Independent Medical Education
Request for Educational Support (RFE)

Date	12/1/2022
RFE Requestor Information	Name: Priya Wanchoo, MD, CHCP Title: Director, Hematology Medical Education E-mail: Priya.wanchoo@bms.com
RFE Code	RFE-23-HEME-100
Therapeutic Area	Myelodysplastic Syndromes (MDS)
Area of Interest	BMS would like to support an educational initiative related to: • LR-MDS disease state education for the multidisciplinary care team, including primary care clinicians • Increased awareness and improved education on the impact of anemia in LR-MDS • The importance of accurate MDS diagnosis, timely referral, and urgency to treat • The long-term impact and safety of red blood cell transfusion and dependency • Safety, efficacy, and dosing of novel and emerging therapies for LR-MDS in the post-ESA setting or high transfusion burden • Relevant updates and emerging data in LR-MDS
Educational Design	BMS is interested in supporting a comprehensive educational initiative that includes the following: • Unique educational design with detailed agenda(s) • Measurable learning objectives for different targeted audiences if applicable • Up to date content • Collaborative partners who may add value to the initiative or enhance learner reach • The activity(ies) should measure improvement of learners' knowledge, confidence, competence, and performance and should achieve at least a Moore's Level 4 impact. Activities that achieve Moore's Levels 5 and/or 6 outcomes and are highly favored and recommended when possible • Detailed timeline of deliverables
Intended Audience	Community- based clinicians including primary care physicians, advanced practice providers nurses, pathologists, and hematologists
Budget/Budget Range	The maximum amount of funding available for this RFE is $175,000 *Only multi-support requests will be considered*
Accreditation	ACCME, ANCC, AAPA, AAFP
Geographic Coverage	United States

Deadline for Submission	1/31/2023 by 5:00PM EST
Expected Grant Approval	2/10/2023

Background/Needs Assessment:

Ineffective erythropoiesis is the hallmark of low-risk MDS (LR-MDS) and is evident by morphologically proven erythroid dysplasia and subsequent anemia.[1] Anemia, the most common symptom in LR-MDS, is present in almost 90% of the cases. With a median age at diagnosis of 71 years, MDS patients can be severely impacted by chronically low levels of hemoglobin, which can lead to worsening cardiopulmonary function, increased falls, and significant cognitive decline.[2]

A diagnosis of anemia is often missed in the primary care setting, where primary care physicians (PCPs) who are at the forefront of diagnosing and referring, may not routinely screen patients for anemia if patients are not presenting with apparent symptoms. Also, many patients with anemia may complain of fatigue, which unfortunately, may be attributed old age. Undiagnosed anemia may lead to delays in referral to hematology specialists and a possible delay in diagnosis of MDS. [3]Possible reasons for these delays include lack of exposure to hematologic malignancies, limited knowledge of associated signs and symptoms, and a reliance on patient symptoms to prompt referral (as opposed to signs and screening).[3]

The diagnosis of anemia includes multiple factors including clinical history, physical examination, and laboratory findings.[4] The first step to diagnosing anemia is to obtain a clear patient history including any prior blood loss, duration of anemia, associated features and comorbidities, and medications (including proton pump inhibitors, aspirin, and anti-inflammatory drugs).[4] Providers must follow their laboratory's parameters but also be cognizant to adjust for patient age, gender, and ethnicity as there is some variability there.[5] Using the information gathered from the history, physical exam, and laboratory data, the type of anemia and source can be identified and then initial treatment can begin. Some patients may be diagnosed with underlying MDS as the source of their anemia based on WHO/NCCN criteria with application of International Prognostic Scoring System (IPSS) or revised IPSS (IPSS-R).[6] Further evaluation of the bone marrow and peripheral blood morphology and cytogenetics and molecular testing may result in a diagnosis of MDS which may require prompt treatment decision-making.

For patients with lower-risk MDS, the primary goals of therapy are hematologic improvement and quality of life enhancement. Supportive care is an integral component of MDS management; many patients have symptomatic anemia that requires transfusions. Erythrocyte-stimulating agents (ESAs) are the standard first-line agents for the treatment of anemia in patients with low-risk MDS with serum erythropoietin levels ≤500 mU/mL, aside from patients with del(5q), for whom lenalidomide is recommended. ESA response rates range from 30% to 60%, with a median duration of response of 20 to 24 months.[7,8] A baseline iron study must be performed to ensure adequate iron stores before ESA therapy is initiated.

