Fact Sheet on Remdesivir for the Outpatient Treatment of Covid-19

You are being offered a medication called remdesivir for the treatment of coronavirus disease 2019 (Covid-19). This fact sheet has been developed by UCLA Health to help guide your decision to choose this treatment.

What is Covid-19?
Covid-19 is caused by a virus called coronavirus. People can get Covid-19 through contact with another person who has the virus.

Covid-19 illnesses have ranged from very mild to severe including illnesses resulting in death. While information so far suggests that most Covid-19 illness is mild, serious illness can happen and may cause other medical conditions to become worse. People of all ages with severe long-lasting medical conditions like heart disease, lung disease, diabetes, obesity or conditions where their immune systems are not functioning as well are at higher risk of being hospitalized for Covid-19. Older age, with or without other conditions, also places people at higher risk of being hospitalized for Covid-19.

What is remdesivir?
Remdesivir is an antiviral drug was first given FDA approval to treat hospitalized patients with Covid-19 on October 20, 2020. It has been the main treatment for patients hospitalized with Covid-19 since that time. Early studies on remdesivir in this population did not show a benefit in preventing death, but did show a reduction in time to recovery and allowed patients to get out the hospital faster.[1,2]

The recent PINETREE study published in the New England Journal of Medicine on December 22, 2021 demonstrated that among unvaccinated patients who were randomized to receive remdesivir within 7 days of symptoms there was an 87% reduction in risk of hospitalizations and death.[3]

Remdesivir was given FDA approval for outpatient treatment on January 21, 2022.[4]

Given this, the NIH Covid-19 Treatment Guidelines Panel has determined that a three-day course remdesivir may be considered to treat non-hospitalized patients with mild-moderate Covid-19 infection who are at high risk of clinical progression.[5] The NIH prioritizes this drug over other infusions in the outpatient setting including bebtelovimab, a monoclonal antibody that has emergency use authorization by the FDA, but little clinical data.

What are the ingredients in remdesivir?
In addition to the active ingredient remdesivir, the solution contains betadex sulfobutyl ether sodium and may include hydrochloric acid and/or sodium hydroxide for pH adjustment.

What should I tell my healthcare provider before I receive remdesivir?
Tell your healthcare provider about all of your medical conditions, including if you:

Have any serious allergies
Have had a serious allergic reaction to remdesivir or any of the ingredients in remdesivir
Are pregnant or plan to become pregnant (this may not exclude you from getting it)
Are breastfeeding or plan to breastfeed
Have any other serious illnesses
Are taking any medicines.

How will I receive remdesivir?
The drug is administered as follows:
Remdesivir 200mg IV on day 1
Remdesivir 100mg IV on day 2-3

You will be observed by your healthcare provider for 1 hour after you receive the initial loading dose and then for 30 minutes after you receive the subsequent doses.

The initial infusion will take 60 minutes, followed by an hour of observation. Subsequent infusions may take 30 minutes with an additional 30 minutes of observation.

What are major side effects?

Major adverse effects have been noted as follows: nausea, headache, infusion related reactions, elevated liver enzymes. We will obtain a baseline liver function test on the first day of your infusion.

As with any medications, allergic reactions are a possible side effect. Signs of an allergic reaction include shortness of breath or rash.

Your healthcare provider will be able to administer medication to treat any allergic reaction.

What are other available treatment choices?
Bebtelovimab is a monoclonal antibody that has emergency use authorization by the FDA. There are fewer clinical data with bebtelovimab than with remdesivir. However, both are presumed to work against the current circulating variants.

You are likely being offered these options because you are not eligible for Paxlovid, an oral antiviral, because you are either outside the window or you are on medications that have multiple contraindications.

What if I am pregnant or breastfeeding?
We have had some experience with remdesivir with pregnant women in the hospital setting. The PINETREE study did not include pregnant women. However, in select cases the benefit of receiving treatment may outweigh the risks.

How do I report side effects with remdesivir:

Report side effects to FDA MedWatch at www.fda.gov/medwatch or call 1-800-FDA-1088.

How can I learn more?
Ask your healthcare provider
Visit https://www.vekluryhcp.com/

Please see this table for a summary of all outpatient antiviral therapies.

