



Depression and Bipolar Support Alliance

March 28, 2016

Re: April 27, 2016 CMS Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) Meeting

Ms. Maria Ellis
Executive Secretary for the MEDCAC
Centers for Medicare & Medicaid Services
Center for Clinical Standards and Quality Coverage and Analysis Group
7500 Security Boulevard
Baltimore, MD 21244

Dear Ms. Ellis:

I am writing to you today to provide comment for consideration with regards to the upcoming panel of the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) that is meeting for the purpose of providing recommendations regarding the definition of treatment resistant depression (TRD) in clinical research as well as to advise CMS on the use of the definition of TRD in the context of coverage with evidence development and treatment outcomes.

About DBSA

DBSA is the leading peer-directed national organization focusing on mood disorders: depression and bipolar disorder. These serious, all-too-often life-threatening—yet also highly treatable—conditions combine to affect more than 21 million Americans adults, cost an estimated \$23 billion in lost work productivity, and account for 90 percent of the nation's suicides every year.

Unlike any other organization of its kind, DBSA is created for and led by individuals who themselves have a mood disorder diagnosis, with our bylaws stipulating that over half of both the governing board of directors and paid professional staff must be people who have, or have had, depression or bipolar disorder. This first-person lived experience informs everything that we do.

Wellness is Possible

DBSA's vision is wellness for people with mood disorders, and we believe that an open and collaborative approach to treatment that accounts for the whole person—where she or he is *right now*—is what allows people to achieve what they personally define as wellness. Our collaborators include a Scientific Advisory Board made up of the nation's leading clinical and research experts on mood disorders. We are nationally recognized for Peer Specialist training services, which weave those of us with lived experience of mental health conditions into the fabric of care as adjunctive providers of education and support. Ultimately, we at DBSA



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believe that our balanced, person-centered, wellness-oriented approach is what has allowed us to educate, empower, support, and inspire individuals to achieve the lives they want to lead for our now-30 years in existence.

Moreover, these three decades of peer-led work have enabled DBSA to coalesce a strong base of active participants. In fact, through the more than 700 free, in-person peer support groups provided by DBSA's network of 300 chapters across the country, along with our printed and virtual educational resources and wellness tools, DBSA reaches over three million people each year with current, readily understandable information about depression and bipolar disorder; connections to treatment and community resources; and—crucially—the hope that wellness is possible.

A Call for More Patient-Centered Research

Because DBSA is and has always been led and driven primarily by people with lived experience of a mood disorder, we have deep understanding and nuanced familiarity of communication and engagement with our peers including surveys on topics related to barriers to wellness.

For example, one such survey revealed how individuals cope with suicidal ideation and seek and utilize sources of support. The survey revealed that some of the more common medical models are not utilized. Most respondents said that they are reluctant to talk to healthcare providers about suicidal thoughts, and emergency departments and crisis lines were the least frequently reported sources of support. Another survey revealed the type of care individuals and family members experiencing agitation found most beneficial when seeking care at the emergency department.

We share the results of our surveys with mental health researchers and with research review boards at universities and health care systems in the hope of bringing this vital, and all-too-often absent, perspective into context for those who facilitate research.

How DBSA Envisions Wellness

As the foregoing hopefully illustrates, our three decades of representation of, and engagement with, people who have mood disorders put DBSA in a unique position to assist MEDCAC as they seek to define treatment resistant depression (TRD) and provide guidance on how to conduct studies for treatment options. Overall, we believe that meaningful innovation in treatment will be aided by understanding first and foremost how those receiving the treatment define success, rather than simply relying upon the assessments of clinicians and researchers. Along these lines, the following are five important areas that DBSA respectfully asks MEDCAC to consider.

- I. *Efforts to improve definition and measurement of success from the perspectives of those who live with TRD.*



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For people who live with TRD, the past 25 years have seen anemic progress in the development of meaningful new treatments. Innovation has been incremental. People are consequently frustrated by, and losing hope for a solution. Modest improvement in clinical outcomes is simply no longer enough.

