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Management Strategies in Children and Adolescents with Mild to Moderate COVID-19

General pediatricians, pediatric subspecialists, and pediatric surgeons have a crucial role in providing frontline medical care to children and adolescents during the COVID-19 pandemic. As of December 16, 2021, over 7.3 million children and adolescents have had laboratory-confirmed SARS-CoV-2 infection, representing 17.3% of all reported COVID-19 cases in the United States.[1,2] Starting in July-August 2021, rates of pediatric COVID-19 hospitalizations increased in certain geographic areas[3-5]; 0.1% to 2% of COVID-19 cases in children and adolescents resulted in hospitalization, and 0 to 0.03% resulted in death.[6] Current epidemiologic data suggest that overall, children and adolescents with COVID-19 have less disease severity and good clinical outcomes when compared with their adult counterparts; some children and adolescents with certain host factors and underlying medical conditions may be at increased risk for severe illness from SARS-CoV-2 infection.[7-15]

COVID-19 vaccination is strongly recommended for all eligible individuals, including children ≥5 years of age and household contacts of children not yet eligible for COVID-19 vaccination. COVID-19 vaccination continues to be one of **the most important and effective tools** in protecting ourselves, our families, and our communities.[16] SARS-CoV-2 monoclonal antibodies (mAb) have emerged as potential treatment and preventive strategies in the outpatient management of patients at highest risk of severe COVID-19 who may not be eligible for COVID-19 vaccination, have an underlying medical condition, or are receiving therapies that are known to result in a poor antibody response to vaccination.

The American Academy of Pediatrics (AAP) strongly supports the equitable distribution and availability of therapeutic medications and vaccinations to eligible children and adolescents. Given rapidly emerging data and changes in mAb indications, while simultaneously acknowledging that mAb may be in short supply or not readily accessible in all geographic

areas and that there continues to be a paucity of pediatric-specific data regarding the safety, efficacy, and pharmacokinetics of mAb across all age groups, this interim guidance is intended to help navigate management challenges and considerations and summarize currently available recommendations for the outpatient management of COVID-19 in children and adolescents.

As of December 23, 2021, the FDA has noted that data show that it is **unlikely** that bamlanivimab and etesevimab administered together or REGEN-COV will retain activity against this variant. Based on similar cell culture data available, sotrovimab **appears to retain** activity against the Omicron variant. **Based on this information, allocations of bamlanivimab and etesvimab together, etesevimab alone, and REGEN-COV have been paused pending updated data from CDC.** Limited shipments of sotrovimab continue.

The US Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) of SARS-CoV-2 mAb in **high-risk** individuals in outpatient settings for (1) the **treatment**[17] of mild to moderate COVID-19, (2) post-exposure prophylaxis[18-20], and (3) **pre-exposure prophylaxis.**[21] The choice of SARS-CoV-2 mAb will be individualized in each high-risk patient and will depend on (a) the indication for mAb and satisfying criteria, (b) age and weight, (c) local circulating SARS-CoV-2 variant susceptibility,1 and (d) local availability of mAb products (refer to Figure 1 and Tables 1-3 for additional information).

The following are the FDA EUA Criteria for SARS-CoV-2 mAb by indication:

(1) COVID-19 Treatment

- Nonhospitalized patient,[b] **and**
- Laboratory-confirmed SARS-CoV-2 infection, **and**
- Mild to moderate[28,29] COVID-19, **and**
- Within 10 days of symptom onset, **and**
- High risk for progressing to severe COVID-19 and/or hospitalization

mAb therapies are **NOT** authorized for use in:

- Patients hospitalized for COVID-19; **or**
- Patients who require oxygen therapy for COVID-19; **or**

- Patients who require an increase in baseline oxygen flow rate in those already receiving chronic oxygen therapy for other, non–COVID-19 related, underlying conditions.

