

Authorization and Informed Consent

I have discussed with my healthcare provider the use of a recommended treatment plan based upon the FLCCC protocol (as modified by my provider) for use in reducing the risk of and/or treatment for COVID-19.

I understand the medical controversies surrounding the elements of the treatment plan, the view of public health agencies, potential adverse reactions, side effects, and contraindications. I have also discussed any FDA-approved therapies for COVID-19 treatment, such as Paxlovid and Molnupiravir. I have been able to ask questions, review materials, and make my own choice.

I understand there is no guarantee that this treatment plan will prevent me from becoming infected with or transmitting the SARS-CoV-2 virus. I understand there is no guarantee as to the outcome of any illness. I agree to assume the risks that could arise, including those which have been explained and which my provider could not have foreseen.

I have requested that my provider prescribe/recommend these treatments. I have been adequately informed about the clinical and legal status of these therapies and any questions I have asked have been satisfactorily answered. I understand and agree to the financial and other notices that have been provided.

I have read and signed the attached sheets for specific treatments prescribed and/or recommended. (Specific information about treatments your provider has recommended is attached for your review and for discussion with your provider.)

Medical Controversies: This use of ivermectin, in particular, has been the subject of professional disagreement and substantial public misinformation. There are also differences of opinion about the significance of clinical evidence for the use of Fluoxetine, Nitazoxanide, Spironolactone, and Nigella Sativa as well as Vitamin C, D3, quercetin, zinc, and melatonin in COVID-19, which may be suggested by your provider as part of your treatment plan. There has been a growing recognition that these nutrients have an important role to play in the course of infection with a coronavirus. Vitamin D deficiency is particularly correlated with poorer outcomes. The medical community has historically been skeptical of therapeutic uses for nutrients and public health officials have acknowledged that there is suggestive evidence but have not made these recommendations. There is evidence that the recommended viricidal mouthwash gargles can reduce viral load with some associated with reduced need for hospitalization when used.

Public Health Measures: The FLCCC prevention protocol (I-PREVENT) is intended to be used as part of an overall strategy that includes common sense public health actions like washing your hands, avoiding crowded gatherings, getting adequate ventilation, and other measures. It can be used by vaccinated or

unvaccinated individuals to enhance protection, particularly where exposure is known, or where an occupational risk exists. The long COVID and post-vaccine (I-RECOVER) protocols are intended to help treat the often-disabling symptoms that recur or persist after recovery from the acute phase of COVID-19 or after vaccination with COVID-19 injections. Patients following these protocols, whether to reduce the risk of contracting the disease or as treatment, cannot assume they are therefore at any less risk of spreading the disease.

Possible Drug Contraindications and Adverse Effects. Please review and sign the attached sheets for the prescribed recommended drugs and dietary supplements.

Additional Notices

Notice to Pregnant/Nursing Women: Alert your healthcare provider if you know or suspect you are pregnant or if you are breastfeeding an infant.

No Guarantees: The optimal prevention and treatment of COVID-19 is still being determined, there are significant individual differences between patients, and there can be no guarantees that a patient will gain any benefit or not suffer any adverse consequences.

Insurance Notice/Financial Responsibility: Patients are responsible for payment at the time of service. This prescription or related office visit may be considered non-covered or denied as “not medically necessary” or as an “experimental” treatment. Patients are responsible for understanding their medical and pharmaceutical coverage and are financially responsible without regard to any denial or other determination by their insurance carrier.

Dated:

Signature of Patient or Legal Guardian

Patient's Printed Name

ATTACHMENT 1: IVERMECTIN

Off-Label Use. Ivermectin is approved for and widely used for the treatment of parasites. It has not been reviewed and approved by the U.S. Food and Drug Administration (FDA) for use in COVID-19 or any other viral illness. As such, its use for COVID-19 is considered “off-label.” The FDA and CDC have cautioned about the possibility of potentially serious side effects at high doses.

