Severity of Illness Categories (Based on NIH Guidelines)

Patients with SARS-CoV-2 infection can experience a range of clinical manifestations, from no symptoms to critical illness.

Asymptomatic or Presymptomatic Infection: Individuals who test positive for SARS-CoV-2 using a virologic test (i.e. a nucleic acid amplification test PCR or an antigen test) but have no symptoms consistent with COVID-19. May habe been found to be COVID + when tested for reasons other than symptoms (e.g., pre-op,behavioral health admission)

Mild Illness: Individuals who have any of the various 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 do not have shortness of breath, dyspnea, or abnormal chest imaging. No oxygen requirement; able to self-hydrate (possibly after initial fluid support).

Moderate Illness: Individuals with evidence of lower respiratory disease during clinical assessment or imaging and have an oxygen saturation (SpO2) ≥94% on room air at sea level.

Severe Illness: Individuals with SpO2 <94% on room air, respiratory rate >30 breaths per min, signs of pneumonia, or lung infiltrates >50%.

Critical Illness: Individuals who have respiratory failure, septic shock, and/or multiple organ dysfunction.

Note: In pediatric patients, radiographic abnormalities are common and should not be the only criteria used to determine the severity of illness. Also, normal values for respiratory rate vary with age in children; so hypoxia should be the primary criterion used to define severe COVID-19, especially in younger children.

For further information: https://www.covid19treatmentquidelines.nih.gov/overview/clinical-spectrum/

In a small number of children and in some young adults, SARS-CoV-2 infection may be followed by a severe inflammatory condition called multisystem inflammatory syndrome in children (MIS-C).

ANMC Acute Pediatric SARS-CoV-2 (COVID-19) Clinical Pathway

ED Management

Evaluate

- Signs/symptoms, vital signs, hydration respiratory status
- Consider possible alternate etiologies for illness
- When influenza is co-circulating, test for influenza A/B and add Oseltamivir if positive Positive COVID-19 Test:
 - Assess for Severity of Illness Category (purple box)
 - Consider MIS-C if cardiac involvement or labs indicative of serve inflammation and/or multiorgan involvement (misC.pdf (anthc.org))

Asymptomatic

Outpatient Supportive Care

- Assess eligibility for anti-SARS-CoV-2 monoclonal antibodies
 - Refer to SCF Outpatient monoclonal antibody pathway OR
 - Call AK Statewide COVID Helpline:
 - (907) 646-6332
 - Offers monoclonal antibody treatment assistance

*Note on Admitting Non-Severe Children

Children with non-severe COVID-19 may require hospital admission if:

- They are at risk for severe disease due to underlying conditions (i.e. immune compromise)
- Febrile infants younger than 90 days
- Admitted for non-COVID related issue (i.e. trauma)

Mild or Moderate Disease*

Supportive Care

- Evaluate and treat suspected coinfections based on symptoms
- Likely safe for discharge
- Outpatient management ideal
- Assess eligibility for anti-SARS-CoV-2 monoclonal antibodies
 - Refer to SCF Outpatient monoclonal antibody pathway OR
 - Call AK Statewide COVID Helpline:
 - (907) 646-6332
 - Offers monoclonal antibody treatment assistance
- Consider observation or local discharge if high risk for decompensation

Contact the Pediatric Hospitalist Service

- Needing admission for other reasons or high risk (blue box)
- Hypoxic, needing supplemental oxygn
- Anyone on HFNC < 2L/kg

Severe Disease

LABS:

- CBC, CMP, CRP, Procalcitonin
- If febrile or in shock:
- Consider blood culture, troponin, pro-BNP, lactate, blood gas

STUDIES:

- CXR
- Consider EKG

INTERVENTIONS:

- Oxygen therapy
- Start steroid therapy see medication dosages on page 3, ideally Dexamethasone
- Remdesivir should be given to all hypoxic children with acute covid and <10 days of symptom onset
- For acute Covid with abnormal CXR or concerns for sepsis: if procalcitonin >0.25 start antibiotics (Ceftriaxone)

ADMISSION to Pediatric Hospitalist Service:

- · Hypoxic, needing supplemental oxygn
- Anyone on HFNC < 2L/kg

Critical

- LABS:
- CBC, CMP, CRP, Procalcitonin
- · If febrile or in shock:
 - Consider blood culture, troponin, pro-BNP, lactate, blood gas

STUDIES:

- CXR
- Consider EKG

INTERVENTIONS:

