



COVID 19: Guidance on Gastrointestinal (GI) and Liver disease certification of eligibility for Vaccination Priority group A3 and medical clearance

[Released on 18 April 2021]

The Department of Health (DOH) released [Department Memorandum No. 2021-0157](#) on March 30, 2021 that provides further guidance on the implementation of simultaneous COVID-19 vaccination to Priority Groups, and the implementing guidelines for Priority Group A3 or adults between 18 and 59 years of age with controlled comorbidities.

The memorandum provides guidance on the simultaneous deployment of the 400,000 doses and one million doses of Sinovac delivered on March 24 and March 29, 2021, respectively, to Priority Group A3. It stressed that Sinovac is not recommended for adults with uncontrolled or poorly controlled comorbidities. DOH is expected to release further guidance on additional vaccines that are arriving soon.

Eligibility

Adults aged 18 to 59 years with the following controlled comorbidities:

1. Chronic respiratory disease
2. Hypertension
3. Cardiovascular disease
4. Chronic kidney disease
5. Cerebrovascular disease
6. Malignancy
7. Diabetes
8. Obesity
9. Chronic liver disease
10. Neurologic disease
11. Immunodeficiency state

The following specific GI and Liver Diseases are at increased morbidity and mortality risk for COVID-19 infection and thus eligible for priority group A3:

- Chronic liver diseases ([Hepatology Society of the Philippines position statement on COVID-19 Vaccination in Adult Patients with Chronic Liver Disease](#)):
 - Chronic Hepatitis B
 - Chronic Hepatitis C
 - Metabolic Associated Fatty Liver Disease (MAFLD) / Non-alcoholic Fatty Liver Disease (NAFLD)
 - Alcohol-related liver disease
 - Autoimmune hepatitis
 - Primary biliary cholangitis
 - Primary sclerosing cholangitis
 - Liver cirrhosis

- Immunodeficiency state:
 - Inflammatory Bowel Disease (IBD)
 - Crohn's Disease (CD)
 - Ulcerative Colitis (UC)
 - Eosinophilic Gastrointestinal Disease (EGID) on steroid and/or immune-modifying therapy
 - Liver transplant recipients
- Malignancy:
 - All gastrointestinal, pancreatic, and hepatobiliary cancers

Any of the following may be provided as proofs of comorbidity, provided these are issued within the past 18 months relative to date of Sinovac vaccination:

- Medical certificate from an attending physician
- Prescription for medicines
- Hospital records such as the discharge summary and medical abstract
- Surgical records and pathology reports

Medical clearance

Medical clearance is required for the following cases regardless of priority group prior vaccination with Sinovac and AstraZeneca vaccines against COVID-19 ([DOH DM2021-0157](#) and [DOH DM 2021-0123](#)):

1. Patients with autoimmune disease
2. Patients with HIV
3. Patients with Cancer/Malignancy
4. Transplant Patients
5. Patients undergoing steroid treatment
6. Patients with poor prognosis/bedridden patients

The specific GI and Liver Diseases requiring medical clearance are listed below:

- Autoimmune disease
 - Inflammatory Bowel Disease (IBD), with or without steroid therapy
 - Crohn's Disease (CD)
 - Ulcerative Colitis (UC)
 - Autoimmune hepatitis
- Transplant Patients
 - Liver transplant
- Undergoing steroid treatment
 - Eosinophilic gastrointestinal disease on steroid therapy
- Cancer/ Malignancy
 - All gastrointestinal, pancreatic, and hepatobiliary cancers currently candidates or are undergoing chemotherapy, radiotherapy, or immunotherapy. "Cancer survivors who are diagnosed as recovered do not need to present medical clearance and may be vaccinated." ([DOH DM2021-0175](#))

STATEMENTS ON SPECIFIC GI AND LIVER CONDITIONS AND SARS-CoV-2 VACCINATION

General Advice:

Patients with the specified conditions below including their caregivers and close contacts are strongly advised to practice prevailing health safety standards even after vaccination.

