Pregnant women and COVID-19

For outpatient treatment of COVID in pregnant patients - are you prioritizing any particular treatment?

An outpatient provider was interested in sotrovimab vs 3 day remdesivir as Paxlovid is not currently available in our area.

date: 1/25/22

What is the risk for pregnant patients?

Among 1,249,634 delivery hospitalizations during March 2020–September 2021:

- women with COVID-19 were at increased risk for stillbirth compared with women without COVID-19
  - adjusted relative risk = 1.90; 95% CI = 1.69–2.15).

Pregnancy had Limited Representation in Patients in Clinical Trials but Are Considered Risk Factors for Progression to Severe COVID-19 by the Centers for Disease Control and Prevention

NIH: Patient Prioritization: 4 Tiers

Updated December 23, 2021

WHERE do pregnant patients fit?

https://www.covid19treatmentguidelines.nih.gov/therapies/statement-on-patient-prioritization-for-outpatient-therapies/

Tier	Risk Group
1	• Immunocompromised individuals not expected to mount an adequate immune response to COVID-19 vaccination or SARS-CoV-2 infection due to their underlying conditions, regardless of vaccine status (see Immunocompromising Conditions below); *or* • Unvaccinated individuals at the highest risk of severe disease (anyone aged ≥75 years or anyone aged ≥65 years with additional risk factors).
2	• Unvaccinated individuals at risk of severe disease not included in Tier 1 (anyone aged ≥65 years or anyone aged <65 years with clinical risk factors)
3	• Vaccinated individuals at high risk of severe disease (anyone aged ≥75 years or anyone aged ≥65 years with clinical risk factors) **Note:** Vaccinated individuals who have not received a COVID-19 vaccine booster dose are likely at higher risk for severe disease; patients in this situation within this tier should be prioritized for treatment.
4	• Vaccinated individuals at risk of severe disease (anyone aged ≥65 years or anyone aged <65 with clinical risk factors) **Note:** Vaccinated individuals who have not received a COVID-19 vaccine booster dose are likely at higher risk for severe disease; patients in this situation within this tier should be prioritized for treatment.

WA state prioritization slightly different

The following recommendations should be used to prioritize equitable administration for those individuals who might receive the greatest benefit from anti-SARS-CoV-2 mAb treatment. These recommendations for allocating access to sotrovimab are not prescriptive, but rather should be used in the context of clinical decision-making with consideration given to other community factors.

- Prioritize patients diagnosed with COVID-19 who present with symptoms ≤ 7 days.
- Prioritize patients who are hospitalized for a diagnosis other than COVID-19, provided they have mild to moderate COVID-19 and are at high risk for progressing to severe disease.
- Among those individuals who are fully vaccinated with a primary series and up to date with a booster, limit use to those who are:
    - ≥ 70 years of age
    - Moderately-to-severely immunosuppressed
    - Women who are pregnant, especially those with comorbidities

https://www.doh.wa.gov/Emergencies/COVID19/Therapeutics/HealthCareProviders

IV Sotrovimab

- ✓ monoclonal antibodies can be considered in pregnant people with COVID-19, especially in those who have additional risk factors for severe disease.
- ✓ no pregnancy-specific data on the use of monoclonal antibodies;
  - ✓other immunoglobulin G products have been safely used in pregnancy when their use is indicated.
- ✓Therefore, these products should not be withheld in the setting of pregnancy.

IV Remdesivir

- ✓ should not be withheld from pregnant patients if it is otherwise indicated
- ✓Most of the published clinical experience with remdesivir in pregnant women comes from Gilead's global safety database, which includes both Ebola virus and COVID-19 patients; and the COVID-19 compassionate use program
- ✓> 67 cases COVID-19
  - ✓Median gestational age: 28 weeks
  - ✓ Amongst 26 deliveries, 69% were delivered very preterm (24–32 weeks gestation).
  - ✓No neonatal deaths

J Antimicrob Chemother 2021 Dec 24;77(1):24-30

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Early Remdesivir to Prevent Progression to Severe Covid-19 in Outpatients

R.L. Gottlieb, C.E. Vaca, R. Paredes, J. Mera, B.J. Webb, G. Perez, G. Oguchi, P. Ryan, B.U. Nielsen, M. Brown, A. Hidalgo, Y. Sachdeva, S. Mittal, O. Osiyemi, J. Skarbinski, K. Juneja, R.H. Hyland, A. Osinusi, S. Chen, G. Camus, M. Abdelghany, S. Davies, N. Behenna-Renton, F. Duff, F.M. Marty,* M.J. Katz, A.A. Ginde, S.M. Brown, J.T. Schiffer, and J.A. Hill, for the GS-US-540-9012 (PINETREE) Investigators†

Study Population:

RCT of unvaccinated ambulatory COVID-19 patients with symptom onset ≤ 7 days and who had at least one risk factor for disease progression

Intervention:

Remdesivir (200 mg on day 1 and 100 mg on days 2 and 3) or placebo

Primary Endpoint:

Composite of Covid-19– related hospitalization or death from any cause by day 28

Findings:

Remdesivir led to 87% lower risk of hospitalization or death
HR 0.13; (95% CI: 0.03-0.59)

Comparison

	IV Sotrovimab	IV Remdesivir
Efficacy in non-pregnant	85% relative risk reduction in death or hospitalization than placebo	87% lower risk of hospitalization or death than placebo
Safety in pregnancy	Safe	Safe
Infusion days	30 min infusion x1	30 minute infusion x 3 days
Cost/Supply	Free/ limited supply	$2K per course/Available

Paxlovid

“SMFM supports the use of Paxlovid (nirmatrelvir tablets and ritonavir tablets) for treatment of pregnant patients with COVID-19 who meet clinical qualifications. Any therapy that would otherwise be given should not be withheld specifically due to pregnancy or lactation.”

There are no available data on the presence of nirmatrelvir in human or animal milk, the effects on the breastfed infant, or the effects on milk production.

https://s3.amazonaws.com/cdn.smfm.org/media/3287/Treatment_1.10.pdf

Molnupiravir

Pregnancy: not recommended during pregnancy.

- individuals of childbearing potential to use effective contraception correctly and consistently, as applicable, for the duration of treatment and for 4 days after the last dose of molnupiravir.
- Based on animal studies, molnupiravir may cause fetal harm when administered to a pregnant individual.
- Prior to initiating treatment with molnupiravir, assess whether an individual of childbearing potential is pregnant or not, if clinically indicated
- Surveillance program: pregnancyreporting.msd.com
- Lactation:

is not recommended during treatment and for 4 days after the last dose of molnupiravir.

- A lactating individual may consider interrupting breastfeeding and may consider pumping and discarding breast milk during treatment and for 4 days after the last dose of molnupiravir.