



Crohn's & Colitis Foundation

# COVID-19 Vaccines

## Position Statement

The Crohn's & Colitis Foundation advocates on behalf of the millions of Americans who are affected by Crohn's disease and ulcerative colitis, collectively known as inflammatory bowel disease (IBD).

The Foundation supports the principles below as they relate to the IBD community and the safety, efficacy, and delivery of COVID-19 vaccines:

- Now that COVID-19 vaccinations are widely available, the Foundation supports eligible IBD patients getting vaccinated.
- The Foundation supports access to safe and effective vaccinations for COVID-19.

- IBD patients are not at increased risk of severe illness from the coronavirus<sup>1 2 3 4</sup>
- Most patients with IBD are not considered immune suppressed and therefore should not need an additional dose of mRNA vaccine. Please see [COVID-19 Vaccine Additional Dose](#) Position statement for additional details.
- The Foundation remains committed to monitoring information as it is made available regarding the status of COVID-19 vaccines and their impact on IBD patients.
- The Foundation continues to support and encourage social distancing, mask wearing, and other strategies designed to mitigate the spread of the coronavirus.
- There have been no recommendations from the FDA or CDC regarding the Johnson & Johnson vaccine. We will continue to update as additional information becomes available.
- The CDC and ACIP do not recommend checking antibody levels currently.

## COVID-19 Vaccine Safety and Effectiveness

All vaccines are developed and approved through a rigorous method, like the clinical trial phases that are used to develop, test, and approve medications. The U.S. Food and Drug Administration (FDA) provides guidance and oversight of all drugs, vaccines, and devices used in the United States. Recognizing the urgency and need for a COVID-19 vaccine, the FDA implemented an expedited process of reviewing and approving a vaccine under an Emergency Use Authorization (EUA).<sup>5</sup> The FDA is now reviewing one of the COVID-19 vaccines for full approval. The Foundation will continue to update the community of full approvals and additional EUAs.

In the development phase, COVID-19 vaccines must go through the three phases of vaccine clinical trials during which time tens of thousands of individuals receive the vaccines. For an EUA to be issued for a vaccine, the FDA performs a comprehensive evaluation of all available information related to each vaccine and determines that the known and potential benefits outweigh the known and potential risks of the vaccine. This EUA evaluation is performed by a team of career scientists and physicians within the FDA and includes a review from external scientists and public health

<sup>1</sup> Allocca, M., Chaparro, M., Gonzalez, H. A., Bosca-Watts, M. M., Palmela, C., D'Amico, F., . . . Fiorino, G. (2020). Patients with Inflammatory Bowel Disease Are Not at Increased Risk of COVID-19: A Large Multinational Cohort Study. *Journal of Clinical Medicine*, 9(11), 3533. doi:10.3390/jcm9113533

<sup>2</sup> Brenner, E. J., Ungaro, R. C., Geary, R. B., Kaplan, G. G., Kissous-Hunt, M., Lewis, J. D., . . . Kappelman, M. D. (2020). Corticosteroids, But Not TNF Antagonists, Are Associated With Adverse COVID-19 Outcomes in Patients With Inflammatory Bowel Diseases: Results From an International Registry. *Gastroenterology*, 159(2). doi:10.1053/j.gastro.2020.05.032

<sup>3</sup> Derikx, L. A., Lantinga, M. A., Jong, D. J., Dop, W. A., Creemers, R. H., Römkens, T. E., . . . Hoentjen, F. (2020). Clinical Outcomes of Covid-19 in Patients With Inflammatory Bowel Disease: A Nationwide Cohort Study. *Journal of Crohn's and Colitis*. doi:10.1093/ecco-jcc/jjaa215

<sup>4</sup> Papa, A., Gasbarrini, A., & Tursi, A. (2020). Epidemiology and the Impact of Therapies on the Outcome of COVID-19 in Patients With Inflammatory Bowel Disease. *American Journal of Gastroenterology*, 115(10), 1722-1724. doi:10.14309/ajg.0000000000000830

<sup>5</sup> United States, Food and Drug Administration. (2020, November 20). Emergency Use Authorization for Vaccines Explained. Retrieved from <https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained>

The information shared in this position statement is meant for educational purposes only. It should not replace the advice or care provided by your healthcare team.

experts not affiliated with the FDA. Importantly, no steps in FDA's review process were skipped for the COVID-19 vaccines currently under the EUA.

