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 areas related to diagnosis and management of atypical hemolytic uremic syndrome (aHUS)

Deadline for Submission	Friday, February 28th, 2025
Decision Notification	Friday, March 28th, 2025
Primary Area of Focus	Rare Disease
Therapeutic Area	Nephrology – atypical Hemolytic Uremic Syndrome
Geographic Focus	Global
CGA Code	AX002
Intended Audience	Nephrologists and aHUS physicians
Budget	Up to $200,000
Educational Need	Atypical hemolytic uremic syndrome (aHUS) is a progressive rare disease that, if untreated, can result in severe kidney damage and death. aHUS is a form of thrombotic microangiopathy (TMA), caused by complement dysregulation that leads to uncontrolled terminal complement activation, that can manifest in the presence or absence of a trigger or associated condition[1-3]. Given the rare nature of the disease, often complex clinical presentation, and no specific diagnostic test for aHUS, timely diagnosis and treatment for aHUS remains a challenge[4]. Terminal complement blockers that act by inhibiting complement component C5 (C5i), such as eculizumab and the next-generation C5i ravulizumab, are the only approved treatments for aHUS, and were first approved for use in 2011 and 2019, respectively[5-10]. Given the continued challenges associated with recognizing and diagnosing aHUS, and the accumulating body of evidence of newer C5i drugs in aHUS, including from recent long-term clinical trials[11-13] and real-world studies[14-17], it is critical for physicians to understand the pathophysiology, strategies for diagnosing aHUS, and the data for C5i drugs including more recently approved medicines, to further improve outcomes for patients. Alexion, AstraZeneca Rare Disease seeks to support independent medical education designed to develop practitioners' understanding of: • the involvement of terminal complement in the pathophysiology of aHUS, and the life-threatening consequences of uncontrolled terminal complement activation • clinical and real-world data from adult and pediatric patients with aHUS that demonstrate how treatment with currently approved terminal complement inhibitors, including next-generation C5i, has altered the landscape of this disease by improving renal outcomes.

	• clinical features of aHUS and strategies for timely diagnosis and management considerations, including using next-generation therapies as first-line treatment for patients with aHUS. With case examples that address the following
	  ○ aHUS occurring in the presence of triggers such as kidney transplantation, pregnancy-associated, systemic lupus erythematosus, or in pediatric patients
	  ○ how aHUS patients are managed in cases where aHUS relapses after C5i therapy discontinuation and how patients are monitored for disease relapse to ensure timely detection
	
	1. Java A, Hematology, 2024, Vol 2024 (1), 200-205.
	2. Goodship T, et al. Kidney Int, 2017, 91 (3), 539-551.
	3. Licht C, et al. Nephrology, 2024, 29, 519–527.
	4. Vivarelli M, et al. Kidney Int, 2024,106(3), 369-391.
	5. Legendre CM, et al. N Engl J Med, 2013, 368 (23), 2169-2181.
	6. Ravulizumab, US Food and Drug Administration, https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/761108s023lbl.pdf
	7. Sheridan D, et al. PLoS One, 2018, 13 (4), Article e0195909.
	8. Ariceta G, et al. Kidney Int, 2021, 100 (1), 225-237.
	9. Rondeau A, et al. Kidney Int, 2020, 97 (6), 1287-1296.
	10. Tanaka K, et al. Pediatr Nephrol, 2021, 36 (4), 889-898.
	11. Dixon BP, et al. Kidney Med, 2024, 6(8): 100855.
	12. Barbour T, et al. Kidney Int Rep, 2021, 6 (6), 1603-1613.
	13. Dixon BP, et al. ASN 2024. Oral presentation for Abstract SA-OR64.
	14. Schafer F, et al. Kidney Int Rep, 2024, 9(9), 2648-2656.
	15. Schonfelder K, et al. BMC Nephrol, 2024, 25(1):202.
	16. Busutti M, et al. J Nephrol. 2024, 37, 2421-2423.
	17. Hanna R, et al. ASN. 2024; abstract SA-PO804.

Educational Design and Focus	Alexion funding is intended to support multi-modal programs (i.e. with live/virtual and/or enduring components) including but not limited to: • Interactive self-directed programs designed for impactful learner engagement using proven distribution channels • Symposium (face-to-face or virtual) that will be developed into a virtual enduring program. 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

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.