

Uptake of Outpatient Monoclonal Antibody Treatments for COVID-19 in the United States: a Cross-Sectional Analysis



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INTRODUCTION

The Food and Drug Administration (FDA) has issued emergency use authorizations for three monoclonal antibodies for the outpatient treatment of symptomatic coronavirus disease 2019 (COVID-19)¹ in patients at high risk for progressing to severe disease, and the federal government has purchased and allocated nearly 1 million antibody treatments.² Monoclonal antibodies remain the only approved outpatient therapies available for COVID-19 and media reports have speculated they may be underutilized;³ however, data on utilization has not been published.

METHODS

We examined outpatient medical claims from Symphony Health, a national medical claims database covering over 200 million US patients, made available through the COVID-19 Research Database consortium.⁴ Receipt of monoclonal antibody treatments (bamlanivimab, casirivimab/imdevimab, and bamlanivimab/etesevimab) between November 9, 2020, and April 11, 2021, was determined by antibody-specific Current Procedural Terminology codes according to Centers of Medicare and Medicaid Services guidance.⁵ Descriptive characteristics of treatment recipients and the underlying study base were compared using 2-sided chi-2 tests, with an alpha set at $P < .05$. Weekly trends in the use of each treatment were plotted. All analyses were conducted using Stata 16.1. The study was classified as exempt by the Beth Israel Deaconess Medical Center Institutional Review Board.

RESULTS

The study base included 211 million patients of whom 69,377 receive monoclonal antibody treatments during the study period (Table 1). Bamlanivimab accounted for 84.6% of administered treatments, casirivimab/imdevimab for 12.8% and

bamlanivimab/etesevimab for 2.6%. The majority of patients receiving antibody treatments were younger than 65 years (57.5%), female (53.8%), had commercial insurance (62.3%), and were located in the South (50.8%). Though patients with Medicaid comprised 10.0% of the study base, they comprised only 3.3% of patients receiving monoclonal antibodies. Weekly use of monoclonal antibodies increased throughout 2020, peaking the week of January 4,

Table 1 Characteristics of Patients Receiving Monoclonal Antibodies for COVID-19 and the Study Base Population

Characteristic	Patients receiving monoclonal antibodies		Patients in symphony health database	
	No.	%	No.	%
Total	69,377	100.0%	211,239,305	100.0%
Gender				
Female	37,344	53.8%	117,181,902	55.5%
Male	32,031	46.2%	94,033,559	44.5%
Unknown	*	*	23,844	<0.1%
Age				
< 18	391	0.6%	39,507,671	18.7%
18–34	3,672	5.3%	42,038,531	19.9%
35–44	5,695	8.2%	24,617,771	11.7%
45–54	10,431	15.0%	26,400,781	12.5%
55–64	19,681	28.4%	30,641,321	14.5%
> 65	29,504	42.5%	44,635,884	21.1%
Unknown	*	*	3,397,346	1.6%
Primary payer				
Commercial	43,191	62.3%	159,647,410	75.6%
Medicare	22,741	32.8%	22,890,227	10.8%
Medicaid	2,303	3.3%	21,099,366	10.0%
Government	762	1.1%	3,357,504	1.6%
Cash	66	0.1%	341,132	0.2%
Unknown	314	0.5%	3,903,666	1.8%
Race/ethnicity				
Caucasian	37,992	54.8%	64,586,764	30.6%
African American	5,595	8.1%	11,645,740	5.5%
Hispanic	4,835	7.0%	8,841,446	4.2%
Asian	564	0.8%	1,694,072	0.8%
Other	823	1.2%	1,475,227	0.7%
Unknown	19,568	28.2%	122,996,056	58.2%
Household income				
<= \$29,999	9,080	13.1%	18,728,477	8.9%
\$30–49,999	7,360	10.6%	14,029,011	6.6%
\$50–74,999	9,687	14.0%	15,799,682	7.5%
\$75–99,999	8,744	12.6%	13,965,483	6.6%
\$100,000 +	13,679	19.7%	23,616,317	11.2%
Unknown	20,827	30.0%	125,100,335	59.2%
Region				
Northeast	10,114	14.6%	42,357,553	20.1%
South	35,091	50.6%	77,759,778	36.8%
Midwest	17,567	25.3%	43,853,111	20.8%
West	5,287	7.6%	36,432,944	17.2%
Unknown	1,318	1.9%	10,835,919	5.1%

