



Joint Statement on COVID-19 Vaccination and Treatment During Pregnancy, Postpartum and/or Lactation

We strongly recommend that all pregnant, postpartum, and lactating persons receive an mRNA (Pfizer or Moderna) SARS-CoV-2 vaccine series, including the two initial doses and a booster dose, per the currently approved dose schedules. We recommend initial vaccination or the booster dose be given promptly, regardless of trimester. We do NOT recommend delaying vaccination during preconception or until after pregnancy as this represents a clear increase in risk for long-term and severe health consequences and pregnancy complications due to COVID-19. We further do not recommend delay of vaccination or booster to later in pregnancy in an attempt to elicit a larger transplacental transfer of protective antibodies. Additionally, there is no longer a recommendation to delay vaccination for any period of time after recovery from COVID-19 infection or administration of any COVID-19 therapeutics including monoclonal antibodies, Remdesivir, steroids, or nirmatrelvir/ritonavir tablets (Paxlovid).

There is an abundance of safety data showing no increased pregnancy-related risks for those vaccinated during preconception or pregnancy and significant protection from asymptomatic infection, symptomatic and hospitalization and severe or critical COVID-19 disease for the pregnant person. This is especially important with our understanding that the risk of severe or critical illness and death from COVID-19 is much higher during pregnancy— independent of other risk factors.

We recommend that pregnant and recently pregnant people be given access to and be prioritized to receive the available therapeutic medications regardless of vaccination status and other risk factors due to the increased risks of severe disease, death, and pregnancy complications outlined above. We recommend against requiring additional criteria to administer these treatments to pregnant people above and beyond those prescribed for the general use of these therapies.

We further call upon all perinatal care providers and those who interact with pregnant people to actively recommend SARS-CoV-2 vaccination, including boosters, offer and facilitate the use of the available therapeutic medications, and to combat the pervasive misinformation. We strongly assert that any healthcare worker or provider who recommends against SARS-CoV-2 vaccination or therapies for the reason of pregnancy or lactation is acting contrary to overwhelmingly supportive medical evidence, the recommendations of all relevant professional societies and public health organizations, and the best interest of our patients.

For your convenience, *COVID-19 Therapeutics Quick Reference for Perinatal Providers* is included in this document. If you have questions or concerns, please reach out to us for additional resources. We appreciate your efforts in countering misinformation with evidence and helping protect pregnant, postpartum, and lactating people.



Literature and Guideline Summary:

Pregnant individuals with COVID-19 infection have a higher risk of a critical course of illness and require more hospitalizations, ICU admissions, and invasive ventilation including ECMO when compared to non-pregnant individuals [1,2]. Pregnant patients are also less likely to have symptoms such as fever, body aches or shortness of breath [2]. Patients who have severe illness due to COVID-19 have increased risk of cesarean section, preterm birth, hypertension, and blood clots [3,18]. Studies also show increased risk of death associated with COVID-19 infection in pregnancy compared to non-pregnant status [6,18]. There also appears to be an increased infection rate in pregnant patients, almost 70% more than similarly aged adults [4,18]. Age, preexisting Diabetes Mellitus, chronic hypertension, obesity, and chronic lung disease seem to increase risk for severe disease [5]. Vertical transmission resulting in congenital COVID-19 infection in newborns is rare but has been reported [7].

COVID-19 vaccines are safe and effective. Vaccination against COVID-19 reduces the risk of infection, hospitalization, and death [8,9]. On August 23, 2021, the U.S. Food and Drug Administration (FDA) approved the first COVID-19 vaccine, Comirnaty, for adults 16 and older [15]. None of the vaccines currently authorized in the United States contain virus that replicates, and hence they do not cause disease. Studies have shown that the COVID-19 vaccine is safe in pregnant and lactating people and has no increased adverse effects [14]. There is no plausible mechanism with which COVID-19 vaccines could affect fertility, and currently available data have not shown a significant effect to fertility [19]. COVID-19 vaccines do not increase the risk of miscarriage or stillbirth [20,21,22]. COVID-19 antibodies have been found in umbilical cord blood and breast milk, thereby providing some level of protection to the fetus/infant [13,17]. Additionally, there is strong evidence that vaccination and/or boosters during pregnancy and the transplacental and breastmilk-mediated antibody transfer provide protection against fetal and neonatal complications, including COVID-19 related hospitalizations prior to 6 months of age [23].

