

**Request for Education ID:** RFE-21-MS-002

**Issue Date:** October 1, 2021

**Deadline for Submission:** November 1, 2021

**Therapeutic Area:** Neurology

**Area of Interest:** Multiple Sclerosis

**Intended Audience:** Neurologists and Advanced Practice Clinicians with a Neurology focus

**Geographic Area:** United States

**Budget:** Up to \$250,000.00

Biogen invites accredited members of the educational provider community to submit applications for independent, certified medical education grants subject to the terms described below. This request for education provides public notice of availability of funds to address areas related to disease modifying therapy benefit/risk profile for multiple sclerosis (MS).

**Background:**

Multiple sclerosis is a chronic relapsing and progressive disorder of the central nervous system that is characterized by that is characterized by inflammation, demyelination, and axonal loss. MS impacts nearly 1 million people in the United States with 85% presenting with a relapsing-remitting disease course.<sup>1,2</sup>

Disease modifying therapies (DMT) utilized for the treatment of MS impact both relapses and accumulation of disability. After decades of focused research there are numerous DMTs of differing benefit/risk profiles and routes of administration. There are numerous considerations for healthcare practitioners (HCPs) and MS patients related to the potential short and long-term immune system impact, adherence, and frequency of treatments which highlights an educational opportunity.<sup>3,4</sup>

The COVID-19 pandemic and emergence of MS-specific COVID outcome and vaccine immune response data has only increased awareness of HCPs and patients of the need for careful consideration of the benefit/risk profile of DMTs when addressing immediate patient needs.<sup>5,6,7,8,9,10,11</sup>

National organizations such as the AAN and National MS Society have released guidance around vaccines in general and the COVID vaccine specifically for MS patients.<sup>12,13,14</sup>

**Educational Need and Professional Practice Gaps:**

Given the importance of both neurologists and advanced practice providers in the complex MS treatment paradigm, we believe it is important that the neurology community is sufficiently educated on DMT benefit/risk profiles, immune response to vaccines, and the implications it may have on long-term MS care.

Specifically, the following existing professional practice gaps for neurologists and advanced practice providers need to be addressed:

- Understand the importance of early treatment of MS considering the benefit/risk profiles of DMTs, particularly considering the reemphasis on safety due to the pandemic.
- Understand the impact of DMTs on the immune system particularly as it relates to COVID-19 outcomes and overall immune response to vaccines (including non-COVID vaccines).
- Highlight the potential for evolving treatment algorithms based on DMT benefit/risk profiles (including recent COVID safety data) in different types of MS patients, taking into account age, comorbidities, prognostic indicators, and/or patient preferences.

### **Educational Design and Focus:**

Biogen funding is intended to support multi-modal programs (i.e. with live/virtual and/or enduring components) which include a minimum of 3 activities that:

- Creates an understanding for neurologists and advanced practice providers about the current MS treatment landscape with consideration for the COVID-19 pandemic
- Educates healthcare practitioners on the mechanism of action, duration of immune system impact and key clinical and safety data from DMTs utilized throughout the MS treatment algorithm with consideration for the ongoing pandemic
- Educates healthcare practitioners on the evolving benefit/risk profiles of DMTs, including the latest safety information, to potentially initiate at MS diagnosis and highlights the value of patient reported outcomes
- Educates healthcare practitioners on the considerations for vaccinations, overall immune response, and treatment sequencing

Grant proposals should include:

- **Needs Assessment/Gaps/Barriers:** Include a comprehensive needs assessment that is well referenced and demonstrates an understating of the specific gaps and barriers of the target audiences. The needs assessment must be independently developed and validated by the educational provider.
- **Target Audience and Audience Generation:** Describe methods for reaching the target audience(s) and any unique recruitment methods that will be utilized. The anticipated participant reach should be included, with a breakdown for each modality included in the proposal.
- **Learning Objectives:** Provide clearly defined and measurable learning objectives that address the identified gaps and barriers.
- **Educational Methods:** The ACCME calls for educational methods that are clearly designed to address the knowledge, competence and/or performance gaps that may underlie an identified healthcare gap<sup>15</sup>. The proposal should demonstrate an understanding of instructional design issues as they relate to the gaps in the knowledge, competence, or performance of the targeted audience.
- **Program Evaluation and Outcomes:** Provide a description of the approach to evaluate the quality of the educational program. Additionally, describe the methods that will be used to determine the extent to which activity has served to close the identified healthcare gap. Programs should include an outcomes plan of at least Moore's level 4<sup>16</sup>.
- **Budget:** Include a detailed budget with rationale, including breakdown of costs for content per activity, out-of-pocket cost per activity and management cost per activity.
- **Accreditation:** Programs must be accredited by the appropriate accrediting bodies and fully compliant with all ACCME Criteria and Standards for Commercial Support<sup>SM</sup>.
- **Communication and Publication Plan:** Provide a description of how the provider will communicate the progress and outcomes of the educational program. Include a description of how the results of this educational intervention will be presented, published, or disseminated.