Note: Cells with fewer than 10 observations redacted for data privacy and marked with *. P values for chi-2 comparison of characteristics between patients receiving monoclonal antibodies and Symphony Health population all $< .001$

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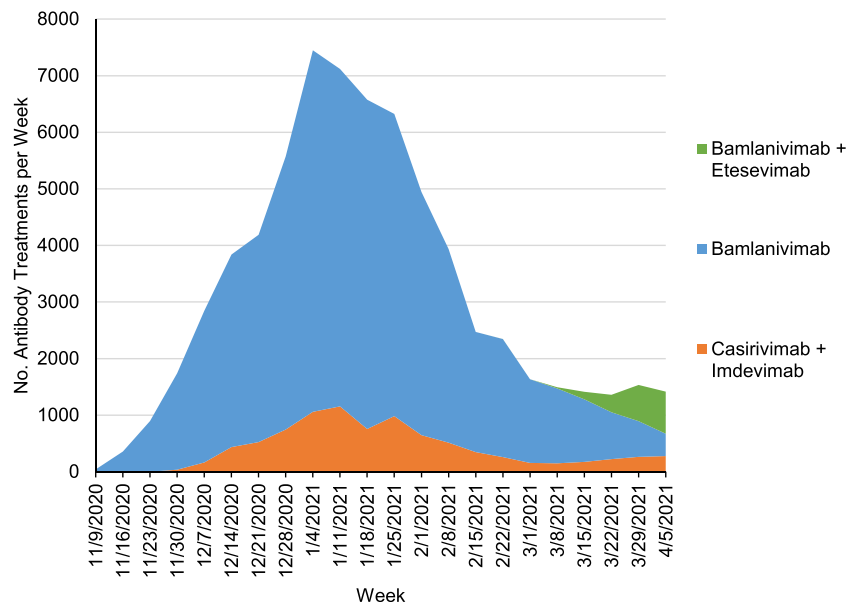


Figure 1 Weekly trends in the administration of monoclonal antibodies for COVID-19. Notes: Analysis of Symphony Health claims from November 9, 2020, and April 11, 2021. Dates on the x-axis refer to the first day of a 7-day week. The dates of emergency use authorizations were November 9, 2020, for bamlanivimab, November 21, 2020, for casirivimab/imdevimab, and February 9, 2021, for bamlanivimab/etesevimab. The emergency use authorization for bamlanivimab administered alone was revoked on April 14th, 2021.

2021, with 7,243 treatments given, and thereafter declined through the end of the study period (Fig. 1).

DISCUSSION

In this medical claims study including 62% of the US population, we observe fewer than 70,000 patients received monoclonal antibody treatments for COVID-19 between first FDA emergency use authorization and April 11, 2021. During this time period, over 20 million cases of COVID-19 were diagnosed, 2.5 million monoclonal antibody treatments were purchased by the US government, and nearly 1 million treatments were allocated to states.²

Our findings of low uptake of monoclonal antibody treatments contrast to prior reports of increased use of unauthorized therapies.⁶ Reasons for low uptake warrant future research and could reflect stockpiling of allocated treatments, limited distribution by health systems, barriers to patient access to treatments which require intravenous infusion, or hesitancy to adopt treatments by providers and patients. The initial authorization of monoclonal antibodies occurred on the cusp of the largest surge in COVID-19 infections and the initial COVID-19 vaccine rollout. If health systems lacked the capacity to immediately develop additional infrastructure for administering antibody treatments due to competing priorities, we would have expected to see gradual growth in the use of monoclonal antibodies; however, we find that antibody use declined throughout 2021.

Despite limitations of missing data, the observed demographic and insurer differences in the treated population

compared to the study base highlight a possible disparity in access. As many patients receive a COVID-19 diagnosis outside of the health system, through government, school, workplace, and other testing sites, our study was unable to determine the symptomatic population who would have been potentially eligible for monoclonal antibody treatments. Furthermore, these testing sites may not be equipped to refer patients to receive monoclonal antibody treatments, particularly if they do not already have a usual source of healthcare.

The public interest would be well-served by improved transparency on the allocation and administration of monoclonal antibody treatments, including data necessary to assess equitable access to treatments.

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Author Contribution Dr. Anderson had full access to all the data in
the study and take responsibility for the integrity of the data and the
accuracy of the data analysis as the guarantor. Dr. Anderson attests
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