

# Defining “flares” in atopic dermatitis: A narrative review

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**Author list:** Joseph F. Merola<sup>1\*</sup>, Stephan Weidinger<sup>2</sup>, Sally Y. Tan<sup>3</sup>, Kassim Rahawi<sup>4</sup>, Cori Gray<sup>4</sup>

**\*Corresponding author**

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| <b>Name</b>      | Joseph Merola                                                                                               |
| <b>Address</b>   | Department of Dermatology, UT Southwestern Medical Center<br>5323 Harry Hines Boulevard, Dallas, Texas, USA |
| <b>Email</b>     | joseph.merola@UTSouthwestern.edu                                                                            |
| <b>Phone/Fax</b> | TX 753909069                                                                                                |

## SUPPLEMENTARY MATERIAL

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**Supplementary Table 1. Research questions and search strings aligned to the PICO framework**

| PICO framework           | Question                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
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| Population               | <ul style="list-style-type: none"> <li>• <b>Worsening in what disease aspects (symptoms, comorbidities, and/or quality of life) constitutes a flare?</b> <ul style="list-style-type: none"> <li>○ (atopic dermatitis OR AD OR eczema) AND (flare OR exacerbation OR relapse OR worsening) AND (signs OR symptoms OR skin OR itch OR area OR coverage OR scaly OR rash OR IGA OR EASI OR impacts OR functioning OR consequences)</li> <li>○ (atopic dermatitis OR AD OR eczema) AND (flare OR exacerbation OR relapse OR worsening) AND (sleep OR depression OR anxiety OR mental health)</li> <li>○ (atopic dermatitis OR AD OR eczema) AND (flare OR exacerbation OR relapse OR worsening) AND (HRQoL OR QoL OR productivity OR lifestyle)</li> </ul> </li> <li>• <b>What degree of worsening constitutes a flare?</b> <ul style="list-style-type: none"> <li>○ (atopic dermatitis OR AD OR eczema) AND (flare OR exacerbation OR relapse OR worsening) AND (disease worsening OR low disease activity OR increased disease activity)</li> </ul> </li> <li>• <b>Is flare defined by or associated with the physical manifestation(s) of worsening symptoms or the signs precipitating onset (e.g., itching/scratching)?</b> <ul style="list-style-type: none"> <li>○ (atopic dermatitis OR AD OR eczema) AND (flare OR exacerbation OR relapse OR worsening) AND (itch OR pain OR scratch OR burn OR itch-scratch-burn OR pruritus OR NRS OR dryness OR redness OR erythema OR stinging OR flaking)</li> </ul> </li> <li>• <b>Is flare defined or described differently in the moderate-severe population versus the overall population?</b> <ul style="list-style-type: none"> <li>○ (atopic dermatitis OR AD OR eczema) AND (moderate-severe) AND (flare OR exacerbation OR relapse OR worsening)</li> </ul> </li> <li>• <b>Is flare defined or described differently by older versus younger patients, males versus females, and/or across geographies or ethnic-racial backgrounds?</b> <ul style="list-style-type: none"> <li>○ (atopic dermatitis OR AD OR eczema) AND (age OR older OR elderly OR younger OR children OR childhood OR pediatric OR adolescent OR adult OR geriatric) AND (flare OR exacerbation OR relapse OR worsening)</li> <li>○ (atopic dermatitis OR AD OR eczema) AND (male OR female OR gender OR sex) AND (flare OR exacerbation OR relapse OR worsening)</li> <li>○ (atopic dermatitis OR AD OR eczema) AND (global OR multinational OR region OR country OR race OR ethnicity) AND (flare OR exacerbation OR relapse OR worsening)</li> </ul> </li> <li>• <b>Is flare defined differently by patients/caregivers versus healthcare professionals versus payors?