Their caregivers and close contacts are encouraged to get vaccinated against SARS-CoV-2 as soon as vaccines are available and upon eligibility based on the priority population group in the vaccine deployment guidelines. (see [DOH DM 2021-0099](#) and [DOH DM 2021-0101](#))

INFLAMMATORY BOWEL DISEASE (IBD)

- Patients with IBD may receive a vaccine against SARS-CoV-2 at the first opportunity to obtain one because its benefit outweighs the risks of vaccine side effects.
- The following SARS-Cov-2 vaccines are safe for patients with IBD, including inactivated vaccines, replication-incompetent vector vaccines, messenger RNA vaccines, and recombinant vaccines administered preferably at least 4 weeks prior to start of immunosuppressive therapy.
- In patients with IBD who are currently receiving immune-modifying medications, live vaccines should be avoided.
- All vaccinated IBD patients must be counselled appropriately about possible diminished vaccine efficacy if they are receiving immunomodulator therapies and systemic corticosteroids.

References:

1. [Siegel CA, et al. Gut April 2021 vol 70 no 4](#)
2. [Alexander JL et al. Lancet Gastro Hepatol 2021; 6: 218-24](#)
3. <https://www.crohnscolitisfoundation.org/coronavirus/vaccine-overview>
4. [Manser CN, et al. Digestion 2020; 101\(suppl 1\):58-68 59 DOI: 10.1159/000503253](#)
5. [Croce E et al. Vaccine 2017;35\(91\):1216-1226](#)

AUTOIMMUNE HEPATITIS (AIH)

- COVID-19 vaccination is recommended for patients with autoimmune hepatitis and should be prioritized for vaccination.
- Medical therapy for autoimmune hepatitis should NOT be withheld while receiving the COVID-19 vaccines.
- Immunosuppressed patients will likely have blunted immune responses when compared to the general population.

Reference:

[Fix et al. "AASLD Expert Panel Consensus Statement: Vaccines to Prevent COVID-19 Infection in Patients with Liver Disease." AASLD COVID-19 Vaccine Working Group, 12 February 2021](#)

LIVER TRANSPLANT (LT)

- COVID-19 vaccination is recommended for liver transplant candidates prior to transplantation and liver transplant recipients after transplantation. These patients should be prioritized for COVID-19 vaccination whenever authorized vaccines are available.
- The ideal time to administer the COVID-19 vaccine in liver transplant recipients is within 3-6 months post-transplantation, when immunosuppression is expected to be lowered and stable. It is also at this time that other prophylactic medications are expected to be tapered.
- A reduction in immunosuppression doses to increase vaccine efficacy is NOT recommended due to the risk of acute cellular rejection. However, this can be expedited to as early as 6 weeks post-transplant if risk of community transmission is deemed high.
- Deferral of COVID-19 vaccination may be considered in liver transplant recipients with active acute cellular rejection or those on high daily doses of corticosteroids, until the episode of rejection has resolved and baseline immunosuppression is re-established.
- Given the life-saving nature of the procedure, liver transplantation should not be delayed in a patient who received COVID-19 vaccination.
- If the patient is due for a second dose of vaccine in the immediate post-transplant period, this may be delayed after 6 weeks to elicit a better immune response.
- Potential liver donors and recipients of liver donation should be prioritized for COVID-19 vaccination and preferably receive the second dose of COVID-19 vaccination at least two weeks before transplantation when feasible based on vaccine availability.
- A lack of COVID-19 vaccination should not delay lifesaving liver transplantation.

References:

1. [Cornberg et al. "EASL position paper on the use of COVID-19 vaccines in patients with chronic liver diseases, hepatobiliary cancer and liver transplant recipients." Journal of Hepatology, vol. 74, 2021, pp. 944 – 951](#)
2. [Fix et al. "AASLD Expert Panel Consensus Statement: Vaccines to Prevent COVID-19 Infection in Patients with Liver Disease." AASLD COVID-19 Vaccine Working Group, 12 February 2021](#)

EOSINOPHILIC GASTROINTESTINAL DISEASE (EGID)

- EGID patients on steroids and/or immune-modifying agents are considered to be in immunodeficiency state and thus eligible under priority group A3 to receive COVID-19 vaccination to significantly reduce the risk of COVID-19-related morbidity and mortality.
- Given the limited data, there is a theoretical risk of suboptimal vaccine response for patients on immunosuppressive drugs like steroids and immune-modifying agents.