On July 30, 2021, The American College of Obstetricians and Gynecologists (ACOG) and the Society for Maternal-Fetal Medicine (SMFM) issued a [statement](#) recommending that all pregnant individuals be vaccinated against COVID-19. Currently, the statement is endorsed by more than 20 leading national organizations representing experts in perinatal and public health, including the American College of Nurse-Midwives (ACNM), the Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN), and the American Academy of Pediatrics (AAP). The Centers for Disease Control and Prevention (CDC) has also made an unequivocal [recommendation](#) in favor of perinatal vaccination. These organizations' recommendations in support of vaccination before, during or after pregnancy, as well as during lactation, reflect evidence demonstrating the safe use of the COVID-19 vaccines during pregnancy and lactation. Recent data have shown that more than 95% of those who are hospitalized and/or dying from COVID-19 are those who have remained unvaccinated. Pregnant individuals who have decided to wait until after delivery to be vaccinated may be inadvertently exposing themselves to an increased risk of severe illness or death. Those who have recently



delivered and were not vaccinated during pregnancy are also strongly encouraged to get vaccinated as soon as possible [16].

Additional Resources:

- [NMDOH](#)
- [CDC](#)
- [SMFM](#)
- [AWHONN](#)
- [ACOG](#)
- [ASRM](#)
- [AAP](#)
- [MotherToBaby](#)

References

1. Zambrano LD, Ellington S, Strid P, Galang RR, Oduyebo T, Tong VT, Woodworth KR, Nahabedian JF 3rd, Azziz-Baumgartner E, Gilboa SM, Meaney-Delman D; CDC COVID-19 Response Pregnancy and Infant Linked Outcomes Team. Update: Characteristics of Symptomatic Women of Reproductive Age with Laboratory-Confirmed SARS-CoV-2 Infection by Pregnancy Status - United States, January 22-October 3, 2020. *MMWR Morb Mortal Wkly Rep.* 2020 Nov 6;69(44):1641-1647. doi: 10.15585/mmwr.mm6944e3. PMID: 33151921; PMCID: PMC7643892.
2. Allotey J, Stallings E, Bonet M, Yap M, Chatterjee S, Kew T, Debenham L, Llavall AC, Dixit A, Zhou D, Balaji R, Lee SI, Qiu X, Yuan M, Coomar D, Sheikh J, Lawson H, Ansari K, van Wely M, van Leeuwen E, Kostova E, Kunst H, Khalil A, Tiberi S, Brizuela V, Broutet N, Kara E, Kim CR, Thorson A, Oladapo OT, Mofenson L, Zamora J, Thangaratnam S; for PregCOV-19 Living Systematic Review Consortium. Clinical manifestations, risk factors, and maternal and perinatal outcomes of coronavirus disease 2019 in pregnancy: living systematic review and meta-analysis. *BMJ.* 2020 Sep 1;370:m3320. doi: 10.1136/bmj.m3320. PMID: 32873575; PMCID: PMC7459193.
3. Metz TD, Clifton RG, Hughes BL, Sandoval G, Saade GR, Grobman WA, Manuck TA, Miodovnik M, Sowles A, Clark K, Gyamfi-Bannerman C, Mendez-Figueroa H, Sehdev HM, Rouse DJ, Tita ATN, Bailit J, Costantine MM, Simhan HN, Macones GA; Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) Maternal-Fetal Medicine Units (MFMU) Network. Disease Severity and Perinatal Outcomes of Pregnant Patients With Coronavirus Disease 2019 (COVID-19). *Obstet Gynecol.* 2021 Apr 1;137(4):571-580. doi: 10.1097/AOG.0000000000004339. PMID: 33560778; PMCID: PMC7984765.
4. Lokken EM, Taylor GG, Huebner EM, Vanderhoeven J, Hendrickson S, Coler B, Sheng JS, Walker CL, McCartney SA, Kretzer NM, Resnick R, Kachikis A, Barnhart N, Schulte V, Bergam B, Ma KK, Albright C, Larios V, Kelley L, Larios V, Emhoff S, Rah J, Retzlaff K, Thomas C, Paek BW, Hsu RJ, Erickson A, Chang A, Mitchell T, Hwang JK, Gourley R, Erickson S, Delaney S, Kline CR, Archabald K, Blain M, LaCourse SM, Adams Waldorf KM; Washington COVID-19 in Pregnancy Collaborative. Higher severe acute respiratory syndrome coronavirus 2 infection rate in pregnant patients. *Am J Obstet Gynecol.* 2021
5. Galang RR, Newton SM, Woodworth KR, Griffin I, Oduyebo T, Sancken CL, Olsen EO, Aveni K, Wingate H, Shephard H, Fussman C, Alaali ZS, Silcox K, Siebman S, Halai UA, Lopez CD, Lush M, Sokale A, Barton J, Chaudhary I, Patrick PH, Schlosser L, Reynolds B, Gaarenstroom N, Chicchelly S, Read JS, de Wilde L, Mbotha D, Azziz-Baumgartner E, Hall AJ, Tong VT, Ellington S, Gilboa SM; Centers for Disease Control and Prevention COVID-19 Response Pregnancy and Infant Linked Outcomes Team. Risk Factors for Illness Severity Among Pregnant Women With Confirmed Severe Acute Respiratory Syndrome Coronavirus 2 Infection-Surveillance for Emerging Threats to Mothers and Babies Network, 22 State, Local, and Territorial Health Departments, 29 March 2020-5 March 2021. *Clin Infect Dis.* 2021 Jul 15;73(Suppl 1):S17-S23. doi:

