SARS-CoV-2 (COVID-19) Treatment Guidance (updated: 4-9-2020)

Disclaimers and additional notes

- There are no antiviral treatments that are FDA approved for COVID-19. The medications listed are considerations based on the best available data.
- The treatment of outpatients and/or pre- and post-exposure prophylaxis of exposed individuals is not recommended at this time
- The routine use of corticosteroids (systemic and inhaled) are discouraged. Consider risk versus benefit in septic shock and acute respiratory distress syndrome (ARDS).
- Based on available data, NSAIDS may be continued, if clinically indicated. Consider risk versus benefit of NSAIDS versus acetaminophen for symptomatic relief.
- There are no data to support starting or stopping ACEI/ARBs on patients with COVID-19. However, please stop if acute kidney injury, hypotension, or other contraindication develops.
- **Penn Medicine Treatment Guideline is available at http://www.uphs.upenn.edu/antibiotics/COVID19.html and are developed by all six Penn Medicine entities based on routine review of literature. This document is specific to LGH based on drug availability, restrictions/criteria, and is approved by the Infectious Diseases of Lancaster (ISL) group. Any questions should be directed to Joseph Kontra, M.D. or Aiman Bandali, Pharm.D.**

Risk Factors and Severity of Disease

Risk Factors	Mild Disease	Moderate Disease	Severe Disease
Age >60, comorbidities (uncontrolled HTN, diabetes, CV diseases, COPD), CKD 4-6, AIDS (uncontrolled HIV), immunocompromised, pregnant women	Fever, cough/cold symptoms without dyspnea or hypoxia. Patient to be discharged or hospitalized for social reasons or medical concerns other than COVID-19.	Dyspnea or hypoxia (O2 sat < 92% on room air) are present without signs of severe pneumonia	Any of the following: RR > 30, O2 sat < 90% on room air, PaO_2/FiO_2 < 300 mmHg, lung infiltrates > 50% of the lung field within 24 – 48 hours, sepsis, altered consciousness, multi-organ failure, ARDS, D-dimer > 1 mg/L, CRP >100 mg/L, ferritin > 300 ng/mL, LDH > 245 IU/L

Management of *Confirmed* COVID-19

Clinical Presentation	Risk Factors	Supportive Care	Treatment
Asymptomatic	N/A	None – surveillance	None
Mild disease – discharged	None	Symptom management	None
	Present	Symptom management	None; close follow-up for worsening symptoms
Mild disease – hospitalized	None	Symptom management	None; close follow-up for worsening symptoms
	Present	Symptom management Daily CBC/diff, BMP, LFTs, Ferritin, D-Dimer, LDH, CRP, CPK, Procalcitonin, PT-INR, triglycerides, **EKG/telemetry (if initiating hydroxychloroquine)**	Consider **Hydroxychloroquine**. ISL consultation required. One – two doses may be administered, pending ISL provider evaluation.
Moderate disease	N/A	Daily CBC/diff, BMP, LFTs, Ferritin, D-Dimer, LDH, CRP, CPK, Procalcitonin, PT-INR, triglycerides, **EKG/telemetry** Empiric antibiotics (based on local guidelines), de-escalate based on cultures	**Hydroxychloroquine –** ISL consultation required. One to two doses may be administered, pending ISL evaluation. **+/- Azithromycin** OR **Remdesivir –** expanded access program (pending approval)

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Severe disease – meets criteria for remdesivir compassionate use or expanded access program **See https://rdvcu.gilead.com for up to date inclusion/exclusion criteria of compassionate use.**	N/A	Daily CBC/diff, BMP, LFTs, Ferritin, D-Dimer, LDH, CRP, CPK, Procalcitonin, PT-INR, triglycerides, **EKG/telemetry** Empiric antibiotics (based on local guidelines), de-escalate based on cultures	**Hydroxychloroquine –** ISL consultation required. One to two doses may be administered, pending ISL evaluation. **+/- Azithromycin** OR **Remdesivir** – expanded access program (pending approval)
Severe disease – does not meet criteria for remdesivir compassionate use or expanded access program	N/A	Daily CBC/diff, BMP, LFTs, Ferritin, D-Dimer, LDH, CRP, CPK, Procalcitonin, PT-INR, triglycerides, **EKG/telemetry**	**Hydroxychloroquine –** ISL consultation required. One to two doses may be administered, pending ISL evaluation. **+/- Azithromycin** AND Consider **Tocilizumab** if cytokine storm suspected. Requires ISL consultation. ISL provider must order during day (0700 – 2100) and any attending provider must order overnight (2101 – 0659). Criteria (below) must be met.

