

Outpatient Prioritization Protocol for COVID-19 Therapies

[Centralized scheduling team determines level based on access]

Level	Eligibility Criteria
Level 0	Meets basic criteria on Slide 2
Level 1	Meets criteria on Slide 3
Level 2	Meets Criteria on Slide 4

Applies to oral and parenteral COVID-19 therapeutics

Comments for Workstream

- Prioritization scheme applies to adults and adolescents (>12 years, >40 kg)
- Based on treatment capacity and/or supply, those with shorter time from symptom onset may be prioritized within any given level
- For each level, if all patients in the queue have been scheduled, OK to schedule patients at a 'lower' level (for example, if Level 2 and all patients are scheduled, can look at Level 1 patients)
- Due to operational realities, patients will not be cancelled once scheduled, even if higher priority patients are identified later.
- **For all levels, restriction criteria and EUA qualifications must be met**

Basic Treatment Criteria (Level 0)

Inclusion Criteria – all must be met

- Confirmed SARS-CoV2 at high-risk for disease progression and/or hospitalization
 - See [definitions](#)
- Not currently admitted to an inpatient facility (in other words, is an outpatient)
- 1 or more mild-to-moderate COVID-19 symptom (for example: fever, cough, sore throat, muscle pain, etc.)
- Meets therapeutic agent-specific criteria including days from symptom onset, age, pregnancy status, concomitant medications, etc
 - Sotrovimab – [EUA](#) | [UNC Criteria](#)
 - Paxlovid – [EUA](#) | [Resource Sheet](#)
 - Molnupiravir – [EUA](#) | [Resource Sheet](#)

Exclusion Criteria

- New or increased supplemental oxygen requirements due to COVID-19

Level 1 Criteria

- Patient is COVID (+) and has 1 or more of the following symptoms: fever, chills, cough, shortness of breath, sore throat, nasal congestion, muscle/body aches

AND

- Patient falls into 1 of the following categories
 - Age \geq 65 years
 - BMI \geq 35 kg/m² or, if 12-17 years, BMI \geq 95th percentile for age and gender (per [CDC growth charts](#))
 - Diabetes if BMI \geq 30 kg/m²
 - Cardiovascular disease or hypertension if BMI \geq 30 kg/m²
 - Diagnosis of immunosuppressive disease (for example: cancer [not in remission]; solid organ transplant recipient; HIV w CD4 <200 cells/m³)
 - Current (or recent, within 3 months) immunosuppressive therapy (for example: chemotherapy; immunosuppressive biologics, anti-rejection transplant therapies, TNF blockers; \geq 20 mg/day or \geq 2 mg/kg/day prednisone or equivalent for \geq 14 days)
 - Chronic lung disease (for example: COPD, cystic fibrosis, PAH, etc)
 - Pregnant or recent pregnancy (in other words, delivered within last 6 weeks)
 - Neurodevelopmental disorders affecting respiratory function (for example: cerebral palsy)
 - Sickle cell disease
 - Congenital heart disease causing significant hemodynamic compromise
 - Medical-related technological dependence (for example: tracheostomy, gastrostomy, or positive pressure ventilation [not related to COVID-19])

Level 2 Criteria

Patient falls into one of the following groups:

- Unvaccinated and age \geq 70 years
- Unvaccinated and BMI \geq 40 kg/m²
- One of the following, without respect to vaccination status:
 - Age \geq 80 years
 - [Severe chronic lung disease](#)*
 - [Severely immunocompromised](#)*

*Requires screening by RN Coordinator team. See [screening questions](#); if additional levels of screening are required, RN refers patient to Virtual Practice Provider team.

