

Pregnancy, Lactation, and COVID-19 Therapeutics

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General Considerations

The COVID-19 Treatment Guidelines Panel (the Panel) **recommends against** withholding COVID-19 treatments or vaccination from pregnant or lactating individuals specifically because of pregnancy or lactation (**AIII**). Pregnant patients should be offered the opportunity to participate in the [COVID-19 International Drug Pregnancy Registry](#) or other pregnancy registries.

The decision to feed the infant breast milk while the lactating patient is receiving therapeutic agents for COVID-19 should be a collaborative effort between the patient and the clinical team, including infant care providers. The patient and the clinical team should consider the benefits of breastfeeding, the postnatal age of the infant, the need for the medication, any underlying risks of exposing the infant to the drug, and the potential adverse outcomes of COVID-19.

If a patient is receiving a treatment for COVID-19 that prevents them from feeding breast milk to their infant for a limited time, the clinical team should still encourage pumping breast milk and provide lactation support. This ensures that lactation can continue after the patient stops receiving the treatment.

While a person with COVID-19 is breastfeeding, prevention measures should be taken to avoid transmitting SARS-CoV-2 to the infant. These measures include practicing appropriate hand hygiene, wearing face coverings, and performing proper pump cleaning before and after breast milk expression.

Table A: Recommendations for the Use of COVID-19 Therapeutics in Pregnant and Lactating People

For the Panel's recommendations on when to use the medications listed below, refer to [Therapeutic Management of Nonhospitalized Adults With COVID-19](#) and [Therapeutic Management of Hospitalized Adults With COVID-19](#). Pregnant patients should be offered the opportunity to participate in the [COVID-19 International Drug Pregnancy Registry](#) or other pregnancy registries. For additional information on the use of these medications during pregnancy and lactation, see the section text below.

Drug Name (in alphabetical order)	Pregnancy	Lactation
Abatacept	Recommended in hospitalized patients, if indicated. Pregnant patients and their health care providers should jointly decide whether to use abatacept during pregnancy, and the decision-making process should include a discussion of the potential risks and benefits.	Should be offered to patients who qualify for this therapy. There is minimal data on the transfer of abatacept to breast milk. Breastfeeding may be considered while a patient receives abatacept.
Baricitinib	Recommended in hospitalized patients, if indicated. Pregnant patients and their health care providers should jointly decide whether to use baricitinib during pregnancy, and the decision-making process should include a discussion of the potential risks and benefits.	Feeding breast milk should be avoided while taking baricitinib and for 4 days after the last dose. Lactation support should be provided during this time. ^a
Dexamethasone	Recommended in hospitalized patients, if indicated.	Should be offered to patients who qualify for this therapy. Breastfeeding can continue while a patient receives dexamethasone.

Drug Name (in alphabetical order)	Pregnancy	Lactation
Heparin (LMWH and UFH)	Recommended in hospitalized patients if indicated and if the patient does not have an obstetric-related bleeding risk (e.g., imminent delivery, bleeding complications of pregnancy) that would preclude use. See Antithrombotic Therapy in Patients With COVID-19 for more information.	Should be offered to patients who qualify for this therapy. Breastfeeding can continue while a patient receives LMWH or UFH.
Infliximab	Recommended in hospitalized patients, if indicated. Pregnant patients and their health care providers should jointly decide whether to use infliximab during pregnancy, and the decision-making process should include a discussion of the potential risks and benefits.	Should be offered to patients who qualify for this therapy. The available data show that the amount of infliximab that transfers through breast milk is negligible. Breastfeeding can continue while a patient receives infliximab.
Molnupiravir	Recommended against , unless there are no other options and therapy is clearly indicated.	Breastfeeding is not recommended while a patient is taking molnupiravir and for 4 days after the last dose. ¹ Lactation support should be provided during this time. ^a
Remdesivir	Recommended , if indicated.	Should be offered to patients who qualify for this therapy. Breastfeeding can continue while a patient receives remdesivir.
Ritonavir-Boosted Nirmatrelvir (Paxlovid)	Recommended , if indicated.	Should be offered to patients who qualify for this therapy. Breastfeeding can continue while a patient receives ritonavir-boosted nirmatrelvir.
Tocilizumab	Recommended in hospitalized patients, if indicated. Pregnant patients and their health care providers should jointly decide whether to use tocilizumab during pregnancy, and the decision-making process should include a discussion of the potential risks and benefits.	Should be offered to patients who qualify for this therapy. Breastfeeding can continue while a patient receives tocilizumab.