- Oxygen therapy
- Start steroid therapy see medication dosages on page 3, ideally Dexamethasone
- Remdesivir should be given to all hypoxic children with acute covid and <10 days of symptom onset
- For acute covid with abnormal CXR or concerns for sepsis: if procalcitonin >0.25 start antibiotics (Ceftriaxone)

ADMISSION to Pediatric Critical Care Service

- HFNC ≥ 2 L/min/kg Or ≥ 20L/min
- Other non-invasive positive pressure
- Endotracheal Intubation
- Shock

ANMC Acute Pediatric SARS-CoV-2 (COVID-19) Clinical **Pathway**

Patient Admitted To Hospital With Confirmed COVID-19 Infection Interventions Based On Illness Severity

Asymptomatic/Exposed **And High Risk**

*Children seen for something other than COVID but incidentally identified with COVID-19 may may require hospital admission if:

- they are at risk for severe disease due to underlying conditions (eg, immune compromise)
- Requiring observation
- · Admitted for non-COVID related issue (i.e. trauma, behavioral health)

Symptomatic:

- Fever
- Sore throat
- Cough
- Mvalgias
- No respiratory distress
- No oxygen requirement
- Adequate hydration

Mild or Moderate*

- Signs or symptoms of COVID-19 requiring hospital admission, but not meeting criteria for critical care
 - New oxygen requirement
 - No requirement for non-invasive ventilation or mechanical ventilation

 - May require ongoing IVF support

Supportive Care

- Supportive care and monitor for increasing severity
- · Assess eligibility for anti-SARS-CoV-2 monoclonal antibodies
 - Refer to SCF Outpatient monoclonal antibody pathway OR
 - Call AK Statewide COVID Helpline:
 - (907) 646-6332
 - Offers monoclonal antibody treatment assistance

Supportive Care Only

- Evaluate and treat suspected co-infections based on symptoms
- For high risk patients who may benefit from mAb infusion:
- Refer to SCF Outpatient monoclonal antibody pathway OR
- Call AK Statewide COVID Helpline:
- (907) 646-6332
- Offers monoclonal antibody treatment assistance
- · No additional tests/treatments needed
- · Manage primary condition

• No need for rapid escalation of care

Severe

Supportive Care, Oxygen, Steroids, Remdesivir

- Start Dexamethasone
- Consider Daily Labs for first few days: CBC/diff, CMP, ESR, Procalcitonin, CRP, albumin
- · Consider lactate, blood gas, troponin, NT-pro-BNP, UA, Resp viral panel
- If patient ≥ 12 yrs old OR has additional VTE risk factors, add:
 - PT/PTT/INR/fibrinogen, d-dimer AND start VTE prophylaxis.
- CXR, EKG if respiratory symptoms
- Evaluate and treat suspected coinfections based on symptoms.
- Remdesivir should be given to all children with acute Covid < 10 days since symptoms onset and saturations <94%

Critical

- Respiratory Distress/Respiratory Failure/Hypoxia
- Requiring non-invasive ventilation or mechanical ventilation
- SIRS/Sepsis/Multi-Systems Organ Failure
- Rapidly deteriorating clinical condition requiring escalation of care
- Requires PICU admission

Follow Severe Plan PLUS Consider Immunomodulating Therapy

- Start Dexamethasone
- Obtain CBC+diff, CRP, procalcitonin. CMP, IgG, PT/PTT/INR/fibrinogen, d-dimer, LDH, ferritin, triglyceride, CPK, troponin, blood culture
- CXR and EKG
- VTE prophylaxis per COVID VTE quidelinlines
- Consult ID and other specialists as indicated.
- Immunomodulating therapy: Tocilizumab or Baricitinib

Medications

Pediatric Dosages

Dexamethasone

- 0.15 mg/kg (max 6 mg/dose) IV/NG/PO q24h for up to 10 days for patients requiring persistent supplemental oxygen or mechanical ventilation
- Can be discontinued when oxygen saturations sustained above 94%
 - Recommend against use in patients not requiring supplemental oxygen

