Side-by-Side Overview of Therapeutics Authorized or Approved for the Prevention of COVID-19 Infection or Treatment of Mild-Moderate COVID-19

This table is a quick reference summarizing key information **for available pre-exposure prophylaxis (PrEP)** for preventing COVID-19 infection and **for all outpatient therapies** currently authorized or approved in the United States for treatment of mild-moderate COVID-19.[1] This resource will be regularly reviewed and updated.

For full details, please review the Fact Sheets for Healthcare Providers for each product (links below).

PRODUCT	MONOCLONAL ANTIBODIES (mAbs)			IV ANTIVIRALS	ORAL ANTIVIRALS	
	Preventative (PrEP)	Treatment		Treatment	Treatment	
	Evusheld (tixagevimab/cilgavimab)	sotrovimab	bebtelovimab	VEKLURY® (remdesivir)	Paxlovid (nirmatrelvir/ritonavir)	molnupiravir
Manufacturer	AstraZeneca Pharmaceuticals LP	GlaxoSmithKline plc / Vir Biotechnology, Inc.	Eli Lilly and Company	Gilead Sciences, Inc.	Pfizer, Inc.	Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc.
Date of Latest Update to Emergency Use Authorization (EUA)[2] and Prescribing Information (PI)	EUA: 02/24/22 PI: n/a	EUA: 02/23/22 PI: n/a	EUA: 02/11/22 PI: n/a	EUA: 01/21/22 PI: 01/21/22	EUA: 12/22/21 PI: n/a	EUA: 02/23/22 PI: n/a
Mechanism of Action	mAb against conserved epitope of spike protein; blocks viral entry	mAb against spike protein; blocks viral attachment and entry	mAb against spike protein; blocks viral attachment to host cells	Nucleotide analog ribonucleic acid (RNA) polymerase inhibitor that halts viral replication	Viral protease inhibitor that halts viral replication	Nucleoside analog that inhibits viral replication by viral mutagenesis
Treatment Efficacy per Clinical Trials[3]	77% reduction in developing symptomatic COVID-19	79% reduction in hospitalizations/deaths	Symptomatic improvement and Day 5 reduction in viral load vs. placebo[4]	87% reduction in hospitalizations/deaths[5]	88% reduction in hospitalizations/deaths	30% reduction in hospitalizations/deaths
Activity Against SARS-CoV- 2 Variants[6]	*Omicron variant:* Likely active *Delta variant:* Active *Other variants:* See Section 12.4 of Evusheld Healthcare Provider Fact Sheet	*Omicron variant:* Likely active *Delta variant:* Active *Other variants:* See Section 15 of sotrovimab Healthcare Provider Fact Sheet	*Omicron variant:* Likely active *Delta variant:* Active *Other variants:* See Section 12.4 of bebtelovimab Healthcare Provider Fact Sheet	*Omicron variant:* Likely active[7] *Delta variant:* Active *Other variants:* See Section 15 of remdesivir Healthcare Provider Fact Sheet See Section 12.4 of remdesivir package insert	*Omicron variant:* Likely active[7] *Delta variant:* Active *Other variants:* See Section 12.4 of Paxlovid Healthcare Provider Fact Sheet	*Omicron variant:* Likely active[7] *Delta variant:* Active *Other variants:* See Section 12.4 of molnupiravir Healthcare Provider Fact Sheet
Authorized Use(s)	Pre-exposure prophylaxis (PrEP)	Treatment of mild-moderate COVID-19	Treatment of mild-moderate COVID-19	Treatment of mild-moderate COVID-19	Treatment of mild-moderate COVID-19	Treatment of mild-moderate COVID-19
Eligible Population(s)	Adult and pediatric patients (at least 12 years of age and older weighing at least 40 kg) who are not currently infected with SARS-CoV-2 and who have not had a known recent exposure to an individual infected with SARS CoV-2, and who have moderate to severe immune compromise or for those who any EUA or approved vaccine is not recommended.	Adult and pediatric patients (at least 12 years of age and older weighing at least 40 kg) at high risk[8] 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 40 kg) at high risk[8] for progressing to severe COVID-19, including hospitalization or death, **and** for whom alternative COVID-19 treatment options approved or authorized by the U.S. Food and Drug Administration (FDA) are not accessible or clinically appropriate	**FDA-approved for:** Adults and pediatric patients (12 years of age and older and weighing at least 40 kg) who are (1) hospitalized or (2) not hospitalized and at high risk[8] for progression to severe COVID-19, including hospitalization or death **EUA for:** Pediatric patients weighing 3.5 kg to less than 40 kg or pediatric patients less than 12 years of age weighing at least 3.5 kg who are (1) hospitalized or (2) not hospitalized and at high risk[8] for progression to severe COVID-19, including hospitalization or death	Adults and pediatric patients (12 years of age and older weighing at least 40 kg) at high risk[8] for progressing to severe COVID-19, including hospitalization or death	Adults at high risk[8] 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
Prescribing Window	Pre-exposure	Initiate within 7 days of symptom onset	Initiate within 7 days of symptom onset	Initiate within 7 days of symptom onset	Initiate within 5 days of symptom onset	Initiate within 5 days of symptom onset

