Commercial Planning for COVID-19 Therapeutic Development

David Parker, PhD
Senior Vice President, Diagnostics Solutions

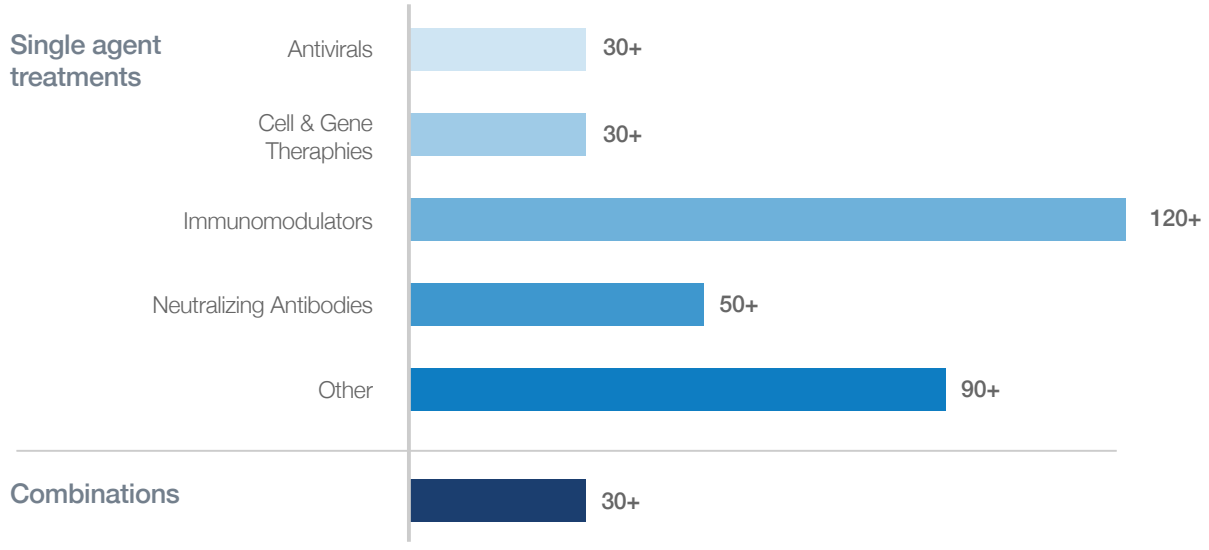
Richard Duong, PharmD
Senior Engagment Manager, Diagnostics Solutions

As we near the end of 2020—nearly ten months into the emergence of the coronavirus pandemic in the United States—there are a handful of COVID-19 therapeutics available, with more in development. Even as the pipeline of treatment options fills, the COVID-19 access landscape continues to evolve, so pharmaceutical manufacturers developing COVID-19 therapeutics need to understand how current and future healthcare funding policies might enable access to these products. In this paper, experts at Precision for Medicine examine the coding, coverage, and payment environment for emerging COVID-19 therapeutics and highlight areas that require particular attention from manufacturers. Note that because the COVID-19 therapeutic development landscape is evolving at a rapid pace, it is likely there have been updates in the time between completion of this paper and its publication.

Overview of COVID-19 Therapeutic Landscape

In April 2020, the FDA launched the Coronavirus Treatment Acceleration Program (CTAP) as part of an effort to move COVID-19 treatments to patients as quickly and safely as possible.[1] According to the CTAP dashboard, which provides a snapshot of potential COVID-19 therapeutics in development, and other FDA information, there are 6 treatments with Emergency Use Authorization (EUA) and the FDA has reviewed more than 370 trials (Figure 1).

Figure 1. Types of COVID-19 Treatment Being Studied in Clinical Trials October 31, 2020[2]



According to BioCentury, which is actively tracking COVID-19 therapeutics in development, there are currently over 400 therapies being studied in clinical trials. These treatments span myriad targets and include oral, subcutaneous, and intravenous medications. Over 150 of these therapies represent repurposed drugs that have already been approved either globally or in select countries for non–COVID-19 indications, with 64 of these treatments in phase 3 or 4 trials.

