

National Psoriasis Foundation COVID-19 Task Force guidance for management of psoriatic disease during the pandemic: Version 2-Advances in psoriatic disease management, COVID-19 vaccines, and COVID-19 treatments.

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Philadelphia, Pennsylvania o Dermatology Associates, Maui, Hawaii p Brigham and Women's Hospital, Harvard Medical School, Boston, Massachusetts q Department of Medicine, Division of Rheumatology, New York University Grossman School of Medicine and New York University Langone Orthopedic Hospital, New York, New York r Department of Rheumatology, Hospital for Special Surgery, New York, New York s Department of Pediatric Dermatology, Children's Hospital of Philadelphia, Philadelphia, Pennsylvania t Department of Dermatology, Eastern Virginia Medical School, Norfolk, Virginia u Division of Allergy, Immunology, and Rheumatology Division, University of Rochester Medical Center, Rochester, New York * Correspondence to: Joel M. Gelfand, MD, MSCE, Department of Dermatology, 3400 Civic Center Blvd, Perelman Center for Advanced Medicine, Philadelphia, PA 19104. 5 2021 7 1 2021 84 5 372293 1254 1268 29 12 2020 07 01 2021 07 01 2021 30 08 2023 © 2021 by the American Academy of Dermatology, Inc. 2021 American Academy of Dermatology, Inc. Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website. Elsevier hereby grants permission to make all its COVID-19-related research that is available on the COVID-19 resource centre - including this research content - immediately available in PubMed Central and other publicly funded repositories, such as the WHO COVID database with rights for unrestricted research re-use and analyses in any form or by any means with acknowledgement of the original source. These permissions are granted for free by Elsevier for as long as the COVID-19 resource centre remains active. Objective To update guidance regarding the management of psoriatic disease during the COVID-19 pandemic.

The task force (TF) includes 18 physician voting members with expertise in dermatology, rheumatology, epidemiology, infectious diseases, and critical care. The TF was supplemented by nonvoting members, which included fellows and National Psoriasis Foundation staff. Clinical questions relevant to the psoriatic disease community were informed by inquiries received by the National Psoriasis Foundation. A Delphi process was conducted.

The TF updated evidence for the original 22 statements and added 5 new recommendations. The average of the votes was within the category of agreement for all statements, 13 with high consensus and 14 with moderate consensus.

The evidence behind many guidance statements is variable in quality and/or quantity.

These statements provide guidance for the treatment of patients with psoriatic disease on topics including how the disease and its treatments affect COVID-19 risk, how medical care can be optimized during the pandemic, what patients should do to lower their risk of getting infected with severe acute respiratory syndrome coronavirus 2 (including novel vaccination), and what they should do if they develop COVID-19. The guidance is a living document that is continuously updated by the TF as data emerge.

severe acute respiratory syndrome coronavirus 2

Capsule Summary • The National Psoriasis Foundation COVID-19 Task Force produced 27 guidance statements to promote optimal management of psoriatic disease during the pandemic.

Shared decision making, adherence to evidence-based treatment, and the urgent use of novel COVID-19 vaccination are recommended. The guidance statements will be updated in accordance with the rapidly evolving science of COVID-19.

The COVID-19 pandemic has substantially worsened since the publication of Version 1 of the National Psoriasis Foundation (NPF) COVID-19 Task Force (TF) recommendations on September 4, 2020. 1 In just the ensuing 15 weeks alone, there have been more than an additional 11,100,000 cases and 125,000 COVID-19 deaths in the United States and an additional nearly 50,000,000 cases and more than 800,000 deaths worldwide. 2 Similar to the exponential growth of COVID-19

cases, basic biological and epidemiologic knowledge related to this pandemic have expanded dramatically. In just a few months since our initial recommendations, there have been major advances in the understanding of how to prevent and treat COVID-19 as well as a substantial increase in data to inform management decisions for patients with psoriatic disease during the pandemic. Therefore, this TF is providing updated scientifically based guidance to promote optimal management of psoriatic disease during the pandemic.

