<table>
<thead>
<tr>
<th>Illness Severity(^1)</th>
<th>Current Potential Therapy Options</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asymptomatic</td>
<td>Supportive care</td>
<td>In both inpatients and outpatients, corticosteroids are not recommended.</td>
</tr>
<tr>
<td>Symptomatic not requiring supplemental oxygen (&gt; 94% on room air)</td>
<td>Supportive care</td>
<td>In both inpatients and outpatients, corticosteroids are not recommended.</td>
</tr>
<tr>
<td></td>
<td><strong>Outpatient:</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>SARS-CoV-2 specific monoclonal antibody therapy is available for patients at high risk of progression to severe COVID-19 – referral can be made through e-mailing <a href="mailto:covidtherapeuticreferrals@mountsinai.org">covidtherapeuticreferrals@mountsinai.org</a> or calling 212-824-8390.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mount Sinai South Nassau in Long Island also provides SARS-CoV-2 specific monoclonal antibody therapy. Referrals for patients at high risk of progression to severe COVID-19 can be referred to the MSSN COVID Infusion Center at 516-632-4998.</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Inpatient:</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Inpatients not hospitalized for COVID-19 but who develop mild to moderate COVID-19 while hospitalized and who are at risk for progression to severe COVID-19 can be considered for EUA SARS-CoV-2 specific monoclonal antibody therapies if not requiring supplemental oxygen. Infectious diseases consultation and site-specific designee approval is required.</td>
<td></td>
</tr>
<tr>
<td>Hospitalized requiring low-flow nasal cannula (SpO2 ≤ 94% on RA)</td>
<td>Supportive care</td>
<td>Remdesivir — requires ID consultation and is non-formulary</td>
</tr>
<tr>
<td></td>
<td><strong>Consider:</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>SARS-CoV-2 specific antibody therapy*</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Dexamethasone</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Remdesivir</td>
<td></td>
</tr>
<tr>
<td></td>
<td>In addition to remdesivir, anticoagulation, and dexamethasone consider referring for enrollment in available Clinical Trials.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>*Not inclusive of EUA casirivimab/imdevimab or sotrovimab</td>
<td></td>
</tr>
</tbody>
</table>

\(^1\) Mount Sinai Health System Adult Treatment Guidance for SARS-CoV-2 Infection (COVID-19) of June 7, 2021.

\(^2\) The FDA issued an EUA on November 21, 2020 for casirivimab/imdevimab, a dual monoclonal SARS-CoV2 antibody cocktail, for select non-hospitalized patients 12 years of age or older (≥ 40kg) with a laboratory-confirmed COVID-19 (i.e., direct SARS-CoV2 viral test), symptom onset within 10 days and risk factors for progression to severe COVID-19.

\(^3\) On August 23, 2020, the FDA issued an EUA for the use of convalescent plasma (CP) in hospitalized patients and updated the EUA to only include high-titer CP on February 4, 2021. The Mount Sinai Health System has a protocol in place for the administration of high-titer convalescent plasma in select immunocompromised individuals with ID physician approval. In patients with evidence of SARS-CoV-2 antibodies, SARS-CoV-2 antibody therapy is not recommended.
### Hospitalized requiring non-rebreather, high flow nasal cannula, or non-invasive ventilation (i.e., BiPAP)

**Supportive care**

**Recommended:**
- SARS-CoV-2 antibody therapy *
- Dexamethasone
- Remdesivir
- Tocilizumab †

In addition to remdesivir, anticoagulation, antibody therapy, and dexamethasone consider referring for enrollment in available [Clinical Trials](#).

*Not inclusive of EUA casirivimab/imdevimab or sotrovimab

### Hospitalized requiring mechanical ventilation or ECMO

**Supportive care**

**Consider**
- Dexamethasone
- Tocilizumab †

In addition to anticoagulation and dexamethasone consider referring for enrollment in available [Clinical Trials](#).

### Dexamethasone 6 mg IV/PO once daily for up to 10 days

Patients with symptom duration of < 7 days have not demonstrated benefit from dexamethasone. Dexamethasone should not be continued after discharge unless patient has a history of being on chronic steroid therapy.