On October 22, 2020, a milestone in the fight against COVID-19 was achieved with the full FDA approval of remdesivir (Veklury®), the first antiviral drug for the treatment of adults and certain pediatric patients with COVID-19 requiring hospitalization. Remdesivir is an intravenous infusion for administration in a hospital or other healthcare setting that has similar acute care capabilities. However, the utility of remdesivir came into question only a month after its approval when the World Health Organization (WHO) recommended against its use in COVID-19 patients due to a lack of evidence that it improves survival and other outcomes. The implications of WHO's recommendation for access to remdesivir are not yet known, but the negative recommendation is likely to cause future controversy given the drug's FDA-approval status and the need for COVID-19 treatments.[3]

In November 2020, the FDA granted 3 Emergency Use Authorizations (EUAs): one to Lilly's antibody treatment, bamlanivimab; another to Regeneron's antibody cocktail, casirivimab and imdevimab; and a third to Lilly's oral rheumatoid arthritis (RA) drug, baricitinib (Olumiant®) in combination with remdesivir.[4] These EUAs add even more options to the COVID-19 treatment armamentarium, and the administration routes of the drugs bring into play several different reimbursement pathways.

Overview of Drug Reimbursement Pathways by Setting of Care

For manufacturers of potential COVID-19 therapeutics, it is important to stay current on potential changes in coding, coverage, and payment for these treatments, as they may be affected by government and commercial payer initiatives to ensure broad access. The usual reimbursement pathways for treatments differ depending on setting of care:

- **Home.** Oral or self-injectable drugs for self-administration by patients at home are reimbursed on the basis of an associated average wholesale price (AWP)-based, wholesale acquisition cost (WAC)-based, or negotiated payment. Certain drugs may be classified as "specialty drugs." The specialty tier of pharmacy benefits is associated with the highest copay or coinsurance, which can be a barrier to access.[5] Because of its high cost and RA indication, Lilly's baricitinib is currently classified as a specialty drug by some pharmacy plans.
- **Outpatient clinic.** Drugs administered by healthcare providers in outpatient clinics, ambulatory surgical centers or hospital outpatient departments are most likely to be given by injection or infusion. Infused and injectable drugs administered in a physician's office are reimbursed through a patient's medical insurance benefit on an average sales price (ASP) basis. Infused and injectable drugs administered through ASCs or HOPDs may be reimbursed separately, or may be part of a bundled payment. For Medicare beneficiaries, the administration of a COVID-19 drugs in the outpatient setting would be covered by Part B, which has a 20% coinsurance.[6]

- **Inpatient hospital.** Oral, injectable, and intravenous medications may be administered in the inpatient acute care setting. Inpatient hospital care is generally reimbursed through a bundled payment or episode of care model in which all care provided in the inpatient setting is reimbursed at a flat rate depending on the patient's diagnosis.[7] It is likely that COVID-19 treatments administered to a patient in the inpatient setting, such as remdesivir, would be included in such bundled payments.

Ensuring Access to Treatment: Key Role of Cost Sharing

Across all settings of care, cost sharing is the variable with greatest impact on access to emerging COVID-19 therapeutics. If cost sharing is high, many patients may lack the means to afford treatment or may refrain from seeking appropriate care. Accordingly, addressing cost-sharing challenges to ensure access has been a key element of COVID–related legislation and policy.

While the Families First Coronavirus Response Act dictates that all public and private insurers must cover any medically appropriate FDA-approved COVID-19 testing with no cost to the individual, there is as yet no comprehensive federal legislation limiting cost sharing for COVID-19 treatment.[6] Standards for cost sharing vary by type of insurance and by state (Table 1).

Table 1. Cost-Sharing Standards for COVID-19 Treatment[6]

	Treatment
Employer Insurance	Cost-sharing can be applied. Cost-sharing may be waived depending on the state, insurer, and/or employer. AHIP details specific insurer decisions here.
Individual Market	Cost-sharing can be applied. Cost-sharing may be waived depending on the state and insurer. AHIP details specific insurer decisions here.
Medicare	Cost-sharing can apply in both Medicare and Medicare Advantage plans. In Medicare Advantage, depends on the insurer. AHIP details specific insurer decisions here.
Medicaid/CHIP	To be eligible for a 6.2 percentage point increase in the regular Medicaid match rate during the public health emergency period, states must cover COVID-19 testing and treatment costs without cost-sharing.
Uninsured	Patients face full price unless they can find free or reduced-cost treatment. Providers can apply to be reimbursed by the federal government ("The Emergency Fund") for treating uninsured patients, though providers are not required to participate in the program and uninsured consumers are not quaranteed free care; Trump Administration guidance is not fully clear on whether people with short-term policies would be considered uninsured for purposes of the Emergency Fund.