(2) COVID-19 Postexposure Prophylaxis

- Nonhospitalized patient, **and**
- Not fully vaccinated or fully vaccinated but not expected to have an adequate serologic immune response (eg, underlying immunocompromising conditions or receiving immunosuppressive medications), **and**
- Close contact (following Centers for Disease Control and Prevention [CDC] definitions) with an individual with laboratory-confirmed SARS-CoV-2, **or**
- At high risk of exposure to an individual infected with SARS-CoV-2 because of occurrence of SARS-CoV-2 infection in other individuals in the same institutional setting (for example, long-term care residences or prisons)[29]

(3) COVID-19 Preexposure Prophylaxis

- Child/adolescent ≥12 years of age and weighing ≥40 kg, **and**
- No SARS-CoV-2 infection or exposure: Not known to be infected with SARS-CoV-2, no past history of laboratory-confirmed COVID-19, or recent exposure to an individual infected with SARS-CoV-2, **and**
- Moderate or severe immunocompromise from an underlying condition or medication that does not allow for an adequate serologic immune response to COVID-19 vaccination or in whom vaccination is medically contraindicated. Examples of conditions leading to moderate or severe immunosuppression include:
    - Receipt of a hematopoietic cell transplantation in the previous 2 years and lack of immune reconstitution or taking immunosuppressive medications
    - Receipt of chimeric antigen receptor (CAR) T-cell therapies in the previous 2 years
    - Known underlying primary immunodeficiency (eg, DiGeorge syndrome, Wiskott-Aldrich syndrome)
    - Untreated or advanced HIV infection (eg, history of having an AIDS-defining illness without immune reconstitution, CD4+ T-lymphocyte count <200/mm^3)
    - Receiving active chemotherapy for underlying hematologic malignancies or solid tumors

- Receipt of a solid organ transplant within the last 3 months and receiving immunosuppressive medications leading to moderate/severe immunocompromise[c]
- Actively receiving treatment with immunosuppressive medications leading to moderate/severe immunocompromise[c]

Figure 1. Summary of available SARS-CoV-2 monoclonal antibody preparations based on indication and age/weight inclusion criteria in children and adolescents at high risk for progressing to severe COVID-19

	Minimum Age & Weight	
Treatment Mild to Moderate COVID-19	**>1 kg and <40 kg** • Bamlanivimab/Etesevimab	**>40 kg** • Bamlanivimab/Etesevimab **>12 years and >40kg** • Casirivimab/Imdevimab • Sotrovimab
POST- Exposure Prophylaxis	**>1 kg and <40 kg** • Bamlanivimab/Etesevimab	**>40 kg** • Bamlanivimab/Etesevimab **>12 years and >40kg** • Casirivimab/Imdevimab
PRE- Exposure Prophylaxis	**<12 years and <40 kg** • No mAb option	**>12 years and >40kg** Tixagevimab and Cilgavimab

Alphabetical order of mAb listing in Figure 1 does not indicate preference of one monoclonal over another; choice of agent will depend on indication, age/weight of patient, local circulating SARS-CoV-2 variant susceptibility, and availability of mAb products by geographic areas.

Note: Circulating SARS-CoV-2 viral variants may develop resistance to any of the mAb preparations; certain mAb products may not be used in geographic areas where the combined frequency of SARS-CoV-2 variants resistant to that specific mAb is >5%. Refer to the most updated information and recommendations.[22,24,26] Sotrovimab is the only mAb with anticipated clinical activity against the omicron variant, which now accounts for the vast majority of SARS-CoV-2 infections in the United States.

Which children and adolescents are considered "high risk" and may qualify for outpatient treatment with SARS-CoV-2 monoclonal antibodies?

Data from randomized studies demonstrate that timely outpatient SARS-CoV-2 mAb therapy reduced the risk for hospitalization and death in adults with COVID-19.[30,31] Use of SARS-CoV-2 mAb for all indications remains investigational in children and adolescents. Lack of proven identifiable risk factors and lack of robust safety and efficacy data across all age pediatric groups precludes the routine use of mAb in all children and adolescents with COVID-19. Instead, an individual risk/benefit assessment should be performed when considering mAb for a child/adolescent who is at high risk for COVID-19.

