

Stewardship of Off-Label Treatments for COVID-19

March 23, 2020

The COVID-19 pandemic has become a public health emergency. While researchers are working to find a treatment for the infection, no medication is currently FDA-approved to treat COVID-19. Novel drugs like remdesivir are currently being studied and some drugs that are already FDA-approved for other indications are being tried as off-label treatments of COVID-19. See the new [ASHP Assessment of Evidence for COVID-19-Related Treatments](#) for more information. This table will be updated as evidence becomes available and can be found in the ASHP COVID-19 Resource Center at ashp.org/coronavirus.

During this crisis, there is understandable concern over the health and safety of loved ones. However, inappropriate prescribing of these experimental treatments to have “just in case” or for patients who are not at high risk of severe illness may lead to an inadequate supply of medications for those who need them most. Similarly, stocking up and hoarding can also create shortages or exacerbate existing shortages.

These recommendations should be used as a general guide for prescribers, pharmacists, and patients when considering the appropriate use of experimental treatments. These especially include [azithromycin](#), [chloroquine](#), and [hydroxychloroquine](#), but also include baloxavir, lopinavir and ritonavir, oseltamivir, remdesivir, sarilumab, tocilizumab, and sirolimus.

Recommendation 1: Any prescription or medication order for a drug that is also being investigated for the off-label treatment of COVID-19 should be reviewed for appropriateness.

1. Patients who are already prescribed these medications for non-COVID-19 indications should continue to have access through new prescriptions or refills of existing prescriptions.
2. Outpatient prescriptions for these medications should include a documented diagnosis from the prescriber consistent with the FDA-approved indication or other literature-supported, off-label use.
3. Pharmacists should verify new prescriptions for these medications are appropriate, recognizing that patients newly diagnosed with conditions like rheumatoid arthritis or lupus may be initiating treatment during the coming weeks or months.

Recommendation 2: Prescriptions or medication orders for the off-label treatment of confirmed COVID-19 patients should be prioritized for inpatient use and limited in duration of treatment.

1. Decisions to use off-label medications to treat confirmed COVID-19 patients should be made by the inter-professional team after weighing supporting evidence, risks, and potential benefits.
2. Informed consent describing the existing evidence, risks, and potential benefits should be established between providers and patients, caregivers, or medical power of attorneys.
3. If patients initiated on treatment during an inpatient admission must continue treatment upon discharge, prescriptions should be coordinated through a meds-to-beds program or through direct communication with an outpatient pharmacy.
4. Outpatient prescriptions should be dispensed only:
 - a) In coordination with discharge planning from an inpatient setting for continuity of care, **or**
 - b) For patients with a confirmed positive test for SARS-CoV-2, **or**
 - c) For patients designated as a [Person Under Investigation \(PUI\)](#).
5. Outpatient prescriptions should be limited to no more than a fourteen-day supply.

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6. Refills should not be permitted.

Recommendation 3: Inventory of drugs being studied for the treatment of COVID-19 should be maintained responsibly

1. Pharmacies, especially outpatient pharmacies, should not attempt to buy up and hoard inventories that will be most appropriately used in inpatient settings.
2. These medications should be stored with limited and documented access similar to controlled substances.

Recommendation 4: Patients already taking medications being studied for off-label treatment of COVID-19 should not stock-up or hoard medications.

1. The [CDC recommends](#) that patients have at least a two-week supply of medications during social distancing for COVID-19; however, pharmacists should be aware of patients attempting to acquire excessive amounts of medications that are being studied for off-label treatment of COVID-19.

Additional resources

1. Stay up to date with the latest COVID-19 resources from ASHP: <https://www.ashp.org/Coronavirus>
1. ASHP is providing free access to its AHFS Clinical Drug Information application, which also includes access to drug shortages information. [AHFS Drug Information®](#) - Open Access for 60 Days Effective March 16, 2020
Username: **ahfs@ashp.org**
Password: **covid-19**

The information contained in this document is based on data that are emerging and rapidly evolving because of ongoing research and, as such, is subject to the professional judgment and interpretation of the practitioner due to the uniqueness of each practitioner's and, if applicable, his or her medical facility's approach to the care of patients with COVID-19 and the needs of individual patients. ASHP provides this information to help practitioners better understand current approaches related to treatment and care. ASHP has made reasonable efforts to ensure the accuracy and appropriateness of the information presented. However, any reader of this information is advised that ASHP is not responsible for the continued currency of the information, for any errors or omissions, and/or for any consequences arising from the use of the information contained in the document in any and all practice settings. Any reader of this document is cautioned that ASHP makes no representation, guarantee, or warranty, express or implied, as to the accuracy and appropriateness of the information contained in this document and will bear no responsibility or liability for the results or consequences of its use.