COVID-19 Monoclonal Antibodies: Recommendation Summary

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Until approved vaccines are widely available, effective treatments are urgently needed to curb the severity, loss of life, and health care impact of COVID-19. Monoclonal antibodies (mAbs) to neutralize the virus are promising treatments for high-risk patients early in the course of their illness, and two antibody treatments have recently been authorized by the Food and Drug Administration (FDA). Enough doses to treat over 1.2 million Americans are expected to be available by the end of January 2021, potentially preventing tens of thousands of COVID-19 hospitalizations, with greater supply thereafter. But the impact of antibody treatment has been limited so far, because new models of care for high-risk COVID-19 patients must be adopted, with timely testing and referral for antibody infusion therapy. Implementing these changes requires new payment models, better evidence to augment the limited clinical trials conducted so far, and effective systems for allocating the limited supply.

Recommendations for Payment

The Centers for Medicare and Medicaid Services (CMS) and private health insurers are adopting new payments for delivering monoclonal antibody treatments, and pilot initiatives are addressing home or mobile access for patients who need it. A Duke-Margolis issue brief provides recommendations on further payment reforms to support effective access to antibody treatments *and* better evidence to guide their use:

- **Adjust payment to providers** to better reflect costs associated with safe infusion in the appropriate setting for all high-risk COVID-19 patients, to support effective access to antibody treatment
- **Implement CMS, HHS, and state collaboration** to track access to COVID-19 treatments and identify gaps
- **Consider Federal funding of deployable antibody administration capacity** to hotspots and underserved populations, such as nursing home residents and rural patients
- **Adjust COVID-19 payment rates for diagnostic tests** based on return time, and increase payments for timely referral for antibody treatment by CMS and private payers
- **Ensure that public and private reimbursements support a limited core data platform** or registry for high-risk COVID-19 patients, to support evidence development on how to best allocate and use antibodies

Recommendations for Better Evidence

Limited clinical trial evidence is available on the impact of antibodies, particularly within high-risk populations. Some additional studies are underway, but there are opportunities to build on existing systems for collecting data and conducting "real-world" assessments to enhance the

evidence base and enable more confident decisions about allocating and using antibodies. A Duke-Margolis issue brief provides recommendations to generate timely evidence:

- **Implement a collaboration with support from the Federal government, manufacturers, and/or payers** to rapidly adapt existing COVID-19 registries and data platforms to support evidence development, in coordination with ongoing clinical trials
- **Conduct shared analyses** to develop evidence on questions related to effective antibody allocation, and on innovative models for antibody administration especially for underserved populations
- **Use this evidence to support further guidance** to health care organizations, payers, and Federal and state policy makers to optimize use of antibody treatments

Recommendations for State Allocation

The Federal government is allocating available antibody supplies to states, based on state case and hospitalization burden. States need to establish allocation protocols for antibody treatments that maximize the public health value of these drugs and support providers and payers in getting antibody treatments to the right patients, at the right time, and in the right place. A Duke-Margolis issue brief provides guidance and recommendations for state allocation decisions:

- **Support development of common state-wide criteria for providers** to allocate the drugs to their patients
- **Promote the use of antibodies in settings that make the therapeutic more accessible to high-risk patients,** such as infusion sites in high-risk communities and skilled nursing facilities
- **Focus allocation on providers that demonstrate readiness** for identifying high-risk patients *early* in disease progression
- **Encourage the use of testing protocols that screen patients for high-risk criteria**, and notify appropriate patients about antibody treatment options