As part of our commitment to improving the lives of people living with rare diseases Alexion, AstraZeneca's Rare Disease supports quality, independent Continuing Medical Education (CME) designed to enhance patient care and health outcomes.

This call for grant applications provides public notice of availability of funds to address updates to the US NMOSD treatment landscape of adult patients with aquaporin-4-positive (AQP4+) NMOSD.

Deadline for Submission	Friday, February 16, 2024
Decision Notification	Friday, March 8, 2024
Primary Area of Focus	Rare Disease
Therapeutic Area	Neuromyelitis Optica Spectrum Disorder (NMOSD)
Geographic Focus	United States
CGA Code	AX001
Intended Audience	Adult Neuro-immunologists, Neuro-radiologists, Neurologists, Internists, and Ancillary Health Care Providers (Physician Assistants, Nurse Practitioners, Pharmacists, etc.)
Budget	Up to $300,000
Educational Need	Neuromyelitis optica spectrum disorder (NMOSD) is a rare, severe, disabling, and potentially life-threatening autoimmune neuroinflammatory disease of the central nervous system (CNS),[1] characterized by devastating and unpredictable attacks (relapses) that result in progressive and irreversible damage to the optic nerves and spinal cord.[1-4] The International Panel for Neuromyelitis Optica Diagnosis (IPND) released an updated set of guidelines in 2015 for diagnosing NMO and NMOSD, and these disorders are now both collectively referred to as NMOSD.[4] In NMOSD, uncontrolled complement activation triggered by anti-aquaporin-4 (AQP4) antibodies is a major underlying mechanism of the disease.[5-8] The complement system is part of the innate and adaptive immune response. It is a collection of blood and cell surface proteins.[1,3-4,10] It serves as a major primary defense against pathogens, thus infections. Three out of 4 patients with NMOSD are anti-AQP4 antibody-positive.[10-12] They will develop anti-AQP4 autoantibodies to the water channel protein, AQP4, which is expressed on astrocytes in the CNS.[6-8] Binding of anti-AQP4 autoantibodies to AQP4 activates the complement cascade, which has been implicated in neuronal injury.[13-15] Complement activation is one of the underlying causes of damage in NMOSD.[13] The role of complement in NMOSD, cardinal patient presentations of NMOSD relapse (i.e., optic neuritis, transverse myelitis, area postrema syndrome), differing specialty providers who may manage these aforementioned clinical presentations, and the evolving therapeutic landscape for NMOSD management justify a need for providers to understand the safety and efficacy aspects of the terminal complement inhibitor mechanism in the context of updates on FDA-approved

	therapies. Given the growing body of literature on the efficacy and safety of existing and emerging NMOSD treatments, educational programs that keep physicians abreast of the latest evidence will facilitate up-to-date clinical treatment paradigms and ensure patients receive the most effective therapy for their individualized clinical phenotype. Alexion, AstraZeneca Rare Disease seeks to support independent medical education designed to develop practitioners' understanding of: • AQP4+ NMOSD pathophysiology and the role of the complement mechanism in the disease state • The importance of AQP4+ NMOSD clinical presentation recognition, early and accurate diagnosis, and regular follow-up to maintain appropriate treatment strategies • Updates to the US NMOSD treatment landscape of adult patients with AQP4+ NMOSD that are FDA-approved • Appropriate diagnostics and pathognomonic clinical findings (e.g., MRI, cell-based assays) that may manifest at various stages of the NMOSD patient journey and disease course • Key considerations and best practices for initiating relapse-preventative therapies to mitigate disability from NMOSD relapse & managing treatment complications via patient case examples
Educational Design and Focus	Live programs at a national conference in the first half of 2024 (e.g., 2024 AAN Annual Meeting [April 13-18], 2024 Annual CMSC Meeting [May 29-June 1], etc.) with a focus on educating healthcare professionals about NMOSD updates in the treatment landscape. Slots should be secured by grant recipient.
Application Requirements	**Proposal must be independently developed and include the following:** • **Needs Assessment/Gaps/Barriers:** Include a comprehensive, well-referenced needs assessment that provides a detailed description of the educational / practice gaps and barriers of the target audiences. The needs assessment must be independently developed and validated by the educational provider. • **Audience Generation:** Describe methods for reaching the target audience(s) and any unique recruitment methods that will be utilized. • **Educational Strategy:** Provide clearly defined and measurable learning objectives that are clearly designed to address the identified gaps and barriers. 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 outcomes methodology that will be employed to measure

	the impact of the educational program and how these results will be presented, published, or disseminated. 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. • **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 and fully compliant with all ACCME Criteria and Standards for Commercial Support℠.

References

1. Sellner J, et al. Eur J Neurol. 2010;17(8):1019-1032.
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3. Trebst C, et al. J Neurol. 2014;261(1):1-16.
4. Wingerchuk DM, et al. Neurology. 2015;85(2):177-189.
5. Saadoun S, et al. Brain. 2010;133(Pt 2):349-361.
6. Duan T, Smith AJ, Verkman AS. Journal of neuroinflammation. 2018;15(1):1-11.
7. Hinson SR, et al. National Academy of Sciences. 2012;109(4):1245-50.
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9. Hinson SR, et al. Archives of neurology. 2009;66(9):1164-7.
10. Holroyd KB, Manzano GS, Levy M. Curr Opin Ophthalmol. 2020;31(6):462-8.
11. Fiala C, Rotstein D, Pasic MD. J Appl Lab Med. 2022;7(1):305-10.
12. Lucchinetti CF, et al. Brain. 2002;125(7):1450-1461.
13. Wingerchuk DM, et al. Lancet Neurology. 2007;6(9):805-815.
14. Papadopoulos MC, Verkman AS. Lancet Neurology. 2012;11(6):535-544.
15. Piatek P, et al. Frontiers in immunology. 2018;9:1694.

Program Requirements: The Program must be planned and executed as an accredited activity and fully compliant with the criteria and/or standards of commercial support for ACCME, AAFP, AOA, ACPE, ANCC, AANP, or NCCPA. Furthermore, the program will be educational and nonpromotional in nature and will be planned, designed and implemented in accordance with the U.S. Food and Drug Administration's Guidance on Industry-Supported Scientific and Educational Activities ("Policy Statement").

The Policy Statement and the ACCME Standards require, among other things, that (i) Institution conduct the Program independently and without control or influence by AstraZeneca over the Program's planning, content (including the selection of speakers or moderators), or execution; (ii) the Program be free of commercial bias for or against any product; (iii) Institution make meaningful disclosure of AstraZeneca support of the Program and any prior relationship between Institution and AstraZeneca, and the relationship, if any, between AstraZeneca and the speakers selected by Institution; and (iv) AstraZeneca not engage in, and Institution not permit any other sponsor to engage in, promotional activities in or near the Program room or advertise its products in any materials disseminated as part of the Program.

In addition, Institution is required by the Policy Statement and, if applicable, accreditation standards to ensure that any product discussions at the Program be accurate, objective, balanced and scientifically rigorous. This includes a balanced discussion of each product and of treatment alternatives, that limitations on data be disclosed, that unapproved uses be identified as such, and that for live presentations there be opportunities for questioning or debate.