^a If a patient is receiving a treatment for COVID-19 that prevents them from feeding breast milk for a limited time, the clinical team should still encourage pumping breast milk and provide lactation support. This ensures that lactation can continue after the patient stops receiving the treatment.

Key: LMWH = low-molecular-weight heparin; the Panel = the COVID-19 Treatment Guidelines Panel; UFH = unfractionated heparin

Rationale

Abatacept

Pregnancy

As there are no data on the use of abatacept during pregnancy in hospitalized patients with COVID-19, this drug should be used only if baricitinib and tocilizumab are not available or feasible to use. When deciding whether to prescribe abatacept to a pregnant individual, clinicians need to consider the severity of the patient's COVID-19, the patient's comorbidities, and the gestational age of the fetus.

There is a paucity of data on the use of abatacept in pregnant individuals. It is currently not known whether abatacept can cross the human placenta; however, abatacept has crossed the placenta in animal studies. One study reported alterations to the immune systems of the offspring of animals that received supratherapeutic doses of abatacept throughout pregnancy.² It is not known whether the immune systems of infants who were exposed to a single dose of abatacept in utero might be impacted. Abatacept should only be used during pregnancy if the benefits clearly outweigh the potential risks.

Lactation

Abatacept should be offered to patients who qualify for this therapy. It is not known whether abatacept is transferred to breast milk during lactation or whether it is absorbed systemically by the infant. Because abatacept is a large molecule, only small amounts are thought to be transferred to breast milk. Patients who are receiving abatacept may consider breastfeeding.

Baricitinib

Pregnancy

When deciding whether to prescribe baricitinib to a pregnant individual, clinicians need to consider the severity of the patient's COVID-19, the patient's comorbidities, and the gestational age of the fetus.

Baricitinib is a Janus kinase inhibitor. As a small-molecule drug, baricitinib is likely to pass through the placenta; therefore, fetal risk cannot be ruled out.³ In animal studies, baricitinib doses that exceeded the therapeutic human dose were associated with embryofetal developmental abnormalities. Pregnancy registries provide some data on the use of tofacitinib, another Janus kinase inhibitor, during pregnancy for other conditions (e.g., ulcerative colitis, rheumatoid arthritis, psoriasis).⁴⁻⁶ Pregnancy outcomes among the participants who received tofacitinib were similar to those among the general population.

Lactation

There is no information on the use of baricitinib in lactating people or on the effects of baricitinib on breastfed infants; however, baricitinib has been detected in the breast milk of lactating rats.⁷ Feeding breast milk should be avoided for 4 days (approximately 5–6 elimination half-lives) after baricitinib is discontinued.

Dexamethasone

Pregnancy

A short course of betamethasone or dexamethasone, which are both known to cross the placenta, is routinely used to decrease neonatal complications of prematurity in people who are at risk of imminent preterm birth.^{8,9} Treating COVID-19 with a short course of dexamethasone can lower the risk of death in pregnant individuals. In addition, dexamethasone carries a low risk of fetal adverse effects.

Lactation

Dexamethasone should be offered to lactating patients with COVID-19 who qualify for this therapy. Breast milk can be fed to the infant while the lactating patient is receiving dexamethasone. Although there are limited data on the use of dexamethasone in lactating patients, some published reports about a related antenatal corticosteroid (betamethasone) reported a time-limited decrease in the volume of breast milk production.^{10,11} Given the benefits of breast milk, additional lactation support has been recommended if needed.

Heparin (Low-Molecular-Weight and Unfractionated)

Pregnancy

In general, the preferred anticoagulants during pregnancy are heparin compounds. Because of its reliability and ease of administration, low-molecular-weight heparin is recommended rather than unfractionated heparin for the prevention and treatment of venous thromboembolism in pregnant people.