Definitions

Severe Chronic Lung Disease*

- Interstitial lung disease (including sarcoidosis)
- Pulmonary embolism
- Bronchopulmonary dysplasia
- Bronchiectasis (including cystic fibrosis)
- Severe COPD (GOLD Classification 3-4; GOLD groups C or D)
- Severe pulmonary hypertension (WHO Functional Class II – IV)

Severely Immunocompromised*,#

- B-cell depleting therapy (for example: rituxumab, ocrelizumab, ofatumumab, alemtuzumab, mycophenolate) within the past 6 months
- Currently receiving BTK inhibitor therapy
- Receipt of Allo-HCT/Auto/CAR-T (for heme malignancies) and within 1 year of transplant
 - *Except Autologous HCT for multiple myeloma, then within 6 months of transplant*
- Active GVHD on at least 10mg/day prednisone for ≥ 14 days
- Multiple myeloma on anti-CD38a, anti-BCMA, or any non-maintenance therapy within the last 3 months
- ALL, B-cell malignancy on chemo/immunotherapy within the last 3 months
- Active CLL (not in remission)
- Solid organ transplant
 - *Within 6 months of transplant (or rejection treatment with antibody-based therapy) AND over 65*
 - *Lung transplant (or rejection treatment with antibody-based therapy) regardless of age or transplant date*
- Severe congenital immunodeficiency impacting B-cell function
- Other severe immunodeficiencies or contraindications to vaccination (due to allergy) to be reviewed on an individual basis

Medications are listed as examples and are not an exhaustive list of therapies that would qualify a patient for treatment; please consult the referring Clinician if there are questions.

* Requires screening by RN Coordinator team. See [screening questions](#); if additional levels of screening are required, RN refers patient to Virtual Practice Provider team.

RN Coordinator Screening Questions (Level 2)

- **Do you have a severe chronic lung disease that keeps you so short of breath that it is difficult for you to go places or requires you to be on oxygen: {Yes/No/Na}**
- **Severely immunocompromised: {Yes/No/Na}**
 - Have you had a solid organ transplant within the past 6 months?
 - Have you had a bone marrow transplant within the past year?
 - Have you had leukemia or lymphoma or multiple myeloma?
 - Are you receiving a medication prescribed by a Rheumatologist or other specialist to control an autoimmune condition like lupus? (for example: rituximab, ocrelizumab, ofatumumab, alemtuzumab, anifrolumab, mycophenolate, etc[#])?
 - Were you born with a severe immunocompromising condition?

If additional levels of screening are required, RN refers patient to Virtual Practice Provider team.

Medications are listed as examples and are not an exhaustive list of therapies that would qualify a patient for treatment; please consult the referring Clinician if there are questions.

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UNC Health

High-Risk Criteria for COVID-19 Progression

Adult & Pediatrics (≥12 years, ≥40 kg)

Patient meets one or more of the following:*

- Older age (eg, age ≥65 years)
- Overweight or obese (BMI ≥25 kg/m² *or*, if 12-17 years, BMI ≥ 95th percentile for age and gender per [CDC growth charts](#))
- Chronic kidney disease (*for example, CrCl <60 mL/min*)
- Diabetes
- Cardiovascular disease, hypertension, or congenital heart disease causing significant hemodynamic compromise.
- Chronic lung disease (*for example, moderate-severe asthma, COPD, cystic fibrosis, PAH*)
- Pregnant or recent pregnancy (*in other words, delivered within last 6 weeks*)
- Sickle cell disease
- Neurodevelopmental disorders affecting respiratory function (*for example, cerebral palsy, etc*)
- Medical-related technological dependence (*for example, tracheostomy, gastrostomy, or positive pressure ventilation [not related to COVID-19]*)
- Diagnosis of immunosuppressive disease (*for example, cancer [not in remission]; solid organ transplant recipient; HIV w CD4 <200 cells/m³*)
- Currently (or recent, within 3 months) receiving immunosuppressive treatment (*for example, chemotherapy; B-cell depleting therapy; steroid use at ≥20 mg/day or ≥2 mg/kg/day prednisone or equivalent for ≥ 14 days*)

Additional guidance for pediatrics age 12-17 can be found [here](#).

**Not all-inclusive; other conditions may apply, per physician discretion. Please refer to the [CDC site](#) for additional information on high-risk factors.*

High-Risk Criteria for COVID-19 Progression

Pediatrics (<18 years and <40 kg or <12 years)

As of 1/24/22: Remdesivir is the only therapeutic option for this population

Please refer to [this document](#) for considerations in pediatric patients <40 kg or <12 years of age

It is strongly recommended to consult with a Pediatric ID Specialist before placing a referral for patients in this age group