

PATIENT CONSENT FORM FOR COVID-19 TREATMENT

PURPOSE OF INFORMED CONSENT

As your physician has discussed with you, you have been diagnosed (or diagnosis is highly suspected) with novel COVID-19 (or SARS-CoV-2). At the present time, there are no FDA (Food and Drug Administration) approved, or clinically proven therapies for treatment of COVID-19. As new clinical data emerges, local treatment guidelines have been developed and will be updated as new information becomes available. Ventura County Medical Center (VCMC) and Santa Paula Hospital (SPH) guidelines reflect what is known about therapies that may work against the SARS-CoV-2 virus, have been used to treat other coronaviruses, or may theoretically target the underlying causes of virus-related severe lung conditions that make breathing difficult.

All therapies offered at VCMC & SPH for COVID-19 are considered “off-label”, meaning they have been approved by the FDA to treat other diseases and conditions, but not COVID-19. Once a medication is approved by the FDA, the FDA depends on doctors to exercise professional judgment in prescribing that medication in a way that is beneficial to the patient. The FDA does not prohibit the use of medications in an “off-label” manner.

The following medications are being considered for off-label use for COVID-19:

Remdesivir

Tocilizumab

Dexamethasone

Convalescent Plasma

Other: _____

In order for you to be treated with the medication(s) listed above, you must sign this form to show that you agree to this off-label use and that you have been informed of the benefits and risks of taking such medications for off-label use, as well as the benefits and risks of declining or refusing such off-label use. **You have the right to refuse to take this medication(s) for any reason.**

The evidence at this time is not clear as to whether the proposed treatment will be beneficial. If you decline this off-label use of the recommended medication(s), you will still be provided all standard treatments but your condition may deteriorate despite use of standard treatments. Even with the recommended proposed off-label medication, your condition may deteriorate. However, due to the serious nature of COVID-19, no FDA approved medication, and no availability of clinical trials, an off-label medication is offered in the hope it could benefit you.

BACKGROUND

Remdesivir is an anti-viral medication that may help stop the virus from replicating in your body. Remdesivir was shown in a clinical trial to shorten the time to recovery in some people with COVID-19. The FDA has issued an Emergency Use Authorization (EUA) to permit the use of this unapproved medication in hospitalized patients with confirmed or suspected COVID-19. Clinical trials are ongoing to study its efficacy.

Dexamethasone is a corticosteroid medication that is used for a variety of conditions for its anti-inflammatory and immunosuppressant effects. It has been tested in clinical trials and may have benefit for those with COVID-19 pneumonia. Dexamethasone is not approved by the FDA for treatment of COVID-19.

Tocilizumab is an antibody (immune system protein) that blocks certain inflammatory processes in your body. By inhibiting or blocking these inflammatory processes, these medications may limit the damage COVID-19 causes to your lungs. Tocilizumab is an FDA- approved medication for the treatment of rheumatoid arthritis. It has not been approved by the FDA for the treatment of COVID-19.

Convalescent Plasma. People who recover from COVID-19 do so, at least in part, because their blood contains substances called antibodies, which are capable of fighting the virus that causes the illness. For some other diseases caused by respiratory viruses, giving people the liquid portion of blood, called plasma, obtained from those who have recovered from the virus, leads to more rapid improvement of the disease. Patients with COVID-19 may improve faster if they receive plasma from those who have recovered from COVID-19, because it may have the ability to fight the virus that causes COVID-19.



For other medications: list background rationale below:

DOSE AND ADMINISTRATION

Remdesivir – 200mg intravenously on day one, followed by 100mg intravenously daily to complete five days total

Dexamethasone – 6mg intravenously or orally, daily for 10 days

Tocilizumab – 400 mg intravenously for one dose

Convalescent Plasma – 1 unit of donor matched plasma infused intravenously once

Other: _____

You will be monitored for improvement or worsening in COVID-19 symptoms, for any signs of new infections, and for signs of latent tuberculosis infection. It is anticipated that blood will be drawn on a daily basis to monitor your condition. Your liver function will be monitored at least weekly.

POSSIBLE BENEFITS

It is possible that the medications listed above may help to control your symptoms, slow or stop the growth of the virus, shorten the duration or lessen the severity of the illness in you. Possible benefits primarily include improvement in lung function (ability to breathe without assistance) and normalization of blood pressure.

However, given the off-label use of the medication(s) there is the possibility that these medications may be of NO direct medical benefit to you. Your condition may get worse.

POSSIBLE RISKS AND KNOWN SIDE EFFECTS

It is possible that the medication prescribed may not improve your symptoms and not shorten the duration nor severity of the illness. It is possible that the medication will unexpectedly interfere with your ability to improve, hastens damage to the lungs or other organs, and shortens your life.

Remdesivir: There are limited clinical data available for remdesivir and unexpected adverse events may occur that have not been previously reported. Side effects may include the need for increased liver function tests, in addition to nausea, vomiting, and low blood pressure during infusion.

Dexamethasone: Corticosteroids can result in elevated blood sugar, high blood pressure, water retention, and difficulty sleeping. They may also increase the risk of other infections with bacteria, fungus, and reactivation of tuberculosis.

Tocilizumab: Many patients receive tocilizumab on a long-term basis for chronic conditions such as rheumatoid arthritis. As your physician is advising that you take only a single dose of this medication, side effects of a single dose of these medications are expected to be limited, but may include: injection site reactions, headache, high blood pressure, impaired liver function, reduced blood cell counts, perforation of the intestines and development of other infections including tuberculosis (TB) which may be serious or life-threatening.

Additionally, the FDA advises that testing for latent TB be conducted prior to administration of the medication and that if the test is

positive, that treatment for latent TB be initiated prior to administration of the medication. This is to prevent development of active TB. As your physician has discussed with you, due to the severity of your COVID-19 symptoms, by agreeing to this off-label use you agree to administration of tocilizumab prior to the availability of your test results for latent TB. You further agree and understand that should test results for latent TB turn out to be positive, treatment for TB will then be initiated after tocilizumab may have been administered.

Convalescent Plasma: Although the risk of contracting COVID-19 infection from receiving the treatment has not been formally tested yet, we believe that it would be very low because the donor has fully recovered from the infection. Transfusion also carries the risk of adverse reactions such as allergic reactions, transfusion-associated circulatory overload or lung damage with profound breathing difficulty, and transmission of infections including HIV and Hepatitis B and C. However, the risk of these infections is very low, as only screened and compatible blood is used for transfusion.

Other: list side effects/risks below

For more information about risks and side effects, please ask your physician. Please be advised that not all risks and side effects in the context of COVID-19 are known. Your physician may give you medication to help lessen the side effects. Some side effects are temporary. In some cases, side effects can be serious and can last a long time. Sometimes they never go away.

CERTIFICATION AND SIGNATURES

I have read this informed consent form and all of my questions have been answered to my satisfaction by my physician. I understand that I have the right to refuse to take this medication(s) for any reason. If I choose not to take this medication(s), this decision will not otherwise affect my status as a patient. I voluntarily consent to take the medication(s) indicated on the first page of this document as discussed with my physician and as described in this consent form.

Name of Patient: _____

Signature of Patient: _____ Date: _____ Time: _____

If patient is a minor; or is unable to sign, Indicate reason (ex: patient in COVID isolation): _____

Name of Person Signing for the Patient: _____

Signature of Person Signing for the Patient: _____ Date: _____ Time: _____

Name of Witness: _____

Signature of Witness: _____ Date: _____ Time: _____

Witness to complete for translation (if applicable):

Translated by: _____ Language used: _____

Relationship to Patient: _____ Date: _____ Time: _____