Adapted from KFF. Five Things to Know About the Cost of COVID-19 Testing and Treatment, May 26, 2020.

In some states, state-regulated insurers are required to waive cost sharing for COVID-19 treatment. In addition, many private plans—and most Medicare Advantage insurers—have voluntarily waived cost sharing for COVID-19 treatment on a temporary basis.[6]

If an insured patient seeks COVID-19 treatment from an out-of-network provider that has received grants from the Coronavirus Aid, Relief, and Economic Security (CARES) Act Provider Relief Fund, the provider must not seek out-of-pocket payments greater than what the patient would have been required to pay for an in-network provider.[8] For uninsured patients who are given COVID-19 treatment, providers can request claims reimbursement through the Health Resources & Services Administration (HRSA), generally at Medicare rates.[9]

The much-debated Health and Economic Recovery Omnibus Emergency Solutions (HEROES) Act, which is still pending a vote in the Senate as of this writing, would limit cost sharing for COVID-19 treatments. The HEROES Act includes provisions that limit or eliminate coverage restrictions and cost sharing for COVID-19 treatment during the public health emergency for all payer types.[10]

Spotlight on CMS: Waivers, Rules, and Coverage Determinations

When it comes to coding, coverage, and payment, private payers often follow the lead of CMS. Therefore, manufacturers of COVID-19 treatments in development should closely monitor newly enacted CMS waivers, rules, and coverage determinations.

In times of disaster or emergency, the Secretary of the Department of Health and Human Services (HHS) has the authority to temporarily modify or waive certain Medicare or Medicaid requirements. These waivers, known as 1135 waivers, include blanket waivers. The Secretary of the HHS can also offer health care providers other flexibilities to help ensure patient access and bridge care gaps.[11] Going into 2021, such waivers may be implemented or extended by the new administration.

CMS issued an Interim Final Rule with Comment Period (IFC) on October 28, 2020 with provisions that increase Medicare payments for new COVID-19 treatments in both the inpatient and outpatient hospital settings.[12] Under this IFC, hospitals treating patients with innovative COVID-19 treatments that have been authorized or approved by the FDA would qualify for additional reimbursement beyond the usual bundled payment for inpatient stays. For outpatient services, treatments that have been authorized or approved to treat COVID-19 are excluded from the Comprehensive Ambulatory Payment Classification (C-APC) payment (ie, the bundled payment described above) as long as they are billed on the same claim as the primary C-APC service. Instead, Medicare will provide separate payment for these therapeutics for the duration of the public health emergency.[13]

On November 10, 2020 CMS indicated that Medicare would cover monoclonal antibody-based COVID-19 treatment with no cost sharing during the public health emergency.[14] This coverage applies to the use of bamlanivimab in Medicare beneficiaries with mild-to-moderate COVID-19.[15] Notably, Medicare will not pay for bamlanivimab that providers receive for free, which is expected to be the case when the product is initially released. However, providers can bill for administering the infusion. Once providers begin to pay for monoclonal antibody products, CMS anticipates setting the payment rate just as the payment rate is set for COVID-19 vaccines.[16]

A Wild Card to Monitor: Government Purchasing of Promising COVID-19 Therapeutics

There are a number of other legislative and policy factors that COVID-19 therapeutic manufacturers should keep an eye on.