Ceftriaxone

- 50 to 75 mg/kg/dose IV every 24 hours (Max: 1 g/day),
- For more serious infections, 100 mg/kg/day IV divided every 12 to 24 hours (Max: 4 g/day)
 Remdesivir
- Labs prior to initiation and daily: BMP, CBC+diff , AST, ALT, alkaline phosphatase, T/D bilirubin, PT (PT at least on initiation)
- 3.5 kg to < 40 kg: 5 mg/kg IV ×1 dose, followed by:
- 2.5 mg/kg q24h x 4 days (if no mechanical ventilation or ECMO) OR
- 2.5 mg/kg q24h ×9 days (if mechanical ventilation or ECMO)
- ≥ 40 kg: 200 mg IV ×1, followed by:
- 100 mg IV q24h ×4 days (if no mechanical ventilation or ECMO).
- If no clinical improvement after a total of 5 days of treatment, treatment can be extended to up to a total of 10 days, OR
- 100 mg IV g24h ×9 days (if mechanical ventilation or ECMO)
- Consider discontinuation if ALT > 10 × ULN during treatment
- $\bullet \ \, \text{Discontinue if ALT elevation is accompanied by s/s of liver inflammation or eGFR < 30 \ mL/min }$

Tocilizumab

- Wt < 30 kg: 12 mg/kg IV x 1 (one) dose
- Wt > 30 kg: 8 mg/kg IV x 1 (one) dose (max 800 mg/dose)
- A 2nd dose can be given after 8 hours based on clinical response.

Baricitinib:

- Age 2 years to less than 9 years old: 2mg PO once daily
- Age 9 years and older: 4 mg PO once daily
- Duration is unknown at this time, though in adults it is given for up to 14 days while hospitalized in combination with remdesivir and dexamethasone
- The NIH Panel **recommends against** the use of **sarilumab** for hospitalized children with COVID-19 or MIS-C, except in a clinical trial.

Alternative Steroid Regimen

- Consider if child has ARDS or contraindications for dexamethasone (Dexamethasone Preferred)
- Prednisolone 1mg/kg PO once daily (maximum dose 40mg)
- Methylprednisolone 0.8mg/kg IV once daily (maximum dose 32mg)
- · Hydrocortisone:
- Age 0-1 month: 0.5mg/kg IV q12h for 7 days, followed by 0.5mg/kg IV once daily for 3 days
- Age > 1 month: 1.3mg/kg IV every 8 hours (maximum dose 50mg; maximum daily dose 150mgMethylprednisolone 0.8 mg/kg/day (max 32 mg)

COVID VTE Prophylaxis

Lovenox

- Age > 2 months to <18 years:
 - < 60 kg: 0.5 mg/kg SQ BID
 - > 60 kg: 40 mg SQ daily
- Discuss dosing and monitoring parameters with Pharmacy

Notes

• Remdesivir: (RDV)

- Remdesivir is an FDA approved therapy in patients ≥ 12 yrs ≥ 40 kg. Order and administer like any other FDA approved therapy.
- Pediatric patients <12 yrs and/or weighing <40 kg are authorized to receive Remdesivir via FDA EUA.
 If decision is made to administer RDV, all criteria outlined within FDA EUA must be met.
- May Consider Use in Neonates < 3.5 kg who are not covered under either FDA EUA or FDA approval
- Remdesivir dosing should be discussed with Gilead Medical Monitor (MM-COVID19@gilead.com).
- In non-immunosuppressed patients, consider discontinuing RDV in patients who are afebrile and no longer require supplemental oxygen (< 38C for 24 hours and otherwise ready for discharge).
- NOT FOR USE:
 - Adult and pediatric patients (> 28 days old) with eGFR < 30 mL/min, OR
- Full-term neonates (≥ 7 days to ≤ 28 days old) with SCr ≥ 1 mg/dL

Tocilizumab:

- Tocilizumab is authorized via FDA EUA for patients >=2 yrs. Follow all criteria outlined in EUA when
 ordering and documenting in provider progress note and ensure Patient Fact Sheet given to parent or
 caregiver.
- Tocilizumab is contraindicated in patients with co-existing active severe bacterial and/or fungal infection, pregnancy, ALT/AST> lox upper limit normal, ANC < 1000/mm3 or PLT < 50,000 mm3
- Severely immunocompromised patients should be considered on a case-by-case basis with an ID consult.
- Second dose is approved via EUA if clinical signs/symptoms worsen or do not improve within 8 hrs after the first dose, though effectiveness is not established and not routinely recommended.