Table 1: Available Options and Considerations

	Paxlovid (nirmatrelavir/ritonavir)	Remdesivir	Bebtelovimab
Standard Dose	Nirmatrelvir 300mg (two 150 mg tablets) with 100 mg ritonavir (one 100mg tablet), with all three tablets taken together twice daily for 5 days with or without food	200mg IV day 1 100mg IV d2-3	Bebtelovimab 175mg IV x1
Window	5 days from sx onset	7 days from sx onset	7 days from sx onset
Efficacy	89% risk reduction	87% risk reduction	Bebtelovimab no clinical data
Drug Interactions	-Substrate and inhibitor of CYP3A4 -**Review Appendix A**, the drug EUA, and https://www.covid19-druginteractions.org/checker	No significant interaction; hydroxychloroquine lowers remdesivir activity	None
Pregnancy/ Lactation	Limited data, must be approved by MFM	Limited data, generally considered safe	Limited data, generally considered safe
Renal adjustment	-For eGFR ≥30 ml/min and ≤60 ml/min: decrease dose to 150 mg nirmatrelvir (one 150 mg tablet) and 100 mg ritonavir (one 100 mg tablet) twice daily x 5 days with or without food -Not recommended for eGFR < 30 ml/min	Discuss with pharmacy if eGFR <30	No adjustment
Hepatic adjustment	Not recommended in severe impairment	Not recommended if AST/ALT >10 x ULN	No adjustment

[1]Gottlieb RL, Vaca CE, Paredes R, Mera J, Webb BJ, Perez G, Oguchi G, Ryan P, Nielsen BU, Brown M, Hidalgo A, Sachdeva Y, Mittal S, Osiyemi O, Skarbinski J, Juneja K, Hyland RH, Osinusi A, Chen S, Camus G, Abdelghany M, Davies S, Behenna-Renton N, Duff F, Marty FM,
Beigel JH, Tomashek KM, Dodd LE, Mehta AK, Zingman BS, Kalil AC, Hohmann E, Chu HY, Luetkemeyer A, Kline S, Lopez de Castilla D, Finberg RW, Dierberg K, Tapson V, Hsieh L, Patterson TF, Paredes R, Sweeney DA, Short WR, Touloumi G, Lye DC, Ohmagari N, Oh MD, Ruiz-Palacios GM, Benfield T, Fätkenheuer G, Kortepeter MG, Atmar RL, Creech CB, Lundgren J, Babiker AG, Pett S, Neaton JD, Burgess TH, Bonnett T, Green M, Makowski M, Osinusi A, Nayak S, Lane HC; ACTT-1 Study Group Members. Remdesivir for the Treatment of Covid-19 - Final Report. N Engl J Med. 2020 Nov 5;383(19):1813-1826. doi: 10.1056/NEJMoa2007764. Epub 2020 Oct 8. PMID: 32445440; PMCID: PMC7262788.

[2]WHO Solidarity Trial Consortium, Pan H, Peto R, Henao-Restrepo AM, Preziosi MP, Sathiyamoorthy V, Abdool Karim Q, Alejandria MM, Hernández García C, Kieny MP, Malekzadeh R, Murthy S, Reddy KS, Roses Periago M, Abi Hanna P, Ader F, Al-Bader AM, Alhasawi A, Allum E, Alotaibi A, Alvarez-Moreno CA, Appadoo S, Asiri A, Aukrust P, Barratt-Due A, Bellani S, Branca M, Cappel-Porter HBC, Cerrato N, Chow TS, Como N, Eustace J, García PJ, Godbole S, Gotuzzo E, Griskevicius L, Hamra R, Hassan M, Hassany M, Hutton D, Irmansyah I, Jancoriene L, Kirwan J, Kumar S, Lennon P, Lopardo G, Lydon P, Magrini N, Maguire T, Manevska S, Manuel O, McGinty S, Medina MT, Mesa Rubio ML, Miranda-Montoya MC, Nel J, Nunes EP, Perola M, Portolés A, Rasmin MR, Raza A, Rees H, Reges PPS, Rogers CA, Salami K, Salvadori MI, Sinani N, Sterne JAC, Stevanovikj M, Tacconelli E, Tikkinen KAO, Trelle S, Zaid H, Røttingen JA,

Swaminathan S. Repurposed Antiviral Drugs for Covid-19 - Interim WHO Solidarity Trial Results. N Engl J Med. 2021 Feb 11;384(6):497-511. doi: 10.1056/NEJMoa2023184. Epub 2020 Dec 2. PMID: 33264556; PMCID: PMC7727327.
Format:

[3]Katz MJ, Ginde AA, Brown SM, Schiffer JT, Hill JA; GS-US-540-9012 (PINETREE) Investigators. Early Remdesivir to Prevent Progression to Severe Covid-19 in Outpatients. N Engl J Med. 2021 Dec 22. doi: 10.1056/NEJMoa2116846. Epub ahead of print. PMID: 34937145.

[4]https://www.fda.gov/news-events/press-announcements/fda-takes-actions-expand-use-treatment-outpatients-mild-moderate-covid-19

[5]https://www.covid19treatmentguidelines.nih.gov/therapies/statement-on-anti-sars-cov-2-mabs-and-rdv-and-omicron/