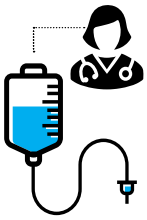
Coverage of Monoclonal Antibody Products to Treat COVID-19

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

Disclaimer: The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law.

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	✓	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 **Program Instruction**.

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, Medicare will pay a national average of approximately $310 for the administration of certain monoclonal antibody products[4].
- 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**.

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Medicaid/CHIP

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

State Plan Amendment (SPA) Required: Potentially, depending on what services the state currently covers. Additionally, payment SPAs may be required if the state wants to pay a different rate for administration than they pay 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.

CHIP Coverage: Therapeutics will generally be covered under an existing benefit (drugs and biologicals or other therapeutic benefits as determined under the State Plan).

SPA Required: No, if covered under an existing benefit

Plans subject to ACA market reforms

Coverage for COVID-19 therapeutics varies among 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 items and services related to the diagnosis and treatment of COVID-19.

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.