Side-by-Side Overview of Outpatient Therapies Authorized for Treatment of Mild-Moderate COVID-19

This table is a quick reference summarizing key information for all outpatient therapies currently authorized in the U.S. for treatment of mild-moderate COVID-19[i,ii]. This resource will be regularly reviewed and updated.

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

Authorized Uses | Administration | Adverse Events | Cost/Payment | References

Product	Casirivimab/Imdevimab (REGEN-COV®) Monoclonal Antibodies	Bamlanivimab/Etesevimab Monoclonal Antibodies	Sotrovimab Monoclonal Antibodies	PAXLOVID® Oral Antivirals	Molnupiravir Oral Antivirals
Manufacturer	Regeneron Pharmaceuticals, Inc.	Eli Lilly and Company	GlaxoSmithKline plc / Vir Biotechnology, Inc.	Pfizer Inc.	Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc.
Date of First EUA[1] Issuance	11/21/20	2/9/21	5/26/21	12/22/21	12/23/21
Mechanism of Action	mAbs against spike protein; blocks viral attachment to host cells	mAbs against spike protein; blocks viral attachment to host cells	mAbs against spike protein; blocks viral entry	Viral protease inhibitor that halts viral replication.	Nucleoside analog that inhibits viral replication by viral mutagenesis
Treatment Efficacy per Clinical Trials[2]	70% reduction in hospitalizations/deaths	87% reduction in hospitalizations/deaths	79% reduction in hospitalizations/deaths	88% reduction in hospitalizations/deaths	30% reduction in hospitalizations/deaths
Activity Against SARS-CoV- 2 Variants	*Delta variant:* Active *Omicron variant:* unlikely to be active *Other variants:* See Section 15 of REGEN-COVHealth Care Provider Fact Sheet	*Delta variant:* Active *Omicron variant:* unlikely to be active *Other variants:* See Section 15 of Bamlanivimab/Etesevimab Health Care ProviderFact Sheet	*Delta variant:* Active *Omicron variant:* likely active *Other variants:* See Section 15 of Sotrovimab Health Care Provider Fact Sheet	*Delta variant:* Active *Omicron variant:* Data pending *Other variants:* See Section 12.4 of PAXLOVID Health Care Provider Fact Sheet	*Delta variant:* Active *Omicron variant:* Data pending *Other variants:* See Section 12.4 of Molnupiravir Health Care Provider Fact Sheet
Authorized Use(s)	Treatment of lab-confirmed mild- moderate COVID-19 Post-exposure prophylaxis (PEP)	Treatment of lab-confirmed mild-moderate COVID-19 Post-exposure prophylaxis (PEP)	Treatment of lab-confirmed mild-moderate COVID-19	Treatment of lab-confirmed mild-moderate COVID-19	Treatment of lab-confirmed mild-moderate COVID-19
Eligible Populations	Adult and pediatric individuals (at least 12	Adult and pediatric individuals, including	Adult and pediatric patients (at least 12	Adults and pediatric patients (12 years of age	Adults at high risk3 for progressing to severe

	years of age and older weighing at least 40 kg) at high risk [3] for progressing to severe COVID- 19, including hospitalization or death Additional eligibility criteria [4] for PEP	neonates, at high risk[3] for progressing to severe COVID-19, including hospitalization or death Additional eligibility criteria [4] for PEP	years of age and older weighing at least 40 kg) at high risk[3] for progressing to severe COVID-19, including hospitalization or death	and older weighing at least 40 kg) at high risk[3] for progressing to severe COVID-19, including hospitalization or death	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	Treatment: Within 10 days of symptom onset PEP: Not specified	Treatment: Within 10 days of symptom onset PEP: Not specified	Treatment: Within 10 days of symptom onset	Treatment: Within 5 days of symptom onset	Treatment: Within 5 days of symptom onset
Testing Requirements	Treatment: Positive direct SARS-CoV-2 viral test PEP*:* No testing required	Treatment: Positive direct SARS-CoV-2 viral test PEP*:* No testing required	Treatment: Positive direct SARS-CoV-2 viral test	Treatment: Positive direct SARS-CoV-2 viral test	Treatment: Positive direct SARS-CoV-2 viral test
Limitations of Authorized Use	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 2 years and older who are hospitalized due to COVID-19 • Patients, regardless of age, who require oxygen therapy and/or respiratory support 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 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 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	• 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 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 REGEN-COV®	None	Patients who have a history of anaphylaxis to sotrovimab or to any of the excipients in the formulation	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)	IV or SC	IV	IV	Oral	Oral
Dosage	*Treatment and Initial PEP*	*Treatment and PEP dose:* in	500 mg single infusion	300 mg nirmatrelvir (two	800 mg (four 200 mg