High-risk criteria in the FDA EUA for SARS-CoV-2 mAb include[32]:

- **Body mass index (BMI) ≥85th percentile** for age and gender based on CDC **growth charts**
- **Immunosuppressive disease or receipt of immunosuppressive therapies**[c]
- Neurodevelopmental disorders (eg, cerebral palsy, trisomy 21)
- A medical-related technological dependence that is not related to COVID-19 (eg, **tracheostomy, positive pressure ventilation,** gastrostomy)
- Sickle cell disease
- Congenital or acquired heart disease
- Chronic lung disease (eg, interstitial lung disease, tuberculosis); asthma or other chronic respiratory disease that requires daily medication for control
- Diabetes
- Chronic kidney disease
- Chronic liver disease (eg, cirrhosis, autoimmune hepatitis)
- Pregnancy; **or**
- Age <1 year
    - The majority of infants have mild, uncomplicated SARS-CoV-2 infection and, therefore, routine use of mAb in all infants <1 year of age is not recommended. Published case report data suggest that young infants, particularly those <90 days of age, are hospitalized more frequently; however, the **indication for hospitalization** may be confounded by need for evaluation of fever in these infants who otherwise have mild COVID-19 symptoms and good outcomes.[33-36]
    - This is a newly added criterion to the recent expanded EUA, based on limited safety and efficacy data extrapolated from adolescents and pharmacokinetic data from pediatric clinical trials or pharmacokinetic modeling.[37-39]

- More recent data evaluating **risk factors for severe COVID-19** in young infants, in whom severity is defined by requiring admission to the intensive care unit or mechanical ventilation, have identified **prematurity** (gestational age <37 weeks) as a risk factor for severe COVID-19.[9,10,40,41] Clinicians can consider mAb in preterm infants, particularly if they have other concurrent comorbid conditions that place them at highest risk for progression to severe disease (eg, chronic lung disease, cardiovascular disease, neurologic or congenital disorders).

Proven risk factors for disease severity and poor outcomes from COVID-19 in children and adolescents have not been confirmed. The **bolded** conditions in the FDA EUA for mAb have been described in observational studies of children with severe COVID-19. Routine SARS-CoV-2 mAb therapies are **not** indicated for children/adolescents with COVID-19 at low risk for progression or hospitalization.

When should mAb therapy be initiated?

Treatment: SARS-CoV-2 mAb should be started as quickly as possible following a positive SARS-CoV-2 test result and **within 10 days of symptom onset** in eligible individuals.

Postexposure prophylaxis: Casirivimab-imdevimab or bamlanivimab-etesevimab should be prescribed as soon as possible to eligible individuals, **optimally within 96 hours** and maximally within 7 days after the confirmed SARS-CoV-2 exposure, on the basis of results of randomized controlled trials.[42]

Preexposure prophylaxis: Tixagevimab and cilgavimab should be given to eligible high risk patients at least 2 weeks after their last COVID-19 vaccine dose. Duration of protection is being evaluated and may continue for at least 6 months.

Are there precautions my practice should take when administering mAb?

mAb should only be administered in settings in which health care clinicians have immediate access to medications to treat a severe infusion reaction, such as anaphylaxis, and the ability to activate the emergency medical system (EMS), as necessary. It may be necessary for pediatricians to collaborate and to coordinate with community health care settings to provide mAb therapy. In addition, patients should be clinically monitored during administration and observed for at least 1 hour following administration.

What adverse reactions have been reported after SARS-CoV-2 mAb therapies?