Drug Name	Dosing/Administration (Adult)	Notes	How to Obtain
Hydroxychloroquine	400 mg PO BID x 2 doses (1 day) *Followed by* 400 mg PO daily x 4 doses (4 days) **Use "Hydroxychloroquine for COVID-19 Treatment" medication panel**	Check EKG/telemetry prior to initiation given risk of QTc prolongation. Risk is increased in patients receiving other QTc-prolonging agents. Most toxicities associated with long-term use. Avoid in known G6PD deficiency. Risks include but are not limited to arrhythmia, cardiomyopathy, bone marrow suppression, LFT abnormalities, and hypoglycemia. Pregnancy: safe	Formulary Supply monitored daily by pharmacy Restricted to ISL. One to two doses can be administered prior to ISL evaluation.
Azithromycin	500 mg PO/IV daily x 3 days	Check EKG/telemetry prior to initiation given risk of QTc prolongation. Risk is increased in patients receiving other QTc-prolonging agents. Risks include but are not limited to QTc prolongation, gastrointestinal (nausea, vomiting, diarrhea), and LFT abnormalities.	Formulary Supply monitored daily by pharmacy.
Remdesivir (RDV)	200 mg IV on day 1, then 100 mg daily until stabilization/discharge, up to 10 days	Investigational agent; not FDA approved. <u>We are awaiting approval for enrollment into expanded access program through Gilead.</u> **<u>COMPASSIONATE USE:</u>** ▪ Pregnancy ▪ Children < 18 years Go to https://rdvcu.gilead.com. Follow prompts and request access to drug. **<u>EXPANDED ACCESS:</u>** *Inclusion Criteria* 1. Age ≥ 18 years 2. Hospitalization 3. SARS-CoV-2 by PCR or known contact of confirmed case with syndrome consistent with COVID-19 with PCR pending 4. Mechanical ventilation 5. eGFR ≥ 30 ml/ml/min 6. ALT ≤ 5 x ULN	Investigational drug Consult with ISL to initiate process to obtain <u>Notify pharmacy of request</u>

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		Exclusion Criteria 1. Multi-organ failure 2. Vasopressor requirement 3. ALT >5 x ULN 4. eGFR < 30 ml/min, dialysis, or CVVH 5. Pregnancy	
Tocilizumab	400 mg IV x 1 dose. A second dose may be given after 12 hours, upon evaluation of clinical status. Consider ordering an **IL-6 level** prior to administration. **Use "Tocilizumab for COVID-19 Treatment" medication panel**	Tocilizumab may improve oxygenation and time to symptom resolution in patients with cytokine storm. Criteria below MUST be met. ***Inclusion Criteria*** <u>The patient MUST meet ALL FIVE of these criteria:</u> 1. SARS-CoV-2 positive by PCR 2. Mechanical ventilation 3. PaO_2/FiO_2 < 150 mmHg 4. Worsening hypoxemia 24 hours after intubation, despite optimal supportive care 5. Received hydroxychloroquine loading dose (400 mg PO BID x 2 doses) **AND** <u>The patient MUST have evidence of increased inflammatory response as defined by AT LEAST ONE of the following:</u> 1. Ferritin > 1000 ng/mL 2. D-dimer > 1 mg/L 3. LDH > 275 IU/L 4. CRP > 100 mg/L ***Exclusion Criteria*** *If <u>any one</u> of the following criteria are met, patient will <u>NOT</u> receive drug.* 1. AST ≥ 200 OR ALT ≥ 260 (These values reflect ≥ 5x ULN) 2. Platelets < 50 x $10^3/\mu L$ 3. Absolute neutrophil count (ANC) < 0.5 x $10^3/\mu L$	Non-formulary Supply monitored daily by pharmacy. *<u>Extremely limited supply.</u>* ISL provider must order during day (0700 – 2100) and any attending provider must order overnight (2101 – 0659). Pharmacists will be confirming patients have met criteria prior to dispensing.

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