

Spotlight on Health

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

Biopharmaceuticals, also known as biological medical products or simply biologics, have revolutionized medicine over the past 2 decades. Most biologics are large, complex molecules or mixtures of molecules. Examples include Lantus® (insulin glargine) for diabetes, Herceptin® (trastuzumab) for HER2+ breast cancer, and Trogarzo™ (ibalizumab) for HIV. Recently, biologics have become widely used for autoimmune disease.

Approximately 23.5 million people in the United States are estimated to have an autoimmune disease.¹ Some of the more common autoimmune diseases that are now treated with biologics are plaque psoriasis, inflammatory bowel disease, and rheumatoid arthritis.²⁻⁴ Because biologics alter the immune system, they can cause latent infections to become active.⁴ Thus, laboratory testing for these infections is important before starting therapy.

This newsletter will discuss biologics and biosimilars used for autoimmune diseases and the importance of identifying infections by laboratory testing prior to treatment.

Biologics and Biosimilars for Autoimmune Diseases

A biologic is a drug that contains components of a living organism or is manufactured in a living system, such as microorganisms, plant cells, or animal cells.⁵ Many biologics are produced using recombinant DNA technology. For example, etanercept is a fusion protein widely used for autoimmune diseases; others are monoclonal antibodies, including adalimumab, ustekinumab, and infliximab.²⁻⁴

A biosimilar is a biologic medical product that is an almost identical copy of an original product.⁵ Biosimilars are manufactured by a different company when the patent on the original biologic expires, and are commonly known as a “follow-on biologics.” A biosimilar is used in the same way as a biologic to treat a medical condition.⁵ Examples include Inflectra™ and Renflexis™, which are biosimilars of Remicade® (infliximab).

Why Is Laboratory Testing So Important Before Starting Therapy With a Biologic or Biosimilar?

Because biologics and biosimilars alter the function of the immune system, laboratory testing for certain infections is essential prior to treatment.

Three infections that remain a serious problem in the United States are HBV, HCV, and TB (see Sidebar on this page). Many individuals with active hepatitis infections do not know they are infected, and all 3 can remain latent and pose a serious problem of reactivation if an individual is treated with a biologic. American College of Rheumatology guidelines recommend testing for HBV, HCV, and TB before



HCV, HBV, and TB Are Still Major Health Concerns in the United States

- Approximately 4 million people in the United States are HCV antibody positive, and half of persons infected with HCV do not know they are infected.⁶
- Up to 2 million people in the United States have chronic HBV infection, and most do not know they are infected.⁷
- Between 3% and 5% of people in the United States have latent TB infection; without treatment, 5% to 10% will develop active TB disease.⁸

beginning a patient with rheumatoid arthritis on a biologic.² For patients with Crohn's disease, American College of Gastroenterology guidelines recommend testing for HBV and TB before beginning a biologic.⁹

Additional testing may need to be considered. The treating healthcare professional should refer to the biologic manufacturer's approved labeling for prescribing, warning, side effects, and other important information.

How the Laboratory Can Help

The Quest Diagnostics Pre-biologic/biosimilar HCV, HBV and TB, Screen Panel with Reflexes tests (test codes 37616 and 37620) provide screening for HCV, HBV, and latent TB. This testing is recommended before beginning a biologic or biosimilar to treat an autoimmune disease.² The panel includes

- Hepatitis C Antibody with Reflex to HCV RNA, PCR w/Reflex to Genotype, LiPA® (test code 94345)
- Hepatitis B Surface Antigen with Reflex Confirmation (test code 498)
- Hepatitis B Surface Antibody Immunity, Quantitative (test code 8475)
- Hepatitis B Core Antibody, Total, with Reflex to IgM (test code 37676)
- QuantiFERON-TB® Gold Plus-1 tube (test code 36970)

Panel components can be ordered separately.

For more information visit Quest at PrebiologicPanels.com.

Quest also offers testing for other infectious diseases such as HIV, herpes, chickenpox, and fungal infections, and biochemical testing (eg, tests of liver and kidney function), which are also important before beginning a patient on a biologic or biosimilar.

References

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