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Unknown Risks with Unapproved COVID-19 Treatments

There are no treatments which have been clinically proven to be safe and effective for the management of COVID-19 infection or illness. Medical communities across the world are engaged in a broad range of pre-clinical and clinical investigations involving both potential treatments and vaccines for COVID-19. A number of case studies and small trials have been conducted over the past few months in an attempt to identify potential medications for further evaluation. However, additional research is necessary to determine safety and efficacy as well as to balance the risks and benefits of therapy.

The [U.S. Centers for Disease Control and Prevention](#) and the [World Health Organization](#) are two reputable resources that provide regularly updated information on medications that are being investigated for the treatment or prevention of COVID-19. Some of these medications are already on the market and clinicians may be tempted to use them for off-label treatment of confirmed COVID-19. While not currently recommended, if these medications are prescribed to patients for confirmed cases of COVID-19, the American Society for Health Systems Pharmacists has provided a guideline entitled [Stewardship of Off-Label Treatments for COVID-19](#). This document is intended to promote the responsible use of medications as investigational drugs, to ensure patient safety, and to prevent shortages from occurring that may affect patients who need them for approved uses.

Serious adverse drug events (ADEs) may occur with certain investigational medications, including cardiomyopathy and conduction problems, dermatitis, bone marrow suppression, acute hepatic failure, and myopathy. They may even cause ADEs that are similar to the symptoms of COVID-19 infection such as fatigue, headache, abdominal pain, nausea, diarrhea, and vomiting. Presently, the National Pharmacy and Therapeutics Committee (NPTC) recommends against off-label use of medications for COVID-19, except as part of an approved clinical investigation.

Until further research is conducted to establish a safe and effective treatment for COVID-19, recommended interventions include physical distancing, effective triage to determine appropriate disposition, and supportive therapy as indicated. Most patients (approximately 81%) will have mild disease, (see Table 1). Despite the severity of disease classified as mild, patients often report feeling uncomfortable and unable to participate in normal activities. In addition to self-isolation, patients with mild disease will require rest at home, fluids, and possibly medications to help manage symptoms such as pain or fever. For patients with moderate to severe disease, especially those with significant comorbidities, a visit to the health care facility is recommended and inpatient services may be required.

Table 1. Classification of Severity of COVID-19 Infections

Severity	Description	% of Cases
Mild	Symptoms such as fever and dry cough but not requiring hospitalization.	81%
Severe	Symptoms also include dyspnea, hypoxia, or >50% lung involvement.	14%
Critical	Symptoms also include respiratory failure, shock, or multi organ dysfunction.	5%

The NPTC continues to monitor the evolving landscape of potential therapeutic treatments for COVID-19 and is regularly communicating with the National Supply Service Center regarding the drug supply chain. We will continue to provide updates, based on a review of the clinical evidence, if and when safe and effective treatments are identified.