The methods have been described in detail previously. ¹ Briefly, the COVID-19 TF includes physicians, fellows, and senior NPF staff with a variety of expertise relevant to decision making in the pandemic. The TF reviews COVID-19 literature weekly in relation to psoriatic disease and meets every 2 to 4 weeks to address 5 core questions related to the pandemic. Existing recommendations were updated based on evolving science and were approved by unanimous consent. New recommendations were generated by using a modified Delphi process based on the RAND appropriateness method, including 2 rounds of voting with discussion in between. ³ (Only 1 round was used for new recommendations that achieved high consensus on the first round.) Panel consensus was determined to be low when 5 or more votes fell into the 1-to-3 rating range with 5 or more votes concurrently falling into the 7-to-9 rating range. Consensus was interpreted as high if all 18 votes fell within a single tertile, with all other combinations considered as moderate levels of consensus. The results were analyzed by the NPF with an independent analysis of the data by a nonvoting member of the TF.

The TF reaffirms the initial 22 guidance statements with updated data and has issued 5 new recommendations (Table I). The median was within the category of agreement for all new statements, with the number of votes outside the range of agreement being only 2 for the 1 new statement for which agreement was not unanimous. All guidance statements were recommended, 13 with high consensus and the 14 with moderate consensus. Table I NPF COVID-19 TF guidance for management of psoriatic disease during the pandemic: Version 2

Bamlanivimab for patients meeting specific criteria and who are at high risk for progressing to severe COVID-19 and/or hospitalization

Casirivimab and imdevimab to be administered together for patients meeting specific criteria and who are at high risk for progressing to severe COVID-19 and/or hospitalization

Dexamethasone (systemic steroids) for patients meeting specific criteria

Remdesivir treatment for patients meeting specific criteria

Baricitinib, in combination with remdesivir, for patients meeting specific criteria

CDC, Centers for Disease Control and Prevention; mRNA, messenger RNA; NPF, National Psoriasis Foundation; SARS-CoV-2, severe acute respiratory syndrome coronavirus 2; TF, Task Force.

Patients with psoriasis are more prone to thrombosis and comorbidities that portend worse COVID-19 outcomes and may be more susceptible to infection, which raised concerns that they could be at increased risk for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection and worse COVID-19 outcomes. ^{4 , 5 , 6 , 7 , 8} Nevertheless, patients with psoriatic disease appear to have similar rates of infection with SARS-CoV-2 and COVID-19 outcomes as the general population, with multiple new studies from Italy, which primarily focused on patients with psoriasis receiving oral or biologic treatment, supporting our initial recommendation (guidance 1.1). ^{9 , 10 , 11} Additional new studies of patients with psoriatic arthritis (PsA) nested within cohorts of patients with rheumatic disease also suggest that they have similar rates of infection with SARS-CoV-2 and COVID-19 outcomes as the general population. ^{12 , 13 , 14} However, the risk of COVID-19 in autoimmune diseases was higher than in control patients (odds ratio [OR], 2.19; 95%

confidence interval [CI], 1.05-4.58) in a meta-analysis of 7 case-control studies. 15

The severity of COVID-19 continues to be primarily driven by risk factors such as current smoking, male sex, older age, and underlying comorbidities (guidance 1.2). 16 , 17 , 18 , 19 New data confirm that age, male sex, and pre-existing comorbidities are also important drivers of poor COVID-19 outcomes in patients with psoriasis. 20

The evolving literature reaffirms the TF conclusion that treatments for psoriasis and/or PsA do not appear to meaningfully alter the risk of acquiring SARS-CoV-2 infection or having worse COVID-19 outcomes; therefore, patients who are not infected with SARS-CoV-2 should continue their biologic or oral therapies for psoriasis and/or PsA in most cases (guidance 2.1 and 2.2). COVID-19 hospitalization was more frequent in patients using nonbiologic systemic therapy than in those using biologics (OR, 2.8; 95% CI, 1.3-6.2) in a registry of 374 patients with psoriasis from 25 countries. 20 A cohort of 6501 patients with psoriasis on biologics at northern Italian centers showed that the standardized incidence ratio of hospitalization and death in patients with psoriasis compared with those in the general population was 0.94 (95% CI, 0.57-1.45) and 0.42 (95% CI, 0.07-1.38), respectively. 11 In a study of 12,807 patients with psoriasis on biologics from 33 Italian dermatology centers, 26 (0.25%) had confirmed SARS-CoV-2 infection (similar to general population in Italy [0.31%]). 21 In a study of patients with psoriasis (100 on topical treatment, 80 on biologics) from a single Italian dermatology center, COVID-19 symptoms were more common, but not statistically significant, in the biologic group (OR, 1.22; 95% CI, 0.58-2.58). 22 A cohort of 2329 patients with psoriasis on systemic therapy in Spain yielded standardized incidence ratios of 1.58 (95% CI, 0.98-2.41), 1.55 (95% CI, 0.67-3.06), and 1.38 (95% CI, 0.03-7.66) for COVID-19 cases, hospitalizations, and deaths, respectively. 23 Finally, a study of a global electronic medical record database that includes information on approximately 53 million people identified no evidence for increased COVID-19 hospitalization for patients prescribed tumor necrosis factor inhibitors (TNFi) (relative risk [RR], 0.73; 95% CI, 0.47-1.14), methotrexate (RR, 0.87; 95% CI, 0.62-1.23), or the combination of TNFi/methotrexate (RR, 0.91; 95% CI, 0.68-1.22) within 1 year of developing COVID-19. 24