The currently approved vaccines do not contain live virus particles. There is no concern of contracting COVID-19 from such non-live vaccines, even among patients on their immune therapies. Non-live vaccines are considered safe for IBD patients regardless of the type of IBD therapy the patient is receiving. Patients with IBD can mount normal immune response to vaccines.

Those on certain immune-modifying treatments, such as anti-TNF biologics, may have a reduced immune response to certain vaccines, but not necessarily all vaccines.<sup>6</sup> We know those on azathioprine therapy have been shown to have a normal vaccine response. However, vaccination should not be deferred solely because they are receiving those treatments. IBD patients receiving systemic corticosteroids should be advised by their healthcare team on potential decreased vaccine efficacy.<sup>7</sup> Studies evaluating immune response of COVID-19 vaccines in solid organ transplant recipients have shown not all patients achieve an immune response (see COVID-19 Vaccine Additional dose guidance). In contrast, the [CORALE-IBD](#), [ICARUS Study](#), and the [PREVENT COVID](#) have all shown IBD patients who received both doses of the mRNA vaccine mounted an immune response. More information on the studies is summarized on our [IBDVisible](#) blog.

In addition, the approved vaccines are also considered safe and have been recommended by the CDC<sup>8</sup> and the American College of Obstetricians and Gynecologists<sup>9</sup> for women with IBD that are planning pregnancy, are pregnant, or are currently lactating.<sup>2</sup>

## Considerations for Receiving a Vaccine

Now that COVID-19 vaccinations are widely available, the Foundation supports eligible IBD patients getting vaccinated.

The decision to be vaccinated should be a partnership between a patient with IBD and their healthcare team. This partnership includes addressing any concerns to help make an informed decision on receiving a vaccine. The Foundation seeks to inform the community with the best available information; however, decisions on vaccinations must be made on an individual basis between a patient and their provider. The Foundation continues to monitor the status of current and future COVID-19 vaccines, including their impact on the IBD community.

---

<sup>6</sup> Normal Response to Vaccines in Inflammatory Bowel Disease Patients Treated with Thiopurines, [Iris Dotan, MD](#),<sup>†</sup> [Lael Werner, PhD](#),<sup>†</sup> [Sharon Vigodman, PhD](#),<sup>†</sup> [Shradha Agarwal, MD](#),<sup>‡</sup> [Jorge Pfeffer, MD](#),<sup>†</sup> [Noya Horowitz, PhD](#),<sup>†</sup> [Lisa Malter, MD](#),<sup>§</sup> [Maria Abreu, MD](#),<sup>§</sup> [Thomas Ullman, MD](#),<sup>§</sup> [Hanan Guzner-Gur, MD](#),<sup>†</sup> [Zamir Halpern, MD](#),<sup>†</sup> and [Lloyd Mayer, MD](#)<sup>‡§</sup>. Retrieved from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3919517/>

<sup>7</sup> United States, Food and Drug Administration. (2020, November 20). Emergency Use Authorization for Vaccines Explained. Retrieved from <https://www.fda.gov/vaccines-b>

<sup>8</sup> New CDC data: COVID-19 Vaccination Safe for Pregnant People. Retrieved from <https://www.cdc.gov/media/releases/2021/s0811-vaccine-safe-pregnant.html>

<sup>9</sup> COVID-19 Vaccination Considerations for Obstetric-Gynecologic Care. Retrieved from <https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2020/12/covid-19-vaccination-considerations-for-obstetric-gynecologic-care>

## **Consideration for IBD Patients of Color**

There is increasing evidence that COVID-19 disproportionately impacts Black, Latino, and Native American communities in the U.S., and that these communities are experiencing higher rates of infection, hospitalizations, and deaths due to COVID-19.<sup>7,8</sup> Socioeconomic factors, lack of access, systemic inequities, biases, and racism play a role in exacerbating the impact of the pandemic in these communities as well as other groups across the country. More studies are needed to further understand this impact, particularly among patients with Crohn's disease and ulcerative colitis.

## **More Information**

Patients and providers can find the latest COVID-19 vaccine information by visiting the Foundation's vaccine resources webpage. Individual inquiries can be addressed to the Irwin M. and Suzanne R. Rosenthal IBD Resource Center (IBD Help Center), Monday through Friday, 9:00 a.m. to 5:00 p.m. ET at 888-MY-GUT-PAIN (888-694-8872) or [info@crohnscolitisfoundation.org](mailto:info@crohnscolitisfoundation.org).