The use of anticoagulant therapy during labor and delivery requires specialized care and planning. The management of anticoagulant therapy in pregnant patients with COVID-19 should be similar to the management used for pregnant patients with other conditions.

Lactation

Low-molecular-weight heparin, unfractionated heparin, and warfarin do not accumulate in breast milk and do not induce an anticoagulant effect in the newborn. Therefore, they can be used by breastfeeding individuals who require venous thromboembolism prophylaxis or treatment.

Infliximab

Pregnancy

As there are no data on the use of infliximab during pregnancy in hospitalized patients with COVID-19, infliximab should be used only if baricitinib and tocilizumab are not available or feasible to use. When deciding whether to prescribe infliximab to a pregnant individual, clinicians need to consider the severity of the patient's COVID-19, the patient's comorbidities, and the gestational age of the fetus.

There are limited data on the use of infliximab to treat COVID-19 in pregnant patients. It has been used to treat autoimmune diseases in pregnant individuals when the benefits outweigh the potential risks. Infliximab crosses the placenta and has been detected in the serum of infants born to patients treated with infliximab during pregnancy. No adverse effects have been reported in these infants.

Lactation

Infants who are breastfed by people receiving infliximab show minimal absorption of this agent.¹² No adverse effects have been reported in these infants. Therefore, infliximab should be offered to patients who qualify. Breastfeeding can continue while a patient receives infliximab.

Molnupiravir

Pregnancy

The Panel **recommends against** the use of **molnupiravir** for the treatment of COVID-19 in pregnant patients unless there are no other options and therapy is clearly indicated (**AIII**).

The Food and Drug Administration (FDA) Emergency Use Authorization states that molnupiravir is not recommended for use in pregnant patients because fetal toxicity has been reported in animal studies of molnupiravir.¹ However, when other therapies are not available, pregnant people with COVID-19 who are at high risk of progressing to severe disease may reasonably choose molnupiravir therapy after being fully informed of the potential risks, particularly if they are beyond the time of embryogenesis (i.e., >10 weeks' gestation).

Lactation

There is no data on the use of molnupiravir in lactating people; however, molnupiravir has been detected in the offspring of lactating rats. Molnupiravir is not authorized for use in children aged <18 years. Because the risk of adverse effects in infants is currently unknown, the FDA Emergency Use Authorization fact sheet does not recommend feeding an infant breast milk from a patient who is taking molnupiravir for the duration of the treatment course and until 4 days after the final dose.¹

Remdesivir

Pregnancy

While pregnant individuals were excluded from the clinical trials that evaluated the safety and efficacy of remdesivir for the treatment of COVID-19, subsequent reports on the use of remdesivir in pregnant individuals have been reassuring. Among 95 pregnant patients with moderate, severe, or critical COVID-19 who were included in a secondary analysis of data from a COVID-19 pregnancy registry in Texas, the composite maternal and neonatal outcomes were similar between those who received

remdesivir (n = 39) and those who did not.¹³

A systematic review of 13 observational studies that included 113 pregnant people also reported few adverse effects of remdesivir in pregnant patients with COVID-19.¹⁴ The most common adverse effect was a mild elevation in transaminase levels.

Lactation

Remdesivir is approved by the FDA for use in pediatric patients aged ≥ 28 days and weighing ≥ 3 kg.¹⁵ Limited data have suggested that the drug is poorly absorbed via the oral route; therefore, the levels of the drug that are absorbed when the infant ingests breast milk are low.^{16,17} One case report described a patient with COVID-19 who received remdesivir during the immediate postpartum period.¹⁷ Based on the concentration of remdesivir in the maternal serum and breast milk, the calculated milk-to-serum ratio was low. Therefore, the levels of remdesivir that would have reached a breastfed infant were estimated to be low.

Ritonavir-Boosted Nirmatrelvir (Paxlovid)

Pregnancy

Ritonavir has been used extensively during pregnancy in people with HIV and has a favorable safety profile during pregnancy. The mechanisms of action for both nirmatrelvir and ritonavir and the results of animal studies and case series suggest that this regimen can be used safely in pregnant individuals.

