**Definition:** The novel coronavirus disease 2019 (COVID-19) is caused by a beta-coronavirus named severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2). (1) This is a RNA virus belonging to the Coronaviridae family. (2)

**Pathophysiology:** Rapid mutation and recombination are properties of coronaviruses which contribute to the spread of the disease. (2) SARS-CoV-2 is most commonly spread by close human-to-human contact within six feet. Close physical contact allows for respiratory droplets of persons infected with SARS-CoV-2 to be inhaled. Exposure of mucus membranes to the virus can occur when in close contact with infected individuals. (3) In aerosol generating situations, airborne transmission can occur in people greater than six feet from the infected host. (4) SARS-CoV-2 attaches to the host cell by binding to the angiotensin converting enzyme 2 (ACE2) receptor and then penetrates the cells. The SARS-CoV-2 spike protein binds to ACE2 receptors present in respiratory epithelium of the upper airway and lungs, heart and blood vessels, intestinal tract, kidney and bladder, among other tissues. Viral mRNA participates in biosynthesis of new viruses that are released into the body. (5)

**Epidemiology:** Globally more than 118 million cases were reported of COVID-19 with 2.6 million deaths as of March 2021. (6) More than 29 million of the reported cases of COVID-19 has occurred in the United States resulting in over 527,000 deaths. (7) All patient age groups are at risk for infection and have the potential to develop life threatening COVID-19 disease; however, in general, the acute severity of disease is lower in children compared to adults. (8) Data from the Centers for Disease Control and Prevention COVID Data Tracker, notes that patients less than 18 years of age represent 11.6% of the total reported cases of COVID-19 with demographic data in the United States as of March 2021 while representing only a small fraction of deaths. (7) The weekly incidence of COVID-19 for infants, children and young adults has increased progressively and is highest in the older age groups. (6) The true incidence of COVID-19 in children remains unknown due to limited testing for milder symptoms. (6)

**Inclusion Criteria**
- Positive SARS-CoV-2 RT-PCR Test
- Age less than 21 years
- Acute care or critical care monitoring

**Exclusion Criteria**
- Multi-System Inflammatory Syndrome in Children (MIS-C)

**Differential Diagnosis** (10)
Multi-System Inflammatory Syndrome in Children (MIS-C)
Community Acquired Pneumonia
Strep Pharyngitis and Other Bacterial Respiratory Infections
Other Viral Syndromes

**Infection Control**
The risk of transmission of COVID-19 can be decreased by infection control measures including maintaining a distance of at least six feet from others, frequent handwashing, covering coughs and sneezes, and wearing a properly fitted mask. (3,4) In the hospital setting, use of personal protective equipment can reduce transmission. Please review the Texas Children’s guidance to personal protective equipment for additional information.

**Diagnostic Evaluation**
The incubation period for SARS-CoV-2 is up to 14 days from the date of exposure with most people exhibiting symptoms by day 4 to 5. (9) The patient should be assessed for the signs and/or symptoms of COVID-19 as well as risk factors for progression to severe disease. Assessment will determine disease severity.

**History: Assess for**
- Risk factors for severe disease including underlying complex medical conditions, obesity, immunocompromised state (e.g. cancer, solid organ or bone marrow transplantation, lymphopenia, HIV and other immune deficiencies or from immunosuppressive medications), chronic heart, lung or kidney disease, diabetes, sickle cell disease, metabolic disorders, age less than one year and pregnancy.
- History of fever, cough, shortness of breath, difficulty breathing, fatigue, headache, myalgia, loss of taste or smell, sore throat, abdominal pain, nausea, diarrhea, poor appetite or feeding

**Physical Examination**
- Fever
- Cough
- Shortness of breath or difficulty breathing
- Presence of crackles, rales, wheezing or other auscultatory findings consistent with pneumonia
- Nasal congestion or rhinorrhea
- Respiratory rate
- Oxygen saturation
- Abdominal tenderness
- Rash