Similarly, the use of immunosuppressive/immunomodulating therapy was not associated with an increased risk for COVID-19 in a cohort of 5302 patients with inflammatory bowel disease. 25 This finding was supported by the Surveillance Epidemiology of Coronavirus Under Research Exclusion (SECURE-IBD) registry, which showed no increase in severe outcomes in patients on TNFi or anti-interleukin (IL) 12/23 monotherapy. 26 Patients with rheumatic disease do not appear to be at higher risk of contracting SARS-CoV-2 infection or of developing severe COVID-19 when on anti-TNF therapy. 15 , 27 , 28

Nevertheless, uncertainty remains based on the quality of the existing data and lack of detailed analysis of patients at high risk because of age and/or comorbidity; therefore, shared decision making between the clinician and patient is recommended (guidance 2.2, 2.4, and 2.5). Chronic systemic corticosteroids should be avoided, if possible, for the management of PsA, because additional research confirms that their use is associated with worse COVID-19 outcomes (guidance 2.3). 15 , 29

Telemedicine remains a critical option for treating patients with psoriatic disease during the pandemic for appropriate patients (guidance 3.1 and 3.2). The evolving literature suggests that a short interruption of in-person patient-rheumatologist interactions had no major detrimental impact on the disease course of PsA as assessed by patient-reported outcomes. 30 Nevertheless, reductions in in-person care during the pandemic may be associated with a delay in diagnosis and treatment of malignancies, including melanoma. 31 , 32

Universal masking for staff, clinicians, and patients; restrictions on visitation; and liberal reverse transcription polymerase chain reaction testing of symptomatic and asymptomatic patients are very effective in limiting SARS-CoV-2 spread, with nosocomial transmission exceptionally rare. 33 , 34 Therefore, patients should be informed that in-person medical care, including phototherapy

(guidance 3.3), can be delivered safely with minimal risk of COVID-19 transmission in the clinical setting when safeguards are maintained. 35 , 36 Outbreaks in the clinical setting that have occurred have been due to lack of masking in patient care areas and a lack of distancing among staff while eating unmasked. 33 Thus, the TF updated guidance 3.2, emphasizing that standard operating procedures for social distancing, hand washing, and masking be observed in clinical settings.

Patients should follow recommended measures to prevent infection with SARS-CoV-2 (guidance 4.1, 4.2, and 4.3). 37 In cases where measures to prevent the transmission of SARS-CoV-2 at work or school cannot be maintained, shared decision making is recommended to determine if specific accommodations are medically necessary (guidance 4.2 and 4.3). In the United States, adherence rates with methods to prevent COVID-19 were lowest among adults aged 18 to 29 years (73%) and highest among those aged older than 60 years (86%). 38 An international survey of patients with psoriasis found that rates of COVID-19 prevention measures were slightly higher in those receiving biologics for psoriasis than in those receiving nonbiologic systemic therapies. 20

Since our first recommendations, the major advance in protection from COVID-19 is the advent of highly effective vaccines using messenger RNA (mRNA) technology, which results in temporary expression of the SARS-CoV-2 spike protein in human cells after injection, triggering an immune response (Table II). The regimen of 2 doses, 21 days apart, for BNT162b2 (manufactured by Pfizer and BioNTech) conferred 95% protection against COVID-19, with an excellent safety profile similar to that of other viral vaccines, and was granted Emergency Use Authorization (EUA) on December 11, 2020, by the US Food and Drug Administration (FDA). 39 , 40 Similarly, the regimen of 2 doses, 28 days apart, for mRNA-1273 (manufactured by Moderna) conferred 94.5% protection against COVID-19 (FDA EUA pending). 41 Therefore, the TF recommends that patients with psoriatic disease who do not have contraindications to vaccination should receive an mRNA-based COVID-19 vaccine as soon as it becomes available to them (guidance 4.5). Additional vaccine platforms are undergoing testing (Table II). 42 Table II Vaccine candidates for COVID-19 and available data on vaccination schedule, efficacy, and safety