Two descriptive case series evaluated outcomes among pregnant patients with COVID-19 who received ritonavir-boosted nirmatrelvir.^{18,19} One case series included 47 patients with COVID-19 and a median gestational age of 28.4 weeks.¹⁸ These patients started taking ritonavir-boosted nirmatrelvir after a median duration of 1 day of COVID-19 symptoms. Thirty patients (64%) in the cohort had clinical characteristics in addition to pregnancy that increased their risk of progressing to severe COVID-19. The patients tolerated ritonavir-boosted nirmatrelvir well, with no serious adverse effects noted in either the pregnant patients or the neonates during the study period.

The other case series included 7 patients with a mean gestational age of 26.4 weeks who initiated ritonavir-boosted nirmatrelvir after approximately 2 days of COVID-19 symptoms.¹⁹ One patient developed dysgeusia and stopped treatment, but the remaining 6 patients completed 5 days of treatment. Six of the patients were fully vaccinated, and 4 of these patients had also received a booster dose. All the patients reported resolution of their COVID-19 symptoms, and no fetal or neonatal adverse effects were observed during the study period.

Ritonavir-boosted nirmatrelvir should be offered to pregnant and recently pregnant patients with COVID-19 who qualify for this therapy based on the results of a risk-benefit assessment. The risk-benefit assessment may include factors such as medical comorbidities, body mass index, vaccination status, and the number and severity of the risk factors for severe disease.

Obstetricians should be aware of potential drug-drug interactions when prescribing this agent. See [Drug-Drug Interactions Between Ritonavir-Boosted Nirmatrelvir \(Paxlovid\) and Concomitant Medications](#) for more information.

Lactation

Studies of infants who were exposed to ritonavir through breast milk suggest that the amount of ritonavir that transfers through breast milk is negligible and not considered clinically significant.²⁰⁻²³

There are no data on the use of nirmatrelvir in lactating people. However, a prebirth-to-lactation study performed in rats reported an 8% decrease in body weight on Postnatal Day 17 in the offspring of

rats that received nirmatrelvir and had systemic exposures that were 9 times higher than the clinical exposures at the authorized human dose.²⁴ This reduction in body weight was not seen in the offspring of rats that had exposures that were 5 times higher than the clinical exposures at the authorized human dose. Because the overall oral absorption of nirmatrelvir is poor, it is unlikely that the levels of nirmatrelvir absorbed from breast milk ingestion would be clinically relevant or expected to cause adverse effects in an infant.²⁵

Tocilizumab

Pregnancy

Pregnant individuals have been excluded from clinical trials that evaluated the use of the anti-interleukin-6 receptor monoclonal antibody tocilizumab for the treatment of COVID-19. An analysis of data from a global safety database reported pregnancy outcomes from 288 women who were exposed to tocilizumab during their pregnancies.²⁶ Eighty-nine percent of these women received tocilizumab as ongoing treatment for rheumatoid arthritis, and most were exposed to tocilizumab during their first trimester. The rates of congenital abnormalities among the infants born to these women were not higher than the rates seen in the general population. However, an increased rate of preterm birth was observed among these individuals when compared with the general population. A retrospective report of 61 pregnant women who were exposed to tocilizumab at conception or during their first trimesters showed no increased rates of congenital abnormalities or spontaneous abortion.²⁷

As pregnancy progresses, monoclonal antibodies are actively transported across the placenta, with the greatest transfer occurring during the third trimester. This may affect immune responses in the exposed fetus. If a pregnant patient receives tocilizumab after 20 weeks' gestation, clinicians should delay administering live viral vaccines to the infant for at least 6 months.