**Disease Severity Categories**
Clinical presentation of patients with COVID-19 can range from asymptomatic to critical illness. The clinical presentation of the patient will guide treatment modalities. Patients should be monitored closely for progression of disease severity until recovery is noted. (4)

<table>
<thead>
<tr>
<th>Severity</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asymptomatic</td>
<td>Positive SARS-CoV-2 RT-PCR with no associated symptoms</td>
</tr>
<tr>
<td>Mild</td>
<td>Patient with any of the signs and symptoms of COVID-19 (e.g., fever, cough, sore throat, malaise, headache, muscle pain, nausea, vomiting, diarrhea, loss of taste and smell) but who do not have lower respiratory symptoms or abnormal chest imaging if obtained.</td>
</tr>
<tr>
<td>Moderate</td>
<td>Patients with symptoms of COVID-19 lower respiratory tract disease or abnormal chest imaging, who have saturation of oxygen (SpO2) ≥ 94%</td>
</tr>
<tr>
<td>Severe</td>
<td>Patients with saturation of oxygen (SpO2) &lt;94% requiring supplemental oxygen or with an increase in respiratory support from baseline not meeting critical criteria</td>
</tr>
<tr>
<td>Critical</td>
<td>Respiratory or multiorgan failure requiring non-invasive positive pressure ventilation (BiPAP or CPAP) or mechanical ventilation and/or hemodynamic support</td>
</tr>
</tbody>
</table>

LRT symptoms: cough, tachypnea, retraction, shortness of breath, dyspnea
**Laboratory Tests**

Suggested laboratory tests for children with COVID-19 disease are listed below. Patients transferred from outside hospitals may need a SARS-CoV-2 RT-PCR test.

<table>
<thead>
<tr>
<th>Severity</th>
<th>Suggested Laboratory Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mild</td>
<td>Consider CBC with differential and DIC Panel if age ≥12 years AND admitted for primary diagnosis of COVID 19</td>
</tr>
<tr>
<td>Moderate</td>
<td>Obtain CBC with differential and DIC Panel if age ≥12 OR in the ICU</td>
</tr>
<tr>
<td>Severe</td>
<td>Obtain CBC with differential, Chem 10, LFTs, CRP, Procalcitonin, Ferritin and COVID-19 serologic testing in patients with comorbidities or worsening clinical condition</td>
</tr>
<tr>
<td>Critical</td>
<td>Obtain CBC with differential, Chem 10, LFTs, CRP, Procalcitonin and Ferritin, COVID-19 serologic testing, BNP and Tropinins</td>
</tr>
</tbody>
</table>

Labs should be trended based upon findings and recommended monitoring related to specific therapies (e.g., remdesivir). Trend CRP in patients with critical disease.

**Imaging**

Depending upon severity of disease, patients with COVID-19 may exhibit radiologic findings on chest x-ray or chest computed tomography (CT). Patients with severe or critical disease should have a chest x-ray performed. Chest CT may be utilized in high risk and severe/critical patients with clinical indications for the procedure. (10) Electrocardiogram (ECG) should be obtained in patients that present with critical disease. (11) Echocardiogram may be considered in critical disease due to risk of myocardial dysfunction.

**Critical Points of Evidence**

**TCH Evidence-Based Recommendations**

**Evidence Supports**

**Dexamethasone**

- Low-dose dexamethasone should be administered to pediatric patients with positive SARS-CoV-2 RT-PCR requiring supplemental oxygen or an increase in baseline respiratory support, in hospitalized patients with progressive disease requiring increasing respiratory support, and in hospitalized patients who require positive pressure or mechanical ventilation. (12-17) **Strong recommendation, low quality evidence**

  **Remarks:** Dexamethasone should be dosed at 0.15 mg/kg/dose (MAX 6mg) once daily for 10 days (or until discharge) unless there is another indication for continuing treatment. Dexamethasone may be discontinued prior to 10 days for patients with rapid improvement and no longer requiring supplemental oxygen. Dexamethasone plus remdesivir should be considered in patients with progressive respiratory disease requiring increasing respiratory support and patients with severe disease.

