

COVID-19 Vaccine Additional Dose

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 diseases (IBD).

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

- 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^{1 2 3 4}

¹ 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

² 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

³ 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

⁴ 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

- COVID-19 vaccinations are widely available, and the Foundation supports eligible IBD patients getting vaccinated. Please see [COVID-19 Vaccine statement](#) for additional details
- Most patients with IBD are not considered immunosuppressed and therefore should not need an additional COVID-19 vaccine.
 - From the beginning of the pandemic, the overall data about IBD patient's COVID-19 risk has been reassuring. For additional insight see [COVID-19 Vaccine statement](#) and [Vaccine Monitoring](#)
- On August 13, 2021, the Advisory Committee on Immunization Practices (ACIP) recommended an additional dose of mRNA COVID-19 vaccine for moderate to severe immunocompromised individuals and to individuals on the following therapies.
 - High-dose [corticosteroids](#) (defined at $\geq 20\text{mg}$ / day of oral prednisone)
 - [Anti-TNF biologics and biosimilars](#)
 - [Immunomodulators](#) (azathioprine, methotrexate, etc.)

The ACIP's recommendation was based on available evidence about solid organ transplant patients and extrapolated for others who may have similar levels of immunosuppression⁵. It's important to recognize that current studies suggest that most patients with IBD can produce an immune response to the vaccination, unlike solid organ transplant recipients.

Patients interested in receiving an additional dose of the vaccine should get the same mRNA vaccine as their initial two doses (Pfizer or Moderna). In other words, if you got Pfizer your third shot should be the Pfizer vaccine, if you got Moderna, the third dose should be Moderna.

- Please note, booster shots should take place at least 28 days after your second dose of Pfizer or Moderna

Individuals wishing to get an additional dose do not need a doctor's order or verification to receive the additional dose.

ACIP and the CDC did not make specific recommendations on other biologics (vedolizumab, ustekinumab), 5-ASAs, thiopurines, and the disease modifying small molecules (tofacitinib and ozanimod). Patients and providers are encouraged to discuss the merits of receiving an additional dose of COVID-19 vaccine. As additional evidence and guidance is available the Foundation will provide updates.

- If you have questions about your IBD treatments, please visit: [medication recommendations](#)

⁵ Retrieved from: <https://www.sciencedirect-com.proxy.library.upenn.edu/science/article/pii/S0016508521031279>

- Currently, there are no recommendations from the FDA or CDC regarding an additional dose of the Johnson & Johnson vaccine. We will update when more information becomes available.
- The Foundation encourages additional research on the impact of the COVID-19 vaccine and 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.
 - CDC/ACIP strongly recommend everyone continue to wear masks and maintain social distancing to help control the spread of disease.
- The Foundation does not recommend serologic testing or cellular immune testing to determine immune (antibody) response to vaccination; data establishing the effectiveness of these tests have not been established. These tests are only currently recommended in the setting of a research study.

Providing an Additional mRNA Vaccine Dose

On August 12, 2021, FDA amended their EUA to allow for the use of an additional dose of the COVID-19 mRNA vaccines in certain immunocompromised individuals, specifically solid organ transplant recipients or those who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

Based on this amendment by the FDA the ACIP, advised the CDC on how to use additional doses of the mRNA vaccines⁶. This committee considered the available evidence supporting the use of an additional mRNA dose and then recommended which conditions or disease qualify for an additional mRNA dose. The ACIP is not able to provide recommendation for every disease state. Because evidence suggests that certain organ transplant recipients do not mount an immune response after completing a two-dose series, the ACIP recommended that moderate to severely immunocompromised should complete a three-dose series. The ACIP went as far as to recommend individuals on certain medications, including high-dose **corticosteroids** (defined at $\geq 20\text{mg}$ / day of oral prednisone), **Anti-TNF biologics and biosimilars, Immunomodulators (azathioprine, methotrexate, etc.)** receive a third dose.

The Foundation is aware of the FDA and CDC updates and supportive of patients with IBD getting an *additional* dose if they are on immune therapies. We also want to reassure the IBD population that the available data at this time from multiple studies *show the vast majority of patients are able to mount an immune response post immunization* and do not show that our patients who are vaccinated are at increased risk of infection or hospitalization. Current data shows that IBD patients are not inherently at increased risk for severe illness from the COVID-19.^{2,3,4,5,6} The **CORALE-IBD**, **ICARUS**, and

⁶Centers for Disease Control and Prevention, Vaccine Recommendations and Guidelines of the ACIP, Retrieved from <https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19.html>

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.

PREVENT COVID studies have all published data in peer reviewed journals demonstrating that IBD patients mount an immune response to the vaccine⁷.

We anticipate that similar to all patients with IBD needing a yearly influenza vaccine boosters, it's highly likely that all patients with IBD will need a COVID-19 booster when its recommended for the general population even those who are not on immune therapies. For more information on maintaining good health and annual vaccinations please visit: [Health Maintenance Checklists](#)

The Foundation encourages patients with IBD to continue to follow practices that mitigate the spread of the coronavirus as recommended by the CDC, including wearing masks. The Foundation will provide updates on additional doses and booster shots of COVID-19 vaccine as guidance is provided by the CDC.

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.

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⁷ Updates on COVID-19 vaccine research in patient with IBD. Retrieved from <https://www.crohnscolitisfoundation.org/blog/updates-covid-19-vaccine-research-patients-with-ibd>

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