 4 - Discussion

- **For each characteristic in Question #4 that receives intermediate confidence (≥ 2.5), please discuss the a priori parameters that define successful or failed treatment.**

- **Characteristics listed in Question #4**
  a) Improvement or decline in function
  b) Improvement or decline in quality of life
  c) Decrease in suicide ideation
  d) Decrease in suicidal attempts
  e) Other

Voting Question # 5

- **How confident are you that the strategies below, when applied to Medicare beneficiaries, represent meaningful and realistic study designs in research investigations performed to evaluate interventions for TRD?**
  a) Randomized sham-controlled double blinded trial
  b) Randomized sham-controlled single blinded trial
  c) Randomized controlled unblinded trial
  d) Randomized crossover study
  e) Nonrandomized crossover study
  f) Pre/post study design
  g) Other

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   *Intermediate*   *High*
Confidence   *Confidence*