**Anticoagulation**

- Anticoagulant prophylaxis should be administered for all hospitalized patients ≥18 years of age who have been diagnosed with primary COVID-19. (18-31) **Strong recommendation, low quality evidence**

  **Consider prophylactic anticoagulation for hospitalized patients <18 years of age diagnosed with primary COVID-19 in the following scenarios after consultation with the Hematology team.** – **Weak recommendation, low quality evidence**

  - Any patient admitted to the intensive care unit and requiring critical care monitoring
  - Any patient ≥12 years of age AND with one or more risk factors for COVID-19 associated thromboembolism (active cancer, presence of central line, personal history of thrombosis, inherited thrombophilia, obesity [BMI >95th percentile of age], D-Dimer ≥2 UG/ML, prolonged prothrombin time [PT], elevated fibrinogen, or thrombocytopenia [platelet count >30 x 10^3/ul and <150 x 10^3/ul]).

  **Remarks:** A multicenter retrospective review including patients from Texas Children’s Hospital found an increased incidence of thrombosis in African Americans and patients of Hispanic ethnicity on univariate analysis.

  **NOTE:** Hold anticoagulation for platelet count <30 x 10^3/ul.

**Remdesivir**

- Consider the use of remdesivir in hospitalized pediatric patients with positive SARS-CoV-2 RT-PCR test result requiring supplemental oxygen or an increase in baseline respiratory support, and in hospitalized patients with progressive disease requiring increasing respiratory support. (32-40) **Weak recommendation, low quality evidence**

  **Remarks:** Evidence suggests that treatment early in the course of illness is most beneficial for patients with moderate to severe disease. The benefit in critically ill patients is less clear. We recommend starting remdesivir as a 5-day course or until hospital discharge. For patients with progressive lung disease, who are critically ill, or have underlined deficiencies that increase the risk of severe disease, we recommend considering extending the course of remdesivir up to 10 days.
Convalescent Plasma

- Consider the use of high titer convalescent plasma in hospitalized pediatric patients with positive SARS-CoV-2 RT-PCR test results requiring supplemental oxygen or an increase in baseline respiratory support who have impaired humoral immunity or an underlined comorbidity that would increase the risk of progression of disease. **Weak recommendation, very low quality evidence**

**Remarks:** Comorbidities that increase the risk of progression of COVID-19 disease include primary or acquired immunodeficiency, cardiac disease, chronic lung disease, chronic kidney disease, obesity, type 2 diabetes mellitus, sickle cell disease, pregnancy and age less than or equal to one year. Evidence suggests that high titer convalescent plasma is most beneficial early in the course of the disease.

*NOTE: The references cited represent the entire body of evidence reviewed to make each recommendation.*

**Condition-Specific Elements of Clinical Management**

**General:** Most patients with mild disease require only supportive care for non-respiratory symptoms. Patients with increased severity of disease may progress to the need for hemodynamic and respiratory support. In addition to supportive care, patients with moderate, severe and critical disease may be considered for the treatments below based upon clinical presentation and risk factors for progression of disease. Along with a varying degree of respiratory disease, patients with COVID-19 may exhibit cardiac, hepatic, renal and/or central nervous system concerns.

Management of critical illness in COVID-19 should parallel that of other infectious disease processes with the addition of infection control measures to prevent the spread of disease. The use of supplemental oxygen is warranted for patients exhibiting hypoxemia without respiratory distress. Advanced ventilatory support should be utilized in patients with respiratory distress including high flow nasal cannula and/or non-invasive positive pressure ventilation. For patients meeting the requirement for invasive ventilatory support, early intubation by an experienced practitioner is recommended.

**Treatment Recommendations:** Treatment for COVID-19 is based upon the patient’s disease severity and presence of risk factors for progression to severe disease.

**Dexamethasone** should be administered to pediatric patients with positive SARS-CoV-2 RT-PCR requiring supplemental oxygen or an increase in baseline respiratory support, in hospitalized patients with progressive disease requiring increasing respiratory support, and in hospitalized patients who require positive pressure or mechanical ventilation. A low-dose regimen of dexamethasone has been shown to be effective in reducing mortality in adult patients with severe or critical disease. The combination therapy of remdesivir and dexamethasone may be considered in patients with progressive respiratory disease requiring increasing respiratory support and patients with severe disease.