	dose: 600 mg casirivimab and 600 mg imdevimab as a single infusion following dilution OR 4 SQ injections (2 injections of 300 mg for each individual antibody) *Repeat PEP dose (q4 weeks):* 300 mg casirivimab and 300 mg imdevimab as a single infusion following dilution OR 2 SQ injections (1 injection of 300 mg for each individual antibody)	adults (18 years and older) and pediatric patients (<18 years and weighing at least 40 kg) is 700 mg bamlanivimab and 1400 mg etesevimab as a single infusion following dilution *For pediatric patients weighing less than 40 kg, see below.*	following dilution	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.*	capsules) taken orally every 12 hours for 5 days, with or without food.
Dosage for Special Populations	**Pediatrics** - If eligible, no dosage adjustment **Pregnancy or Lactation** - No dosage adjustment **Renal** - No dosage adjustment **Hepatic** - Not specified	**Pediatrics:** For pediatric patients <18 years and weighing at least 40 kg, no dosage adjustment For pediatric patients <18 years and weighing less than 40 kg, the dosage will vary by body weight: >20 kg to <40 kg: 350 mg bamlanivimab and 700 mg etesevimab >12 kg to 20 kg: 175 mg bamlanivimab and 350 mg etesevimab 1 kg to 12 kg: 12 mg/kg bamlanivimab and 24 mg/kg etesevimab **Pregnancy or Lactation** - No dosage adjustment **Renal** - No dosage adjustment **Hepatic** - No dosage adjustment for patients with mild hepatic impairment	**Pediatrics** - If eligible, no dosage adjustment **Pregnancy or Lactation** - No dosage adjustment **Renal** - No dosage adjustment **Hepatic** - Not specified	**Pediatrics:** For pediatric patients/individuals ≥12 years 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. (2.2) 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	None	None
Adverse Events (from Clinical Trials)[5]	Infusion-related reactions (IV), including anaphylaxis; Injection site reactions (SC) *Clinical worsening vs. adverse events:* fever, hypoxia, increased respiratory difficulty, arrhythmia, fatigue, altered mental status	Infusion-related reactions (1.1%), including anaphylaxis (0.07%) *Other adverse events (all <1%):* nausea, dizziness, pruritis *Clinical worsening vs. adverse events:* fever, hypoxia, increased respiratory difficulty, arrhythmia, fatigue, altered mental status	Infusion-related reactions (1%); One case of anaphylaxis *Other adverse events:* pyrexia, chills, dizziness, dyspnea, pruritus, rash *Clinical worsening vs. adverse events:* fever, hypoxia, increased respiratory difficulty, arrhythmia, fatigue, altered mental status	Adverse events (incidence ≥1% and ≥5 patient difference) dysgeusia (6%), diarrhea (3%), hypertension (1%), and myalgia (1%).	Adverse events (incidence ≥1%) Diarrhea (2%), nausea (1%), dizziness (1%)
Potential for Drug-Drug Interactions	Unlikely	Unlikely	Unlikely	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
Cost to Patients for USG procured drug 6	Medicare/Medicaid[7]: $0 Private insurers: $0	Medicare/Medicaid[7]: $0 Private insurers: $0	Medicare/Medicaid[7]: $0 Private insurers: $0	Medicare/Medicaid[7]: $0 Private insurers: $0	Medicare/Medicaid[7]: $0 Private insurers: $0
Provider Payment (Administration or dispensing fee)[6, 8, 9, 10]	Medicare: $450 (most settings); $750 (beneficiary's home or residence, in certain circumstances[6]) Medicaid/Private insurers: Variable	Medicare: $450 (most settings); $750 (beneficiary's home or residence, in certain circumstances[6]) Medicaid/Private insurers: Variable	Medicare: $450 (most settings); $750 (beneficiary's home or residence, in certain circumstances6) Medicaid/Private insurers: Variable	Provider may bill applicable insurance or program for dispensing fees	Provider may bill applicable insurance or program for dispensing fees
Product Availability	Variable by jurisdiction and healthcare facility	Variable by jurisdiction and healthcare facility	Variable by jurisdiction and healthcare facility	Variable by jurisdiction and healthcare facility	Variable by jurisdiction and healthcare facility
Other Considerations	Infusion/injection 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	REGEN-COV website	Bamlanivimab/Etesevimab website	Sotrovimab website	PAXLOVID website	Molnupiravir website
Fact Sheets for	REGEN-COV Health Care	Bamlanivimab/Etesevimab	Sotrovimab Health Care	PAXLOVID Health Care	Molnupiravir Health

Health Care Providers	Provider Fact Sheet	Health Care ProviderFact Sheet	Provider Fact Sheet	Provider Fact Sheet	Care Provider Fact Sheet
Fact Sheets for Patients, Parents, and Caregivers (English)	REGEN-COV Patient Fact Sheet (English)	Bamlanivimab/Etesevimab Patient Fact Sheet (English)	Sotrovimab Patient Fact Sheet (English)	PAXLOVID Patient Fact Sheet (English)	Molnupiravir Patient Fact Sheet (English)
Fact Sheets for Patients, Parents, and Caregivers (Spanish)	REGEN-COV Patient Fact Sheet (Spanish)	Bamlanivimab/Etesevimab Patient Fact Sheet(Spanish)	Sotrovimab Patient Fact Sheet (Spanish)	PAXLOVID Patient Fact Sheet (Spanish)	Molnupiravir Patient Fact Sheet (Spanish)

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

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

[3.] 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 webpage listing underlying medical conditions associated with higher risk for severe COVID-19.

[4.] Individuals eligible for PEP include those who are not fully vaccinated (see CDC guidance) or who are not expected to mount an adequate immune response to vaccination (e.g., individuals with immunocompromising conditions including those taking immunosuppressive medications); AND have been exposed to an individual infected with SARS-CoV-2 consistent with close contact criteria per CDC or who are 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 (e.g., nursing homes, prisons).

[5.] 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 mAb administration, see Section 5.

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

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

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

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

[10.] 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.

[i.] 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

[ii]VEKLURY® (Remdesivir) is an RNA-dependent RNA polymerase inhibitor that blocks replication of SARS-CoV-2. It is approved for hospitalized individuals with COVID-19. Outpatient treatment is based on information from the literature (Dec 22, 2021; DOI: 10.1056/NEJMoa2116846).

This page last reviewed: December 31, 2021