- 10.1093/cid/ciab432. PMID: 34021332; PMCID: PMC8194562. Jul;225(1):75.e1-75.e16. doi: 10.1016/j.ajog.2021.02.011. Epub 2021 Feb 16. PMID: 33607103; PMCID: PMC7884918.
6. Martinez-Portilla RJ, Sotiriadis A, Chatzakis C, Torres-Torres J, Espino Y Sosa S, Sandoval-Mandujano K, Castro-Bernabe DA, Medina-Jimenez V, Monarrez-Martin JC, Figueras F, Poon LC. Pregnant women with SARS-CoV-2 infection are at higher risk of death and pneumonia: propensity score matched analysis of a nationwide prospective cohort (COV19Mx). *Ultrasound Obstet Gynecol.* 2021 Feb;57(2):224-231. doi: 10.1002/uog.23575. PMID: 33320401.
 7. Kotlyar AM, Grechukhina O, Chen A, Popkhadze S, Grimshaw A, Tal O, Taylor HS, Tal R. Vertical transmission of coronavirus disease 2019: a systematic review and meta-analysis. *Am J Obstet Gynecol.* 2021 Jan;224(1):35-53.e3. doi: 10.1016/j.ajog.2020.07.049. Epub 2020 Jul 31. PMID: 32739398; PMCID: PMC7392880.
 8. Haas EJ, Angulo FJ, McLaughlin JM, Anis E, Singer SR, Khan F, Brooks N, Smaja M, Mircus G, Pan K, Southern J, Swerdlow DL, Jodar L, Levy Y, Alroy-Preis S. Impact and effectiveness of mRNA BNT162b2 vaccine against SARS-CoV-2 infections and COVID-19 cases, hospitalisations, and deaths following a nationwide vaccination campaign in Israel: an observational study using national surveillance data. *Lancet.* 2021 May 15;397(10287):1819-1829. doi: 10.1016/S0140-6736(21)00947-8. Epub 2021 May 5. Erratum in: *Lancet.* 2021 Jul 17;398(10296):212. PMID: 33964222; PMCID: PMC8099315.
 9. Chodick G, Tene L, Rotem RS, Patalon T, Gazit S, Ben-Tov A, Weil C, Goldshtein I, Twig G, Cohen D, Muhsen K. The effectiveness of the TWO-DOSE BNT162b2 vaccine: analysis of real-world data. *Clin Infect Dis.* 2021 May 17:ciab438. doi: 10.1093/cid/ciab438. Epub ahead of print. PMID: 33999127; PMCID: PMC8240867.
 10. FDA. Emergency Use Authorization (EUA) . Pfizer-BioNTech COVID-19 Vaccine/ BNT162b2 <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccine> (Accessed on February 25, 2021).
 11. Emergency Use Authorization (EUA). Moderna COVID-19 Vaccine/mRNA-1273 <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccine> (Accessed on February 25, 2021).
 12. CDC National Center for Immunization & Respiratory Diseases. COVID 19 vaccine safety update. Advisory Committee on Immunization Practices (ACIP) March 1, 2021 <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-02/28-03-01/05-covid-Shimabukuro.pdf> (Accessed on March 02, 2021).
 13. Gray KJ, Bordt EA, Atyeo C, Deriso E, Akinwunmi B, Young N, Baez AM, Shook LL, Cvrk D, James K, De Guzman R, Brigida S, Diouf K, Goldfarb I, Bebell LM, Yonker LM, Fasano A, Rabi SA, Elovitz MA, Alter G, Edlow AG. Coronavirus disease 2019 vaccine response in pregnant and lactating women: a cohort study. *Am J Obstet Gynecol.* 2021 Mar 26:S0002-9378(21)00187-3. doi: 10.1016/j.ajog.2021.03.023. Epub ahead of print. PMID: 33775692; PMCID: PMC7997025.