Baricitinib:

- Although the FDA has issued an emergency use authorization for barticitinib in patients ≥2 years of age who are hospitalized with COVID-19 and require oxygen or ventilatory support, or extracorporeal membrane oxygenation, there is limited information about the benefits and risks of baricitinib in children with COVID-19.
- Hospitalized adult patients with severe COVID-19 on high-flow devices or noninvasive ventilation (e.g. BIPAP) can receive baricitinib 4 mg PO daily for up to 14 days while hospitalized in combination with remdesivir and dexamethasone. Barticitinib should not be given with tocilizumab, or if a patient has received tocilizumab.
- Baricitinib is contraindicated in patients on dialysis or ESRD (eGFR < 15), active tuberculosis or co-existing active severe bacterial/fungal infection.
- \circ Consider withholding therapy in patients with absolute lymphocyte count < 200 cells/ μ l, ANC < 500 cells/ μ L
- $\,{\scriptstyle \circ}\,$ Severe immunocompromised patients should be assessed on a case by case basis.
- Thrombosis, including DVT/PE have been observed. DVT prophylaxis is recommended unless contraindicated.
- Baricitinib requires renal adjustment in patients with eGFR < 60. Check with pharmacy prior to ordering.
- Follow all criteria outlined in EUA when ordering and documenting in provider progress note and ensure Patient Fact Sheet given to parent or caregiver.

ANMC Pediatric SARS-CoV-2 (COVID-19) Monoclonal Antibody (mAb) Clinical Pathway

Given the rapidly evolving guidelines and recommendations for monoclonal antibody treatment and other therapeutics in pediatric patients, contact the **ANMC On-Call Pediatrics** available via Tiger Text (Tiger Text number is (907) 782-4825) or through the ANMC Transfer Center Coordinator (907) 729-2337

Eligibility Criteria per FDA EUA For Identifying High Risk Individuals

The EUA eligibility criteria are listed below for monoclonal antibody treatment of mild to moderate COVID-19 in adults and pediatric patients with positive results of direct SARS-CoV-2 viral testing and who are at high risk for progressing to severe COVID-19 and/or hospitalization.

- · Criteria include one or more of the following:
- ∘ Age ≥ 65 years of age
- < 1 year of age</p>
- BMI ≥ 25, or if 12-17 years of age, have BMI ≥ 85thpercentile for their age and gender based on CDC growth charts,https://www.cdc.gov/growthcharts/clinical_charts.htm
- Pregnant
- Chronic kidney disease
- Diabetes
- Immunosuppressive disease or receiving immunosuppressive treatment
- Cardiovascular disease (including congenital heart disease) or hypertension
- Have chronic lung diseases (for example, chronic obstructive pulmonary disease, asthma [moderate-to-severe], interstitial lung disease, cystic fibrosis, and pulmonary hypertension
- Sickle cell disease
- Neurodevelopmental disorders (for example, cerebral palsy) or other conditions that confer medical complexity (for example, genetic or metabolic syndromes and severe congenital anomalies)
- Have a medical-related technological dependence (for example, tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID-19))
- Other medical conditions or factors (for example, race or ethnicity) may also place individual patients at high risk for progression to severe COVID-19 and authorization of COVID-19 monoclonal antibody treatment under the EUA is not limited to the medical conditions or factors listed above. For additional information on medical conditions and factors associated with increased risk for progression to severe COVID-19, see the CDC website:

https://www.cdc.gov/coronavirus/2019-ncov/need-extraprecautions/people-with-medical-conditions.html

Healthcare providers should consider the benefit-risk for an individual patient.

Monoclonal antibodies are NOT authorized for use in patients:

- · who are hospitalized due to COVID-19, OR
- who require oxygen therapy due to COVID-19, OR
- who require an increase in baseline oxygen flow rate due to COVID-19 in those on chronic oxygen therapy due to underlying non-COVID-19 related comorbidity.
- Monoclonal antibody treatments for Covid-19 may interfere with the vaccine-induced immune response.
- Deferral of Covid-19 immunization for 90 days is recommended.

Links

Links to Other Pathways/Guidelines and Outside Resources

- Gilead Remdesivir EUA Fact Sheet For Healthcare Providers
- Gilead Remdesivir EUA Fact Sheet For Parents and Caregivers
- Alaska Department of Health and Human Services COVID-19 Resources for Healthcare Providers
 - Includes Monoclonal Antibody guidance
- misC.pdf (anthc.org)

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- Fact Sheet for Parents and Caregivers Emergency Use Authorization (EUA) of VEKLURY® (remdesivir) for Hospitalized Children Weighing 8 pounds (3.5 kg) to Less Than 88 pounds (40 kg) or Hospitalized Children Less Than 12 Years of Age Weighing at least 8 pounds (3.5 kg) with Coronavirus Disease 2019 (COVID-19). https://www.gilead.com/remdesivir

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