- Counseling regarding risk-benefit assessment and safety of the available vaccines in preventing COVID-19 infection in this subset of population must be provided for informed decision making.

References:

1. [Steinbach et al. Eosinophilic Esophagitis and the Eosinophilic Gastrointestinal Diseases: Approach to diagnosis and management. J Allergy Clin Immunol Pract. 2018 Sep-Oct; 6\(5\): 1483–1495.](#)
2. [Savarino, et.al., Clinical and Psychological Impact of COVID-19 Infection in Adult Patients with Eosinophilic Gastrointestinal Disorders during the SARS-CoV-2 Outbreak. J Clin Med. 2020 Jun; 9\(6\): 2011.](#)
3. [Lukin, et.al., Baseline Disease Activity and Steroid Therapy Stratify Risk of COVID-19 in Patients With Inflammatory Bowel Disease. Gastroenterology. 2020 Oct; 159\(4\): 1541–1544.e2.](#)
4. [Lee, et.al., Eosinophilic gastroenteritis: 10 years experience. Am J Gastroenterol. 1993 Jan;88\(1\):70-4.](#)
5. [Tan et al. Eosinophilic gastroenteritis treated with non-enteric-coated budesonide tablets. Eur J Gastroenterol Hepatol. 2001 Apr;13\(4\):425-7.](#)
6. [Hirano et.al. AGA Institute and the Joint Task Force on Allergy-Immunology Practice Parameters Clinical Guidelines for the Management of Eosinophilic Esophagitis. Gastroenterology 2020;158:1776–1786.](#)
7. [Fauci et al. The effect of in vivo hydrocortisone on subpopulations of human lymphocytes. J Clin Invest. 1974;53:240–246. doi:10.1172/JCI107544.](#)
8. [Clinical Trial of Efficacy and Safety of Sinovac's Adsorbed COVID-19 \(Inactivated\) Vaccine in Healthcare Professionals \(PROFISCOV\).](#)
9. [Phase III Double-blind, Placebo-controlled Study of AZD1222 for the Prevention of COVID-19 in Adults.](#)
10. [Chakravarthy, et.al., Recommendations and Guidance for Steroid Injection Therapy and COVID-19 Vaccine Administration from the American Society of Pain and Neuroscience \(ASPN\). Journal of Pain Research 2021;14 623–629.](#)
11. [Implementing Guidelines for Priority Group A3 and Further Clarification of the National Deployment and Vaccination Plan for COVID-19 Vaccines DOH Department Memorandum No. 2021-0157](#)

GASTROINTESTINAL, PANCREATIC, AND HEPATOBILIARY CANCERS

- COVID-19 vaccination is recommended for patients with active and past history of gastrointestinal (GI), pancreatic, and hepatobiliary cancer. These patients should be prioritized for vaccination.
- Patients with GI, pancreatic, and hepatobiliary cancer undergoing locoregional therapy, radiation or systemic therapy (cytotoxic chemotherapy, targeted therapy, immunotherapy, tyrosine kinase inhibitors) should consider COVID-19 vaccination whenever the vaccine is available and without interruption to their treatment.
- The [Philippine Society of Medical Oncology Position Statement on COVID-19 Vaccine and Patients with Cancer](#) is the recommended reference for the appropriate timing of vaccination.
- Patients with recent infections or fever should NOT receive the COVID-19 vaccine until they are medically stable.

