



May 16, 2022

The Honorable Xavier Becerra
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

RE: Payment for Monoclonal Antibodies for COVID-19

Dear Secretary Becerra:

On behalf of the National Home Infusion Association (NHIA), I am writing to express my concern about the future expiration of Medicare payment for COVID-19 monoclonal antibodies, following the expiration of the COVID-19 public health emergency (PHE). NHIA is a trade association that represents companies that provide infusion therapy to patients in their homes, as well as companies that manufacture and supply infusion and specialty pharmacy products. As the leading voice for the home and specialty infusion community, we write to share our concerns about this issue.

Monoclonal antibodies have been critical in the fight against the COVID-19 pandemic, providing an important tool to treat and prevent severe illness, hospitalization, and death. The Centers for Medicare & Medicaid Services (CMS) has been paying for COVID-19 monoclonal antibodies under the Medicare Part B vaccine benefit. In May 2021, CMS implemented an equitable payment rate for home administration of these treatments, allowing qualified pharmacies to provide COVID-19 antibodies to thousands of patients across the country. This program has been highly successful and has served as a model for the private sector and Medicare Advantage.

Under the policies set out in the Medicare physician fee schedule for calendar year 2022, coverage for home infusion of COVID-19 monoclonal antibodies will expire at the end of the year in which the PHE expires.¹ While the PHE was recently renewed for another 90 days, we anticipate that it will expire sometime in 2022, and therefore coverage for home infusion of COVID-19 monoclonal antibodies will expire on December 31, 2022. NHIA asks that you reconsider this decision and make coverage permanent for home infusion supplies and services for home administration of COVID-19 monoclonal antibodies under the vaccine benefit. After the PHE ends, the monoclonal antibodies themselves would be covered under Medicare Part D,

¹ 86 Fed. Reg. 64996 (Nov. 19, 2021)



however there is no other mechanism for providers to be reimbursed for the extensive services and supplies associated with making these treatments available to patients at home.

Currently, payment for home infusion administration, supplies, and services only apply to drugs covered under the Medicare Part B DMEPOS benefit. COVID monoclonal antibodies do not require the use of a pump and therefore patients would be required to pay out of pocket for all supplies, pharmacy services, and nursing. We believe this financial burden will create significant barriers to access for patients in need of these treatments, particularly for Medicare beneficiaries who live in rural areas and for whom transportation is a burden or presents a significant health risk. In addition, at this time, the oral treatments for COVID-19 are not indicated for a prophylactic purpose and the only prophylactic treatment for COVID-19 is available through infusion or injection. The availability of prophylactic treatments for patients for whom vaccination is not effective will be significantly diminished if CMS does not continue to pay for the adjunct components to facilitate home administration of monoclonal antibodies beyond the expiration of the PHE. Many of the beneficiaries currently taking advantage of home administration of monoclonal antibodies for prophylaxis (e.g., post-transplant, cancer, immunodeficiencies) are the most vulnerable to infection and prefer to avoid facility settings for these treatments. In addition, it is likely that that CMS's change in policy would extend beyond Medicare to the commercial and Medicare Advantage programs, as these payors often rely on and adopt Medicare's coverage guidance.

Finally, NHIA believes that having an established framework for home administration of COVID-19 monoclonal antibody treatments is a worthwhile investment toward maintaining the network of providers who have already enrolled to offer these services, which enhances preparedness should future variants emerge that require rapid deployment of monoclonal antibodies.

NHIA appreciates the opportunity to raise this important issue with you and welcomes the opportunity to work with HHS to improve access to home infusion of monoclonal antibodies for COVID-19 beyond the end of the year. For questions or additional information, please contact me at connie.sullivan@nhia.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Connie Sullivan". The signature is fluid and cursive, with a large initial "C" and "S".

Connie Sullivan, B.S. Pharm
President and Chief Executive Officer