**Eligibility Criteria:**

Applicants must be U.S.-based and in good standing and accredited to provide CME/CE by an official accrediting agency (e.g. ACCME, APA, ANCC, ACPE, etc.). The accrediting provider and, if applicable, the medical education provider (MEP) or other third-party vendors executing the activities are expected to comply with current ethical codes and regulations.

**Submission Instructions:**

If your organization wishes to submit an educational grant request, please visit [www.biogengrantsandgivingportal.com](http://www.biogengrantsandgivingportal.com) to access the online submission portal. Please include the RFE code (RFE-21-MS-002) in the "Request for Education (RFE) ID Number" field in the online application.

**Grant Decision-Making Criteria:**

For information about the decision-making criteria, visit <https://grantsandgiving.biogen.com/>.

**Award Decision Date:**

Approvals and denials will be communicated via email notification no later than December 10, 2021.

**Terms and Conditions:**

- All grant applications received in response to this RFE will be reviewed in accordance with all Biogen policies and policy guidelines. Please visit our website <https://grantsandgiving.biogen.com/> for details on the grant structure, eligibility criteria, and requirements for participation.
- This RFE does not commit Biogen to award a grant or pay any costs incurred in the preparation of a response to this request.
- Biogen reserves 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 RFE.
- All communications about this RFE must be submitted through Biogen's Grants & Giving Portal at [www.biogengrantsandgivingportal.com](http://www.biogengrantsandgivingportal.com). Failure to comply will automatically disqualify applicants.

**References:**

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2. Thompson et al. Diagnosis of multiple sclerosis: 2017 revisions of the McDonald criteria. *Lancet Neurol.* 2018 Feb;17(2):162-173. doi: 10.1016/S1474-4422(17)30470-2
3. Pardo G, Jones DE. *J Neurol.* 2017;264:2351-2374
4. Zrzavy T et al. *Front Immunol.* 2019;10:1883. doi:10.3389/fimmu.2019.01883
5. Bhise V, Dhib-Jalbut S. Potential Risks and Benefits of Multiple Sclerosis Immune Therapies in the COVID-19 Era: Clinical and Immunological Perspectives. *Neurotherapeutics.* 2021 Feb 2:1–8 doi: 10.1007/s13311-021-01008-7
6. Zrzavy et al. Immunology of COVID-19 and disease-modifying therapies: the good, the bad and the unknown. *Eur J Neurol.* 2020 Oct 8;10.1111/ene.14578. doi: 10.1111/ene.14578
7. Salter A et al. Outcomes and Risk Factors Associated With SARS-CoV-2 Infection in a North American Registry of Patients With Multiple Sclerosis. *JAMA Neurol.* 2021 doi:10.1001/jamaneurol.2021.0688

8. Sormani MP et al. DMTs and Covid-19 severity in MS: a pooled analysis from Italy and France. *Annals Clin Trans Neurol*. 2021. doi: 10.1002/acn3.51408
9. Achiron A et al. Humoral immune response to COVID-19 mRNA vaccine in patients with multiple sclerosis treated with high-efficacy disease-modifying therapies. *Ther Adv Neurol Disord*. 2021 doi.org/10.1177/17562864211012835
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13. National Multiple Sclerosis Society. Vaccinations. Accessed Sept 7, 2021. <https://www.nationalmssociety.org/Living-Well-With-MS/Diet-Exercise-Healthy-Behaviors/Vaccinations>
14. National Multiple Sclerosis Society. Timing MS Medications with COVID-19 Vaccines. Accessed Sept 7, 2021. <https://www.nationalmssociety.org/coronavirus-covid-19-information/multiple-sclerosis-and-coronavirus/covid-19-vaccine-guidance/Timing-MS-Medications-with-COVID-19-Vaccines>
15. Accreditation Criteria. Accreditation Council for Medical Education. <https://www.accme.org/accreditation-rules/accreditation-criteria>
16. Moore, D.E., Jr., J.S. Green, and H.A. Gallis. Achieving desired results and improved outcomes: integrating planning and assessment throughout learning activities. *J Contin Educ Health Prof*. 2009.29(1): p.1-15