References:

1. [Williamson et al. Factors associated with COVID-19-related death using OpenSAFELY. Nature. 2020:1–17.](#)

2. [Kuderer et al. Clinical impact of COVID-19 on patients with cancer \(CCC19\): a cohort study. The Lancet. 2020;395\(10241\):1907–18.](#)
3. [Wang et al. Analyses of risk, racial disparity, and outcomes among US patients with cancer and COVID-19 infection. JAMA Oncol. 2020:1–8.](#)
4. [Nordøy et al. Cancer Patients Undergoing chemotherapy show adequate serological response to vaccinations against influenza virus and streptococcus pneumoniae. Med Oncol. 2002;19\(2\):71–8](#)
5. [Wumkes et al. Serum antibody response to influenza virus vaccination during chemotherapy treatment in adult patients with solid tumours. Vaccine. 2013;31\(52\):6177–84.](#)
6. [Läubli et al. Influenza vaccination of cancer patients during PD-1 blockade induces serological protection but may raise the risk for immune-related adverse events. J Immunother Cancer. 2018;6\(1\):40.](#)
7. [Gambichler et al. On the use of immune checkpoint inhibitors in patients with viral infections including COVID-19. J Immunother Cancer. 2020;8\(2\):e001145-e1149.](#)
8. [Antonio et al. PSMID Statement on COVID-19 Vaccines and the Immunocompromised Host. Philippine Society for Microbiology and Infectious Diseases Website \(psmid.org\). February 12, 2021.](#)
9. [Ting et al. COVID-19 Vaccine and Patients with Cancer The Philippine Society of Medical Oncology \(PSMO\) Position Statement. April 8, 2021](#)
10. [Cornberg et al. "EASL position paper on the use of COVID-19 vaccines in patients with chronic liver diseases, hepatobiliary cancer and liver transplant recipients." Journal of Hepatology, vol. 74, 2021, pp. 944 – 951](#)
11. [Fix et al. "AASLD Expert Panel Consensus Statement: Vaccines to Prevent COVID-19 Infection in Patients with Liver Disease." AASLD COVID-19 Vaccine Working Group. 12 February 2021](#)
12. [NCCN: Cancer and COVID-19 Vaccination. "Recommendations of the NCCN COVID-19 Vaccination Advisory Committee." 10 March 2021.](#)

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ANNEX 1: Template of Eligibility Certification for patients with GI and liver diseases to the Vaccine Priority group A3

MEDICAL CERTIFICATE

Date: _____

TO WHOM IT MAY CONCERN:

This is to certify that the bearer, Mr./Ms./Mrs. _____, age _____ yo
Sex: _____ and residing at _____ has the following
comorbidity/ies:

Above stated conditions/s are at present stable and under good control with his/her medications:

Therefore, the patient is eligible for vaccination under the Priority Group A3 of the National Deployment and Vaccination Plan for COVID-19 ([DOH DM 2021-0157](#)) provided that the patient is without known allergy to the vaccine or component/s of the vaccine.

Patient has been counseled on the benefits and potential risks associated with the currently administered COVID-19 vaccines.

This certificate is issued upon patient's request for COVID-19 vaccination purposes only.

_____, MD, FPCP, FPSG, FPSDE
(Name and signature)
PRC Lic No. _____

ANNEX 2: Template of Medical Clearance as required for patients specified in the DOH [DM 2021-0157](#) and [DM 2021-0123](#)

MEDICAL CLEARANCE

Date: _____

TO WHOM IT MAY CONCERN:

In compliance with the Department of Health Implementing Guidelines on the National Deployment and Vaccination Plan for COVID-19 Vaccines, this medical clearance is hereby issued to:

Mr./Ms./Mrs. _____ age _____ yo and residing at _____ has the following medical condition/s requiring medical clearance according to DOH [DM 2021-0157](#) and [DM 2021-0123](#): (Check applicable condition and provide diagnosis)

- HIV
Diagnosis: _____
- Cancer/malignancy
Diagnosis: _____
- Transplant
Diagnosis: _____
- Undergoing steroid medication/ treatment
Diagnosis: _____
- Bedridden, terminal illness, less than 6 months prognosis
Diagnosis: _____
- Autoimmune disease
Diagnosis: _____

Recommendation/s:

After risk-benefit assessment based on the history, physical exam and available data, above patient is:

- medically cleared to receive the available COVID-19 vaccine.
- advised to defer COVID-19 vaccination for _____ (specify duration) after the acute attack/flare or hospitalization or until her condition is deemed controlled and stable.

_____, MD, FPCP, FPSG, FPSDE
(Name and signature)

PRC Lic No. _____

Clinic/Hospital Add: _____

Contact No.: _____