Bristol Myers Squibb
Independent Medical Education
Request for Educational Support (RFE)

Date	March 27, 2024
RFE Requestor Information	Name: Sylvia Nashed, PharmD, RPh Title: Director, Global Medical Education E-mail: Sylvia.Nashed@bms.com
RFE Code	RFE-24-IM-102
Therapeutic Area	Immunology/Rheumatology
Area of Interest	Psoriatic Arthritis (PsA) It is our intent to support a comprehensive, innovative, and engaging initiative that educates on the pathophysiology of PsA, the unmet needs of PsA patients, and the correlating mechanisms and recent clinical trial data for current and emerging therapies.
Educational Design	Bristol Myers Squibb is interested in supporting a comprehensive educational initiative. Various formats and designs will be considered, with priority given to those that are most innovative, engaging, and provide resources/tools that will further aid rheumatologists, dermatologists, and allied healthcare professionals in their practice, as well as patient educational resources. 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 6 outcomes are highly favored and recommended when possible. A successful proposal should include: • Clear and concise statement of the goal, learning objectives, and expected outcomes of the educational initiative • Instructional design that incorporates innovative techniques designed to engage learners, promotes application of education into practice, and incorporates a patient-centered approach to care • Tools that provide HCP learners the opportunity to facilitate change to improve patient outcomes and address healthcare inequities

	• Measurement of outcomes, inclusive of learner progression throughout the activity, extent to which the activity closed the identified practice gaps, and patient impact
Intended Audience (may include, but not limited to)	US and Canadian Rheumatologists, Dermatologists, NPs and PAs who practice in the rheumatology and/or dermatology space
Budget/Budget Range	The maximum amount of funding available for this RFE is $150,000 - $200,000. Single or multi-supported initiatives will be considered.
Accreditation	ACCME, AANP, ANCC, AAPA and others as appropriate to the target audience Royal College of Physicians and Surgeons of Canada (CPD credit)
Geographic Coverage	United States, Canada
Deadline for Submission	May 1, 2024, by 5 PM EST

Background

Psoriatic arthritis (PsA) is a chronic, immune-mediated disease that impacts the joints and skin, affecting both men and women equally, with an estimated prevalence of 133 per 100,000 individuals worldwide.[1,2,3] The estimated US prevalence ranges from 0.06% to 0.25%.[4] It affects approximately 20% of patients diagnosed with psoriasis (PsO), increasing to about 25% for patients with moderate-to-severe PsO.[5,6] PsA is often misdiagnosed or underdiagnosed and the estimated prevalence is likely higher than reported.[7] The clinical manifestations of PsA are characterized by a high degree of heterogeneity and involve multiple organ systems including peripheral joints, axial skeleton, skin, enthesis, and dactylitis.[8,9] In addition, PsA is associated with comorbidities such as osteoporosis, uveitis, subclinical bowel inflammation, and cardiovascular disease.[8] A recent study found that PsA manifestations were independently associated with worse general and PsA specific quality of life, physical function, and work disability.[10] Given the various phenotypes, clinical manifestations, and comorbidities, it is important that PsA patients are managed and treated with a multidisciplinary team.[11] Early recognition, diagnosis, and treatment of PsA is critical to relieve pain and inflammation and help prevent permanent joint damage.[8]

The pathogenesis of PsA involves genetic, immunologic, and environmental factors that trigger an immune response leading to the production of a cytokine cascade.[8,12] The interleukin (IL)-23-IL-17 signaling pathway has been identified as one pathway in the pathogenesis of PsA.[12,13] Tyrosine kinase 2 (TYK2) is an intracellular kinase that is a member of the Janus kinase (JAK) family that is responsible for mediating signals by cytokines such as IL-12, IL-23, and interferons.[12-15] IL-23 is involved in the activation and proliferation of type 17 helper (Th17) cells linked to sustained inflammatory responses in the skin and joints.[14]