Prognostic factors for better response to ESAs include low red blood transfusion requirement, low serum erythropoietin (EPO) level, and lower-risk disease per the IPSS-R. Treatment with ESAs may also be associated with improved survival compared with RBC transfusions alone. However, most responders will experience relapse and become RBC transfusion dependent. [9,10] Early ESA failure (no response to ESA or relapse within 6 months) is a prognostic marker of poor disease outcome and progression to AML.[11,12]

The treatment of patients with transfusion dependent lower-risk MDS post-ESA has been an area of significant unmet need. Luspatercept is a second line treatment choice for management of anemia in patients with lower risk MDS-RS. [13,14]

Other novel therapies have demonstrated the potential for benefit, including roxadustat, a hypoxia-inducible factor prolyl hydroxylase inhibitor being evaluated in a phase 3 study.[15] Another is imetelstat, a novel telomerase inhibitor that demonstrated durable TI in lower-risk MDS patients with high transfusion burden in a phase 2 study.[16]

Anemia is a hallmark of patients with lower-risk myelodysplastic syndromes and is often associated with poor risk prognosis and impaired health-related quality of life. Obtaining a prompt and accurate explanation for an anemia diagnosis is critical for treatment decision-making.

Educational Needs and Professional Practice Gaps:

High scientific standards and quality assurance for medical learning programs is required to maximize transparency and quality and minimize stakeholder bias in the provision of medical education. Applying modern, evidence-based learning standards significantly contributes to increasing the scientific knowledge and professional competencies of healthcare professionals (HCPs) to improve patient outcomes.

BMS has identified, through insights from educational needs assessments, literature search, learning outcomes, and other methods, the need to address the following existing professional practice gaps by providing clinician education on:

- MDS disease state education for the multidisciplinary care team, including primary care clinicians
- Awareness on the impact of anemia
- Accurate MDS diagnosis, timely referral, and urgency to treat
- The long-term impact and safety of red blood cell transfusion and dependency
- Safety, efficacy, and dosing of novel and emerging therapies for LR- MDS in the post-ESA setting or high transfusion burden
- Relevant updates and emerging data in LR-MDS

Specific Area of Interest:

BMS is interested in funding an innovative, interactive, educational activity that addresses the above educational needs and professional practice gaps. The content and/or the format of the CME/CE activity and its related materials must be current and designed in such a way that it addresses the educational needs of the intended audiences as described in this RFE.

Grant Proposals should include, but not be limited to, the following information:

- Executive Summary: The Executive Summary should consist of 1-2 pages and highlight the key areas as described below.

- Needs Assessment/Gaps/Barriers: Needs assessment should be referenced and demonstrate an understanding 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: Target audience for educational program must be identified within the proposal. In addition, please describe methods for reaching target audience(s) and any unique recruitment methods that will be utilized. The anticipated or estimated participant reach should also be included, with a breakdown for each modality included in the proposal, as applicable (e.g., number of participants for the live activity, the live webcast, and enduring activity).

- Learning Objectives: The learning objectives must be written in terms of what the learner will achieve because of attending. The objectives must be clearly defined, measurable, and attainable and address the identified gaps and barriers.

- Program Evaluation and Outcomes Reporting: Description of the approach to evaluate the quality of the educational program. Describe methods used for determining the impact of the educational program on closing identified healthcare gaps.

    - Please refer to "Guidance for Outcomes Report" (on the BMS grants website) for a detailed explanation of preferred outcomes reporting methods and timelines.
    - Remember that knowledge, performance, and competency-based outcome measures according to Moore's Level 4 is required. Level 5 outcomes are highly favored and recommended when possible.

- Educational Design and Methods: Describe the approach used to address knowledge, competence, and performance gaps that underlie identified healthcare gaps. The proposal should include strategies that ensure reinforcement of learning through use of multiple educational interventions and include practice resources and tools, as applicable.

- Communication and Publication Plan: Provide a description of how the provider will communicate the progress and outcomes of the educational program to the supporter. It is highly recommended to describe how the results of the activity will be presented, published, or disseminated.

- Innovation: Describe how this project is innovative and engages the learners to improve knowledge, competence and/or performance. Further describe how this project might build on existing work, pilot projects or ongoing projects developed either by your institution or other institutions related to this topic.

- Budget: Detailed budget with rationale of expenses, including breakdown of costs, content cost per activity, out-of-pocket cost per activity, and management cost per activity.

Note: The accredited provider and, if applicable, the medical education partner or other third party executing the activities, are expected to comply with current ethical codes and regulations. They must have a conflict-of-interest policy in place to identify and resolve all conflicts of interest from all contributors and staff involved in developing the content of the activity prior to delivery of the program and must have a separate company providing/accrediting independent medical education if they are also performing promotional activities.

If your organization wishes to submit an educational grant request, please use the online application available on the Bristol Myers Squibb Independent Medical Education website. http://www.bms.com/responsibility/grantsandgiving

References:

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15. Henry DH, Glaspy J, Harrup R, et al. Roxadustat for the treatment of anemia in patients with lower risk myelodysplastic syndrome: Open-label, dose-selection, lead-in stage of a phase 3 study. Am J Hematol. 2022;97(2):174-184. doi:10.1002/AJH.26397
16. Steensma DP, Fenaux P, van Eygen K, et al. Imetelstat Achieves Meaningful and Durable Transfusion Independence in High Transfusion-Burden Patients with Lower-Risk Myelodysplastic Syndromes in a Phase II Study. J Clin Oncol. 2021;39(1):48-56. doi:10.1200/JCO.20.01895