Most common solicited adverse reactions: injection site reactions (84.1%), fatigue (62.9%), headache (55.1%), muscle pain (38.3%), chills (31.9%), joint pain (23.6%), and fever (14.2%)

Severe adverse reactions occurred in 0.0% to 4.6% of participants, were more frequent after dose 2 than after dose 1, and were generally less frequent in participants ≥ 55 years.

The incidence of serious adverse events was similar in the vaccine and placebo groups (0.6% and 0.5%, respectively).

Four cases of Bell palsy in the vaccine group compared with no cases in the placebo group, consistent with the expected rate

Most common solicited adverse reactions: injection site pain (91.6%), fatigue (68.5%), headache (63.0%), muscle pain (59.6%), joint pain (44.8%), and chills (43.4%).

Severe adverse reactions occurred in 0.2% to 9.7% of participants, were more frequent after dose 2 than after dose 1, and were generally less frequent in participants ≥ 65 years.

Unsolicited adverse events possibly related to vaccine:

Local lymphadenopathy: 1.1% in the vaccine group and 0.63% in the placebo group

Hypersensitivity: 1.5% in the vaccine group vs 1.1% placebo group

Frequency of serious adverse events was similar in vaccine and placebo groups (1.0% for both).

Four cases of Bell palsy in the vaccine group compared with 1 case in the placebo group

Serious adverse events: 79 in treatment and 89 in control group

Adverse events: vaccine (n = 12,021) vs control (n = 11,724)

Anaphylactic reaction: 1 (vaccine) vs 0 (control)

EP, Electroporation; EUA, Emergency Use Authorization; FDA, US Food and Drug Administration; ID, intradermal; IM, intramuscular; mRNA, messenger RNA; rS, recombinant spike; TBD, to be determined.

The effect of psoriasis treatment on the efficacy of COVID-19 vaccines is unknown. Based on a review of the literature, methotrexate treatment with doses commonly used in patients with psoriatic disease lowers the humoral response to seasonal influenza and pneumococcal vaccines, and temporary discontinuation of methotrexate for 2 weeks after influenza immunization improves the immunogenicity of the seasonal influenza vaccine. 43, 44 TNFi and tofacitinib do not significantly affect the humoral immune response to influenza vaccination but have been reported to result in both reduced and sufficient immune responses to the pneumococcal vaccine. 44, 45, 46, 47, 48 Abatacept, 49 ustekinumab, 50 and anti-IL-17 treatment 51, 52, 53 do not interfere with the immune response to either influenza or pneumococcal vaccination, although large prospective studies of vaccine efficacy are lacking. No data were available at the time of analysis for cyclosporine (as used for psoriasis and other inflammatory diseases), anti-IL-23 biologics, apremilast, or acitretin on the efficacy of any approved vaccine.

Extrapolating from this literature and based on current available evidence, the TF recommends that patients who are to receive an mRNA-based COVID-19 vaccine continue their biologic or oral therapies for psoriasis and/or PsA during the vaccination period (guidance 4.6). Many trials of COVID-19 treatment and vaccines have excluded patients with immune-mediated diseases or patients taking immune-modulating therapy. The TF encourages the inclusion of patients with psoriatic disease, including those on systemic treatments, in future studies of COVID-19 vaccines and treatments and recommends that patients participate in such experiments based on shared decision making among the patient, researcher, and provider (guidance 4.7).

