

YNHHS recommendations on ambulatory prescribing of medications with possible efficacy against COVID

Situation: Guidance on the outpatient prescribing of medications with possible activity against COVID-19 is required.

Background: There are currently no FDA approved medications for treatment of COVID-19; but several readily available oral medications have demonstrated possible activity against SARS CoV-2 including hydroxychloroquine, HIV-1 protease inhibitors (e.g., lopinavir-ritonavir, atazanavir, tipranavir), and azithromycin.

None of these agents have been studied in large clinical trials (with or without placebo) to support their off label use in the ambulatory setting for the treatment/prevention of COVID 19 patients.

Assessment:

The use of these “re-purposed” medications in the outpatient setting is inappropriate, and will result in shortages, which will impact treatment of patients for whom these medications are indicated by FDA approval, established clinical experience, or for the severely ill inpatients with COVID-19.

Outpatient prescribing of hydroxychloroquine, HIV-1 protease inhibitors, and azithromycin should be reserved **ONLY** for patients who have medical conditions where their use has been established and there are no other alternatives.

Recommendation as of March 23, 2020:

The prescribing of the outpatient medications should be limited as follows:

- 1) Hydroxychloroquine:
 - Rheumatoid arthritis
 - Systemic Lupus Erythematosus (SLE) & other collagen vascular diseases when appropriate
 - Dermatologic manifestations of collagen vascular diseases (e.g., discoid lupus, dermatomyositis, etc.)
- 2) HIV-1 Protease Inhibitors:
 - ART for patients with HIV-1 infection
- 3) Azithromycin:
 - Community Acquired Pneumonia (CAP) in pregnancy or in children < 8 years of age (as doxycycline should be avoided in both groups).
 - CAP therapy for patients who are allergic/intolerant to the following alternative options:
 - Cefuroxime + doxycycline, levofloxacin, moxifloxacin
 - Treatment of Group A pharyngitis in patients who are allergic to beta-lactams (allergic to penicillins and cephalosporins) and clindamycin
 - Treatment of *Chlamydia trachomatis* infection
 - Prophylaxis in COPD patients at risk for frequent exacerbations
 - Prophylaxis in cystic fibrosis patients
 - Treatment of non-tuberculous mycobacterial infections (e.g., MAC or MAI)
 - Treatment / Prevention of Chronic Allograft Dysfunction S/P lung transplant
 - Treatment of Bronchiolitis Obliterans Syndrome (BOS) in Patients S/P Allogenic Stem Cell Transplant

There may be additional indications for the use of these agents in other disease(s), but based upon the available evidence, the use of these agents for the treatment or prevention of COVID-19 patients is not appropriate.

We realize patients may be scared or confused given COVID-19 and the media reports of possible therapeutic efficacy of these drugs, but it is our duty to help guide our patients to the best of our ability during this challenging time.

- a. Employed and affiliated healthcare workers will receive priority scheduling at 150 Sargent Drive from 06:30- 08:30 AM and 4:30 - 5:30 pm Monday - Friday and from 9:00 am - 3 pm on Saturday.
 - b. Our Orchard Street specimen collection site will be dedicated to healthcare workers once operational on Tuesday, March 24.
2. Results will be tracked by Occupational Health and communicated back to the healthcare worker.

Reviewed by the following stakeholders:

Infectious Diseases:

- J. Topal, MD for the YNHHS COVID-19 Treatment Team & YNHHS Antimicrobial Stewardship Committee
- E. Paintsil, MD for Pediatric Infectious Diseases, Yale School of Medicine

Outpatient Internal Medicine:

- K. Brown, MD for the YNHHS COVID-19 Ambulatory Task Force

Rheumatology:

- F. Koumpouras, MD and V. Chowdhary, MD, Yale School of Medicine

Dermatology:

- R. Edelson, MD; M. Girardi, MD; and S. Ramachandran, MD, Yale School of Medicine

Pulmonary Medicine

- J. Koff, MD, Yale School of Medicine