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- Dexamethasone
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In addition to anticoagulation and dexamethasone consider referring for enrollment in available [Clinical Trials](#).
Medications:

Anticoagulation
The Mount Sinai Health System COVID-19 Anticoagulation Protocol

Casirivimab/Imdevimab (REGEN-COV™)

The FDA issued an EUA for outpatient infusion of casirivimab/imdevimab on November 21, 2020 for the treatment of mild-moderate COVID-19. Casirivimab/Imdevimab is a monoclonal antibody cocktail targeting the spike protein of SARS-CoV2. Benefit has not been observed in patients who require oxygen or who are hospitalized. Casirivimab/imdevimab is not considered standard of care. On June 4, 2021, the EUA was updated to include a lower dose and subcutaneous administration if intravenous administration is not feasible.

- Patients 12 years or older (and over 40 kg) referred for casirivimab/imdevimab must have a documented direct SARS-CoV2 viral test (antigen or PCR), symptoms of COVID-19 for ≤ 10 days and be at high risk for progressing to severe COVID-19. These high-risk conditions are described in the fact sheet for health care providers.
- The following must be documented in the medical record prior to prescribing casirivimab/imdevimab: the patient/caregiver has received the appropriate fact sheet and that the patient has been informed of potential alternatives, and that casirivimab/imdevimab is not FDA-approved but is authorized for use under an EUA.
- A monoclonal antibody consent form will need to be completed.
- If the patient receives SARS-CoV-2 specific monoclonal antibody therapy, receipt of EUA COVID-19 vaccination will be delayed for 90 days.

Dosing:
600 mg of casirivimab with 600mg of imdevimab administered intravenously x 1 dose infused over 20 minutes to 50 minutes

Subcutaneous dosing is authorized for emergency use using a co-formulation, however, IV administration is currently the preferred route of administration.

Caution:
Monitor for infusion reactions and/or anaphylaxis for 1 hour after infusion

- Adverse events should be reported to FDA Medwatch.

Sotrovimab

The FDA issued an EUA for outpatient infusion of sotrovimab on May 26, 2021 for the treatment of mild-moderate COVID-19. Sotrovimab is a monoclonal antibody targeting the spike protein of SARS-CoV2. Benefit has not been observed in patients who require oxygen or who are hospitalized. Sotrovimab is not considered standard of care.

- Patients 12 years or older (and over 40 kg) referred for sotrovimab must have a documented direct SARS-CoV2 viral test (antigen or PCR), symptoms of COVID-19 for ≤ 10 days and be at high risk for progressing to severe COVID-19. These high-risk conditions are described in the fact sheet for health care providers.
- The following must be documented in the medical record prior to prescribing sotrovimab: the patient/caregiver has received the appropriate fact sheet and that the patient has been informed of potential alternatives, and that sotrovimab is not FDA-approved but is authorized for use under an EUA.
- A monoclonal antibody consent form will need to be completed.
- If the patient receives SARS-CoV-2 specific monoclonal antibody therapy, receipt of EUA COVID-19 vaccination will be delayed for 90 days or repeat vaccination may be recommended.

Dosing:
500 mg of sotrovimab x 1 dose infused over 30 minutes
Caution:
Monitor for infusion reactions and/or anaphylaxis for 1 hour after infusion

- Adverse events should be reported to FDA Medwatch.

**Corticosteroids**

- Dexamethasone is recommended in patients with confirmed COVID-19 who require supplemental oxygen including those who require mechanical ventilation. Corticosteroid use has not been found to be beneficial in patients who do not require respiratory support and use in this population could be potentially harmful.
- The benefit of dexamethasone was observed in patients > 7 days out from symptom onset.
- Corticosteroids prescribed specifically for the treatment COVID-19 should not be continued after 10 days or discharge whichever is earlier.
- Oral or inhaled corticosteroids prescribed prior to the diagnosis of COVID-19 for an underlying condition should not be discontinued.