Lactation

There is limited information on the use of tocilizumab in lactating patients. Based on case report data, the amount of tocilizumab transferred to the infant via breast milk appears to be very low, with no reports of adverse effects.²⁸

References

1. Food and Drug Administration. Fact sheet for healthcare providers: Emergency Use Authorization for Lagevrio (molnupiravir) capsules. 2023. Available at: <https://www.fda.gov/media/155054/download>.
2. Abatacept (Orencia) [package insert]. Food and Drug Administration. 2021. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/125118s240lbl.pdf.
3. Sammaritano LR, Bermas BL, Chakravarty EE, et al. 2020 American College of Rheumatology guideline for the management of reproductive health in rheumatic and musculoskeletal diseases. *Arthritis Rheumatol*. 2020;72(4):529-556. Available at: <https://pubmed.ncbi.nlm.nih.gov/32090480>.
4. Clowse ME, Feldman SR, Isaacs JD, et al. Pregnancy outcomes in the tofacitinib safety databases for rheumatoid arthritis and psoriasis. *Drug Saf*. 2016;39(8):755-762. Available at: <https://pubmed.ncbi.nlm.nih.gov/27282428>.
5. Mahadevan U, Dubinsky MC, Su C, et al. Outcomes of pregnancies with maternal/paternal exposure in the tofacitinib safety databases for ulcerative colitis. *Inflamm Bowel Dis*. 2018;24(12):2494-2500. Available at: <https://pubmed.ncbi.nlm.nih.gov/29982686>.
6. Wieringa JW, van der Woude CJ. Effect of biologicals and JAK inhibitors during pregnancy on health-related outcomes in children of women with inflammatory bowel disease. *Best Pract Res Clin Gastroenterol*. 2020;44-45:101665. Available at: <https://pubmed.ncbi.nlm.nih.gov/32359679>.
7. Baricitinib (Olumiant) [package insert]. Food and Drug Administration. 2022. Available at: <https://www>.

accessdata.fda.gov/drugsatfda_docs/label/2022/207924s006lbl.pdf.

