Allergan - Call for Grants Notification
Issue Date: March 31, 2017
Therapeutic Area: Non-alcoholic Steatohepatitis (NASH)

Purpose: Allergan is interested in providing grant support for independent continuing professional development and education of healthcare professionals in the United States who diagnose and treat patients with NASH. This Call for Grants Notification (CFG) provides public notice of the availability of funds in a general topic area for activities for which recognized scientific or educational needs exist and funding is available.

Allergan Medical Education is committed to supporting independent educational activities in specific therapeutic areas that foster increased understanding of scientific, clinical, or healthcare issues; and that serve to improve patient care. All grants are awarded at Allergan’s sole discretion. Approval of grant funding is never related to or conditioned upon past prescriptions or purchases of Allergan products. Furthermore, Allergan does not offer or provide educational grants to encourage or to reward the prescription, purchase, ordering, or recommending of Allergan products.

Intended Audience
- Gastroenterologists, Hepatologists

Educational Design
- Satellite Symposium at The Liver Meeting® 2017
- Enduring materials inclusive of accredited online material and/or print supplement

Application Title: “CFG GI 13 – Program Title”
- Your grant title must begin with the Call for Grants ID number
- Refer to the submission instructions for further guidance on submitting your grant application

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<thead>
<tr>
<th>Submission Timeframe</th>
<th>April 1, 2017 – May 5, 2017</th>
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<tr>
<td>Proposal</td>
<td>Live satellite symposium</td>
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<tr>
<td>Program Format</td>
<td>Live symposium with enduring materials/print accredited supplements</td>
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<tr>
<td>Program Cost</td>
<td>&lt;$275,000</td>
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Eligibility Criteria
- Applicants must be US-based, registered on Allergan’s Grant Management website at www.allerganmededgrants.com, and in good standing and accredited to provide CME/CE by an official accrediting agency (e.g. ACCME, AOA, AAFP, AMA, ADA CERP, ANCC, ACPE, AANP, NCCPA, etc.).
- Our grant application system requires the registration of accredited providers and third parties before a grant application can be submitted.
- We recommend that your organization register in the system before the deadline if you are not currently registered.

Educational Needs
Non-alcoholic Steatohepatitis (NASH) is usually described as a silent, severe form of Non-alcoholic Fatty Liver Disease (NAFLD) and is highly associated with metabolic disorders including obesity and Type 2 Diabetes (T2DM); and is considered the hepatic manifestation of metabolic syndrome.¹ NASH a serious chronic liver disease defined by the presence of hepatic steatosis, lobular inflammation, and hepatocyte injury (hepatocellular ballooning), with or without fibrosis.² Presence of fibrosis in NASH is the most important independent predictor of clinical outcomes and mortality.³,⁴,⁵ The incidence of NAFLD/NASH has been rapidly increasing globally in line with the increased prevalence of obesity, and is currently the most common chronic liver disease.⁶
A survey of US gastroenterologists and hepatologists suggests that clinical practice patterns among gastroenterologists and hepatologists for the diagnosis and management of NASH frequently diverge from published practice guidelines. Although liver biopsy remains the gold standard to diagnose NASH, less than 25% of respondents routinely require it to make the diagnosis of NASH. Additionally, a study of 152 gastroenterologists and 150 primary care physician (PCPs) showed significant gaps in physician awareness and familiarity with NAFLD and NASH in the US. Currently, the principal management for NAFLD/NASH is lifestyle modification by diet and exercise and treatment of the underlying disease states (e.g. obesity, T2DM). While specialists were generally more knowledgeable, not all specialists were following the diagnosis and management guidelines.

Patients have limited awareness of the risks and are not fully aware of the intensity of the outcomes of NAFLD and NASH since there are little to no bothersome symptoms present early in the course of disease and symptoms may not exclusively be associated with NASH when patients are in the advanced stages. This highlights the need for enhanced physician-patient communication of NAFLD and NASH.

To date, there is no formally approved pharmacotherapy for NASH. Establishment of pharmacological therapy is crucial because obese patients with NAFLD often have difficulty maintaining improved lifestyles. In addition to lifestyle changes capable of removing the metabolic factors which drive disease progression in NASH, there is an urgent need for agents to reduce inflammation and fibrosis. More recently, a series of drugs have shown potential evidence of beneficial effects in Phase II studies and few have progressed to Phase III studies.

We request that educational providers independently assess whether an educational need exists to improve diagnosis and management of patients with NASH as well as demonstrate that an educational intervention(s) is needed to address knowledge, performance, and/or practice gaps. Requestors should be able to describe the specific quality gaps or barriers in practice, and what they will do to close these gaps or problems.

Proposed and implemented educational activities must be fully compliant with all applicable accrediting organization and industry standards, guidelines, and requirements as they apply to the conduct of independent medical education. If an accredited provider chooses to submit an educational grant request in response to this CFG, a complete and independent needs assessment including identified barriers to patient care, must be provided with the grant application.

**Outcomes Measurement**

Applications should include a detailed plan to provide quantitative evidence to show that the educational initiative had impact on healthcare provider knowledge, competence, and/or performance outcomes (Moore level 3 - 5). The proposal should include pre- and post-educational assessments or a comparison to a control group who has not been exposed to the intervention. A description of the methodology used to evaluate the reach and quality of the activity should be provided.

**Submission Instructions**

Submit applications through Allergan’s Grant Management website at www.allerganmededgrants.com.

When submitting the application, please ensure the following are completed:
1. Select *Gastroenterology* as the therapeutic area
2. Include the following, “CFG GI 13,” in the program title of the grant application
3. Complete all sections of the grant application
4. Upload all documents requested by the system

**Deadline for Submission of Application**

May 5, 2017
Decision Date and Notification
You will receive an acknowledgement email once the Allergan Medical Education Department has reviewed your completed grant application, approximately the second week of June. After your request has been completely reviewed by Allergan’s Grant Review Committee, Allergan will provide you a written response regarding your request. If your request is approved, the response will be accompanied by a Letter of Agreement, which must be signed and returned to the Allergan Medical Education Department. Please do not consider any request approved until you have received written documentation from the Allergan Medical Education Department stating that your grant request has been approved.

Terms and Conditions
We reserve the right to approve or deny any or all applications received as a result of this request or to cancel, in part or in its entirety, this CFG. Allergan is not responsible for any costs associated with the response to questions associated with the submission of a CFG application.

Transparency
The Allergan grant approval process is in full accordance with the recommendations and the guidance of the Office of Inspector General (OIG), Pharmaceutical Research and Manufacturers of America (PhRMA), Advanced Medical Technology Association (AdvaMed), the Accreditation Council for Continuing Medical Education (ACCME), “National Physician Payment Transparency Program: OPEN PAYMENTS” commonly known as the “Sunshine Act,” and internal Allergan Compliance policies.

Allergan, at its sole discretion, has the right to disclose the details of funded independent medical education activities, including those that may be required by federal, state, and/or local laws and regulations. This disclosure may include, but shall not be limited to, details of the activity and the grant amount.

References