

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

Date	April 29, 2024
RFE Requestor Information	Name: Sylvia Nashed, PharmD, RPh Title: Director, Medical Education E-mail: Sylvia.Nashed@bms.com
RFE Code	RFE-24-IM-103
Therapeutic Area	Immunology (IM)
Area of Interest	Psoriasis It is our intent to support a comprehensive, innovative, and engaging initiative that educates on the pathophysiology of psoriasis, the recent clinical trial data for current and emerging small molecule treatment for patients with moderate to severe psoriasis, and enhances learners' competence in identifying appropriate patients who may benefit from such treatment.
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 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: <ul style="list-style-type: none"> • 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

	<ul style="list-style-type: none"> 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 Dermatologists, NPs and PAs who practice in the 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	June 4, 2024 by 5 PM EST

Background

Psoriasis, an immune-mediated disease, is estimated to affect ≥ 100 million people worldwide, according to the World Health Organization.¹ Psoriasis is associated with many comorbidities, including cardiovascular disease, obesity, diabetes, Crohn’s disease, ulcerative colitis, and malignancies.²⁻⁹ Additionally, 45-56% of people living with psoriasis have scalp psoriasis which can extend beyond the scalp and affect the forehead, back of the neck, and skin around the ears.¹⁰ The disfiguring hallmark psoriatic skin lesions can lead to significant psychological distress, while concomitant pain can cause functional disability and reduced quality of life.^{11,12} Despite the availability of effective systemic therapy, many patients with moderate to severe psoriasis remain undertreated or even untreated.¹³ In fact, a review of health claims data from 2007 to 2012 showed that the majority of patients diagnosed with moderate to severe psoriasis (n=1,700,266) were either untreated (not treated during the 5 years studied, 32%) or under-treated (discontinued therapy during the 5 years studied, 47%).¹⁴ A survey conducted by the National Psoriasis Foundation (NPF, n=4,862) from 2003 to 2011 revealed that >50% of psoriasis patients were dissatisfied with their treatments.¹⁵ Patients’ dissatisfaction with current treatment alludes to the need for more effective and well-tolerated therapies.¹⁶ Current standards of care include a wide range of immunosuppressive agents, however more targeted therapies are being studied to provide durable efficacy and mitigate toxicity profiles.¹⁷

Psoriasis is a chronic, inflammatory disorder characterized by cytokine-mediated keratinocyte hyperproliferation.¹⁷ Pro-inflammatory cytokines such as interleukin-23 (IL-23), interleukin-17 (IL-17), interleukin-19 (IL-19) and tumor necrosis factor alpha (TNF- α) are overexpressed in psoriasis and targeting them has been a major therapeutic approach.¹⁸⁻¹⁹ Cytokine signaling is predominately generated through the Janus kinase/signal transducers and activators of transcription (JAK/STAT) pathway. The JAK enzyme family includes 4 members: JAK1, JAK2, JAK3, and TYK2.²⁰ It is important for clinicians to understand that there are distinct differences between these members, despite being part of the same JAK family.

There are a number of targeted small molecule therapeutic options emerging, with a few recently approved in the treatment armamentarium for patients with moderate to severe psoriasis.^{21,22} As such, it is important for dermatologists and advanced practice providers (NPs and PAs working in the dermatologic space) to be aware of these current and emerging therapies, understand their mechanism of action, selectivity, and differences in their efficacy and safety profiles based on their mechanistic profiles. It will also be important for them to be able to select an optimal therapeutic option for individual patients with various considerations in mind, such as disease severity, disease subtypes, patient's quality of life, preferences for treatment, treatment goals, and comorbidities.

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 practice gaps:

- Review the unmet medical needs in the management of moderate to severe psoriasis (eg, significant under-treatment and its impact, comorbidities, need for more effective and well-tolerated treatment)
- Describe the TYK2 vs JAK1, JAK2, and JAK3 signaling pathways, and differentiate the efficacy, safety, and selectivity profiles of treatment targeting these pathways
- Summarize the recent and ongoing clinical trial data for current and emerging small molecule treatment for patients with moderate to severe psoriasis
- Identify patients who would be appropriate candidates for small molecule treatment and develop an individualized treatment plan, while taking patient preference, efficacy, and safety into account

BMS is seeking grant applications for development and implementation of a well-designed, innovative, interactive, and educational program that addresses the above educational needs and professional practice gaps. Based on a series of systematic reviews conducted by Dr. Cervero to assess the impact of CME, activities that are more interactive, apply multiple methods and multiple exposures, and are focused on outcomes that are considered important by physicians, lead to more positive outcomes.²³ Proposals that incorporate such findings into the design and development of the educational activity will be given higher priority.