</b> <ul style="list-style-type: none"> <li>○ (atopic dermatitis OR AD OR eczema) AND (flare OR exacerbation OR relapse OR worsening) AND (patient OR caregiver OR parents)</li> <li>○ (atopic dermatitis OR AD OR eczema) AND (flare OR exacerbation OR relapse OR worsening) AND (healthcare professional OR HCP OR dermatologist OR physician)</li> <li>○ (atopic dermatitis OR AD OR eczema) AND (flare OR exacerbation OR relapse OR worsening) AND (patient OR caregiver versus healthcare professional OR dermatologist OR physician OR HCP perspectives versus payor OR NICE OR HTA OR health technology assessor/assessment)</li> </ul> </li> <li>• <b>What is the typical duration of flare?</b> <ul style="list-style-type: none"> <li>○ (atopic dermatitis OR AD OR eczema) AND (flare OR exacerbation OR relapse OR worsening) AND (duration OR length OR time OR extent OR interval OR period)</li> </ul> </li> <li>• <b>How is the end of flare defined?</b> <ul style="list-style-type: none"> <li>○ (atopic dermatitis OR AD OR eczema) AND (flare OR exacerbation OR relapse OR worsening) AND (end OR stability OR baseline OR normal OR low disease activity OR return OR resolution OR resolve)</li> </ul> </li> <li>• <b>How much variation is there in the definition of flare between individual patients?</b> <ul style="list-style-type: none"> <li>○ (atopic dermatitis OR AD OR eczema) AND (flare OR exacerbation OR relapse OR worsening) AND (patient) AND (definition) AND (variation OR variability)</li> </ul> </li> </ul> |
| Intervention or exposure | <ul style="list-style-type: none"> <li>• <b>Does use of or response to treatments define flare (e.g., becoming refractory, needing escalation, received rescue treatment or hospitalization)?</b> <ul style="list-style-type: none"> <li>○ (atopic dermatitis OR AD OR eczema) AND (treatment OR treatment response OR escalation OR refractory OR rescue OR hospitalization) AND (flare OR exacerbation OR relapse OR worsening)</li> </ul> </li> <li>• <b>Does the definition of flare incorporate the use of topical anti-inflammatory medicines? If so, is flare defined by the use of these medicines for a set number of days and/or a threshold for total use?</b> <ul style="list-style-type: none"> <li>○ (atopic dermatitis OR AD OR eczema) AND (flare OR exacerbation OR relapse OR worsening) AND (topical anti-inflammatory) OR (topical corticosteroid OR TCS)</li> </ul> </li> <li>• <b>What is the difference between flare and sustained worsening of disease?</b> <ul style="list-style-type: none"> <li>○ (atopic dermatitis OR AD OR eczema) AND (disease relapse) AND (flare OR exacerbation OR relapse OR worsening)</li> <li>○ (atopic dermatitis OR AD OR eczema) AND (disease worsening) AND (flare OR exacerbation OR relapse OR worsening)</li> <li>○ (atopic dermatitis OR AD OR eczema) AND (disease progression) AND (flare OR exacerbation OR relapse OR worsening)</li> <li>○ (atopic dermatitis OR AD OR eczema) AND (disease relapse OR disease worsening OR disease progression) AND (flare OR exacerbation OR relapse OR worsening)</li> <li>○ (atopic dermatitis OR AD OR eczema) AND (difference between flare and disease relapse OR disease worsening OR disease progression OR increased disease activity)</li> </ul> </li> <li>• <b>How is flare defined in other dermatology conditions (e.g., psoriasis, chronic spontaneous urticaria)?</b> <ul style="list-style-type: none"> <li>○ (flare OR exacerbation OR relapse OR worsening) AND (psoriasis OR chronic spontaneous urticaria OR CSU OR hidradenitis suppurativa OR cutaneous lupus OR prurigo nodularis)</li> </ul> </li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| Comparator and outcome   | <ul style="list-style-type: none"> <li>• <b>Is flare defined by or associated with changes in healthcare resource use (e.g., hospitalization for skin infections, primary care visits, prescriptions)?</b> <ul style="list-style-type: none"> <li>○ (atopic dermatitis OR AD OR eczema) AND (flare OR exacerbation OR relapse OR worsening) AND (healthcare resource OR hospitalization OR primary care visit OR prescription OR outpatient visit OR inpatient visit OR dermatologist)</li> </ul> </li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |

