Allergan - Call for Grants Notification

**Issue Date:** December 23, 2016

**Therapeutic Area:** Irritable bowel syndrome (IBS)

**Purpose:** Allergan is interested in providing grant support for independent continuing professional development and education of healthcare professionals in the United States who treat patients with IBS. 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**

*Live Meeting*
- Primary Audience: Physician Assistants
- Secondary Audiences: Nurse Practitioners, Nurses

*Enduring*
- Primary Audience: Physician Assistants
- Secondary Audiences: Nurse Practitioners, Nurses

**Educational Design**
- Satellite Symposium at AAPA 2017
- Enduring materials inclusive of accredited online material and/or print supplement

**Application Title:** “CFG PA 08– 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

<table>
<thead>
<tr>
<th>Submission Timeframe</th>
<th>December 24, 2016 – January 20, 2017</th>
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</thead>
<tbody>
<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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<td>Program Cost</td>
<td>≤$250,000</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

Irritable bowel syndrome (IBS) is a functional gastrointestinal condition with an unknown etiology that affects 5-15% of the general population. IBS is characterized by a variety of abdominal and bowel symptoms which can include pain, bloating, constipation (IBS-C), or diarrhea (IBS-D).

According to a recent survey conducted by the American Gastroenterological Association (AGA), IBS symptoms can be extremely burdensome and affect patients’ quality of life, including interference with work, school, or productivity. The most bothersome symptoms reported by IBS-C patients included constipation, abdominal pain, and bloating; and for IBS-D, the most bothersome were incontinence, abdominal pain, and urgency.

The same survey reported that it takes patients an average of four years to be diagnosed with IBS, with three-quarters of those with IBS symptoms trying an average of 3.6 OTC products before talking to a healthcare provider about their symptoms. More than 80% of those with IBS symptoms were proactive in bringing up IBS symptoms with their healthcare provider; however, the majority of those patients who had not sought treatment for gastrointestinal (GI) symptoms reported that their doctor had not asked about GI symptoms or regularity during an annual check-up. Additionally, when asked how well patients felt their HCP understands how bothersome their symptoms were, only about half felt that it was very well or extremely well.

A patient-centered approach with an emphasis on effective communication between clinicians and the patients has been recommended for management of functional bowel diseases such as IBS and has been associated with improved outcomes, increased patient satisfaction, and decreased utilization of care. Physician Assistants may be uniquely qualified to improve management of IBS; according to the AAPA, “Effectively treating patients with gastroenterological conditions requires provider availability for education, counseling, and follow up care. PAs are a perfect resource for providing that extra measure of time and attention.”

Formal guidelines are currently available to assist healthcare providers in the diagnosis and management of IBS. Physician practice patterns and attitudes related to IBS have been investigated by several research groups. The first found that the majority (72%) of general practitioners surveyed approach the diagnosis of IBS through a process of exclusion and often order uninformative or unnecessary diagnostic tests, despite diagnostic guidelines that recommend that such tests are not necessary in the absence of alarm features.

Many therapies are currently used for treating the symptoms of IBS, although they vary widely in their respective mechanisms of action and quality of evidence. While the pathophysiological mechanisms underlying IBS are not fully understood, visceral hypersensitivity may be a key factor. Recently, guanylyl cyclase 2C (GC-C), and its endogenous peptide GC-C stimulators guanylin and uroguanylin, have been found to play important roles in secretion, intestinal transit, as well as in sensory signaling in the gut. The latter may be of particular relevance for IBS-C, as patients’ satisfaction with IBS-C treatments may be more related to the resolution of abdominal symptoms such as pain, rather than bowel symptoms (i.e. stool consistency as measured by BSFS). Opioid receptors, including mu, delta, and kappa, are expressed along the GI tract and may also play a key role in regulating gastrointestinal motility, secretion, and visceral sensation in IBS-D.

A study assessing the effect of direct-to-consumer-advertising on IBS practice patterns found that there was a significant, yet transient, increase in doctor visits and IBS diagnoses. While little data are available regarding healthcare provider practice patterns and attitudes related to IBS, the available findings suggest educational gaps may exist pertaining to diagnosis and treatment of the condition. Based on the gaps documented in the literature, funding is available to support independent certified educational activities developed by accredited providers that address practice gaps for Physician Assistants in the diagnosis and management of patients with IBS.

Regarding the format of the educational initiative, AAPA 2017 will be the largest national PA meeting, with an expected 8,000+ PAs to be in attendance. While many PAs are planning to attend the live meeting, many will still utilize websites and/or print materials as sources of medical information. These enduring formats will further extend the educational message to those practitioners who are unable to attend the live session.
We request that educational providers independently assess whether an educational need exists to improve communication, diagnosis, and management of patients with IBS, 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 describe 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, including methods for measuring each activity and the extent to which the program met the stated objectives, should also 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 PA 08,” in the program title of the grant application
6. Complete all sections of the grant application
7. Upload all documents requested by the system

Deadline for Submission of Application
January 20, 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 first week of February 2017. 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 and Ironwood are not responsible for any costs associated with the response to questions associated with the submission of a CFG application.
Transparency
Call for Grants applications will be jointly reviewed and funded by Ironwood Pharmaceuticals. 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
12. Taylor, D, et al. P342 - Impact of Linaclotide and Stool Form on Bowel Movement Satisfaction in Patients with Irritable Bowel Syndrome with Constipation or Chronic Idiopathic Constipation: Results from the CONTOR Study. *Am J Gastroenterol.* 2016; 111:S238–S239