**Dosing:**

Dexamethasone 6 mg PO or IV q 24 hours for up to 10 days
Alternative corticosteroids (dose equivalent to dexamethasone): Methylprednisolone 32 mg IV q 24 hours, Hydrocortisone 160 mg, or Prednisone 40 mg PO q 24 hours for up to 10 days

In the setting of escalating acuity, escalating dosing of corticosteroids, including stress-dose steroids, may be recommended in consultation with critical care. In a prospective meta-analysis of 7 trials, administration of corticosteroids was associated with lower all-cause mortality with the greatest benefit in those not receiving vasoactive medications. There was no evidence of mortality benefit when comparing high-dose and low-dose corticosteroids.10-12

Caution:

- Monitor for hyperglycemia, psychiatric effects, and secondary infections.

**Remdesivir (Veklury®)**

Remdesivir was FDA-approved for the treatment of COVID-19 on October 22, 2020 in hospitalized patients 12 years of age and older weighing at least 40 kg. The Adaptive COVID-19 Treatment Trial (ACTT-1) is a randomized placebo-controlled trial. In this trial hospitalized patients with lab-confirmed COVID-19 on low-flow oxygen had shorter median symptom duration (10 versus 15 days) and improved 29-day survival (HR for death 0.3). The trial was not powered to evaluate for differences in recovery time or mortality in patients receiving non-invasive ventilation. The WHO SOLIDARITY study combined data from four trials including ACTT-1. In the analysis, low and high flow oxygen were combined and did not demonstrate a mortality benefit.

- Exclusions for initiation and continuation of remdesivir include ALT > 5 times the upper limit of normal and those patients mechanically ventilated or requiring extracorporeal membrane oxygenation (ECMO).
- Consult Infectious Diseases for consideration for remdesivir therapy. Remdesivir is non-formulary and requires ID approval.
- Use of remdesivir in pediatric patients (< 12 years of age) and patients weighing < 40 kg would be considered off-label use of remdesivir. Use of the lyophilized powder for hospitalized pediatric patients weighing ≥ 3.5 kg is available under an emergency use authorization. Due to the lack of data in adults <40 kg, using the EUA to document the off-label use is recommended at this time.

**Dosing:**

Patients ≥ 40 kg: 200 mg IV on day 1 then 24 hours later start 100 mg IV q 24h for 4 days for a total duration of 5 days or until hospital discharge, whichever is sooner. Patients should not remain hospitalized solely to complete course of remdesivir if discharge is appropriate. Dose adjustment for renal replacement therapy recommended.
Caution:
- Hepatic function tests should be checked prior to initiating remdesivir and daily. Elevation in transaminases have been observed in clinical trials including in both healthy volunteers and patients with COVID-19.
- Remdesivir should be discontinued if ALT > 5 times the upper limit of normal or if there is signs and symptoms of liver inflammation (e.g., increased bilirubin, alkaline phosphatase, or INR).
- Adverse events should be reported to FDA Medwatch.

Tocilizumab (Actmera®16-22)

The role of IL-6 receptor antagonists (i.e., tocilizumab, siltuximab, sarilumab) remains under study and results of prospective trials are mixed. COVACTA, a phase 3 RCT, noted a decrease time to discharge and ICU length of stay but no impact on mortality. EMPACTA noted that hospitalized patients were less likely to progress to mechanical ventilation or death. A randomized open label trial in Brazil, TOCIBRAS, noted use of tocilizumab was not associated with improved clinical outcomes and potentially associated with increased mortality. The RE-MAP trial demonstrates a decrease in mortality in patients requiring HFNC, BiPAP, or mechanical ventilation receiving a single dose of an IL-6 receptor antagonist administered within 24 hours of ICU admission and with symptoms less than 14 days. The RECOVERY trial demonstrated a 4% decrease in all-cause 28-day mortality for patients requiring supplemental oxygen.