- Local injection site reactions are the most frequently reported events (4%-12%). Infusion-related reactions, including fever, chills, shortness of breath, dizziness, abdominal pain, nausea, vomiting and flushing, and pruritus, have been reported to occur during and up to 24 hours after administration. Serious hypersensitivity reactions, including anaphylaxis, may also occur.[43]
- Pediatricians should report all medication errors and serious adverse reactions potentially related to mAb to the **FDA MedWatch Adverse Event Reporting program** or by calling 1-800-FDA-1088 to request a reporting form. Refer to the **FDA** for more details.

What are additional considerations for children receiving SARS-CoV-2 mAb?

- Despite receiving SARS-CoV-2 mAb therapy, clinical worsening of COVID-19 has been reported and may include fever, hypoxia or increased respiratory distress, dysrhythmias, and altered mental status. Pediatricians should advise parents/caregivers on how to monitor for clinical worsening, occurring most frequently in the first 7 to 10 days after symptom onset, and provide further instructions on when to seek emergency medical attention.
- Children/adolescents who receive mAb for treatment or as postexposure prophylaxis should continue to isolate or quarantine and adhere to public health department policies and local recommendations for discontinuing isolation and quarantine precautions.
- Receipt of mAb does not preclude the need to continue to follow preventive measures, including wearing an appropriately fitted mask in children and adolescents ≥2 years of age, physical distancing, and performing hand hygiene.
- Neither acute SARS-CoV-2 infection nor treatment with mAb are substitutes for COVID-19 vaccination. Eligible children ≥5 years of age and their household contacts should be vaccinated optimally as soon as the COVID-19 vaccine is available to them. After SARS-CoV-2 infection, COVID-19 vaccination can be provided once symptoms resolve and at **least 90 days after receiving mAb for treatment** and **30 days after receiving mAb for postexposure prophylaxis.**

- Pediatricians are encouraged to discuss participation in anti-SARS-CoV-2 mAb **clinical trials** with patients who have mild to moderate COVID-19, if available locally.

What are potential options for prescribing SARS-CoV-2 mAb to eligible children and adolescents at highest risk?

- Availability of SARS-CoV-2 mAb therapy may vary geographically. Pediatricians are encouraged to partner with their local pediatric hospitals, pediatric infectious disease specialists, and health departments to inquire about the availability of mAb therapies, receive guidance on recommended mAb depending on local epidemiology, and help to establish a reliable process for safe and timely administration of SARS-CoV-2 mAb to eligible patients.
- In an effort to reduce COVID-19-related health care resource burden on hospitals, some facilities (eg, infusion centers, urgent care centers), medical practices, and home health companies may be equipped and able to provide subcutaneous administration of SARS-CoV-2 mAb; these sites are required to follow quality standards and clinically monitor patients for at least 1 hour after therapy, including having a reaction management kit, providing basic life support, and activating emergency medical services, if needed.[44-46]

What strategies may be considered in communities with resource constraints or limited access to SARS-CoV-2 mAb?

- In geographic areas with limited access to SARS-CoV-2 mAb where further prioritization may be required, additional risk stratification based on host, situational, and ethical[47] factors may need to be considered when assessing COVID-19 risk and appropriateness of mAb therapies for an individual patient, including:
    - Accessibility and availability of mAb products. Prioritizing the treatment of SARS-CoV-2 infection over postexposure prophylaxis. Prioritizing preexposure prophylaxis to patients identified to be at highest risk of COVID-19 complications.
    - Continuing to prioritize mAb for patients deemed at highest risk for COVID-19 complications and hospitalizations.[37,38]

- Individual comorbidities (see above), including the presence of multiple high-risk criteria.
- Underlying host factors: Obesity, defined as BMI ≥95th percentile for age and gender in children or BMI ≥30 kg/m^2 in older adolescents, has been described in children and adolescents with severe COVID-19[14,39] and may need to be used preferentially over the overweight criterion in the EUA (BMI 85th-95th percentile for age and gender or BMI 25-29.9 kg/m^2).
- COVID-19 vaccination status: Individuals who are unvaccinated or partially vaccinated against COVID-19 or fully vaccinated individuals ≥2 weeks after completing their COVID-19 mRNA primary vaccine series but not expected to mount an adequate vaccine immune response are at higher risk for hospitalization than fully vaccinated, nonimmunocompromised individuals.[48,49] Prioritizing severely immunocompromised children who are unlikely to respond to vaccination (eg, children <12 years of age who received the 2 vaccine doses and those 12 to 15 years of age who received the 3 doses in the primary vaccine series) for treatment and postexposure prophylaxis.
- Details of COVID-19 exposure: Type and extent of exposure (eg, highest risk of transmission with prolonged and household exposures) and time postexposure.