AD, atopic dermatitis; CSU, chronic spontaneous urticaria; EASI, Eczema Area and Severity Index; IGA, Investigator Global Assessment; HCP, healthcare professional; HRQoL, health-related quality of life; HTA, health technology assessment; NICE, National Institute for Health and Care Excellence; PICO, Population, Intervention, Comparison, and Outcome; QoL, quality of life; TCS, topical corticosteroids.

## **Supplementary information: How is flare defined in other inflammatory dermatological conditions?**

Disease flares are a dominant aspect of the course of other inflammatory dermatological conditions, such as hidradenitis suppurativa (HS), psoriasis (PsO), and cutaneous lupus erythematosus (CLE)/systemic lupus erythematosus (SLE). However, similar challenges around consensus of a flare definition exist in these therapy areas [1–3].

### **Flare in hidradenitis suppurativa**

Similarly to atopic dermatitis (AD), while more than 80% of patients with HS experience flare at least monthly, consistent definitions are lacking in the literature [4, 5].

Across an HS randomized controlled trial (RCT), a retrospective study, and an international consensus working group, three different definitions of flare have been used [1, 5, 6]. All three definitions were broadly based on worsening of the disease symptoms, and none included the patient perspective [1, 5, 6].

The international consensus on a definition of flare in HS raised concerns over the following definition used in clinical trials: “ $\geq 25\%$  increase in the abscess and/or nodule count with a minimum increase of two relative to baseline”; this was due to the lack of validation, insensitivity to certain flares, and poor to moderate interrater reliability [5]. Instead, the definition of HS flare as “new or substantial worsening of clinical signs or symptoms” was proposed, although this remains to be validated [5].

### **Flare in psoriasis**

The criteria for defining flare in PsO are similarly heterogeneous, with the terms “relapse” and “flare” often being used interchangeably (Supplementary Table 2)

This literature search identified seven studies investigating several forms of PsO, the majority of which used a definition of flare based on loss of disease improvement from baseline or worsening of existing disease based on objective scales [2, 7–10, 13]. The only patient-centric definition was based on patient-reported worsening of disease symptoms (Supplementary Table 2)

An RCT in 2023 assessed the safety and efficacy of spesolimab in controlling disease flares in patients with generalized pustular PsO [10,11]. The trial inclusion criteria employed a composite definition of flare, a Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) score of  $\geq 3$ , new appearance or worsening of existing pustules, a GPPGA pustulation subscore of  $\geq 2$ ,  $\geq 5\%$  of body surface covered with erythema, and the presence of pustules [10,11].

### **Flare in cutaneous lupus erythematosus/systemic lupus erythematosus**

Understanding of the role of flare in the progression of CLE to SLE has been limited by a lack of consensus around a definition of flare in CLE [3, 12].

A retrospective cohort study of 69 patients with CLE between December 2008 and December 2019, sought to identify risk factors for developing SLE [3]. The authors believed that CLE flares and worsening of disease may be an indicator of progression to SLE. Worsening of disease activity was defined as an average change in Cutaneous Lupus Erythematosus Disease Area and Severity Index (CLASI) scores of  $\geq 3$  between patient visits to healthcare professionals, compared with baseline. However, while they suspected CLE flares may be an indicator of progression to SLE, the lack of a consistent definition of flare restricted this element from being assessed.

In 2022, Keyes et al. highlighted that while a quantitative definition of flare exists and is used in SLE clinical research, flare in CLE has not been similarly defined [12]. The authors conducted a retrospective review of 25 patients across 118 visits, where patient skin health and quality of life were scored. The authors subsequently defined flare in CLE as a CLASI-A increase of 7 or more, which was equivalent to a Physician Global Assessment (PGA) activity score decrease of  $\geq 2$ . On this scale, a PGA change of 1 indicated a worsening of disease but this was found to be too sensitive to delineate flare, and noted that a change of  $\geq 3$ , being rarely encountered, would exclude many flares. The authors hoped that this definition of flare could be used as an endpoint in clinical trials to indicate the need for medication change or to chart disease progression.

Taken together, there is a lack of consensus around the definition of flare in inflammatory dermatological conditions, beyond AD. While there are signs that definitions in PsO are becoming more stringent, and a consensus definition has been proposed in HS, there is still a lack of validation and acceptance within the clinical trial community. There is also a lack of a patient-centric element to these definitions. The heterogenous nature of these diseases suggests the need for a broad definition of flare, which may be of limited value across multiple patient subsets and clinical trials.

**Supplementary Table 2.** Studies referencing flare in other inflammatory dermatological conditions, identified by systematic literature search using PICO framework