8. Liggins GC, Howie RN. A controlled trial of antepartum glucocorticoid treatment for prevention of the respiratory distress syndrome in premature infants. *Pediatrics*. 1972;50(4):515-525. Available at: <https://pubmed.ncbi.nlm.nih.gov/4561295>.
9. Gyamfi-Bannerman C, Thom EA, Blackwell SC, et al. Antenatal betamethasone for women at risk for late preterm delivery. *N Engl J Med*. 2016;374(14):1311-1320. Available at: <https://pubmed.ncbi.nlm.nih.gov/26842679>.
10. Henderson JJ, Hartmann PE, Newnham JP, Simmer K. Effect of preterm birth and antenatal corticosteroid treatment on lactogenesis II in women. *Pediatrics*. 2008;121(1):e92-e100. Available at: <https://pubmed.ncbi.nlm.nih.gov/18166549>.
11. Henderson JJ, Newnham JP, Simmer K, Hartmann PE. Effects of antenatal corticosteroids on urinary markers of the initiation of lactation in pregnant women. *Breastfeed Med*. 2009;4(4):201-206. Available at: <https://pubmed.ncbi.nlm.nih.gov/19772378>.
12. Ben-Horin S, Yavzori M, Kopylov U, et al. Detection of infliximab in breast milk of nursing mothers with inflammatory bowel disease. *J Crohns Colitis*. 2011;5(6):555-558. Available at: <https://pubmed.ncbi.nlm.nih.gov/22115374>.
13. Gutierrez R, Mendez-Figueroa H, Biebighauser JG, Bhalwal A, Pineles BL, Chauhan SP. Remdesivir use in pregnancy during the SARS-CoV-2 pandemic. *J Matern Fetal Neonatal Med*. 2022;35(25):9445-9451. Available at: <https://pubmed.ncbi.nlm.nih.gov/35168447>.
14. Budi DS, Pratama NR, Wafa IA, Putra M, Wardhana MP, Wungu CDK. Remdesivir for pregnancy: a systematic review of antiviral therapy for COVID-19. *Heliyon*. 2022;8(1):e08835. Available at: <https://pubmed.ncbi.nlm.nih.gov/35128114>.
15. Remdesivir (Veklury) [package insert]. Food and Drug Administration. 2023. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/214787s019lbl.pdf.
16. National Institute of Child Health and Human Development. Drugs and lactation database (LactMed) [Internet]. Remdesivir. 2023. Available at: <https://www.ncbi.nlm.nih.gov/books/NBK556881>. Accessed February 26, 2024.
17. Wada YS, Saito J, Hashii Y, et al. Remdesivir and human milk: a case study. *J Hum Lact*. 2022;38(2):248-251. Available at: <https://pubmed.ncbi.nlm.nih.gov/35189734>.
18. Garneau WM, Jones-Beatty K, Ufua MO, et al. Analysis of clinical outcomes of pregnant patients treated with nirmatrelvir and ritonavir for acute SARS-CoV-2 infection. *JAMA Netw Open*. 2022;5(11):e2244141. Available at: <https://pubmed.ncbi.nlm.nih.gov/36445705>.
19. Loza A, Farias R, Gavin N, Wagner R, Hammer E, Shields A. Short-term pregnancy outcomes after nirmatrelvir-ritonavir treatment for mild-to-moderate coronavirus disease 2019 (COVID-19). *Obstet Gynecol*. 2022;140(3):447-449. Available at: <https://pubmed.ncbi.nlm.nih.gov/36356238>.
20. Rezk NL, White N, Bridges AS, et al. Studies on antiretroviral drug concentrations in breast milk: validation of a liquid chromatography-tandem mass spectrometric method for the determination of 7 anti-human immunodeficiency virus medications. *Ther Drug Monit*. 2008;30(5):611-619. Available at: <https://pubmed.ncbi.nlm.nih.gov/18758393>.
21. Palombi L, Pirillo MF, Andreotti M, et al. Antiretroviral prophylaxis for breastfeeding transmission in Malawi: drug concentrations, virological efficacy and safety. *Antivir Ther*. 2012;17(8):1511-1519. Available at: <https://pubmed.ncbi.nlm.nih.gov/22910456>.
22. Corbett AH, Kayira D, White NR, et al. Antiretroviral pharmacokinetics in mothers and breastfeeding infants from 6 to 24 weeks post-partum: results of the BAN Study. *Antivir Ther*. 2014;19(6):587-595. Available at: <https://pubmed.ncbi.nlm.nih.gov/24464632>.
23. Gandhi M, Mwesigwa J, Aweeka F, et al. Hair and plasma data show that lopinavir, ritonavir, and efavirenz all transfer from mother to infant in utero, but only efavirenz transfers via breastfeeding. *J Acquir Immune Defic*

- Syndr.* 2013;63(5):578-584. Available at: <https://pubmed.ncbi.nlm.nih.gov/24135775>.
24. Ritonavir-boosted nirmatrelvir (Paxlovid) [package insert]. Food and Drug Administration. 2023. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/217188s000lbl.pdf.
25. Eng H, Dantonio AL, Kadar EP, et al. Disposition of nirmatrelvir, an orally bioavailable inhibitor of SARS-CoV-2 3c-like protease, across animals and humans. *Drug Metab Dispos.* 2022;50(5):576-590. Available at: <https://pubmed.ncbi.nlm.nih.gov/35153195>.
26. Hoeltzenbein M, Beck E, Rajwanshi R, et al. Tocilizumab use in pregnancy: analysis of a global safety database including data from clinical trials and post-marketing data. *Semin Arthritis Rheum.* 2016;46(2):238-245. Available at: <https://pubmed.ncbi.nlm.nih.gov/27346577>.
27. Nakajima K, Watanabe O, Mochizuki M, Nakasone A, Ishizuka N, Murashima A. Pregnancy outcomes after exposure to tocilizumab: a retrospective analysis of 61 patients in Japan. *Mod Rheumatol.* 2016;26(5):667-671. Available at: <https://pubmed.ncbi.nlm.nih.gov/26873562>.
28. Saito J, Yakuwa N, Kaneko K, et al. Tocilizumab during pregnancy and lactation: drug levels in maternal serum, cord blood, breast milk and infant serum. *Rheumatology (Oxford).* 2019;58(8):1505-1507. Available at: <https://pubmed.ncbi.nlm.nih.gov/30945743>.