Medical Controversies. The use of ivermectin for COVID-19 has been the subject of professional disagreement and substantial public misinformation. The medical literature contains a significant number of clinical studies, meta-analyses, and systematic reviews that analyze available studies, including epidemiological investigations following populations that have used ivermectin in the prevention or early treatment of COVID-19. Some meta-analyses have concluded that ivermectin is safe, with moderate to strong, statistically significant effectiveness, particularly at the early stages of the disease. Others found the evidence as yet inconclusive, and research is ongoing. Conclusions vary in part because of the level of dosing used in some studies, and because of disagreements over how some studies were designed and conducted.

Part of a Combination Therapy. The use of ivermectin is part of a protocol developed by FLCCC, in combination with other therapies, to address COVID-19 and works best when followed in its entirety rather than relying entirely on ivermectin.

Timing. In treatment for COVID-19, ivermectin has the best chance to work when taken early in the course of the disease. Treatment should be started as soon as possible.

Dosing. Concerns regarding ivermectin arise in part because it requires higher dosing to achieve antiviral and therapeutic impacts than the doses originally approved for parasitic diseases. Dose levels vary by patient weight and stage of the disease.

Variants. Many of the studies on ivermectin were conducted before the emergence of the Delta and Omicron variants, which create much higher viral loads than previous variants. The clinical experience of providers treating with ivermectin shows that it still has clinical effectiveness, though higher doses or additional medications may be required.

Veterinary Forms. Patients should only take medications prescribed and obtained from a pharmacy. Patients should not take veterinary ivermectin or purchase medications without a prescription on the internet, as these forms may contain higher concentrations of impurities and are of unknown safety to humans.

Public Health Agency Positions. Ivermectin is not authorized or approved by the FDA for the prevention or treatment of COVID-19. The National Institutes of Health (NIH) COVID-19 Treatment Guidelines Panel recommends against the use of ivermectin for the treatment of COVID-19, except in clinical trials. The World Health Organization also recommends that the drug only be used within clinical trials.

Potential Side Effects. Ivermectin has been administered in over 4 billion doses worldwide for parasitic diseases and is generally considered to have an excellent safety profile. Side effects are generally mild and can include gastrointestinal symptoms such as nausea, vomiting, and diarrhea; hypotension and neurologic effects such as low blood pressure, anemia, headache, blurred vision, dizziness, tachycardia, visual hallucinations, altered mental status, confusion, loss of coordination and balance, orthostatic hypotension, central nervous system depression, and seizures. Cardiovascular side effects have included myocardial infarction and tachycardia but these are rare. EKG changes have been reported in rare cases including prolonged PR interval, flattened T waves and peaked T waves. Significant overdoses are associated with effects such as decreased consciousness, confusion, hallucinations, seizures, coma, and death. Other adverse events that have been reported include acidosis, kidney injury, elevated liver enzymes. Patients should discuss any concerns about potential side effects with their provider before beginning treatment.

Get emergency medical help if you have signs of an allergic reaction to Ivermectin: hives; difficult breathing; swelling of your face, lips, tongue, or throat.

Drug interactions. Ivermectin has few major drug interactions; the most notable are with the anti-coagulant warfarin and immunosuppressive medications most often taken by organ transplant recipients. Some drugs can enhance or reduce the blood levels and effects of ivermectin. Make sure your provider has reviewed all the other medicines that you are taking.

Date:

Patient signature

ATTACHMENT 2: NITAZOXANIDE

Nitazoxanide (NTZ) is an antiprotozoal medicine usually used to treat infections caused by protozoa (single-cell parasites that live in moist places such as lakes, streams, and soil). The combination of NTZ and ivermectin has been shown to reduce viral clearance and symptom progression in outpatients with COVID-19. NTZ should be considered as an alternative to ivermectin, or as part of a multi-drug combination that includes ivermectin.

Possible contraindications. Be sure to tell your provider if you have liver or kidney disease; HIV or AIDS; or a weakened immune system.

Potential Adverse Effects. Nitazoxanide can cause abdominal pain, headache, abnormal urine color, nausea, and diarrhea. It can also cause dizziness, heartburn, hives or welts, itching or skin rash, redness of the skin, trouble breathing, or vomiting. These generally do not require immediate medical attention unless they are particularly bothersome or persistent.