**Remdesivir** is an antiviral approved for use in hospitalized pediatric patients (12 years of age and older and weighing at least 40 kg) for treatment of COVID-19. According to the FDA, the benefits of remdesivir outweigh the potential risk of the medication for hospitalized pediatric patients weighing 3.5kg to less than 40kg or age less than 12 years weighing at least 3.5kg which has led to an emergency use authorization for patients meeting these criteria. The guideline panel suggests to consider the use of remdesivir in hospitalized pediatric patients with a positive SARS-CoV-2 RT-PCR test result requiring supplemental oxygen or an increase in baseline respiratory support, and in hospitalized patients with progressive disease requiring increasing respiratory support. Early treatment has been found to be beneficial for patients with moderate to severe disease. Remdesivir should be started as a 5-day course or until discharge. For patients with progressive lung disease, who are critically ill, or have underlined deficiencies that increase the risk of severe disease, the course of remdesivir may be extended up to 10 days.

Due to adverse effects and drug interactions, liver function tests (LFTs), partial thromboplastin time (PTT), renal function tests and signs or symptoms of infusion reaction should be monitored. Consider discontinuation of remdesivir with elevation of LFTs or signs/symptoms of liver inflammation. Please read the [FDA Emergency Use Authorization](https://www.fda.gov/emergency-preparedness-response-antip preparedness-response-antipandemic/emergency-use-authorization) for more information on remdesivir.

**Convalescent plasma** is a human blood-derived product thought to have pathogen neutralization properties. An emergency use authorization (EUA) for COVID-19 convalescent plasma was issued based upon historical evidence of convalescent plasma in prior respiratory virus outbreaks and available evidence. The use of high titer convalescent plasma may be considered in hospitalized pediatric patients with positive SARS-CoV-2 RT-PCR test results requiring supplemental oxygen or an increase in baseline respiratory support who have impaired humoral immunity or an underlined comorbidity that would increase the risk of progression of disease. Comorbidities that increase the risk of severe disease include primary or acquired immunodeficiency, cardiac disease, chronic lung disease, chronic kidney disease, obesity, type 2 diabetes mellitus, sickle cell disease, pregnancy and age less than or equal to one year. Recent evidence in adult patients has suggested that high titer convalescent plasma utilized early in the course of the disease may be beneficial. Please review the [Convalescent Plasma EUA and Fact Sheet](https://www.fda.gov/emergency-preparedness-response-antipandemic/emergency-use-authorization) for additional information on remdesivir.

**Anticoagulants** are suggested for the care of hospitalized patients with COVID-19 due to the increased incidence of thrombotic complications in patients with severe and critical disease. Recent evidence in adult patients found that COVID-19 is associated with increases in coagulation laboratory measures including D-Dimer and fibrinogen. The content expert team recommends that anticoagulant prophylaxis be administered for all hospitalized patients ≥18 years of age. For hospitalized patients <18 years of age diagnosed with primary COVID-19, anticoagulation may be considered if admitted to the intensive care unit and requiring critical care monitoring after consultation with the Hematology team. Research in pediatric patients have noted that certain clinical characteristics are associated with an increased incidence of thrombotic complications. As a result, anticoagulation may also be considered in hospitalized patients with age ≥12 years diagnosed with primary COVID-19 and with risk factors for...
COVID-19 associated thromboembolism. Please review the COVID-19 and Thromboembolism Prophylaxis: Recommendations in Children, Adolescents and Young Adults TXCH Supportive Care Practice Standard for details on anticoagulation therapy in this population.

Other Therapy may considered in patients with severe and critical disease with worsening clinical condition in consultation with specialty services.