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Testing Requirements	None	Positive direct SARS-CoV-2 viral test	Positive direct SARS-CoV-2 viral test	Positive direct SARS-CoV-2 viral test Baseline renal function required under EUA for pediatric patients Pediatric patients (greater than 28 days old) must have an estimated glomerular filtration rate (eGFR) determined. Full-term neonates (at least 7 days to less than or equal to 28 days old) must have serum creatinine determined before starting VEKLURY and be monitored during treatment as clinically appropriate Before starting and during treatment as clinically appropriate, perform renal and hepatic laboratory testing Assess prothrombin time before starting and monitor as clinically appropriate	Positive direct SARS-CoV-2 viral test	Positive direct SARS-CoV-2 viral test
History Requirements	Not specified	Not specified	Not specified	Not specified	Not specified	Assessment of pregnancy status
Limitations of Authorized Use	Not authorized for: • For treatment of COVID-19 • For post-exposure prophylaxis of COVID-19 in individuals who have been exposed to someone infected with SARS-CoV-2. In individuals who have received a COVID-19 vaccine, Evusheld should be administered at least two weeks after vaccination.	Not authorized for: • Patients who are hospitalized due to COVID-19 • Patients who require oxygen therapy due to COVID-19 **OR** 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)	Not authorized for: • Patients less than 12 years of age and less than 40 kg • Patients who are hospitalized due to COVID-19 • Patients who require oxygen therapy due to COVID-19 **OR** Require an increase in baseline oxygen flow rate and/or respiratory support due to COVID-19 and are on chronic oxygen therapy and/or respiratory support due to underlying non-COVID-19 related comorbidity	Not authorized for: • Patients weighing less than 3.5 kg	Not authorized for: • Patients requiring hospitalization due to severe or critical COVID-19. • Pre-exposure or post-exposure prophylaxis for prevention of COVID-19. • Use for longer than 5 consecutive days	Not authorized for: • Patients less than 18 years of age • Initiation in patients who are hospitalized due to COVID-19. • Use for longer than 5 consecutive days. • Pre-exposure or post-exposure prophylaxis for prevention of COVID-19
Family Planning Considerations	None	None	None	None	Ritonavir may reduce the efficacy of combined hormonal contraceptives. Patients should use an effective alternative contraceptive method or an additional barrier method of contraception.	Not recommended for use during pregnancy because may cause fetal harm when given to pregnant individuals based on animal reproduction studies. Authorized for use in pregnancy only if benefits would outweigh risks for the individual patient; documentation requirements apply. Females of childbearing potential should be advised of potential risk to a fetus and should use a reliable method of contraception correctly and consistently, as applicable, for the duration of

