Coverage of Monoclonal Antibody Products to Treat COVID-19

Monoclonal antibody products to treat Coronavirus disease 2019 (COVID-19) help the body fight the virus or slow the virus's growth. Medicare beneficiaries have coverage without beneficiary cost sharing for these products when used as authorized or approved by the Food and Drug Administration (FDA).

Medicare

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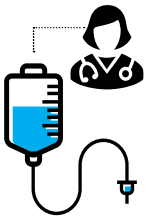
Site of Care[1]	Payable by Medicare	Expected Patient Cost-Sharing
 Inpatient Hospital	✓	No patient cost-sharing
 Outpatient Hospital or "Hospital without Walls[2]"	✓	No patient cost-sharing
 Outpatient Physician Office/ Infusion Center	✓	No patient cost-sharing[3]
 Nursing Home *(See third bullet in Key Facts on CMS enforcement discretion)*	✓	No patient cost-sharing
 Home or Residence	✓	No patient cost-sharing

[1] Services must be furnished within the scope of the product's FDA authorization or approval and within the provider's scope of practice.

[2] Under the Hospital Without Walls initiative, hospitals can provide hospital services in other healthcare facilities and sites that would not otherwise be considered to be part of a healthcare facility; or can set up temporary expansion sites to help address the urgent need to increase capacity to care for patients.

[3] Cost-sharing may apply to Medicare beneficiaries when they receive care from a provider that doesn't participate in Medicare.

[4] Certain monoclonal antibody products to treat COVID-19 have been authorized under Food and Drug Administration Emergency Use Authorizations since November 10, 2020. More information including the level II HCPCS codes for the administration/ infusion and post administration monitoring of these products can be found online in the **Provider Toolkit**.

Expected Payment to Providers: Key Facts

- Medicare payment for monoclonal antibody products to treat COVID-19 is **similar across sites of care**, with some small differences.
- Medicare **pays for the administration** of monoclonal antibody products to treat COVID-19. For example, beginning on May 6, 2021, Medicare will pay approximately $450 in most settings, or approximately $750 in the beneficiary's home or residence, for the administration of certain monoclonal antibody products[4] to treat COVID-19. For monoclonal antibody products to treat COVID-19 that are administered before May 6, 2021, the Medicare payment rate in all settings is approximately $310.
- CMS will exercise **enforcement discretion** to allow Medicare-enrolled immunizers working within their scope of practice and subject to applicable state law to **bill directly and receive direct reimbursement from the Medicare program for administering monoclonal antibody treatments** to Medicare Part A Skilled Nursing Facility residents.
- Medicare will pay the provider for these monoclonal antibody products **when they are purchased by the provider**. Medicare won't pay if the product is given to the provider for free by, for example, a government entity.
- When purchased by the provider, Medicare payment is typically at **reasonable cost or at 95% of the Average Wholesale Price** (an amount determined by the manufacturer). These payment amounts vary depending on **which type of provider** is supplying the product. Original Medicare will pay for these products for beneficiaries enrolled in Medicare Advantage.
- For more specific information about Medicare payments to providers for these monoclonal antibody products, please see these **Frequently Asked Questions**.

May 2021

Medicaid/CHIP

Medicaid Coverage Required: Yes, in states subject to section 6008(b)(4) of the Families First Coronavirus Response Act[1].

Additionally, beginning March 11, 2021, states are required to cover, without cost sharing, COVID-19 treatment under amendments made to the Social Security Act (Act) by section 9811 of the American Rescue Plan Act of 2021 (ARP). This requirement begins on March 11, 2021, and generally ends on the last day of the first calendar quarter that begins one year after the last day of the COVID-19 emergency period described in section 1135(g)(1)(B) of the Act. Under these amendments, states are required to cover, without cost sharing, treatments for COVID-19, including specialized equipment and therapies (including preventive therapies), and must also cover, without cost-sharing, the treatment of a condition that may seriously complicate the treatment of COVID-19, if otherwise covered under the state plan (or a waiver of such plan), for individuals who are diagnosed with or presumed to have COVID-19, during the period such an individual has (or is presumed to have) COVID-19. The ARP amendments also require coverage of the same services, without cost-sharing, for individuals eligible for the optional COVID-19 group authorized at section 1902(a)(10)(A)(ii)(XXIII) of the Act at 100% federal match, but only through the last day of the COVID-19 PHE. Monoclonal antibodies are included in these treatment mandates. The ARP amendments also provide that drugs covered under the new mandatory Medicaid benefit for COVID-19 treatment could be subject to section 1927 manufacturer rebates, if they would otherwise meet the criteria for being a covered outpatient drug.

State Plan Amendment (SPA) Required: CMS will be issuing additional guidance regarding SPAs to implement these ARP amendments. States may need to add additional coverage, depending on what services they currently cover. Additionally, payment SPAs may be required if the state wants to pay a different rate for administration of these mandatory covered drugs than it pays for other types of drug administration. States should seek technical assistance from CMS regarding SPAs that might be necessary.

[1] Under section 6008 of the Families First Coronavirus Response Act (FFCRA), state and territorial Medicaid programs may receive a temporary 6.2 percentage point increase in the Federal Medical Assistance Percentage (FMAP). This temporary FMAP increase is available through the end of the quarter in which the COVID-19 PHE ends, if the state claims the increase in that quarter. To receive the temporary FMAP increase, a state or territory must cover COVID-19 testing services and treatments, including vaccines and their administration, specialized equipment, and therapies for most Medicaid enrollees without cost sharing. This includes therapeutics approved under Food and Drug Administration Emergency Use Authorizations and their administration.

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CHIP Coverage Required: Yes, because the ARP also added new mandatory coverage, without cost-sharing, of COVID-19 treatment to the CHIP statute. This new coverage is identical to the new Medicaid coverage requirement.

SPA Required: CMS will be issuing additional guidance regarding SPAs to implement the ARP.

Plans subject to ACA market reforms

Most individual and small group market insurance **must cover essential health benefits**. Essential health benefits generally include coverage for many items and services related to the diagnosis and treatment of COVID-19. These plans are also required to cover COVID-19 diagnostic testing for individuals with health coverage who are asymptomatic, and who have no known or suspected exposure to COVID-19. Such testing must be covered without cost sharing, prior authorization, or other medical management requirements imposed by the plan or issuer[1].

Furthermore, these plans are also required to cover without cost sharing the COVID-19 vaccine and its administration when provided by a network provider, and during the COVID-19 PHE, are also required to cover without cost sharing the vaccine and its administration when provided by an out-of-network provider[2].

The exact coverage details for individual services may vary by plan, and some plans may require prior authorization or other medical management before these services are covered. Cost sharing amounts, such as a deductible, coinsurance, or copay, for individual services may also vary by plan.

If a plan does not provide coverage of a specific prescription drug on its formulary, individuals may request coverage through the plan's drug exceptions process.

If a plan denies coverage for a COVID-19 therapeutic, for example, for being experimental, an individual can appeal the decision.

Some state laws require issuers to waive cost sharing for certain COVID-19 treatment. Other issuers have voluntarily opted to do so.

Some plans are not required to offer essential health benefits.

[1] **https://www.cms.gov/files/document/faqs-part-44.pdf**
[2] **https://www.cms.gov/files/document/COVID-19-toolkit-issuers-MA-plans.pdf**