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. This resource will be regularly reviewed and updated. New therapies that are issued Emergency Use Authorizations will also be added.

For full details, please review the Fact Sheets for Health Care Providers for each product on the resources table below.

MONOCLONAL ANTIBODIES (mAbs)	***Casirivimab/Imdevimab (REGEN-COV™)***	***Bamlanivimab/Etesevimab***	***Sotrovimab***
Manufacturer	Regeneron Pharmaceuticals, Inc.	Eli Lilly and Company	GlaxoSmithKline plc / Vir Biotechnology, Inc.
Date of First EUA[1] Issuance	11/21/20	2/9/21	5/26/21
Mechanism of Action	mAbs against spike protein; blocks viral attachment and entry	mAbs against spike protein; blocks viral attachment and entry	mAb against conserved epitope of spike protein; blocks viral entry
Treatment Efficacy per Clinical Trials[2]	70% reduction in hospitalizations/deaths	87% reduction in hospitalizations/deaths	79% reduction in hospitalizations/deaths
Efficacy Against SARS-CoV-2 Variants	*Delta variant:* Active *Other variants:* See Section 15 of REGEN-COV Health Care Provier Fact Sheet	*Delta variant:* Active *Other variants:* See Section 15 of Bamlanivimab/Etesevimab Health Care Provider Fact Sheet	*Delta variant:* Active *Other variants:* See Section 15 of Sotrovimab 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

MONOCLONAL ANTIBODIES (mAbs) PRODUCT	*Casirivimab/Imdevimab (REGEN-COV™)*	*Bamlanivimab/Etesevimab*	*Sotrovimab*
Eligible Populations	Adult and pediatric[3] individuals at high risk[4] for progressing to severe COVID-19, including hospitalization or death Additional eligibility criteria[5] for PEP	Adult and pediatric[3] individuals at high risk[4] for progressing to severe COVID-19, including hospitalization or death Additional eligibility criteria[5] for PEP	Adult and pediatric[3] patients at high risk[4] for progressing to severe COVID-19, including hospitalization or death
Prescribing Window	*Treatment:* Within 10 days of symptom onset *PEP:* Not specified	*Treatment:* Within 10 days of symptom onset *PEP:* Not specified	Within 10 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	Positive direct SARS-CoV-2 viral test
Limitations of Authorized Use	Not for use in patients who are hospitalized due to COVID-19 or require O_2 due to COVID-19	Not for use in patients who are hospitalized due to COVID-19 or require O_2 due to COVID-19 Not authorized for use in states, territories, and US jurisdictions in which the combined frequency of variants resistant to bamlanivimab and etesevimab exceeds 5%[6]	Not for use in patients who are hospitalized due to COVID-19 or require O_2 due to COVID-19
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
Administration Route(s)	IV or SC	IV	IV

MONOCLONAL ANTIBODIES (mAbs) PRODUCT	*Casirivimab/Imdevimab (REGEN-COV™)*	*Bamlanivimab/Etesevimab*	*Sotrovimab*
Dosage	*Treatment and Initial PEP dose:* 600 mg casirivimab + 600 mg imdevimab as a single infusion following dilution OR 4 injections *Repeat PEP dose (q4 weeks):* 300 mg casirivimab + 300 mg imdevimab as a single infusion following dilution OR 2 injections	*Treatment and PEP dose:* 700 mg bamlanivimab + 1400 mg etesevimab as a single infusion following dilution	500 mg single infusion following dilution
Special Populations	• ***Pediatrics***[3] - If eligible, no dosage adjustment • **Pregnancy -** No dosage adjustment • **Renal -** No dosage adjustment • **Hepatic -** Not specified	• ***Pediatrics***[3] **-** If eligible, no dosage adjustment • **Pregnancy -** No dosage adjustment • **Renal -** No dosage adjustment • **Hepatic -** No dosage adjustment for patients with mild hepatic impairment	• ***Pediatrics***[3] - If eligible, no dosage adjustment • **Pregnancy -** No dosage adjustment • **Renal -** No dosage adjustment • **Hepatic -** Not specified
Post-Administration Observation Period	One hour	One hour	One hour
Adverse Events (from Clinical Trials)[7]	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
Potential for Drug-Drug Interactions	Unlikely	Unlikely	Unlikely

MONOCLONAL ANTIBODIES (mAbs) PRODUCT	*Casirivimab/Imdevimab (REGEN-COV™)*	*Bamlanivimab/Etesevimab*	*Sotrovimab*
Potential for Patient Non-Compliance	Minimal	Minimal	Minimal
Cost to Patients[8]	*Medicare/Medicaid:*[9] $0 *Private insurers:* Variable[10]	*Medicare/Medicaid:*[9] $0 *Private insurers:* Variable[10]	*Medicare/Medicaid:*[9] $0 *Private insurers:* Variable[10]
Provider Payment (Administration)[8,11,12]	*Medicare:* $450 (most settings); $750 (beneficiary's home or residence, in certain circumstances[8]) *Medicaid/Private insurers:* Variable	*Medicare:* $450 (most settings); $750 (beneficiary's home or residence, in certain circumstances[8]) *Medicaid/Private insurers:* Variable	*Medicare:* $450 (most settings); $750 (beneficiary's home or residence, in certain circumstances[8]) *Medicaid/Private insurers:* Variable
Product Availability	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
Product websites	REGEN-COV website	Bamlanivimab/Etesevimab website	Sotrovimab website
Fact Sheets for Health Care Providers	REGEN-COV Health Care Provider Fact Sheet	Bamlanivimab/Etesevimab Health Care Provider Fact Sheet	Sotrovimab Health 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)
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)

[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] Eligible pediatric patients/individuals must be 12 years of age and older weighing at least 40 kg.

[4] 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.

[5] 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).

[6] FDA will make this determination considering current variant frequency data, trends in variant frequency over time, the precision of the estimates and information regarding emerging variants of concern. FDA will update the list of states, territories, and US jurisdictions in which bamlanivimab and etesevimab are and are not currently authorized as new data and information becomes available. Health Care providers should refer to the FDA website regularly for updates.

[7] 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..

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

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

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

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

[12] 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.