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						treatment and for 4 days after the last dose of molnupiravir. Males of reproductive potential who are sexually active with females of childbearing potential should use a reliable method of contraception correctly and consistently during treatment and for at least 3 months after the last dose.
Contraindications	Individuals with previous severe hypersensitivity reactions, including anaphylaxis, to any component of Evusheld	Patients who have a history of anaphylaxis to sotrovimab or to any of the excipients in the formulation	None	Patients with a history of clinically significant hypersensitivity reactions to VEKLURY or any components of the product. Consider discontinuing VEKLURY if ALT levels increase to greater than 10 times the upper limit of normal. Discontinue VEKLURY if ALT elevation is accompanied by signs or symptoms of liver Inflammation.	Individuals with significant hypersensitivity reactions to any component of Paxlovid. Co-administration with drugs highly dependent on CYP3A for clearance and for which elevated concentrations are associated with serious and/or life-threatening reactions. Co-administration with potent CYP3A inducers where significantly reduced nirmatrelvir or ritonavir plasma concentrations may be associated with the potential for loss of virologic response and possible resistance.	None
Administration Route(s)	IM Injection	IV Infusion	IV Injection	IV Infusion	Oral	Oral
Dosage	300 mg of tixagevimab (100 mg/mL) and 300 mg of cilgavimab (100 mg/mL) via two separate 3.0 mL consecutive intramuscular (IM) injections of each product. Patients who received previously (150 mg of tixagevimab and 150 mg of cilgavimab) should receive a second dose (150 mg of tixagevimab and 150 mg of cilgavimab) as soon as possible. The SARS-CoV-2 variants circulating in the US when Evusheld may need to be redosed are not known at this time, therefore, repeat dosing recommendations cannot be made.	500 mg single infusion following dilution administered over 15 minutes for 50-mL infusion bag or 30 minutes for 100-mL infusion bag	175 mg/2 mL (87.5 mg/mL) administered via IV injection over 30 seconds	**For adults and pediatric patients age at least 12 years and older and weight at least 40 kg or greater:** 200 mg on Day 1 followed by once-daily maintenance doses of 100 mg on Day 2 and Day 3 via intravenous infusion *For other non-hospitalized populations, see below*	300 mg nirmatrelvir (two 150 mg tablets) with 100 mg ritonavir (one 100 mg tablet) with all three tablets taken together orally twice daily for 5 days, can be taken with or without food [see Clinical Pharmacology (12.3)]. The tablets should be swallowed whole and not chewed, broken, or crushed *For patients with renal impairment, see below*	800 mg (four 200 mg capsules) taken orally every 12 hours for 5 days, with or without food

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Dosage for Special Populations	**Pediatric patients at least 12 years or older, and weighing at least 40 kg:** no dosage adjustment **Pregnancy or Lactation -** No dosage adjustment **Geriatrics:** No dosage adjustment **Renal:** No dosage adjustment **Hepatic:** Not specified	**Pediatrics:** If eligible, no dosage adjustment **Pregnancy or Lactation:** No dosage adjustment **Renal:** No dosage adjustment **Hepatic:** Not specified	**Pediatrics:** If eligible, no dosage adjustment **Pregnancy or Lactation:** No dosage adjustment **Geriatrics:** No dosage adjustment **Renal:** No dosage adjustment **Hepatic:** No dosage adjustment for mild hepatic impairment	**Pediatric patients weighing at least 3.5 kg and less than 40 kg:** 5 mg/kg on Day 1 followed by 2.5 mg/kg once daily Days 2-3 **Pediatric patients age younger than 12 years and weighing 40 kg or greater:** 200 mg on Day 1 followed by once-daily maintenance doses of 100 mg on Day 2 and Day 3 via intravenous infusion. **Renal:** Not recommended in adult patients or pediatric patients (greater than 28 days old) with eGFR less than 30 mL/min. Not recommended in full-term neonates (at least 7 days to less than or equal to 28 days old) with serum creatinine greater than or equal to 1 mg/dL.	**Pediatric patients at least 12 years or older, and weighing at least 40 kg,** no dosage adjustment **Pregnancy or Lactation:** No dosage adjustment **Renal**: No dosage adjustment is needed in patients with mild renal impairment. Dose reduction for moderate renal impairment (eGFR ≥30 to <60 mL/min): 150 mg nirmatrelvir (one 150 mg tablet) with 100 mg ritonavir (one 100 mg tablet), with both tablets taken together twice daily for 5 days. Paxlovid is not recommended in patients with severe renal impairment (eGFR <30 mL/min). **Hepatic:** No dosage adjustment for mild or moderate hepatic impairment. Paxlovid is not recommended for use in patients with severe hepatic impairment.	**Pediatrics:** Not eligible, as it may affect bone and cartilage growth. **Pregnancy or Lactation:** Not recommended for use during pregnancy. Breastfeeding not recommended during treatment or for 4 days after final dose. **Renal:** No dosage adjustment **Hepatic:** No dosage adjustment
Post-Administration Observation Period	One hour	One hour	One hour	One hour	None	None
Adverse Events (from Clinical Trials)[9]	Injection site reactions (1%); One case of anaphylaxis *Other adverse events:* Headache (6%), fatigue (4%), and cough (3%) Injection site reactions (1%); One case of anaphylaxis	Infusion-related reactions (1%); one case of anaphylaxis *Other adverse events:* pyrexia, chills, dizziness, dyspnea, pruritus, and rash	Adverse reactions were infusion-related reactions (0.3%), pruritus (0.3%), and rash (0.8%) Most common adverse events: nausea (0.8%) and vomiting (0.7%)	Adverse events[5] (incidence ≥1%) were nausea (10.8%), headache (5.7%), cough (3.6%), diarrhea (3.9%), dyspnea (2.5%), fatigue (3.6%), ageusia (2.9%), anosmia (3.2%), dizziness (1.8%), and chills (2.2%)	Adverse events (incidence ≥1% and ≥5 patient difference) were dysgeusia (6%), diarrhea (3%), hypertension (1%), and myalgia (1%)	Adverse events (incidence ≥1%) were diarrhea (2%), nausea (1%), and dizziness (1%) *Lab abnormalities:* Selected Grade 3 and 4 laboratory abnormalities in chemistry (ALT, AST, creatinine, and lipase) and hematology