Operation Warp Speed (OWS) is a public-private partnership among components of HHS, the Department of Defense, and other private firms and federal agencies. The most-publicized goal of this initiative is to manufacture and deliver 300 million doses of safe and effective COVID-19 vaccines beginning in December 2020. However, OWS also encompasses a broader effort to accelerate the development, manufacturing, and distribution of COVID-19 diagnostics and therapeutics.[17] To date, actions to support OWS therapeutic development and supply include:

June 2020	HHS secured more than half a million treatment courses of remdesivir from Gilead Sciences. According to this agreement, U.S. hospitals would be allowed to purchase the drug at no more than the manufacturer's WAC price and the supply would be allocated based on COVID-19 burden[18]
July 2020	$450 million in funds were allocated to support the large-scale manufacturing of Regeneron's REGN-COV2 antibody cocktail, with the manufactured doses to be owned by the federal government. If EUA or product approval is granted, the federal government has committed to making these doses available to Americans at no cost.[19] Regeneron submitted an EUA to the FDA on October 7, 2020[20]
October 2020	HHS announced that it would provide AstraZeneca with approximately $486 million to support late-stage development and large-scale manufacturing of AZD7442, an investigational monoclonal antibody cocktail. As with REGN-COV2, if the FDA authorizes the use of AZD7442 to prevent COVID-19, the federal government will distribute the doses at no cost[21]
October 2020	HHS announced a $375 million agreement with Eli Lilly and Company to purchase the first 300,000 doses of bamlanivimab. Under this agreement, the federal government can purchase up to 650,000 additional doses through end of June 2021. Similar to REGN-COV2 and AZD7442, upon authorization by the FDA, these government-purchased doses would be available to Americans at no cost, but health care providers would be able to charge for medication administration
November 2020	Following the issuance of an EUA for bamlanivimab on November 9, 2020, HHS announced plans to allocate initial doses of the monoclonal antibody to state and territorial health departments proportionally based on COVID-19 burden[22]

Conclusion: Considerations and Watch-Outs

Like the landscape for therapeutic development, the access and reimbursement landscape for COVID-19 treatments is dynamic and evolving rapidly. During the current state of emergency, ordinary coverage and reimbursement pathways and processes may not apply. Given current public health needs, time is of the essence and access to emerging COVID-19 treatment options is a priority. Federal legislators and CMS officials are working to ensure broad access to COVID-19 treatments with little or no cost-sharing during the public health emergency period.

Manufacturers of potential COVID-19 therapeutics should monitor evolving policy changes carefully and adjust their commercialization planning accordingly. Some currently unknown key considerations that are relevant for COVID-19 therapeutic commercialization planning include:

Clinical development costs: Can the cost of running expensive clinical trials be mitigated by receiving governmental aid or investment, similar to the path followed by AstraZeneca? If a company receives governmental aid, how would the aid impact the pricing of the product once it launches?

Product distribution: Which distribution channel is the right fit for the product (ie, retail pharmacy, specialty pharmacy, physician office, or hospital) based on acuity of the indicated patient population? Is there a clear path to reimbursement for providers that would use an innovative COVID-19 treatment?