Consider a single dose of tocilizumab in combination with dexamethasone (as outlined above), in patients within 5 days of hospital admission and within 24 hours of rapidly escalating oxygen requirements (e.g., requiring HFNC, BiPAP, or mechanical ventilation with a FiO2 >40%) with a recent CRP of ≥75. Site designated ID and Critical Care approval is required.

- Exclusions from initiation of tocilizumab include ALT or AST > 3 times the upper limit of normal, thrombocytopenia (platelets < 50,000), and neutrophil count < 1,000.
- Use of tocilizumab and other immunosuppressants or immunomodulatory agents including corticosteroids may place the patient at higher risk for bacterial, viral, and fungal infections including opportunistic infections. In patients on concomitant immunosuppressants or immunomodulators (e.g., organ transplant or hematopoietic stem cell transplant), discuss use of tocilizumab with primary attending physician.
- The use of tocilizumab in a pregnant person must be discussed with maternal fetal medicine.

A monoclonal antibody consent form will need to be completed and discussion regarding off-label use must be documented in the EMR.

Dosing:
Patients ≥30 kg: 8 mg/kg (actual body weight) IV x single dose (maximum dose: 800 mg)

Caution:
- Interaction: Tocilizumab may reduce levels of apixaban and rivaroxaban but does NOT interfere with enoxaparin or heparin
- Associated with lower gastrointestinal perforations in patients on concomitant steroids (> 10 mg prednisone daily or equivalent), NSAIDS, and/or methotrexate and in patients with diverticulitis
- Due to potential increased risk for infectious complications, the combination of tocilizumab and baricitinib is not recommended
### Medications not currently recommended for the treatment of SARS-CoV2 (COVID-19), please consult Infectious Diseases:

<table>
<thead>
<tr>
<th>Medication</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ACE inhibitors and ARBs</strong></td>
<td>Patients prescribed ACE inhibitors and ARBs for preexisting conditions should be continued on their ACE inhibitor and ARB therapy. Currently, there is no scientific or clinical evidence that taking ACE inhibitors or ARBs increases the risk of acquiring COVID-19 or that use may increase the severity of illness for those acquiring infections.</td>
</tr>
<tr>
<td><strong>Azithromycin</strong></td>
<td>Azithromycin with or without hydroxychloroquine is <strong>NOT</strong> recommended for the treatment of COVID-19.</td>
</tr>
<tr>
<td><strong>Bamlanivimab and Bamlanivimab/Etesevimab</strong></td>
<td>The FDA issued an emergency use authorization (EUA) for outpatient infusion of bamlanivimab on November 9, 2020 and for bamlanivimab/etesevimab on February 9, 2021. Bamlanivimab is a monoclonal antibody targeting the spike protein of SARS-CoV-2 and bamlanivimab/etesevimab is a dual monoclonal antibody cocktail also targeting the spike protein. Due to increasing recovery of variants of interest and variants of concern (e.g., P.1) with decreased susceptibility to bamlanivimab, neither bamlanivimab nor bamlanivimab/etesevimab are recommended.</td>
</tr>
<tr>
<td><strong>Baricitinib</strong> and kinase inhibitors (Janus kinase (JAK) inhibitors and Bruton’s tyrosine kinase (BTK) inhibitors)</td>
<td>On November 19, 2020, a EUA was issued for the combination of baricitinib, a JAK inhibitor, with remdesivir for the treatment of COVID-19 in hospitalized patients requiring supplemental oxygen age 2 and older based on data from ACTT-2. Patients treated with the combination had a median time to recovery of 1 day less compared to those treated with remdesivir alone. In a subsequent analysis, a day 29 mortality benefit was noted in patients who at baseline required low-flow, high flow oxygen, or non-invasive ventilation. More recently, data from the COV-BARRIER trial became available in pre-print. A survival benefit was demonstrated in patients receiving baricitinib with corticosteroids (primarily dexamethasone) and with or without remdesivir who required non-invasive ventilation for laboratory-confirmed COVID-19. Due to potential increased risk for infectious complications, the combination of tocilizumab and baricitinib is not recommended. Currently, use of baricitinib for the off-label treatment of COVID-19 always requires ID consultation and non-formulary approval.</td>
</tr>
<tr>
<td><strong>Colchicine</strong></td>
<td>Use of colchicine for the treatment of COVID-19 is currently not recommended for ambulatory patients outside of a clinical trial. Inpatient use of colchicine specifically for the treatment of COVID-19 is not recommended. Patients prescribed colchicine for gout should complete their limited course of colchicine.</td>
</tr>
<tr>
<td><strong>Famotidine</strong></td>
<td>Use of H2 blockers or proton pump inhibitors specifically for the treatment of COVID-19 is not recommended.</td>
</tr>
<tr>
<td><strong>Fluvoxamine</strong></td>
<td>Limited published data exist for the use of fluvoxamine, a selective serotonin-uptake inhibitor, for the treatment of COVID-19. Fluvoxamine is currently not recommended for the treatment of COVID-19 for ambulatory or hospitalized patients outside of a clinical trial.</td>
</tr>
<tr>
<td><strong>Hydroxychloroquine</strong></td>
<td>Hydroxychloroquine is <strong>NOT</strong> recommended for prophylaxis or treatment of COVID-19. Co-administration of remdesivir and hydroxychloroquine or may result in reduced antiviral activity of remdesivir. Patients prescribed hydroxychloroquine for preexisting rheumatologic conditions should be continued on their current dose.</td>
</tr>
<tr>
<td><strong>Interferons</strong></td>
<td>Data specific to SARS CoV-2 are lacking. Interferon is currently <strong>NOT</strong> recommended for the treatment of COVID-19. Clinical trials are ongoing.</td>
</tr>
<tr>
<td><strong>Ivermectin</strong></td>
<td><em>In vitro</em> studies demonstrate ivermectin inhibits SARS-CoV-2 replication and suggest the dosing required would be above what is recommended by the FDA for parasitic infections. Observational studies and small clinical trials evaluating the use of ivermectin for COVID-19 have been published or are available in pre-print. Most patients included in these reports are prescribed ivermectin early in diagnosis and/or hospitalization and variable comparators are used to determine outcomes including mortality. Regimens are variable in dose and duration. Randomized controlled trials evaluating the potential role of ivermectin for COVID-19 are ongoing.</td>
</tr>
</tbody>
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MSHS COVID-19 Treatment Guidance June 7, 2021
Ivermectin are limited especially in hospitalized patients with severe or critical disease. Use of ivermectin for the treatment or prophylaxis of COVID-19 is currently considered unlabeled use and is not recommended outside of a clinical trial. If disseminated strongyloidiasis is being considered, ivermectin remains the treatment of choice and requires ID approval.\(^{44,45}\)

<table>
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<tr>
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<th>Notes</th>
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<tr>
<td><strong>IVIG</strong></td>
<td>Use of IVIG for COVID-19 is not recommended outside of use for MIS-C and MIS-A.</td>
<td></td>
</tr>
<tr>
<td><strong>Lopinavir/ritonavir (Kaletra)</strong>(^{46,47})</td>
<td>Lopinavir/ritonavir is not recommended for the treatment of COVID-19.</td>
<td></td>
</tr>
<tr>
<td><strong>Nitazoxanide</strong>(^{48})</td>
<td>Displays inhibitory activity against the SARS-CoV-2 in vitro. Nitazoxanide is currently not recommended for the treatment of COVID-19 for ambulatory or hospitalized patients with COVID-19.</td>
<td></td>
</tr>
<tr>
<td><strong>Oseltamivir</strong></td>
<td>SARS-CoV-2 does not use neuraminidase as part of the viral replication cycle therefore neuraminidase inhibitors are not likely to provider therapeutic value.</td>
<td></td>
</tr>
<tr>
<td><strong>Ribavirin</strong></td>
<td>There are insufficient data to recommend the use of ribavirin for the treatment of COVID-19.</td>
<td></td>
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<tr>
<td><strong>Zinc</strong>(^{49})</td>
<td>There are insufficient data to recommend the use of for the treatment of COVID-19.</td>
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