14. Shimabukuro TT, Kim SY, Myers TR, Moro PL, Oduyebo T, Panagiotakopoulos L, Marquez PL, Olson CK, Liu R, Chang KT, Ellington SR, Burkel VK, Smoots AN, Green CJ, Licata C, Zhang BC, Alimchandani M, Mba-Jonas A, Martin SW, Gee JM, Meaney-Delman DM; CDC v-safe COVID-19 Pregnancy Registry Team. Preliminary Findings of mRNA Covid-19 Vaccine Safety in Pregnant Persons. *N Engl J Med*. 2021 Jun 17;384(24):2273-2282. doi: 10.1056/NEJMoa2104983. Epub 2021 Apr 21. PMID: 33882218; PMCID: PMC8117969.
15. <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/comirnaty-and-pfizer-biontech-covid-19-vaccine>
16. ACOG and SMFM Issue Statement on WHO Recommendations Regarding COVID-19 Vaccines and Pregnant Individuals.
17. Prabhu M, Murphy EA, Sukhu AC, Yee J, Singh S, Eng D, Zhao Z, Riley LE, Yang YJ. Antibody Response to Coronavirus Disease 2019 (COVID-19) Messenger RNA Vaccination in Pregnant Women and Transplacental Passage Into Cord Blood. *Obstet Gynecol*. 2021 Aug 1;138(2):278-280. doi: 10.1097/AOG.0000000000004438. PMID: 33910219; PMCID: PMC8288193.
18. Villar J, Ariff S, Gunier RB, et al. Maternal and Neonatal Morbidity and Mortality Among Pregnant Women With and Without COVID-19 Infection: The INTERCOVID Multinational Cohort Study. *JAMA Pediatr*. 2021;175(8):817–826. doi:10.1001/jamapediatrics.2021.1050
19. Amelia K Wesselink, Elizabeth E Hatch, Kenneth J Rothman, Tanran R Wang, Mary D Willis, Jennifer Yland, Holly M Crowe, Ruth J Geller, Sydney K Willis, Rebecca B Perkins, Annette K Regan, Jessica Levinson, Ellen M Mikkelsen, Lauren A Wise, A Prospective Cohort Study of COVID-19 Vaccination, SARS-CoV-2 Infection, and Fertility, *American Journal of Epidemiology*, 2022;, kwac011, <https://doi.org/10.1093/aje/kwac011>
20. Shimabukuro, Tom T., et al. "Preliminary Findings of MRNA Covid-19 Vaccine Safety in Pregnant Persons ." *New England Journal of Medicine*, vol. 384, no. 24, 17 June 2021, pp. 2273–2282., <https://doi.org/10.1056/NEJMoa2104983>.
21. <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-09-22/09-COVID-Olson-508.pdf>
22. Zauche, Lauren H., et al. "Receipt of MRNA Covid-19 Vaccines and Risk of Spontaneous Abortion." *New England Journal of Medicine*, vol. 385, no. 16, 14 Oct. 2021, pp. 1533–1535., <https://doi.org/10.1056/nejmc2113891>.
23. Halasa NB, Olson SM, Staat MA, et al. Effectiveness of Maternal Vaccination with mRNA COVID-19 Vaccine During Pregnancy Against COVID-19–Associated Hospitalization in Infants Aged <6 Months — 17 States, July 2021–January 2022. *MMWR Morb Mortal Wkly Rep* 2022;71:264–270. DOI: <http://dx.doi.org/10.15585/mmwr.mm7107e3>
24. Lipkind HS, Vazquez-Benitez G, DeSilva M, et al. Receipt of COVID-19 Vaccine During Pregnancy and Preterm or Small-for-Gestational-Age at Birth — Eight Integrated Health Care Organizations, United States, December 15, 2020–July 22, 2021. *MMWR Morb Mortal Wkly Rep* 2022;71:26–30. DOI: <http://dx.doi.org/10.15585/mmwr.mm7101e1>

COVID THERAPEUTICS

Quick Reference for Perinatal Prescribers

What therapeutic options are available for pregnant COVID positive patients?