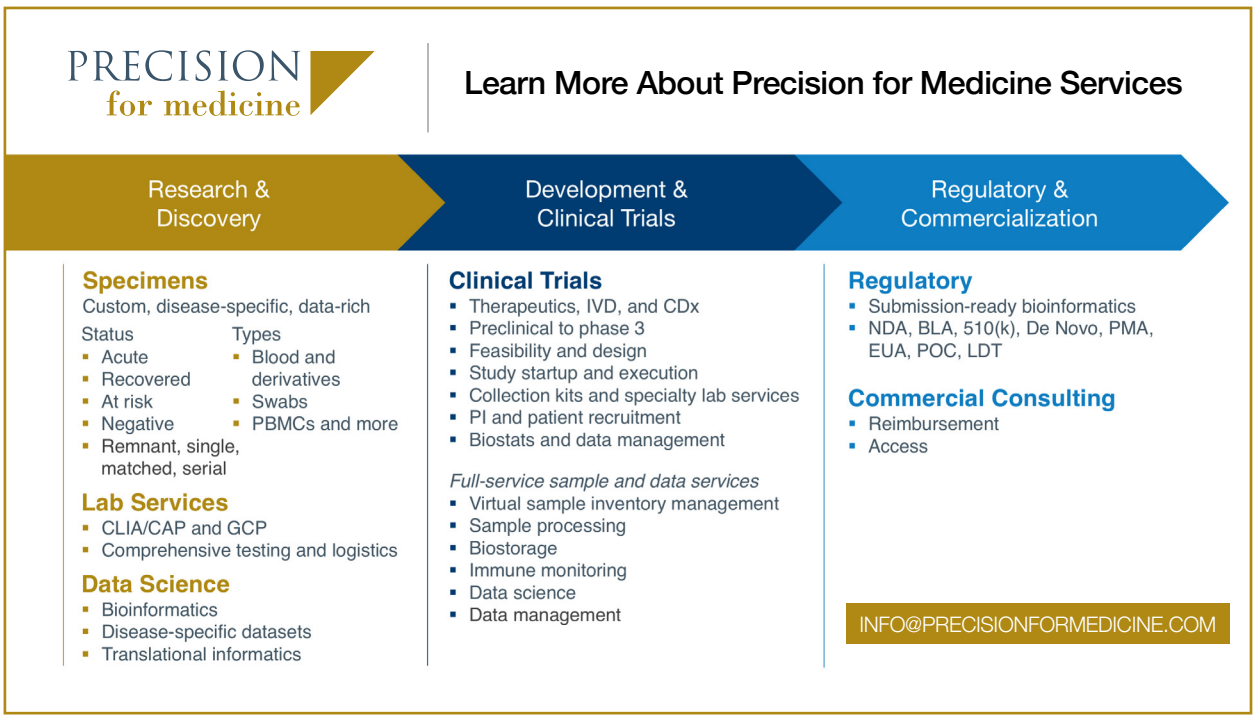
Pricing and payment strategy: If the government negotiates prepurchase deals, how might this affect product pricing at launch and throughout the remainder of the product's life cycle? After the Public Health Emergency (PHE) period, will providers and payers expect to pay and reimburse for COVID-19 treatments at rates similar to those offered to the government? What will be the impact of emergency-based government purchasing on post-PHE ASP?

Short-term coverage and access planning: How might private/commercial payers react if the HEROES act is passed and there is a requirement to cover and waive cost sharing for expensive COVID-19 treatments? Providing coverage and payment for COVID-19 therapeutics without the ability to recoup copay or coinsurance negatively impacts insurers' bottom lines—will they implement profit-preserving initiatives in other areas?

Long-term coverage and access planning: Although coverage may not be an issue at launch and throughout the PHE, what will the coverage environment look like after the PHE is lifted? Will insurance companies prefer particular treatments in a competitive environment? On what basis will they do so—will typical contracting strategies come into play? How can pharmaceutical manufacturers differentiate their COVID-19 treatment from others?

In 2021, considerable public good will be provided by innovative public and private programs to ensure access to emerging COVID-19 treatments. Savvy treatment developers will look past the health emergency and also plan for a more normalized postpandemic market in which endemic SARS-CoV-2 remains the cause of serious disease requiring effective treatments.

Precision for Medicine experts know how payers think—and how to get them to think the right way about your COVID-19 product. We understand the payment processes, the codes, and the coverage standards that payers use. And, we know the most effective ways to weave them together, so when you go to market you get maximum access in minimum time. **To learn more about our services,** contact us today**.**



