# COVID-19 Therapeutics Authorized by FDA

## At a Glance

### Monoclonal Antibody

#### REGEN-COV* (casirivimab plus imdevimab)
- **Testing Requirements:** Positive direct SARS-CoV-2 viral test
- **Prescribing Window:** Within 10 days after symptom onset
- **Eligible Populations:** Adult and adolescent individuals (12 years of age and older who weigh at least 88 pounds [40 kg]) who are at high risk for severe COVID-19, including hospitalization or death. Please refer to FDA fact sheet for full list of Risks and Limitations: [Regen-COV FDA](#).

#### BAMLANIVIMAB PLUS ETSEVIMAB*
- **Testing Requirements:** Positive direct SARS-CoV-2 viral test
- **Prescribing Window:** Within 10 days after symptom onset
- **Eligible Populations:** Adult and pediatric individuals, including neonates, at high risk for progressing to severe COVID-19, including hospitalization or death. Please refer to FDA fact sheet for full list of Risks and Limitations: [Bamlanivimab plus Etesevimab FDA](#).

#### SOTROVIMAB
- **Testing Requirements:** Positive direct SARS-CoV-2 viral test
- **Prescribing Window:** Within 10 days after symptom onset
- **Eligible Populations:** Adult and pediatric patients (at least 12 years of age and older weighing at least 88 pounds [40 kg]) at high risk for progressing to severe COVID-19, including hospitalization or death. Please refer to FDA fact sheet for full list of Risks and Limitations: [Sotrovimab FDA](#).

#### EVUSHeld (tixagevimab co-packaged with cilgavimab)
- **Testing Requirements:** Positive direct SARS-CoV-2 viral test
- **Prescribing Window:** Pre-exposure
- **Eligible Populations:** Adult and adolescent individuals (12 years of age and older weighing at least 88 pounds [40 kg]) for pre-exposure prophylaxis for prevention of COVID-19. Please refer to FDA fact sheet for full list of Risks and Limitations: [Evusheld FDA](#).

### Oral Antiviral

#### PAXLOVID
- **Testing Requirements:** Positive direct SARS-CoV-2 viral test
- **Prescribing Window:** Within 5 days of symptom onset
- **Eligible Populations:** Adults and pediatric patients (12 years of age and older weighing at least 88 pounds [40 kg]) at high risk for progressing to severe COVID-19, including hospitalization or death. Please refer to FDA fact sheet for full list of Risks and Limitations: [Paxlovid FDA](#).

#### MOLNUPIRAVIR
- **Testing Requirements:** Positive direct SARS-CoV-2 viral test
- **Prescribing Window:** Within 5 days of symptom onset
- **Eligible Populations:** Adults at high risk for progressing to severe COVID-19, including hospitalization or death, and for whom alternative COVID-19 treatment options authorized by FDA are not accessible or clinically appropriate. Please refer to FDA fact sheet for full list of Risks and Limitations: [Molnupiravir FDA](#).

*Not expected to be effective against Omicron variant.

## TESTING REQUIREMENTS

- Positive direct SARS-CoV-2 viral test

## PRESCRIBING WINDOW

- Within 10 days after symptom onset
- Pre-exposure
- Within 5 days of symptom onset

## ELIGIBLE POPULATIONS

- Adult and adolescent individuals (12 years of age and older who weigh at least 88 pounds [40 kg]) who are at high risk for severe COVID-19, including hospitalization or death.
- Adult and pediatric individuals, including neonates, at high risk for progressing to severe COVID-19, including hospitalization or death.
- Adult and pediatric patients (at least 12 years of age and older weighing at least 88 pounds [40 kg]) at high risk for progressing to severe COVID-19, including hospitalization or death.
- Adult and adolescent individuals (12 years of age and older weighing at least 88 pounds [40 kg]) for pre-exposure prophylaxis for prevention of COVID-19.
- Adults and pediatric patients (12 years of age and older weighing at least 88 pounds [40 kg]) at high risk for progressing to severe COVID-19, including hospitalization or death.
- Adults at high risk for progressing to severe COVID-19, including hospitalization or death, and for whom alternative COVID-19 treatment options authorized by FDA are not accessible or clinically appropriate.