

Spotlight on Health

Biologic and Biosimilar Drugs: Laboratory Testing Is Essential Prior to Treating Autoimmune Diseases

Biologics and biosimilars are drugs. They are especially useful for treating autoimmune diseases. In these diseases, your own body mistakenly attacks itself instead of germs. Biologics help by stopping this attack from happening in different parts of the body. For example, they can help treat diseases that attack the joints, skin, and bowel. But biologics can cause some germs (bacteria and viruses) to become more active. So it is important for your healthcare provider to find out if you have these infections before starting treatment.

This newsletter will discuss biologics and the importance of testing for infections before beginning treatment.

What Are Biologics and Biosimilars?

Most drugs are simple chemicals. Examples of simple drugs include aspirin for pain and penicillin for infections. Biologic drugs are complex. They are based on substances produced in the body.¹ For example, your body produces substances called antibodies to fight infection. Many biologics are man-made antibodies that block how a disease works.² Biosimilars work the same way as biologics. They are identical or almost identical to the biologic, but are made by a different company.³

Common Autoimmune Diseases Treated With Biologics or Biosimilars

An estimated 23.5 million people in the United States have an autoimmune disease.⁴ Rheumatoid arthritis is one of the more common autoimmune diseases. In this disease, the immune system mistakenly attacks the joints. In plaque psoriasis, the body attacks the skin, and in inflammatory bowel disease, it attacks the bowel. An example of a biologic is Remicade® (infliximab). This drug and its biosimilars (Inflectra™ and Renflexis™) are used to treat autoimmune diseases in many people.^{2,5}

Why Is Laboratory Testing Important Before Taking a Biologic?

When the immune system is working normally, some infections can be dormant. This means the infection is present, but there are no symptoms. Three very serious infections that can be dormant are hepatitis C, hepatitis B, and tuberculosis (TB).⁶⁻⁸

Hepatitis C and hepatitis B are viruses that infect the liver. They are both very serious. Both can damage the liver so much that a person may need a liver transplant. TB is a serious lung infection caused by a type of bacteria. A person can have any of these infections and not know it because they do not have any symptoms (see Sidebar on this page).

Biologics and biosimilars can weaken the immune system, and let these dormant infections become active. Symptoms can quickly develop, and patients become very sick. So, before starting a patient on these drugs, healthcare providers often will test for hepatitis and TB.^{5,9}



Hepatitis C and B and TB Are Major Health Concerns

In the United States

- About 4 million people have a hepatitis C virus infection. Half do not know they are infected.⁶
- Around 2 million people have a chronic hepatitis B infection. Most do not know they are infected.⁷
- Between 3 and 5 out of 100 people have a dormant TB infection. Of these people, between 5 and 10 out of 100 will develop an active TB infection if the dormant infection is not treated.⁸

Your doctor may know of other serious diseases in your area that should also be considered for testing.

How Your Healthcare Provider Can Help

Your healthcare provider can find out if you have an autoimmune disease. If you do have an autoimmune disease, your doctor may discuss biologic treatments with you. Your doctor can also order tests to see if you have hepatitis or TB. They can also order different tests, to find out if your body is healthy enough to be treated with a biologic. Talk to your doctor about these treatments and tests to decide if they are the right choice for you.

How the Laboratory Can Help

Quest Diagnostics offers a combination of tests done with one blood draw (called a test panel) to see if you have a hepatitis C or B infection, or TB. Other testing can also help your healthcare provider decide if a biologic is a good choice for you.

Additional Information

For more information, visit the Quest at PrebiologicPanels.com, the American Pharmacists Association website, Pharmacist.com/biosimilar-basics-patients, or these helpful websites:

- WebMD: WebMD.com/rheumatoid-arthritis/biologics#1
- From Hope to Cures: FromHopeToCures.org/fighting-disease-with-biologics
- Arthritis Foundation: Arthritis.org/living-with-arthritis/treatments/medication/drug-types/biologics/risks-benefits.php
- American Autoimmune Related Diseases Association: AARDA.org/
- Centers for Disease Control and Prevention. Tuberculosis: CDC.gov/tb/default.htm

References

1. Biologics (biologic drug class). MedicineNet website. https://www.medicinenet.com/biologics_biologic_drug_class/article.htm#what_are_the_medical_uses_for_biologics? Accessed May 8, 2019.
2. Monoclonal antibodies. MedicineNet website. https://www.medicinenet.com/monoclonal_antibodies/article.htm#what_are_human_monoclonal_antibodies? Accessed May 8, 2019.
3. McCamish M, Yoon W, McKay J. Biosimilars: biologics that meet patients' needs and healthcare economics. *Am J Manag Care*. 2016;22(suppl 13):S439-S442.
4. Rose R, Mackay R, eds. *The Autoimmune Diseases*. 5th ed. Cambridge, MA: Academic Press; 2014.
5. Singh JA, Furst DE, Bharat A, et al. 2012 update of the 2008 American College of Rheumatology recommendations for the use of disease-modifying antirheumatic drugs and biologic agents in the treatment of rheumatoid arthritis. *Arthritis Care Res (Hoboken)*. 2012;64:625-639.
6. HCV epidemiology in the United States. Hepatitis C Online website. <https://www.hepatitis.cuw.edu/go/screening-diagnosis/epidemiology-us/core-concept/all>. Updated February 26, 2019. Accessed May 8, 2019.
7. Surveillance for viral hepatitis – United States, 2016. Centers for Disease Control and Prevention website. <https://www.cdc.gov/hepatitis/statistics/2016surveillance/index.htm>. Accessed May 8, 2019.
8. Talwar A, Tsang CA, Price SF, et al. Tuberculosis — United States, 2018. *MMWR Morb Mortal Wkly Rep*. 2019; 68:257-262.
9. Lichtenstein GR, Loftus EV, Isaacs KL, et al. ACG Clinical Guideline: management of Crohn's disease in adults. *Am J Gastroenterol*. 2018;113:481-517.

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