Are there additional adjunctive therapies or interventions to treat or prevent the progression of COVID-19 in children and adolescents?

- New oral antiviral medications (molnupiravir,[50] paxlovid[51]) are currently being evaluated in controlled clinical trials among high-risk adults with mild to moderate COVID-19 on outcomes including hospitalization, disease progression, and death; at this time, there are no data regarding the safety, efficacy, or pharmacokinetics of these medications in children. Additional information will be added to this interim guidance as paxlovid, which received an EUA on December 22, 2021, becomes more available to pediatric populations.
- Data are emerging regarding the clinical utility of inhaled corticosteroids in treating mild acute COVID-19 in older adults with mild, acute SARS-CoV-2 to prevent progression to

severe COVID-19.[52,53] There are no data regarding the safety and efficacy of this approach in children and adolescents to recommend their routine use presently.

- There is **NO** conclusive evidence to support the efficacy and safety of the following medications for routine use in the treatment or prevention of COVID-19 in children and adolescents. It is strongly recommended that these unproven interventions not be prescribed and parents be counseled against their use. In addition to showing no efficacy against COVID-19, inappropriate use of these antimicrobials cause significant harm.[54,55] The following **are NOT recommended** to be prescribed for COVID-19:
  - Azithromycin: Results of randomized trials in ambulatory subjects conclude that azithromycin did not result in more or faster COVID-19 symptom improvement compared with placebo and had no meaningful benefit in preventing COVID-19 hospitalizations.[56,57]
  - Ivermectin[58]: IInappropriate use of this antiparasitic in patients with COVID-19 is causing increased reports of severe illness to poison control centers and has prompted a CDC Health Advisory.[59]
  - Hydroxychloroquine/chloroquine: Moderate-quality evidence suggests that these agents lack efficacy in reducing short-term mortality or need for hospitalization in patients with COVID-19[60]; in addition, serious cardiac events, including QTc prolongation, have been reported.[61]

There is much misinformation on the internet/social media. Pediatricians are encouraged to refer patients and families to reputable, up-to-date COVID-19 resources:

- **National Institutes of Health** (NIH) COVID-19 treatment guidelines
- **Infectious Diseases Society of America** guidelines (see recommendation 14)
- AAP Red Book chapter: Coronaviruses, Including SARS-CoV-2 and MERS-CoV
- The **Healthy Children** website

[a] SARS-CoV-2 variants with mutations that affect the spike protein have emerged and may result in reduced susceptibility to available mAb therapies. Local circulating variant susceptibility should be considered when choosing among mAb products for management in an individual patient. The majority of delta variants are susceptible to currently available mAb products that have received EUA.[22] However, individuals who reside in, have traveled to, or had close contact with an individual from an area where the frequency of SARS-

CoV-2 variants resistant to bamlanivimab and etesevimab is >5% should **not** receive this mAb; other mAb products should be considered instead, as available.[23] The SARS-CoV-2 omicron variant is associated with multiple mutations in the spike protein and is currently the predominant circulating variant in the United States22 Early data suggest that most mAb preparations are unlikely to be active against this variant. Although sotrovimab retains in vitro activity against omicron, its supply is extremely limited[24,25] Given changing epidemiology, pediatricians should refer to the most up-to-date data and recommendations in their geographic area.[22,24,26]

[b] The authorization allows for young children (birth to 2 years of age) with mild to moderate COVID-19 to receive the mAb bamlanivimab and etesevimab while hospitalized, given the reasons for hospital admission may be different and the threshold for hospital admission may be lower for neonates, young infants, and toddlers with COVID-19 compared with older children and adults.[27] Patients >2 years of age admitted to the hospital under observation status or for reasons other than COVID-19, who otherwise meet EUA criteria for treatment, may be candidates for mAb treatment.