| Therapeutic | Reduction In hospitalization & death | Route | Treatment Initiation from Symptom Onset | Treatment Duration | Considerations | Preference |
|---|---|-------|---|--------------------|---|--|
| Paxlovid (Nirmatrelvir/ Ritonavir) 300mg/100mg po BID x 5days | 88% | Oral | Within 5 days | 5 days | Patients age 12+ and ≥ 40kg Multiple drug interactions Adjust dosing for renal impairment Not recommended in severe hepatic impairment | Preferred - Tier 1 |
| Remdesivir | 87% | IV | Within 7 days | 3 days (1-2 hr) | Patients ≥ 3.5kg Renal and hepatic considerations | Preferred - Tier 2 |
| Bebtelovimab | Clinical trial not powered or designed to determine difference in clinical outcomes | IV | Within 7 days | 1 minute | Patients age 12+ and ≥ 40kg | Alternative - Tier 3 Utilize only when preferred therapies are contraindicated or unavailable. |
| Molnupiravir 200mg 4 tabs po BID x 5 days | 30% | Oral | Within 5 days | 5 days | Patients age 18+ Not recommended in pregnancy Contraceptive recommendations for males and females. | Alternative - Tier 3 Not recommended in pregnancy May be considered in pregnancy if all other therapies are unavailable, patient is at >10 weeks gestation, patient is fully informed of all risks, and documentation of patients informed decision is made. |

Where should I refer a patient for IV treatments (Remdesivir or Bebtelovimab)?

Check cv.nmhealth.org/treatments for a list of providers. Send a referral. Appointments may be required.

How do I prescribe oral therapeutics?

- Please check cv.nmhealth.org/treatments for a list of pharmacy locations. **Ask patients to use the drive-thru.**
- Please include date of symptom onset. It helps ensure the patient receives the medication within the treatment window.

Where can I find up-to-date NIH treatment recommendations for non-hospitalized adults?

www.covid19treatmentguidelines.nih.gov

COVID-19 Drug Interaction tool:

<https://www.covid19-druginteractions.org>

QUESTIONS? EMAIL COVID.THERAPEUTICS@STATE.NM.US

For more information, visit CV.NMHEALTH.ORG and click on the provider information tab



COVID THERAPEUTICS

Quick Reference for Perinatal Prescribers

PAXLOVID

NIH treatment panel recommends Paxlovid for pregnant patients because the potential benefits outweigh the risk.¹

REMEDSIVIR

According to NIH treatment guidelines, Remdesivir should not be withheld from pregnant patients if it is otherwise indicated. Pregnant patients were excluded from the clinical trials that evaluated the safety and efficacy of remdesivir. Preliminary reports of remdesivir use in pregnant patients from small studies and case reports are reassuring. Among 86 pregnant and postpartum hospitalized patients with severe COVID-19 who received compassionate use remdesivir, the therapy was well-tolerated, with a low rate of serious adverse effects.²

NIH funded study IMPAACT 2032 will compare remdesivir use in pregnant and non-pregnant women of reproductive age who are hospitalized with COVID-19.³

BEBTELOVIMAB

According to NIH, bebtelovimab should not be withheld during pregnancy.

The use of bebtelovimab can be considered for pregnant people with COVID-19, especially those who have additional risk factors for severe disease. Bebtelovimab would be expected to cross the placenta. There are no pregnancy-specific data. However, other IgG products have been safely used in pregnant people when their use is indicated.⁴

MOLNUPIRAVIR

The FDA EUA states that molnupiravir is not recommended for use in pregnant patients due to concerns about the instances of fetal toxicity observed during animal studies.

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 risks, particularly if they are beyond the time of embryogenesis (i.e., >10 weeks' gestation). The prescribing clinician should document that a discussion of the risks and benefits occurred, and that the patient chose this therapy.⁵

References

1. <https://www.covid19treatmentguidelines.nih.gov/management/clinical-management/nonhospitalized-adults--therapeutic-management/>
2. <https://www.covid19treatmentguidelines.nih.gov/therapies/antiviral-therapy/remdesivir/>
3. <https://www.nih.gov/news-events/news-releases/nih-funds-study-evaluate-remdesivir-covid-19-pregnancy#:~:text=Although%20it%20has%20not%20been,pregnant%20women%20with%20COVID%2D19>
4. <https://www.covid19treatmentguidelines.nih.gov/therapies/anti-sars-cov-2-antibody-products/anti-sars-cov-2-monoclonal-antibodies/>
5. <https://www.covid19treatmentguidelines.nih.gov/therapies/antiviral-therapy/molnupiravir/>

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