Special Populations
Pregnancy
According to the National Institute of Health, vertical transmission of SARS-CoV-2 is rare. (4) When caring for pregnant women, clinicians should be aware that physiologic changes during pregnancy can alter oxygen requirement and laboratory values. The additional need for oxygen may have an impact on disease severity categories. (4) Please review the PFW COVID-19 Resources site for more information and pathways for the management of COVID-19 in pregnant women at Texas Children’s Hospital.

Discharge Criteria
Discharge criteria for patients with COVID-19 is consistent with that of other viral syndromes. A negative SARS-CoV-2 PCR is not necessary for discharge.
- No oxygen requirement
- Tolerating PO
- Appropriate mental status for age
- Signs of clinical improvement
- Appropriate support system (e.g., PCP, caregivers)

Consider Consults to Specialty Services
- Infectious Disease
- Hematology
- Rheumatology
- Cardiology

Measures
Process
- Length of Stay (Inpatient, ICU)
Outcome
- Mortality Rate
- Ventilation Days
- Rate of Acute Respiratory Distress Syndrome
- Days on ECMO support
- Rate of Thrombotic Events
- Rate of Cardiac Complications
### Dosing for Treatment and Adjunctive Therapy *(29, 59)*

<table>
<thead>
<tr>
<th>Medication</th>
<th>Dose</th>
<th>Additional Details</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Dexamethasone</strong></td>
<td><strong>Children and Adolescents &lt;40 kg:</strong></td>
<td>• Equivalent steroid may be indicated for pregnant women based upon gestational age</td>
</tr>
<tr>
<td></td>
<td>• 0.15 mg/kg/dose (<em>MAX</em> 6mg) once daily for 10 days (or until discharge)</td>
<td>• Contact pharmacy for equivalent steroid</td>
</tr>
<tr>
<td></td>
<td><strong>Children and Adolescents ≥40 kg:</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• 6mg once daily for 10 days (or until discharge)</td>
<td></td>
</tr>
<tr>
<td><strong>Remdesivir</strong></td>
<td><strong>Infants and Children &lt;12 years:</strong></td>
<td>• Monitor at baseline and trend liver function tests (LFTs), partial thromboplastin time (PTT), renal function tests and signs/symptoms of infusion reaction.</td>
</tr>
<tr>
<td></td>
<td>• 3.5 kg to &lt;40 kg:</td>
<td>• Consider discontinuation with elevation of LFTs or signs/symptoms of liver inflammation.</td>
</tr>
<tr>
<td></td>
<td>• IV: Loading dose: 5 mg/kg/dose on day 1, followed by 2.5 mg/kg/dose once daily</td>
<td>• Review <a href="https://www.fda.gov/emergency-preparedness-and-response/an-p-h/emergency/authorizations-and-proclamations">FDA Emergency Use Authorization</a> and <a href="https://www.fda.gov">Fact Sheet</a></td>
</tr>
<tr>
<td></td>
<td>• ≥40 kg:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• IV: Loading dose: 200 mg on day 1, followed by 100 mg once daily</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Children ≥12 years and Adolescents:</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• &lt;40 kg:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• IV: Loading dose: 5 mg/kg/dose on day 1, followed by 2.5 mg/kg/dose once daily</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• ≥40 kg:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• IV: Loading dose: 200 mg on day 1, followed by 100 mg once daily</td>
<td></td>
</tr>
<tr>
<td><strong>Convalescent Plasma</strong></td>
<td>Review the Convalescent Plasma Order Set [4005] for details on dosing.</td>
<td></td>
</tr>
<tr>
<td><strong>Anticoagulation</strong></td>
<td>Review the <a href="https://www.fda.gov">COVID-19 and Thromboembolism Prophylaxis: Recommendations in Children, Adolescents and Young Adults TXCH Supportive Care Practice Standard</a> for details on dosing</td>
<td></td>
</tr>
</tbody>
</table>
References


23. TCH Thrombosis and CVD 19 Clinical Pathway


58. Food & Drug Administration. (2020, October 22). Fact sheet for healthcare providers emergency use authorization (EUA) of Veklury® (remdesivir) for hospitalized pediatric patients weighing 3.5 kg to less than 40 kg or hospitalized pediatric patients less than 12 years of age weighing at least 3.5kg. https://www.fda.gov/media/137566/download

Clinical Standards Preparation
This clinical standard was prepared by the Evidence-Based Outcomes Center (EBOC) team in collaboration with content experts at Texas Children’s Hospital. Development of this clinical standard supports the TCH Quality and Patient Safety Program initiative to promote clinical standards and outcomes that build a culture of quality and safety within the organization.