Date:

Patient signature

ATTACHMENT 3: FLUOXETINE

Fluoxetine (Prozac) is a selective serotonin reuptake inhibitor (SSRI) antidepressant. There has been evidence suggesting its use is significantly and substantially associated with reduced risk of intubation or death due to antiviral effects. SSRIs can take up to 4 weeks to have an effect on mood. Use for COVID will likely be shorter-term and discontinued prior to obtaining psychiatric effects. Dosing and discontinuation should be done under medical supervision.

Contraindications. Inform your provider if you take any of these medications, as you should not use fluoxetine with thioridazine, linezolid, pimozide, or methylene blue injection. Patients already on an SSRI (such as Celexa, Lexapro, Paxil, or Zoloft) or who have used an MAO inhibitor in the past 14 days (such as Marplan, Nardil, Parnate, Emsam, Azilect, or Eldepyrl) should not take fluoxetine. You must wait at least 14 days after stopping an MAO inhibitor before you take fluoxetine. You must wait 5 weeks after stopping fluoxetine before you can take thioridazine or an MAOI.

Potential Adverse Effects. Some people, especially the young, have acute anxiety or thoughts about suicide when first taking an antidepressant. Stay alert to changes in mood or symptoms. Fluoxetine could impair judgment, thinking, or motor skills. Use caution when operating machinery. Report any new or worsening symptoms to your healthcare provider, such as: mood or behavior changes, anxiety, panic attacks, trouble sleeping, or if you feel impulsive, irritable, agitated, hostile, aggressive, restless, hyperactive (mentally or physically), more depressed, or have thoughts about suicide or hurting yourself.

Alert your provider at once if you have blurred vision, tunnel vision, eye pain or swelling, or you are seeing halos around lights; fast or pounding heartbeats, fluttering in your chest, shortness of breath, and sudden dizziness (like you might pass out); low levels of sodium in the body - headache, confusion, slurred speech, severe weakness, vomiting, loss of coordination, feeling unsteady; or a severe nervous system reaction—very stiff (rigid) muscles, high fever, sweating, confusion, fast or uneven heartbeats, tremors, feeling like you might pass out.

Seek medical attention right away if you have symptoms of serotonin syndrome, such as: agitation, hallucinations, fever, sweating, shivering, fast heart rate, muscle stiffness, twitching, loss of coordination, nausea, vomiting, or diarrhea.

Common side effects, which do not require immediate medical care, may include: sleep problems (insomnia), strange dreams; headache, dizziness, drowsiness, vision changes; tremors or shaking, feeling anxious or nervous; pain, weakness, yawning, tired feeling; upset stomach, loss of appetite, nausea, vomiting, diarrhea; dry mouth, sweating, hot flashes; changes in weight or appetite; stuffy nose, sinus pain, sore throat, flu symptoms; or decreased sex drive, impotence, or difficulty having an orgasm.

Date:

Patient signature

ATTACHMENT 4: NIGELLA SATIVA

Nigella sativa is a widely used medicinal plant for a variety of conditions including as an antihypertensive, liver tonic, diuretic, digestive aide, anti-diarrheal, appetite stimulant, analgesics, anti-bacterial and in skin disorders. A randomized placebo-controlled study demonstrated that the combination of honey and Nigella sativa hastened recovery, decreased viral shedding, and reduced mortality in patients with both moderate and severe COVID-19 infection.

Possible Contraindications and Adverse Effects. Patients with kidney or liver disease should review the use of this herb with their provider. It may lower blood pressure and should be used with caution in patients with hypotension. It may slow blood clotting and increase the risk of bleeding disorders interviews and caution in patients on blood thinners and should be discontinued before surgery. In some patients, it may cause stomach upset, vomiting, or constipation.

It should be noted that thymoquinone (the active ingredient of Nigella sativa) decreases the absorption of cyclosporine and phenytoin. Patients taking these drugs should, therefore, avoid taking Nigella sativa. Furthermore, two cases of serotonin syndrome have been reported in patients taking Nigella sativa who underwent general anesthesia (probable interaction with opiates).

Date:

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