[c] Regarding assessment of immunosuppression: Moderate to severe immunocompromise by host factors as described above. In addition, receipt of immunosuppressive therapies leading to severe immunocompromise including receipt of: T lymphocyte-depleting (eg, leading to CD4+ T-lymphocyte count <100-300 cells/mm3 or CD4+ T-lymphocyte percentage <15% for children) or B lymphocyte-depleting (eg, rituximab) agents; daily systemic corticosteroids with a prednisone dose equivalent of ≥20 mg/day (or ≥2 mg/kg/day in children who weigh <10 kg) for ≥2 weeks; alkylating agents, antimetabolites, transplant-related immunosuppressive medications, cancer chemotherapeutic agents classified as severely immunosuppressive, and other biologic agents that are considered immunosuppressive or immunomodulatory, particularly when used in combination.

Additional Information

- **Resources for Administration Sites** (PHE)
- **The mAbs Calculator** (PHE)
- **Therapeutics Distribution Locations** (HHS)
- **Infusion Center Locator** (NICA)
- **Coding During the COVID-19 Public Health Emergency** (AAP)

References

Table 1. SARS-CoV-2 Monoclonal Antibodies Authorized for Use in Eligible Children and Adolescents

Monoclonal Antibody (mAb), (route of administration)	COVID-19 Indication, per EUA	Dosage	Additional Dosing Information	mAb Fact Sheet for Health Care Providers	mAb Fact Sheets and Frequently Asked Questions (FAQ) for Patients (English and Spanish)
Bamlanivimab/ etesevimab (IV)	Treatment,# depending on geographic location[62] and travel history	Bamlanivimab/etesevimab dosage depends on weight: – 1 kg to 12 kg: 12 mg/kg and 24 mg/kg >12 to 20 kg: 175 mg/350 mg >20 kg to 40 kg: 350 mg/700 mg ≥40 kg, max 700 mg/1400 mg	**This is the only mAb product currently available for infants and young children <12 y for this indication** Provide ASAP after positive SARS-CoV-2 test **and** within 10 days of symptom onset	• https://www.fda.gov/media/145802/download	• http://pi.lilly.com/eua/bam-and-ete-eua-factsheet-patient.pdf • http://pi.lilly.com/eua/span/bam-and-ete-eua-factsheet-patient-span.pdf • Frequently Asked Questions on the Emergency Use Authorization for Bamlanivimab and Etesevimab
	Postexposure prophylaxis (PEP#), depending on geographic location[62] and travel history	Depends on weight: 1 kg to 12kg: 12 mg/kg and 24 mg/kg >12 to 20 kg: 175 mg /350 mg >20 kg to 40 kg: 350 mg/700 mg ≥40 kg, max 700 mg/1400 mg	**This is the only mAb product currently available for infants and young children <12 yo for this indication** Provide ASAP after exposure to SARS-CoV-2 and within 96 hours to max of 7 days after exposure	• https://www.fda.gov/media/145802/download	• http://pi.lilly.com/eua/bam-and-ete-eua-factsheet-patient.pdf • http://pi.lilly.com/eua/span/bam-and-ete-eua-factsheet-patient-span.pdf • Frequently Asked Questions on the Emergency Use Authorization for Bamlanivimab and Etesevimab
Casirivimab/ imdevimab (IV preferred; SC alternative if IV not feasible or available)	Treatment	600 mg/600 mg	Provide ASAP after positive SARS-CoV-2 test **and** within 10 days of symptom onset	• https://www.fda.gov/media/145611/download	• https://www.fda.gov/media/143893/download https://www.fda.gov/media/145713/download • Frequently Asked Questions on the Emergency Use

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ASAP indicates as soon as possible; EUA, Emergency Use Authorization; IV, intravenous; IM, intramuscular; PEP, postexposure prophylaxis; PrEP, preexposure prophylaxis; SC, subcutaneous.