References

1. U.S. Food and Drug Administration. The Path Forward: Coronavirus Treatment Acceleration Program. Available at https://www.fda.gov/news-events/fda-voices/path-forward-coronavirus-treatment-acceleration-program. Accessed November 14, 2020.
2. U.S. Food and Drug Administration. Coronavirus Treatment Acceleration Program (CTAP). Available at https://www.fda.gov/drugs/coronavirus-covid-19-drugs/coronavirus-treatment-acceleration-program-ctap. Accessed November 14, 2020.
3. World Health Organization. WHO recommends against the use of remdesivir in COVID-19 patients, November 20, 2020. https://www.who.int/news-room/feature-stories/detail/who-recommends-against-the-use-of-remdesivir-in-covid-19-patients. Accessed December 1, 2020.
4. U.S. Food and Drug Administration. Emergency Use Authorization. https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs. Accessed December 1, 2020.
5. Prescription Process. Specialty Tiers. http://prescriptionprocess.com/barriers-to-access/special-tiers/. Accessed November 14, 2020.
6. KFF. Five Things to Know About the Cost of COVID-19 Testing and Treatment, May 26, 2020. https://www.kff.org/coronavirus-covid-19/issue-brief/five-things-to-know-about-the-cost-of-covid-19-testing-and-treatment/. Accessed November 14, 2020.
7. NEJM Catalyst. What Are Bundled Payments? Available at https://catalyst.nejm.org/doi/full/10.1056/CAT.18.0247. Accessed November 14, 2020.
8. HHS.gov. CARES Act Provider Relief Fund: For Patients. https://www.hhs.gov/coronavirus/cares-act-provider-relief-fund/for-patients/index.html. Accessed November 14, 2020.
9. Health Resources & Services Administration. COVID-19 Claims Reimbursement to Health Care Providers and Facilities for Testing, Treatment, and Vaccine Administration for the Uninsured. https://www.hrsa.gov/CovidUninsuredClaim. Accessed November 14, 2020.
10. Congress.gov. H.R.6800 – The Heroes Act. https://www.congress.gov/bill/116th-congress/house-bill/6800. Accessed November 14, 2020.
11. CMS.gov. Coronavirus waivers & flexibilities. https://www.cms.gov/about-cms/emergency-preparedness-response-operations/current-emergencies/coronavirus-waivers. Accessed November 14, 2020.
12. CMS.gov. Fourth COVID-19 Interim Final Rule with Comment Period (IFC-4), October 28, 2020. https://www.cms.gov/newsroom/fact-sheets/fourth-covid-19-interim-final-rule-comment-period-ifc-4. Accessed November 14, 2020.
13. CMS.gov. Trump Administration Acts to Ensure Coverage of Life-Saving COVID-19 Vaccines & Therapeutics, October 28, 2020. https://www.cms.gov/newsroom/press-releases/trump-administration-acts-ensure-coverage-life-saving-covid-19-vaccines-therapeutics. Accessed December 1, 2020.
14. CMS.gov. CMS Takes Steps to Ensure Medicare Beneficiaries Have Wide Access to COVID-19 Antibody Treatment, November 10, 2020. https://www.cms.gov/newsroom/press-releases/cms-takes-steps-ensure-medicare-beneficiaries-have-wide-access-covid-19-antibody-treatment. Accessed November 14, 2020.
15. U.S. Food and Drug Administration. Coronavirus (COVID-19) Update: FDA Authorizes Monoclonal Antibody for Treatment of COVID-19, November 9, 2020. https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-monoclonal-antibody-treatment-covid-19. Accessed November 14, 2020.
16. CMS.gov. Medicare Monoclonal Antibody COVID-19 Infusion Program Instruction. https://www.cms.gov/files/document/covid-medicare-monoclonal-antibody-infusion-program-instruction.pdf. Accessed November 14, 2020.
17. HHS.gov. Fact Sheet: Explaining Operation Warp Speed. https://www.hhs.gov/coronavirus/explaining-operation-warp-speed/index.html. Accessed November 14, 2020.
18. HHS.gov. Trump Administration Secures New Supplies of Remdesivir for the United States, June 29, 2020. https://www.hhs.gov/about/news/2020/06/29/trump-administration-secures-new-supplies-remdesivir-united-states.html. Accessed November 14, 2020.
19. Regeneron. Regeneron Announces Manufacturing and Supply Agreement for BARDA and U.S. Department of Defense for REGN-COV2 Anti-Viral Antibody Cocktail, July 7, 2020. https://investor.regeneron.com/news-releases/news-release-details/regeneron-announces-manufacturing-and-supply-agreement-barda-and. Accessed November 14, 2020.
20. Regeneron. Statement on REGN-COV2 Emergency Use Authorization Request, October 7, 2020.
21. HHS.gov. Trump Administration Expands Collaboration with AstraZeneca to Develop and Manufacture an Investigational Monoclonal Antibody to Prevent COVID-19, October 9, 2020. https://www.hhs.gov/about/news/2020/10/09/trump-administration-expands-collaboration-with-astrazeneca-to-develop-and-manufacture-an-investigational-monoclonal-antibody-to-prevent-covid-19.html. Accessed November 14, 2020.
22. HHS.gov. HHS allocates Lilly therapeutic to treat patients with mild to moderate COVID-19, November 9, 2020. https://www.hhs.gov/about/news/2020/11/10/hhs-allocates-lilly-therapeutic-treat-patients-mild-moderate-covid-19.html. Accessed November 14, 2020.