The goals of therapy are to achieve minimal disease activity, improve quality of life, prevent structural damage, and avoid or minimize complications.[7] Currently, there are multiple classes of treatments for patients with PsA and new mechanisms are in development.[8] The current treatment landscape includes non-biological and biological agents, however, additional therapies are necessary.[12,14,16,17] A study of 873 patients with PsA from North America and Europe found that despite treatment, about 91% of patients still

experienced musculoskeletal pain and about 60% still experienced skin and nail symptoms. Greater than 66% of patients from the same study wished they had more medication choices and >84% wanted to change something about their medication.[18] A Multinational Assessment of Psoriasis and Psoriatic Arthritis (MAPP) survey of 712 patients who self-reported having PsA found that 24.3% discontinued conventional oral medications and 22.3% reported that lack of effectiveness was the reason for discontinuation.[19] This suggests that new treatment options and approaches to PsA management are necessary.[18,19] Moreover, during an episode of HCPLive discussing the management of PsA, Dr. John Tesser emphasized the need for a wider range of therapies. He highlighted that while approximately 70% of patients may experience a 20% improvement, less than 50% achieve a 50% improvement. This underscores the necessity for novel and diverse treatment options to effectively address the disease.[20]

Educating rheumatologists, dermatologists, and advanced practice providers on the pathophysiology of PsA, the significant unmet need for this patient population, comorbidities, as well as the corresponding mechanisms of action, efficacy, and safety of current and emerging therapies will help develop competence in managing PsA and reducing the associated morbidity. Providing comprehensive education to clinicians regarding the treatment of patients with PsA, while considering their comorbidities, will enable them to make informed decisions when selecting the most appropriate treatment approach. Ensuring clinicians are updated on key and emerging data via expert viewpoints will play a vital role in achieving these outcomes.

Educational Needs and Professional Practice Gaps:

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:

- Review the pathophysiology of PsA, including key inflammatory cytokines, and unmet medical needs in the management of PsA (eg, significant under-treatment and its impact, comorbidities, need for more effective and well-tolerated treatment)
- Summarize the new mechanisms and ongoing clinical trial data for current and emerging treatments for patients with PsA
- Describe the TYK2 vs JAK1, JAK2, and JAK3 signaling pathways, and the efficacy, safety, and selectivity profiles of treatment targeting these pathways
- Identify patients who would be appropriate candidates for treatment, while taking patient preference, comorbidities, efficacy, and safety into account

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.

References

1. American College of Rheumatology. “Psoriatic Arthritis.” https://rheumatology.org/patients/psoriatic-arthritis. Accessed March 15, 2024.
2. National Psoriasis Foundation. "About Psoriatic Arthritis." https://www.psoriasis.org/about-psoriatic-arthritis. Accessed March 15, 2024.

3. Scotti L, Franchi M, Marchesoni A, Corrao G. Prevalence and incidence of psoriatic arthritis: A systematic review and meta-analysis. *Semin Arthritis Rheum*. 2018;48 (1):28-34. doi: 10.1016/j.semarthrit.2018.01.003
4. Ogdie A and Weiss P. The epidemiology of psoriatic arthritis. *Rheum Dis Clin North Am*. 2015;41(4):545-568. doi: 10.1016/j.rdc.2015.07.001
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6. Alinaghi F, Calov M, Kristensen LE, et al. Prevalence of psoriatic arthritis in patients with psoriasis: A systematic review and meta-analysis of observational and clinical studies. *J Am Acad Dermatol*. 2019;80:251–265.e19. doi: 10.1016/j.jaad.2018.06.027
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8. Ocampo D V, Gladman D. Psoriatic arthritis. *F1000Res*. 2019;8:F1000 Faculty Rev-1665. doi:10.12688/f1000research.19144.1
9. Azuaga AB, Ramirez J, and Canete JD. Psoriatic Arthritis: Pathogenesis and Targeted Therapies. *Int J Mol Sci*. 2023;24,4901. doi:10.3390/ijms24054901
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11. Jadon DR and Helliwell PS. The role of the multidisciplinary team in the management of psoriatic arthritis. *Musculoskeletal Care*. 2022;20(S1):S32-S40. doi: 10.1002/msc.1690
12. Martins A, Le AM, Torres T. Deucravacitinib for the treatment of psoriatic arthritis: the evidence so far. *Drugs Context*. 2023;12(2023):2-7. doi: 10.7573/dic.2023-2-7
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19. Kavanaugh A et al. Psoriatic Arthritis and Burden of Disease: Patient Perspectives from the Population-Based Multinational Assessment of Psoriasis and Psoriatic Arthritis (MAPP) Survey. *Rheumatol Ther*. 2016;3:91-102. doi: 0.1007/s40744-016-0029-z
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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 through triangulation.

- **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 as a result of attending. The objectives must be clearly defined, measurable, 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 are required. Levels 5 and 6 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 (MEP) 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