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 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>

References:

1. Deitelzweig SB, Johnson BH, Lin J, et al. Prevalence of clinical venous thromboembolism in the USA: current trends and future projections. *Am J Hematol*. 2011;86:217-220.
2. Kimball AB, Szapary P, Mrowietz U, et al. Underdiagnosis and undertreatment of cardiovascular risk factors in patients with moderate to severe psoriasis. *Journal of the American Academy of Dermatology*. 2012;67(1):76-85.
3. Neimann AL, Shin DB, Wang X, et al. Prevalence of cardiovascular risk factors in patients with psoriasis. *J Am Acad Dermatol*. 2006;55:829-835.
4. Yeung H, Takeshita J, Mehta NN, et al. Psoriasis severity and the prevalence of major medical comorbidity: a population-based study. *JAMA Dermatol*. 2013;149:1173-1179.
5. Egeberg A, Mallbris L, Warren RB, et al. Association between psoriasis and inflammatory bowel disease: a Danish nationwide cohort study. *Br J Dermatol*. 2016;175:487-492.
6. Fu Y, Lee CH, Chi CC. Association of psoriasis with inflammatory bowel disease: a dsystematic review and meta-analysis. *JAMA Dermatol*. 2018;154(12):1417.
7. Vaengebjerg S, Skov L, Egeberg A, Loft ND. Prevalence, incidence, and risk of cancer in patients with psoriasis and psoriatic arthritis: a systematic review and meta-analysis. *JAMA Dermatol*. 2020;156(4):421.
8. Chiesa Fuxench ZC, Shin DB, Ogdie Beatty A, Gelfand JM. The risk of cancer in patients with psoriasis: a population-based cohort study in the health improvement network. *JAMA Dermatol*. 2016;152(3):282.
9. Kimball AB, Gladman D, Gelfand JM, et al. National Psoriasis Foundation clinical consensus on psoriasis comorbidities and recommendations for screening. *J Am Acad Dermatol*. 2008;58:1031-1042.
10. National Psoriasis Foundation. "Scalp Psoriasis." <https://www.psoriasis.org/scalp/>. Accessed April 10, 2024.
11. Armstrong AW, Schupp C, Wu J, et al. Quality of life and work productivity impairment among psoriasis patients: Findings from the National Psoriasis Foundation Survey Data 2003-2011. *PLOS One*. 2012;7:e52935. Doi:10.1371/journal.pone.0052935.
12. Hrehorów E, Salomon J, Matusiak L, et al. Patients with psoriasis feel stigmatized. *Acta Derm Venereol*. 2012;92:67-72.
13. Lebwohl M, Langley RG, Paul C, et al. Evolution of patient perceptions of psoriatic disease: results from the Understanding Psoriatic Disease Leveraging Insights for Treatment (UPLIFT) survey. *Dermatol Ther (Heidelb)*. 2022;12:61-78.
14. Armstrong AW, Koning JW, Rowse S, et al. Under-Treatment of patients with moderate to severe psoriasis in the United States: Analysis of medication usage with Health Plan Data. *Dermatol Ther (Heidelb)*. 2017;7:97-109.

15. Armstrong AW, Robertson AD, Wu J, et al. Undertreatment, treatment trends, and treatment dissatisfaction among patients with psoriasis and psoriatic arthritis in the United States. *JAMA Dermatol.* 2013;149(10):1180-1185.
16. Menter A, Gottlieb A, Feldmen SR, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. *J Am Acad Dermatol.* 2008;58:826-50.
17. Ortiz-Lopez LI, Choudhary V, Bollag WB. Updated perspectives on keratinocytes and psoriasis: keratinocytes are more than innocent bystanders. *PTT.* 2022;Volume 12:73-87.
18. Chan TC, Hawkes JE, Krueger JG. Interleukin 23 in the skin: role in psoriasis pathogenesis and selective interleukin 23 blockade as treatment. *Ther Adv Chronic Dis.* 2018;9(5):111-9.
19. Bugaut H, Aractingi S. Major role of the il17/23 axis in psoriasis supports the development of new targeted therapies. *Front Immunol.* 2021;12:621956.
20. Howell MD, Kuo FI, Smith PA. Targeting the janus kinase family in autoimmune skin diseases. *Front Immunol.* 2019;10:2342.
21. Chen WJ, Peng C, Lu JJ, Ding YF, Li XZ. Advances in small molecule inhibitors for treatment of psoriasis. *Chinese Medical Journal.* 2021;134(11):1364-1366.
22. Carmona-Rocha E, Rusinol, L, and Puig, L. New and emerging oral/topical small-molecule treatments for psoriasis. *Pharmaceutics.* 2024;16(239).
23. Cervero RM, Gaines JK. The impact of CME on physician performance and patient health outcomes: An updated synthesis of systematic reviews. *Journal of Continuing Education in the Health Professions.* 2015;35(2):131-138.