

Friday, March 20, 2020



Message from the CEO

We have all heard a lot about COVID-19 and the actions that are being taken to prevent the transmission and spread of the virus. All of us sympathize with those that have contracted the virus.

I am sure that you will agree, COVID-19 is having a significant impact on the way we live and work, and will continue to do so until we are able to slow the spread, introduce drugs to treat the disease or develop a vaccine to prevent its transmission. As you have read, the virus can be very serious, especially in immunosuppressed or immunocompromised patients. As a result, press releases from major dermatologic organizations have recommended consideration of changes in treatment paradigms when managing chronic skin conditions, such as psoriasis. The appropriate use of biologics is being discussed on a variety of platforms with a consensus that if a patient has an active infection, treatment should be held or stopped. This reconsideration is highlighted in the attached statement from the American Academy of Dermatology, "Guidance on the Use of Biologic Agents During COVID-19 Outbreak", released on March 19th, 2020. During this period of treatment transitions, it is well known that the safety and efficacy of Narrow Band UV-B (NB-UVB) phototherapy is well established for the treatment of mild to moderate psoriasis and other skin conditions.

We believe that the Clarify Medical Home Phototherapy System may be an important treatment option for the management of your patients with mild to moderate psoriasis. The System is used under physician control via prescription. Patients can be remotely treated and managed via our connected smartphone technology. They can administer the proper NB-UVB dosing in the safety and security of their homes. Furthermore, physicians can stay actively involved with their patients as the connected system provides seamless remote interactions by providing important clinical feedback to the treating physician if desired. In short, the Clarify System connects the physician and patient without the need for personal contact.

At Clarify Medical, we are adequately staffed and prepared to implement and support treatment for patients using the System. Our manufacturing and delivery supply chains are unaffected by the situation with COVID-19. Our professional staff stands ready to provide excellent patient support when called.

We have, and will, always put patients first.

A handwritten signature in black ink, appearing to read "George W. Mahaffey". The signature is fluid and cursive, with a prominent flourish at the end.

George W. Mahaffey

CEO, Clarify Medical, Inc.



Guidance on the use of biologic agents during COVID-19 outbreak

Due to the recent pandemic, there is concern about the immunomodulatory effects of biologic therapy in the context of coronavirus (COVID-19). Currently, the Centers for Disease Control and Prevention (CDC) and the World Health Organization (WHO) have no guidelines on the use of biologics during the pandemic. In addition, there is no data on the specific risk of COVID-19 infection with biologic therapy. Specifically, we do not have direct evidence to support any preferred biologic class or mechanism-of-action with regard to COVID-19 infection risk at this moment; although we will continue to monitor the situation as more data becomes available. A main priority for dermatologists, at this point, is to keep our patients out of emergency rooms and urgent care so as to not tax the healthcare system unnecessarily. Dermatologists must delicately balance the risk of immunosuppression with the risk of disease flare requiring urgent intervention. **Therefore, the Academy strongly recommends that patients should not stop biologic therapy without consulting their physicians.** To better serve patients and their physicians, the Academy is putting forth the following interim recommendations.

Patients already on biologic therapy

- 1) Patients on biologic therapy who have not tested positive or exhibited signs/symptoms of COVID-19: There is insufficient evidence to recommend discontinuation of biologics at this time. Physicians should continue to weigh the risk vs. benefits of the use of biologic medication on a case-by-case basis. The discussion, at the level of the individual patient, should include the original indication for the biologic, the severity of the original indication, the patient's age (whether they are ≥ 60 years old) and comorbidities. Comorbidities that may put patients at higher risk for serious illness from COVID-19 include serious chronic medical conditions such as cardiovascular disease, diabetes, severe hypertension, liver disease, kidney disease, respiratory system compromise, internal malignancies or tobacco use, among others.¹⁻³
- 2) Patients on biologic therapy who have tested positive for COVID-19: We recommend physicians discontinue or postpone the biologic therapy until the patient recovers from COVID-19, consistent with guidelines on the management of patients with active infections on biologics therapy ([AAD Biologic Guideline](#)).



Patients not on biologic therapy

- 3) Patients being considered for biologic therapy initiation: We recommend physicians assess the risk vs. benefits in low-risk patients before initiating biologics therapy on a case-by-case basis. In a high-risk population (e.g.: individuals 60 years and older, or patients with recognized comorbidities such as cardiovascular disease, diabetes, severe hypertension, liver disease, kidney disease, respiratory system compromise, internal malignancies or tobacco use, among others),¹⁻³ we recommend that physicians consider deferring initiation of biologic therapy. Alternative therapeutic approaches can be considered to treat high-risk patients.

This document was prepared on March 18, 2020, and will be updated as new data evolves in this area. For the latest information on the COVID-19 outbreak, refer to the [World Health Organization](#) (WHO) and the [Centers for Disease Control and Prevention](#) (CDC) website. Also, refer to the [International Psoriasis Council](#) (IPC) recommendations and the [American College of Rheumatology](#) (ACR) recommendations for additional insights on the use of biologics

References

1. Wang T, Du Z, Zhu F, et al. Comorbidities and multi-organ injuries in the treatment of COVID-19. *Lancet*. 2020.
2. Yang J, Zheng Y, Gou X, et al. Prevalence of comorbidities in the novel Wuhan coronavirus (COVID-19) infection: a systematic review and meta-analysis. *Int J Infect Dis*. 2020.
3. Fang L, Karakiulakis G, Roth M. Are patients with hypertension and diabetes mellitus at increased risk for COVID-19 infection? *Lancet Respir Med*. 2020.