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	Other adverse events: Headache (6%), fatigue (4%), and cough (3%) Insomnia (1%), dizziness (1%) Cardiac serious adverse events (SAE) were 0.6% vs 0.2% in the Evusheld and placebo groups, respectively.	*Clinical worsening vs. adverse events:* fever, hypoxia, increased respiratory difficulty, arrhythmia, fatigue, and altered mental status *Post-Authorization Experience:* Immune System Disorders: Anaphylaxis	*Infusion-related reactions may include* fever, difficulty breathing, reduced oxygen saturation, chills, fatigue, arrhythmia, chest pain or discomfort, weakness, altered mental status, nausea, headache, bronchospasm, hypotension, hypertension, angioedema, throat irritation, rash including urticaria, pruritus, myalgia, vasovagal reactions dizziness, and diaphoresis	*Lab abnormalities*[5]*:* All grade 3 or higher (10.8%) Limited clinical data available for VEKLURY in pediatric patients weighing 3.5 kg to less than 40 kg or pediatric patients less than 12 years of age weighing at least 3.5 kg. Serious and unexpected adverse events may occur that have not been previously reported with VEKLURY use		(hemoglobin, platelets, and leukocytes) parameters all occurred at a rate ≤2% *Post-Authorization Experience:* Immune System Disorders: hypersensitivity, anaphylaxis, angioedema Skin and Subcutaneous Tissue Disorders: erythema, rash, urticaria
Potential for Drug-Drug Interactions	Unlikely	Unlikely	Unlikely	Low Fact Sheet [Drug Interactions Section (10)] PI [See Section (7)]	Moderate/High [see Fact Sheet Drug Interactions Section (7)]	No drug interactions have been identified based on the limited available data
Potential for Patient Non-Compliance	Minimal	Minimal	Minimal	Moderate	Moderate	Moderate
Cost to Patients for USG-Procured Drug[10]	Medicare/Medicaid[10]: $0 Private insurers: $0	Medicare/Medicaid[10]: $0 Private insurers: $0	Medicare/Medicaid[10]: $0 Private insurers: $0	Currently not procured by USG; cost to patient for drug product varies	Medicare/Medicaid[10]: $0 Private insurers: $0	Medicare/Medicaid[10]: $0 Private insurers: $0
Provider Payment (Administration or Dispensing Fee)[10, 11, 12, 13, 14]	Medicare: $150.50 (most settings); $250.50 (beneficiary's home or residence, in certain circumstances[11])) Medicaid/Private insurers: Variable	Medicare: $450 (healthcare settings); $750 (beneficiary's home or residence, in certain circumstances[11]) Medicaid/Private insurers: Variable	Medicare: $350.50 (healthcare settings); $550.50 (beneficiary's home or residence, in certain circumstances[11]) Medicaid/Private insurers: Variable	Medicare: For outpatient setting refer to cms.gov/covid-19-FAQS (ref Q30) Medicaid/Private insurers: Variable	Provider may bill applicable insurance or program for dispensing fees. Medicare: CMS encourages Part D sponsors to pay higher than the usual negotiated dispensing fees given the unique circumstances of the PHE and administrative requirements associated with dispensing US Government-procured oral antivirals	Provider may bill applicable insurance or program for dispensing fees. Medicare: CMS encourages Part D sponsors to pay higher than the usual negotiated dispensing fees given the unique circumstances of the PHE and administrative requirements associated with dispensing US Government-procured oral antivirals
Product Availability	Variable by jurisdiction and healthcare facility	Variable by jurisdiction and healthcare facility	Variable by jurisdiction and healthcare facility	Commercially available, not subject to USG allocation limits	Variable by jurisdiction and healthcare facility	Variable by jurisdiction and healthcare facility
Other Considerations	Healthcare provider who can legally prescribe drugs, trained staff; immediate access to resuscitation meds;	Infusion supplies; trained staff; IV access; immediate access to resuscitation meds; ability to activate EMS	Infusion supplies; trained staff; IV access; immediate access to resuscitation meds; ability to activate EMS	Infusion supplies; trained staff; IV access; immediate access to resuscitation meds; ability to activate EMS	May only be prescribed for an individual patient by physicians, advanced practice registered nurses, and physician assistants that are licensed or authorized under state law to prescribe drugs in the therapeutic class to which Paxlovid belongs (i.e., anti-infectives).	May only be prescribed for an individual patient by physicians, advanced practice registered nurses, and physician assistants that are licensed or authorized under state law to prescribe drugs in the therapeutic class to which molnupiravir belongs (i.e., anti-infectives).
Product Websites	Evusheld website	sotrovimab website	bebtelovimab website	remdesivir website	Paxlovid website	molnupiravir website
Package Insert	N/A	N/A	N/A	remdesivir package insert	N/A	N/A
Fact Sheets for Healthcare Providers	Evusheld Healthcare Provider Fact Sheet	sotrovimab Healthcare Provider Fact Sheet	bebtelovimab Healthcare Provider Fact Sheet	remdesivir Healthcare Provider Fact Sheet	Paxlovid Healthcare Provider Fact Sheet	molnupiravir Healthcare Provider Fact Sheet