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No relevant financial or intellectual conflicts to report.

Development Process
This clinical standard was developed using the process outlined in the EBOC Manual. The literature appraisal documents the following steps:

1. Review Preparation
   - PICO questions established
   - Evidence search confirmed with content experts

2. Review of Existing External Guidelines
   - List titles of existing guidelines or write N/A

3. Literature Review of Relevant Evidence
   - Searched: PubMed, Cochrane

4. Critically Analyze the Evidence
   - List number (alpha, not written out) of meta-analyses, randomized controlled trials, and nonrandomized studies, as applicable

5. Summarize the Evidence
   - Materials used in the development of the clinical standard, literature appraisal, and any order sets are maintained in a Care of the Hospitalized Patient with COVID-19 evidence-based review electronic file within EBOC.

Evaluating the Quality of the Evidence
Published clinical guidelines were evaluated for this review using the AGREE II criteria. The summary of these guidelines are included in the literature appraisal. AGREE II criteria evaluate Guideline Scope and Purpose, Stakeholder Involvement, Rigor of Development, Clarity and Presentation, Applicability, and Editorial Independence using a 4-point Likert scale. The higher the score, the more comprehensive the guideline.

This clinical standard specifically summarizes the evidence in support of or against specific interventions and identifies where evidence is lacking/inconclusive. The following categories describe how research findings provide support for treatment interventions.

- "Evidence Supports" provides evidence to support an intervention
- "Evidence Against" provides evidence against an intervention.
- "Evidence Lacking/Inconclusive" indicates there is insufficient evidence to support or refute an intervention and no conclusion can be drawn from the evidence.

The GRADE criteria were utilized to evaluate the body of evidence used to make practice recommendations. The table below defines how the quality of the evidence is rated and how a strong versus weak recommendation is established. The literature appraisal reflects the critical points of evidence.

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>Quality</th>
<th>Type of Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>STRONG</td>
<td>High</td>
<td>Consistent evidence from well-performed RCTs or exceptionally strong evidence from unbiased observational studies</td>
</tr>
<tr>
<td>WEAK</td>
<td>Moderate</td>
<td>Evidence from RCTs with important limitations (e.g., inconsistent results, methodological flaws, indirect evidence, or imprecise results) or unusually strong evidence from unbiased observational studies</td>
</tr>
<tr>
<td>Very Low</td>
<td>Low</td>
<td>Evidence for at least 1 critical outcome from observational studies, RCTs with serious flaws or indirect evidence</td>
</tr>
</tbody>
</table>

Recommendations
Practice recommendations were directed by the existing evidence and consensus amongst the content experts. Patient and family preferences were included when possible. The Content Expert Team and EBOC team remain aware of the controversies in the diagnosis/management of COVID-19 in children. When evidence is lacking, options in care are provided in the clinical standard and the accompanying order sets (if applicable).

Approval Process
Clinical standards are reviewed and approved by hospital committees as deemed appropriate for its intended use. Clinical standards are reviewed as necessary within EBOC at Texas Children’s Hospital. Content Expert Teams are involved with every review and update.

Disclaimer
Practice recommendations are based upon the evidence available at the time the clinical standard was developed. Clinical standards (guidelines, summaries, or pathways) do not set out the standard of care and are not intended to be used to dictate a course of care. Each physician/practitioner must use his or her independent judgment in the management of any specific patient and is responsible, in consultation with the patient and/or the patient’s family, to make the ultimate judgment regarding care.

Version History
<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>May 2021</td>
<td>Originally Completed</td>
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</tbody>
</table>