Transcript Details

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A Guide for Off-Label Use of Treatments for COVID-19 from the ASHP

Announcer:
You're listening to *The Drug Report* on ReachMD, hosted by Linda Bernstein, Pharm.D., Clinical Professor on the Volunteer Faculty of the School of Pharmacy, University of California, San Francisco.

Dr. Bernstein:
Welcome to *The Drug Report* with a special focus on the COVID-19 pandemic.

There is currently no FDA-approved medication to treat the virus. But novel drugs like remdesivir and some drugs already FDA-approved for other indications are being tried as off-label treatments.

The American Society of Health Systems Pharmacists (ASHP) recently published recommendations that should be used as a general guide for prescribers, pharmacists, and patients when considering the proper use of experimental treatments. Inappropriate prescribing of experimental treatments “just in case” or for patients not at high risk of severe illness, may lead to insufficient supplies of critical medicines that are needed to treat other patients who depend on these medicines. Drug shortages and worsening of existing shortages can occur when practitioners and patients stock up and hoard their medication supplies. This is already happening.

For example, the mention of chloroquine, hydroxychloroquine, and azithromycin by President Trump as having potential to treat mild-to-moderate COVID-19 led to a clamoring for these drugs, which are now listed on the ASHP’s list of drug shortages.

The experimental treatments ASHP wants us to pay special attention are azithromycin, chloroquine, and hydroxychloroquine, but also include baloxavir, lopinavir and ritonavir, oseltamivir, remdesivir, sarilumab, tocilizumab, and sirolimus.

The ASHP recommendations for Stewardship of Off-Label Treatments for COVID-19 are:

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.

- 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.
- 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.
- 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.

- Decisions to use off-label medications to treat confirmed COVID-19 patients should be made by the interprofessional team after weighing supporting evidence, risks, and potential benefits.
- Informed consent describing the existing evidence, risks, and potential benefits should be established between providers and patients, caregivers, or medical power of attorneys.
- 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.
- Outpatient prescriptions should be dispensed only:

- In coordination with discharge planning from an inpatient setting for continuity of care, or
- For patients with a confirmed positive test for SARS-CoV-2, or
- For patients designated as a Person Under Investigation (PUI).
- Outpatient prescriptions should be limited to no more than a fourteen-day supply.
- Refills should not be permitted.

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

- Pharmacies, especially outpatient pharmacies, should not attempt to buy up and hoard inventories that will be most appropriately used in inpatient settings.
- 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.

- 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.

As a side note, for an updated review of the top treatment candidates see ASHP.org and the new ASHP Assessment of Evidence for COVID-19 Related Treatments for more information.

For *The Drug Report*, I'm pharmacist, Dr. Linda Bernstein.

Announcer:
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