Bamlanivimab and etesevimab, administered together, are not to be used in states in which the combined frequency of variants resistant to these monoclonals is >5% or if the patient has traveled to a state with >5% resistance to this mAb in the preceding 2 weeks.[22,62]

* Time window for mAb prescribing from the phase 3 clinical trial was within 96 hours after positive SARS-CoV-2 diagnostic test result in index case.

Table 2. Subcutaneous (SC) Dosing and Administration of Casirivimab/Imdevimab[63,64]

	Initial Dosing	Subsequent Dosing
Casirivimab dose/imdevimab dose	**600 mg/600 mg**	**300 mg/300 mg**, if needed
Coformulated vials	Withdraw 2.5 mL solution/syringe **into 4 separate syringes**	Withdraw 2.5 mL solution/syringe into **2 separate syringes**
Individual vials and dose packs	Casirivimab: withdraw 2.5 mL solution/syringe into **2 separate syringes plus** Imdevimab: withdraw 2.5 mL solution/syringe into 2 separate syringes For a total of **4 separate syringes**	Casirivimab: withdraw 2.5 mL solution/syringe into **1 syringe plus** Imdevimab: withdraw 2.5 mL solution/syringe into **1 syringe** For a total of 2 **separate syringes**
Administration instructions	Administer SC injections consecutively, at 4 different injection sites (thighs, upper arms, abdomen, but avoiding the 2 inches around the navel and waistline) Observe patient for at least 1 hour after injection	Administer SC injections consecutively, at 2 different injection sites (thighs, upper arms, abdomen, but avoiding the 2 inches around the navel and waistline) Observe patient for at least 1 hour after injection
Materials needed	3-mL or 5-mL polypropylene Luer lock syringes with Luer connection and 21-gauge 1½-inch transfer needles; 25-gauge or 27-gauge needle for SC injection	
Dispensing	Product is preservative free and should be dispensed immediately after preparation	
Storage	Refrigerate unopened vials at 2°C to 8°C (36°F to 46°F) in the individual original carton to protect from light. Do NOT freeze, shake, or expose to direct light. Remove product from refrigerated storage and allow to equilibrate to room temperature for approximately 20 minutes before use.	

Table 3. Intramuscular (IM) Dosing and Administration of Tixagevimab Co-packaged with Cilgavimab (Evusheld)[65]

	Initial Dosing
Tixagevimab copackaged with cilgavimab dose	**150 mg/150 mg**
Individual single-dose vials	Tixagevimab: 1.5 mL (dark grey vial cap) **plus** Cilgavimab: 1.5 mL solution (white vial cap) Do not shake the vials. Withdraw 1.5 mL of tixagevimab and 1.5 mL of cilgavimab into **2 separate syringes**
Administration instructions	Administer IM injections consecutively, at 2 different injection sites, preferably one in each gluteal muscle, one after the other. Observe patient for at least 1 hour after injection.
Dispensing	Product is preservative free and should be dispensed immediately after preparation.
Storage	Prepared syringes should be administered immediately; if immediate administration not possible, the syringes need to be stored in a refrigerator at 2° to 8° C (36° to 46°F) or at room temperature up to 25 °C (77°F). the total time from vial puncture to administration should not exceed 4 hours.

Interim Guidance Disclaimer: The COVID-19 clinical interim guidance provided here has been updated based on current evidence and information available at the time of publishing. Guidance will be regularly reviewed with regards to the evolving nature of the pandemic and emerging evidence. All interim guidance will be presumed to expire on June 30, 2022 unless otherwise specified.

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