**Takeda and Lundbeck Call for Grant Application (CGA)**

<table>
<thead>
<tr>
<th>Date Issued</th>
<th>August 28, 2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deadline for application</td>
<td>October 3, 2014</td>
</tr>
<tr>
<td>Award(s) Announced</td>
<td>October</td>
</tr>
<tr>
<td>Therapeutic Area</td>
<td>Central Nervous System</td>
</tr>
<tr>
<td>CGA Identifier</td>
<td>Please reference the appropriate code listed below in the “Activity Title” field on the Educational Grant online application form</td>
</tr>
</tbody>
</table>
|                   | **CGA-2014-MDD-01: Nurse Practitioner & Physician Assistant Initiative**  
|                   | **CGA-2014-MDD-02: Primary Care Physician Initiative.** |

**Purpose**

The purpose of this CGA is to increase Primary Care Providers ability to:

- Recognize and provide optimal care for patients with major depressive disorder (MDD) including regular assessment of symptom resolution, treatment adherence, and tolerability concerns
- Understand the impact of acute and residual symptoms of cognitive dysfunction in depression on patient function, quality of life, relapse risk and long-term outcomes
- Identify patients who might benefit from new pharmacologic treatment options (e.g., those with inadequate response to therapy or tolerability concerns)
- Effectively and safely integrate care changes into the MDD treatment regimen as needed to achieve long-term treatment success
- Foster optimal patient-HCP communication and engagement

**Summary of Health Care Gaps**

Major depressive disorder (MDD) is a relatively common disorder associated with substantial morbidity, mortality and health care costs (1). As primary care providers (PCPs) manage nearly a third to half of depressed younger adults and nearly two thirds of depressed older adults, addressing primary care practice gaps may significantly improve MDD patient outcomes and reduce health care costs (1,2).

While the underlying pathophysiology of MDD has not been fully elucidated, current antidepressants primarily target the monoaminergic systems. Despite the availability of these treatments, only about 50% of patients respond reasonably well to treatment, and only one third reach remission (2). It has also been reported that up to 68% of patients diagnosed with depression discontinue their antidepressants by 3 months (3), and this lack of adherence to treatment contributes to the undertreatment of depression identified in the primary care setting (3).
While there are many reasons for nonadherence to medication, good tolerability, patient education, and the quality of the relationship between physicians and patients are all common determining factors of patient adherence. (4-5) Side effects frequently reported by depressed patients taking antidepressants include weight gain, sexual dysfunction, and gastrointestinal effects (6). In order to effectively balance efficacy and tolerability in the management of MDD, physicians in primary care should have expertise in working with a number of current antidepressant approaches and an awareness of new and emerging treatments. (7)

The goal of MDD treatment is remission with good functional and psychosocial outcomes. Although remission is difficult to define consistently; full remission should encompass resolution of all symptoms of depression and the restoration of overall functioning to a premorbid state. Of note, clinical studies often allow patients to have some residual symptoms and still be considered in remission (8). However, studies have also demonstrated that residual symptoms after treatment are prevalent (e.g., cognitive problems, lack of energy, and sleeping problems) and that residual symptoms are associated with a greater risk for relapse, long-term chronic course, higher risk of suicide attempts, poor social functioning, and poor outcome of comorbid medical illnesses (9-10). In particular, residual cognitive symptoms are often underappreciated and associated with earlier illness onset and longer episode duration (11).

Given that the use of standardized measures is not routinely utilized in clinical practice to measure side effect burden, adherence, depressive symptoms, or safety, awareness of measurement based care (MBC) initiatives and/or making use of clinically practical screening instruments to manage MDD may be meaningful to a primary care audience (12). Indeed, “evidence in practice settings continues to demonstrate high rates of inadequate antidepressant medication treatment in terms of dose and duration, inappropriate and frequent changes in treatment, as well as low adherence and high dropout rates, all contributing to low rates of remission for depression (13).” As a result, MBC may provide a paradigm shift in how clinical decision making is incorporated into clinical practice.

Ultimately, education regarding the above health gaps should enhance treatment of MDD and provide patients the much needed relief from this devastating disorder.

**Potential learner**

We intend to support one initiative for each learner group listed below. As stated in the CGA identifier section, please ensure the correct identifier is included in the “Activity Title” field on the grant application form.

1. Nurse Practitioners and Physician Assistants who treat patients with MDD
2. Primary Care Physicians who treat patients with MDD
**Educational format**

Integrated educational curriculum comprised of multiple activities and including delivery formats and learning techniques based on adult learning principles and tailored to independently identified gaps of the learners. (i.e., combination of live, online, print, and other formats proven to be effective in changing knowledge, attitudes and skills.)

**Outcome measures**

At minimum, the educational evaluation plan must be designed to objectively measure improvements in HCP knowledge and competence (Level 4) (14).

**Funding guide**

Multi or sole support. Budget should demonstrate fiscal responsibility and cost effectiveness and total budget should not exceed $1M.

**Submission Requirements**

When responding to this CGA, please follow the established guidelines for the Takeda medical education grant submission process. All applications must be submitted at [www.takedaeducationalgrants.com](http://www.takedaeducationalgrants.com)

The education must be accredited by the appropriate accrediting bodies, be fully compliant with ACCME criteria and the Standards for Commercial Support and must be in accordance with the U.S. Food and Drug Administration’s Guidance on Industry-Supported Scientific and Educational Activities. If accepted, must attest to the terms, conditions and purposes of an educational grant as described in the Takeda- Lundbeck letter of agreement.

---

**References**