Of course the first priority for treatment is ensuring that a person living with TRD is provided a pathway out of crisis and onto stability. However, all too often, this baseline stability is also the end goal established for successful long-term care. “Stable” or “better” are not always synonymous with “well.”

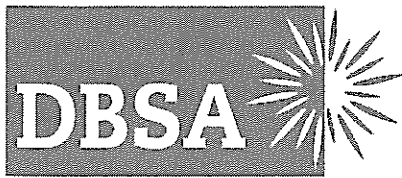
DBSA believes that every person deserves the opportunity not just to survive, but to thrive, and to do that, we need to ensure true wellness as the end-goal for TRD treatment. Consider this: successful treatment for cancer targets the removal of every cancerous cell—the achievement of complete remission. Why, then, do we consider treatment for TRD to be successful when symptoms persist, even if the person is considered to be stable? The cost of settling for reduced symptoms is simply too great. And for many, it can be a matter of life and death.

II. *DBSA believes measures of treatments’ efficacy need to evolve.*

Changing measurement tools to include wellness outcomes as defined by people with TRD would greatly improve treatment. For example, MEDCAC could recommend elevating the importance of existing clinical measurement tools that address function, such as the Sheehan Disability Scale, and/or that address wellness, such as the WHO-5 Scale. The Sheehan Scale is a comparative tool that asks people to evaluate disruptions in various areas of life such as work/school, family, and social life. Meanwhile, the WHO-5 evaluation tool asks a person to report on the active presence of certain positive aspects of overall well-being, such as feeling “calm and relaxed,” or “active and vigorous.” Both are useful in allowing not only for the mood-related improvements necessary to achieving complete wellness, but also the interpersonal and relational aspects of individuals’ experiences of TRD.

III. *DBSA participants with TRD look to MEDCAC to increase consideration of the whole-health implications of interventions for TRD symptoms.*

The weight of TRD negatively affects people with co-occurring conditions, which are frequent and diverse, ranging from diabetes to cardiovascular conditions to cancer. Choosing between effective treatment for a co-morbidity and TRD is counter-productive: individuals living with mental health conditions on average die 25 years sooner, not as a result of suicide, but as a result of myriad co-occurring conditions that can be exacerbated by and/or exacerbate mood disorders. Treating both TRD and any co-occurring conditions—recognizing and allowing for their complex interrelationships—is imperative to achieving optimal outcomes.



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IV. DBSA urges MEDCAC to consider implications of chronic, versus episodic, experiences of TRD.

Success should not be defined by controlling this week's, month's or even year's episode, but by reducing the severity and eliminating the reoccurrence of symptoms over the entire lifetime. This is not often the defined objective for clinicians or researchers, but it is of vital importance to people experiencing TRD, as well as their families. DBSA envisions exploration of chronic versus episodic experiences, and how treatments may need to differ for the chronic recurrence of TRD symptoms.

V. DBSA notes that payers, including the Centers for Medicare and Medicaid Services (CMS), hesitate to include novel treatments for depression.

The current measures and criteria for determining that a new treatment is "safe and effective" do not answer payers' questions about whether a new treatment offers benefit over existing treatments and whether these added benefits justify an added cost. Because payers tend to resist coverage for new treatments, an inadvertent disincentive for research and innovation exists.

Conclusion

DBSA supports MEDCACs initiative around TRD. We sincerely hope that the committee's work will promote an environment that supports the development of better treatment options and encourages exploration of the steps that need to be taken in order to break out from the current dynamic of incremental, slow improvement, to one of exciting breakthroughs. Part of this depends upon a transformation of the way we currently measure success. We urge the committee to look for guidance from those living with to bend the focus of scientific discovery towards the things that matter most to us.

Sincerely,

Phyllis Foxworth
Advocacy Vice President
Depression and Bipolar Support Alliance