Major advances have occurred in the management of SARS-CoV-2 since Version 1 of the TF recommendations. For outpatients meeting specific criteria and at high risk for progressing to severe COVID-19, the use of monoclonal antibodies specifically directed against the spike protein of SARS-CoV-2 are recommended (guidance 5.2). 54, 55, 56, 57, 58 For hospitalized patients meeting specific criteria, in addition to remdesivir and dexamethasone, baricitinib in combination with remdesivir is an option as because reduces recovery time and new infections in hospitalized patients with COVID-19 compared to remdesivir alone. 59 However, baricitinib had no mortality benefit, can be prothrombotic, and is recommended only when corticosteroids cannot be used. 59, 60 Furthermore, the remdesivir efficacy is modest, and international trials did not find mortality benefit. 61, 62

Additional evidence suggests that hydroxychloroquine is not effective for the prevention or treatment of COVID-19; therefore, the TF emphasizes that its use be restricted to clinical trials (guidance 5.4.1). 63, 64, 65, 66, 67 The evidence that convalescent plasma is effective for COVID-19 is limited despite the FDA EUA; therefore, the TF recommends that it be used primarily in clinical trials (guidance 5.4.2). 68, 69 Ivermectin has in vitro activity against SARS-CoV-2; however, doses up to 100 times higher than those approved for use in humans would be required to achieve antiviral effects against COVID-19, raising safety concerns even if therapeutic levels could feasibly be achieved. 70, 71, 72, 73 Therefore, the TF recommends ivermectin be used only in the setting of a clinical trial (guidance 5.4.3).

Based on limited available data and to be consistent with prescribing information, it may be prudent to hold treatments that target the immune system in the setting of suspected or confirmed SARS-CoV-2 infection, but the ultimate decision should be made case by case. Patients with psoriatic disease should be aware that infection with SARS-CoV-2 may result in a flare of psoriasis, including pustular flares (guidance 5.6). 74 , 75 , 76 , 77 , 78 , 79 , 80 , 81

Patients with psoriatic disease who become infected with SARS-CoV-2 should follow Centers for Disease Control and Prevention guidance on home isolation and discuss with their health care providers when they can end home isolation (guidance 5.7; Version 1, Supplemental Table IX available via Mendeley at <https://doi.org/10.17632/w5m8jf94m8.2>). 1 , 82 , 83 , 84 In the event that someone with psoriatic disease has close contact (Version 1, Supplemental Table X) with an individual with suspected or confirmed SARS-CoV-2 infection, he or she should follow local public health authority guidance for the recommended duration of quarantine. 1 The Centers for Disease Control and Prevention recommends a quarantine period of 14 days after last contact with a person who has COVID-19, assuming one remains asymptomatic, but offers an option to shorten quarantine to end after day 10 from last contact or day 7 with appropriately timed diagnostic testing (guidance 5.8). 85 Individuals who have had COVID-19 within the past 3 months do not need to quarantine after close contact with someone who is infected, as long as they do not develop symptoms again. 86 The decision regarding continuing or holding psoriasis treatments during a period of quarantine should be individualized on a case-by-case basis between patient and provider.

Resumption of psoriasis and/or PsA treatments held during SARS-CoV-2 infection should be decided on a case-by-case basis (guidance 5.5). The persistence of 1 or more symptoms of COVID-19, such as fatigue or joint pain, beyond the acute phase of the illness can occur 87 and may complicate the decision to restart psoriasis or PsA medications. Therefore, shared decision making between the patient and provider(s) is recommended (guidance 2.5).

The NPF COVID-19 TF guidance statements serve to promote optimal management of psoriatic disease during the pandemic. Several limitations are acknowledged. First, the TF did not formally grade the strength of our recommendations. 88 With the exception of guidance statements 4.4, 4.5, 5.2, 5.4.1, and 5.4.2, which are based on large-scale randomized controlled trials, the evidence behind many guidance statements is limited in quality or quantity. Large-scale, longer-term, population-based studies of patients with psoriatic disease (particularly those with increased COVID-19 risk due to age and/or comorbidity), with appropriate comparator groups, adjustment for relevant confounding variables, and complete ascertainment of clinically important COVID-19 outcomes are urgently needed. 89 Second, the guidance is intended to be neither proscriptive nor comprehensive. The ultimate judgment regarding how these recommendations should be followed is best left with the treating clinician and the patient in light of the circumstances presented by the individual patient and the variability and biological behavior of the disease and therapeutics.

The recommendations are a living document that will be updated and amended when necessary by the rapidly evolving science of COVID-19. Readers are encouraged to visit <https://www.psoriasis.org/covid-19-resource-center> regularly for the latest guidance from the TF to promote optimal care and outcomes for patients with psoriatic disease during the pandemic.

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