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Fact Sheets for Patients, Parents, and Caregivers (English)	Evusheld Patient Fact Sheet (English)	sotrovimab Patient Fact Sheet (English)	bebtelovimab Patient Fact Sheet (English)	remdesivir Patient Fact Sheet (English)	Paxlovid Patient Fact Sheet (English)	molnupiravir Patient Fact Sheet (English)
Fact Sheets for Patients, Parents, and Caregivers (Spanish)	Evusheld Patient Fact Sheet (Spanish)	sotrovimab Patient Fact Sheet (Spanish)	bebtelovimab Patient Fact Sheet (Spanish)	remdesivir Patient Fact Sheet (Spanish)	Paxlovid Patient Fact Sheet (Spanish)	molnupiravir Patient Fact Sheet (Spanish)

1 COVID-19 convalescent plasma with high titers of anti-SARS-CoV-2 antibodies is authorized for the treatment of COVID-19 in patients with immunosuppressive disease or receiving immunosuppressive treatment, in either the outpatient or inpatient setting. Fact Sheet for Healthcare Providers.

2 Emergency Use Authorization: The most recent EUAs, including updates and amendments, are available on the product websites.

3 For more details on clinical trial results, see Section 18 of each respective product's Fact Sheet for Health Care Providers.

4 The placebo-controlled phase 2 data are limited by enrollment of only subjects without risk factors for progression to severe COVID-19, and the trial was not powered or designed to determine a difference in the clinical outcomes of hospitalization or death between the placebo and bebtelovimab treatment arms [EUA Section 14.4]

5 For more details, see Early Remdesivir to Prevent Progression to Severe Covid-19 in Outpatients | NEJM.

6 Reference NCATS open data website.

7 Reference Nirmatrelvir, Molnupiravir, and Remdesivir maintain potent in vitro activity against the SARS-CoV-2 Omicron variant | bioRxiv.

8 See each product's Fact Sheet for Health Care Providers for additional details and criteria for identifying high risk patients/individuals. CDC also maintains a listing underlying medical conditions associated with higher risk for severe COVID-19.

9 For more details on adverse events from clinical trials, see Section 6 of each respective product's Fact Sheet for Health Care Providers. For more details on clinical worsening after administration, see Section 5.

10 For Medicaid beneficiaries, $0 cost-sharing for COVID-19 treatments is required only during the American Rescue Plan Act coverage period.

11 For more details, see the CMS COVID-19 Monoclonal Antibodies Infographic and the CMS COVID-19 Monoclonal Antibodies Toolkit.

12 Some patients/individuals may be responsible for co-pays, deductibles, and/or other charges.

13 CMS billing codes, Medicare allowances, and effective dates for COVID-19 vaccines and monoclonal antibodies.

14 For uninsured patients/individuals, healthcare providers can claim reimbursement, generally at Medicare rates, via the HRSA COVID-19 Uninsured Program for testing, treatment, and vaccine administration.