2024 Independent Medical Education Call for Grant Applications

CGA-MDD-RS-2024: Addressing Residual Symptoms in MDD

Takeda is committed to supporting high-quality, un-biased, evidence-based independent medical education for healthcare professionals, teams, patients, payers, and systems designed to:

- Improve knowledge, enhance skills, and support behavior change
- Close clinical and practice gaps
- Improve the quality and delivery of patient care
- Enable patients to take an active role in their healthcare

Independent Medical Education is defined as education that is evidence-based, fair-balanced, unbiased educational programs, planned and implemented independent of industry influence, free of bias and not influenced by Takeda or its Alliance partners.

Takeda is issuing the following Call for Grant Applications (CGA) and invites accredited educational providers to submit applications for independent, certified medical education grants that align with the educational needs outlined below.

Statement of Need:

Major depressive disorder (MDD) is one of the most common mental health disorders in the US with an estimated 15 million adults experiencing at least one major depressive episode.[1] Despite the availability of evidence-based antidepressants for MDD, up to two-thirds of patients do not achieve full remission with their first-line treatment,[2] and most patients require several treatment steps to achieve remission.[3] Moreover, even after achieving clinical remission, many patients continue to experience residual symptoms such as reduced ability to focus, sleep disturbances, and emotional blunting, which can significantly impact their quality of life and increase the risk of relapse, functional impairment, and suicide.[4-6]

Healthcare providers (HCPs) need to be able to select the most appropriate available treatment option with their patients from the very beginning to potentially achieve remission and minimize the risk of residual symptoms.[7] This requires knowledge and competence of benefit-risk profiles of antidepressants and the confidence to select treatment that offer benefits for patients with specific residual symptoms. Identifying first-line treatment failure early is also essential to optimize treatment outcomes for patients with MDD.[8-10] This includes recognizing and addressing medication non-adherence, treatment resistance, and comorbid conditions that may affect treatment response.[10] In addition, HCPs must be able to recognize and address residual symptoms for all patients equally, including those from underserved and minority communities.[11]

Therefore, Takeda is interested in supporting educational initiatives that provide HCPs with up-to-date knowledge and skills to identify and manage residual symptoms effectively, including the use of appropriate assessment tools, carefully selecting treatment interventions that can address current symptoms as well as residual symptoms, and patient education and engagement for all patients. Initiatives should also address health equity and be designed to report real world outcomes. Please include a description of any plans for publication or presentation of the outcomes of the initiative.

CGA Details:

Educational Focus:	**Addressing Residual Symptoms in MDD**
Educational Design:	Accredited continuing medical education in any format (e.g., virtual, hybrid, live in person, enduring)
Support Available:	Up to $250,000.00
Learning Audience:	Healthcare professionals who specialize in psychiatry with a strong emphasis on psychiatrists, psychiatry physician assistants and nurse practitioners involved in the management of patients with major depressive disorder
Intended Outcomes Level:	Level 5 (Performance) or above
Submission Deadline:	February 11, 2024
Anticipated Decision Date:	March 1, 2024

CGA Eligibility:

The educational programs submitted in response to the CGA must be accredited by the appropriate accrediting bodies, be fully compliant with ACCME criteria and the Standards for Integrity and Independence and must be in accordance with the U.S. Food and Drug Administration's Guidance on Industry-Supported Scientific and Educational Activities. If approved, requestors must attest to the terms, conditions and purposes of an educational grant as described in the Takeda letter of agreement (LOA).

Providers who meet the eligibility criteria and are interested in submitting a response to this CGA will need to complete a full submission through the Takeda Support system by the submission deadline listed above in the CGA Details area.

CGA Submission Instructions:

Submissions in response to a CGA's need to be made through the Takeda Support system at (https://takeda.envisionpharma.com/ienv_takeda/visiontracker/portal/login.xhtml?pgm=CME).

1. Submissions should be made designating "Neuroscience" as the Therapeutic Area and "Major Depressive Disorder (MDD)" as the disease state of interest.
2. Please select "Yes" from the drop down in response to the question "Are you responding to a CGA?"
3. Please select "CGA-MDD-RS-2024" from the drop down in the "CGA Number" field.

Any questions related to the CGA may be directed to Anne Roc at anne.roc@takeda.com.

Terms and Conditions:

1. All grant applications received in response to this CGA will be reviewed in accordance with all Takeda policies and guidelines.
2. This CGA does not commit Takeda to fund any CGA submission, or the costs associated with such submissions.
3. Takeda reserves the right to cancel, in part or in its entirety, this CGA.
4. For compliance reasons, and in fairness to all providers, all communications about this CGA must come exclusively to Takeda's Department of Medical Education. Failure to comply will automatically disqualify providers.
5. Failure to follow the instructions within this CGA will result in a denial.
6. Takeda Medical Education personnel will notify (via email) the requestor whose submission was selected for up to 2 weeks from the anticipated decision date as listed in the CGA details above.

References:

1. Major depression. National Institute of Mental Health. Accessed January 2, 2024. https://www.nimh.nih.gov/health/statistics/major-depression
2. Rush AJ, Trivedi MH, Wisniewski SR, et al. Acute and longer-term outcomes in depressed outpatients requiring one or several treatment steps: a STAR*D report. Am J Psychiatry. 2006;163:1905-1917.
3. Huynh NN, McIntyre RS. What Are the Implications of the STAR*D Trial for Primary Care? A Review and Synthesis. Prim Care Companion J Clin Psychiatry. 2008;10:91-96.
4. McIntyre RS, Cha DS, Soczynska JK, et al. Cognitive deficits and functional outcomes in major depressive disorder: Determinants, substrates, and treatment interventions. Depression and Anxiety. 2013;30:515-527.

5. Franzen PL, Buysse DJ. Sleep disturbances and depression: risk relationships for subsequent depression and therapeutic implications. Dialogues in Clinical Neuroscience. 2008;10:4:473-481.
6. Christensen CR, Ren H, Faet A. Emotional blunting in patients with depression. Part I: clinical characteristics. Annals of General Psychiatry. 2022;21:10.
7. Israel JA. The Impact of Residual Symptoms in Major Depression. Pharmaceuticals (Basel). 2010 Aug 3;3(8):2426-2440.
8. Paykel ES. Partial remission, residual symptoms, and relapse in depression. Dialogues in Clinical Neuroscience. 2008;10:4,431-437.
9. Kudlow PA, Cha DS, McIntyre RS. Predicting treatment response in major depressive disorder: the impact of early symptomatic improvement. Can J Psychiatry. 2012;57:782-788.
10. Dodd S, Bauer M, Carvalho AF, et al. A clinical approach to treatment resistance in depressed patients: What to do when the usual treatments don't work well enough? The World Journal of Biological Psychiatry. 2021;22:483-494.
11. Office of Disease Prevention and Health Promotion Healthy People 2030 Framework. Accessed January 2, 2024. https://health.gov/healthypeople/about/healthy-people-2030-framework