

Monoclonal Antibodies: Medical Uses for the Prevention and Treatment of Disease

January 26, 2022

Monoclonal antibodies are laboratory made proteins designed to act like human antibodies by binding to specific proteins in the body called antigens. These antigens may include proteins from cancers, bacteria, viruses, or inflammatory cells. Monoclonal antibodies can act to help our immune system by directly recognizing and destroying dangerous antigens such as viruses (Figure 1).

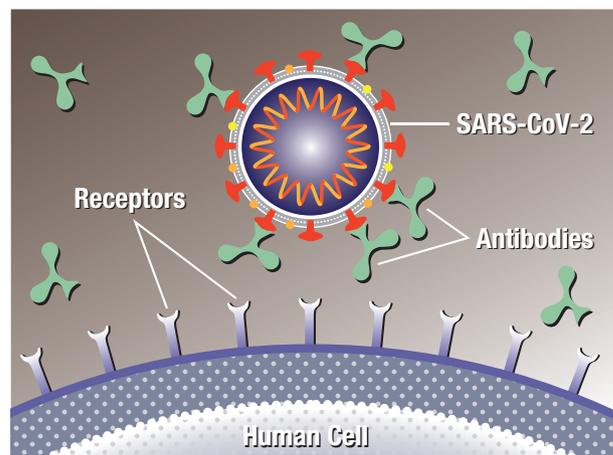


Figure 1: Image of antibodies (green) binding to the surface of a SARS-CoV-2 virus and blocking entry of the virus into a human cell
Source: <https://www.nih.gov/news-events/news-releases/clinical-trials-mono-clonal-antibodies-prevent-covid-19-now-enrolling>

The History of Monoclonal Antibodies

The idea of using a person's blood who has recovered from an illness to help another person recover from the same illness is not new. During the influenza virus pandemic of 1918, physicians would use blood serum from people who had recovered from influenza and administer it to those infected with influenza to prevent progression of disease.¹ This blood was believed to contain antibodies made by the immune system to detect and eliminate pathogens. Over the past century, numerous infectious diseases have been treated through this type of therapy including: Lassa fever, hemorrhagic fever, measles, and various respiratory viruses.

Through scientific advancement over the last 30 years, we are able to isolate and manufacture *specific* antibodies to fight a variety of diseases. These specific antibodies are called monoclonal antibodies. Currently there are over 30 monoclonal antibodies approved for use in medicine for various diseases. (Table 1)

Table 1. Monoclonal antibody uses in modern medicine.

Cancers	<ul style="list-style-type: none"> • leukemia • lymphoma • breast • lung • colon
Asthma	
Autoimmune Disorders	<ul style="list-style-type: none"> • Rheumatoid arthritis • Crohn's disease • Ulcerative colitis • Ankylosing spondylitis
Osteoporosis	
Kidney transplant rejection	
Infections	<ul style="list-style-type: none"> • Hepatitis C infection • Respiratory Syncytial Virus (children) • SARS-CoV-2 coronavirus

Monoclonal Antibodies for SARS-CoV-2 (COVID-19 Infection)

On November 9, 2020, the FDA authorized the first monoclonal antibody against a spike protein on SARS-CoV-2 for treatment for mild-to-moderate COVID-19 in adults and children in the outpatient setting.² The safety and effectiveness of this therapy continues to be evaluated in clinical trials of patients with COVID-19.³ All monoclonal antibodies that have been approved to date are for “emergency use.” Emergency use authorization or “EUA” allows the FDA, during public health emergencies, to use an unapproved medical product based on the best available evidence, to treat or prevent serious or life-threatening diseases or conditions when there are no adequate, approved, or available alternatives.⁴

Monoclonal antibodies were approved for emergency use in COVID-19 because there are clinical trial data showing that they reduce harm from COVID-19. There are several approved monoclonal antibodies approved for emergency use in positive COVID-19 patients. Sometimes more than one type of monoclonal antibody is given in combination. Different monoclonal antibodies may be used depending on the viral variant causing infection.⁵

As of December 2021, the FDA has expanded the emergency use of monoclonal antibodies to include pediatric patients and newborns with COVID-19. In addition, the FDA has authorized the use of certain long-acting monoclonal antibodies to help prevent COVID-19 in high-risk immunocompromised patients.

For severe COVID-19 inflammatory syndromes such as the acute respiratory distress syndrome (ARDS), monoclonal antibodies are also used to decrease inflammatory proteins called cytokines. This may help patients recover better from severe illness. Examples include tocilizumab which binds to the receptor of a cytokine called interleukin-6.

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R_x Action Steps

- ✓ Consider getting tested for COVID-19 if you develop symptoms during the pandemic (such as, cough, fever, shortness of breath, loss of smell)⁶
- ✓ Contact your doctor if you are tested positive for COVID-19 to see if you may qualify to get monoclonal antibodies to prevent severe illness.
- ✓ Talk with your healthcare provider about the risks and benefits of monoclonal antibody treatment if you have one of the diseases listed in Table 1.

Healthcare Provider’s Contact Number:

For More Information

American Thoracic Society

- www.thoracic.org/patients/

Centers for Disease Control and Prevention

- <https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/how-to-wear-cloth-face-coverings.html>

References

1. Garraud O. Use of convalescent plasma in Ebola virus infection. *Transfus Apher Sci* 2017;56:31-4.
2. FDA Monoclonal Antibody Approvals <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-monoclonal-antibody-treatment-covid-19>
3. Chen P, Nirula A, Heller B, et al. SARS-CoV-2 Neutralizing Antibody LY-CoV555 in Outpatients with Covid-19. *N Engl J Med*. Published online October 28, 2020.
4. Emergency Use Authorization <https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained>
5. <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-monoclonal-antibodies-treatment-covid-19-0>
6. <https://www.thoracic.org/patients/patient-resources/resources/covid-19-how-do-we-stay-safe.pdf>

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