| Disease                        | Authors              | Publication year | Flare or relapse   | Definition type   | Study type                                       | Drug evaluated | Definition                                                                                                                                                                     | Objective or subjective measure | Patient perspective (measures)     | Patients                                                                  |
|--------------------------------|----------------------|------------------|--------------------|-------------------|--------------------------------------------------|----------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|------------------------------------|---------------------------------------------------------------------------|
| Hidradenitis suppurativa       | LeWitt et al[5]      | 2022             | Flare              | Symptoms          | International consensus                          | N/A            | New or substantial worsening of clinical signs or symptoms                                                                                                                     | Subjective                      | No                                 | HISTORIC group, including physicians, industry reps, and patients with HS |
| Hidradenitis suppurativa       | Van der Zee et al[6] | 2020             | Flare              | Arbitrary cut-off | Phase 3 RCT                                      | Adalimumab     | ≥25% increase in the total abscess and/or nodule count with a minimum increase of 2 abscesses or nodules relative to baseline                                                  | Objective                       | No                                 | Adults with HS                                                            |
| Hidradenitis suppurativa       | Garg et al[4]        | 2020             | Flare              | Patient-reported  | Prospective patient survey                       | N/A            | Not defined                                                                                                                                                                    | Subjective                      | N/A                                | Adults with HS                                                            |
| Hidradenitis suppurativa       | Iannone et al[1]     | 2022             | Flare              | Symptoms          | Retrospective, non-interventional                | N/A            | An acute development of at least one inflammatory lesion or the recurrence of a previous lesion                                                                                | Objective                       | No                                 | Adults with HS with and without psychiatric comorbidities                 |
| Severe psoriasis               | Khemis et al[8]      | 2018             | Relapse            | Arbitrary cut-off | Retrospective study                              | Secukinumab    | 50% loss of the maximum PASI improvement from baseline                                                                                                                         | Objective                       | No                                 | Adults with severe psoriasis                                              |
| Plaque psoriasis               | Cantrell et al[9]    | 2021             | Relapse            | Arbitrary cut-off | RCT                                              | Tildrakizumab  | 50% loss of the maximum PASI benefit from baseline                                                                                                                             | Objective                       | No                                 | Adults with moderate-to-severe plaque psoriasis                           |
| Psoriasis                      | Egeberg et al[7]     | 2019             | Flare              | Patient-reported  | Non-interventional prospective study             | N/A            | One or more consecutive days with significant worsening of symptoms requiring escalation of treatment or seeking additional medical advice                                     | Subjective                      | Patient-reported disease worsening | Adults                                                                    |
| Chronic plaque psoriasis       | Bellinato et al[2]   | 2022             | Flare              | Arbitrary cut-off | Real-world non-interventional                    | N/A            | 50%-100% increase in PASI                                                                                                                                                      | Objective                       | No                                 | Adults                                                                    |
| Generalized pustular psoriasis | Choon et al[10]      | 2021             | Flare              | Composite         | RCT protocol                                     | Spesolimab     | GPPGA score of ≥3, new appearance or worsening of existing pustules, a GGPA pustulation subscore of ≥2, ≥5% of body surface covered with erythema and the presence of pustules | Objective                       | No                                 | Adults experiencing an acute GPP flare of moderate-to-severe intensity    |
| Generalized pustular psoriasis | Morita et al[11]     | 2023             | Flare              | Arbitrary cut-off | RCT                                              | Spesolimab     | GPPGA pustulation/ total score ≥2)                                                                                                                                             | Objective                       | No                                 | Adults experiencing an acute GPP flare of moderate-to-severe intensity    |
| Psoriasis                      | Kresch et al[13]     | 2023             | Flare/exacerbation | Composite         | Retrospective cohort study                       | N/A            | ≥10% increase in body surface area, a change in psoriasis type from plaque to pustular or erythrodermic, or worsening of PsA                                                   | Objective                       | No                                 | Adults with psoriasis                                                     |
| Cutaneous lupus erythematosus  | Walocko et al[3]     | 2021             | Flare/worsening    | Arbitrary cut-off | Retrospective cohort study                       | N/A            | Average change of ≥3 CLASI scores between patient visits to HCP, compared to baseline                                                                                          | Objective                       | No                                 | Adults with CLE                                                           |
| Cutaneous lupus erythematosus  | Keyes et al[12]      | 2022             | Flare/worsening    | Arbitrary cut-off | Retrospective review of prospective CLE database | N/A            | PGA activity score decrease of ≥2, CLASI-A increase of 7 points                                                                                                                | Objective                       | No                                 | Patients with CLE                                                         |

CLASI, Cutaneous Lupus Erythematosus Disease Area and Severity Index; CLASI-A, CLASI activity; CLE, cutaneous lupus erythematosus; GPP, generalized pustular psoriasis; GGPA, GGP Assessment; GPPGA, GPP Physician Global Assessment; HCP, healthcare professional; HISTORIC, Hidradenitis Suppurativa Core Outcomes Set International Collaboration; HS, hidradenitis suppurativa; N/A, not applicable; PASI, Psoriasis Area and Severity Index; PGA, Physician Global Assessment; PsA, Psoriatic arthritis; PICO, Population, Intervention, Comparison, and Outcome; QoL, quality of life; RCT, randomized controlled trial.

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