

Lupus

THE PROTOTYPICAL AUTOIMMUNE DISEASE

Fact Sheet

What is lupus?

Systemic lupus erythematosus (SLE), commonly referred to as lupus, is a debilitating autoimmune disease that affects each person differently and can change over time. This complexity makes it one of the hardest diseases to diagnose and treat.ⁱ

What goes wrong with the immune system?

In lupus, the immune system mistakenly attacks the body's own tissues and vital organs.

What are the signs and symptoms?

The most common symptoms include extreme fatigue, severe joint and muscle pain, fevers and skin rashes. These symptoms can come and go.ⁱⁱ



How common is lupus?

According to the U.S. Centers for Disease Control and Prevention, a conservative estimate suggests 322,000 Americans have definite or probable SLE.ⁱ 90% of people diagnosed with lupus are women, typically during childbearing years, ages 15-44. Lupus is two to three times more common and its symptoms tend to be more severe among Blacks/African Americans, Hispanics/Latinos, Native Americans and Asians than Caucasians.ⁱⁱⁱ



How is lupus diagnosed?

There is no single laboratory test that can definitively identify lupus. Yet, early detection and treatment can often lessen the progression and severity of the disease.^{iv}

What are the complications of lupus?

Complications can be severe, leading to organ damage and even death.^v Among young Black and Hispanic women ages 15-34, lupus is the 5th and 6th leading cause of death just behind cancer, heart disease and HIV.^{vi} Lupus nephritis (kidney inflammation) is among the most common and serious complications.^{viii}

How is lupus treated?

- There is no cure for lupus; treatment focuses on managing symptoms, stopping flare-ups, lowering disease activity, preventing organ damage and improving quality of life.
- Anti-inflammatory drugs like ibuprofen and acetaminophen help reduce pain and lower a fever.
- Corticosteroids can also reduce pain and swelling due to inflammation. At a higher dose, corticosteroids can help calm down the immune system.
- Antimalarial drugs like hydroxychloroquine may help prevent lupus flares and can treat common symptoms like joint pain, skin rash, tiredness and inflammation in the lungs.
- Immunosuppressive drugs/chemotherapy are used in severe cases to stop the immune system from attacking major organs.^x
- B-lymphocyte stimulator (BlyS) protein inhibitor, a type of biologic medication, can help lower the number of abnormal B cells that create antibodies. Benlysta® (belimumab), one of two medications now approved specifically for lupus treatment, is a BlyS-specific inhibitor. Belimumab was approved in 2011 as a treatment for general systemic lupus erythematosus, and in 2020 as a treatment for lupus nephritis.^x It was also approved for children with SLE in 2019^{xi} and in 2022 for children with lupus nephritis.^{xii}
- Lupkynis™ (voclosporin) is a calcineurin inhibitor used as an immunosuppressant medication. It was approved by the U.S. Food and Drug Administration for the treatment of lupus nephritis in January, 2021.^{xiii}
- In August 2021, the U.S. Food and Drug Administration (FDA) approved anifrolumab-fnia (Saphnelo™), a first-in-class type I interferon receptor antagonist indicated for adults with moderate to severe systemic lupus erythematosus (SLE).^{xiv} The approval represents the first new treatment for generalized SLE in more than a decade and is the result of significant seminal research funded originally by the Lupus Research Alliance.
- Other medications are used to treat symptoms that can develop because of lupus such as high blood pressure or infection.



Why are new treatments needed?

Just three drugs specifically for lupus have been approved by the U.S. Food and Drug Administration in more than 70 years, with over a decade in between. Because lupus is so heterogeneous, affecting each person differently with widely varying symptoms, no one medication can work for everyone. A variety of medications that target different mechanisms involved in causing the disease as well as options with fewer and less severe side effects are critically needed.

Today's research progress

Continued, accelerated research spanning the full continuum from fundamental lab work to clinical trials testing potential drugs is the only way to discover better ways to diagnose, prevent, control and ultimately cure this devastating disease.

The Lupus Research Alliance (LRA), the world's largest and most influential private funder of innovative research, has invested over \$259 million in more than 560 research grants and lupus research programs. Projects funded by the LRA investigate what causes lupus; why its prevalence is affected by race, genetics and gender; and how to manage the damage lupus causes to major organs. The LRA has helped identify and validate 15+ disease pathways in lupus that are currently targeted by many therapeutic approaches.

The goal is to develop ways to treat every person with the right medication that targets how lupus affects them.

With hundreds of clinical trials in progress and many potential treatments in late stages of testing, the outlook for lupus treatment has never been better. To further accelerate the drug development process, the LRA founded Lupus Therapeutics. This clinical affiliate of the LRA established and oversees the Lupus Clinical Investigators Network of over 50 academic medical centers throughout North America to conduct lupus clinical trials. The LRA and Lupus Therapeutics will not stop working with the lupus community until treatment can be personalized to every person and a cure is discovered.

- i Helmick CG, Felson DT, Lawrence RC, et al. Estimates of the prevalence of arthritis and other rheumatic conditions in the United States: Part I. *Arthritis Rheum.* 2008;58(1):15–25. PubMed PMID: 18163481. doi: 10.1002/art.23177. abstract
- ii Systemic Lupus Erythematosus. <https://www.cdc.gov/lupus/facts/detailed.html#sle>
- iii Yen EY, Singh RS. Lupus – An Unrecognized Leading Cause of Death in Young Females: A Population-Based Study Using Nationwide Death Certificates, 2000–2015. (*ARTHRITIS & RHEUMATOLOGY*, Vol. 70, No. 8, August 2018, pp 1251–1255) abstract
- iv Diagnosing and Treating Lupus. CDC. <https://www.cdc.gov/lupus/basics/diagnosing.htm>
- v Hospital for Special Surgery. Top 10 Series: Lupus and Organ Damage. https://www.hss.edu/conditions_top-ten-lupus-and-organ-damage.asp
- vi Centers for Disease Control and Prevention. Systemic Lupus Erythematosus (SLE). How serious is SLE? <https://www.cdc.gov/lupus/facts/detailed.html#serious>.
- vii Yen EY, Singh RS. Lupus – An Unrecognized Leading Cause of Death in Young Females: A Population-Based Study Using Nationwide Death Certificates, 2000–2015. (*ARTHRITIS & RHEUMATOLOGY*, Vol. 70, No. 8, August 2018, pp 1251–1255) abstract.
- viii Lupus and Kidney Disease (Lupus Nephritis). <https://www.niddk.nih.gov/health-information/kidney-disease/lupusnephritis#:~:text=Lupus%20is%20an%20autoimmune%20disease,transplant%20to%20maintain%20your%20health>.
- ix Diagnosing and Treating Lupus. Office on Women’s Health, U.S. Health and Human Services.
- x FDA approves GSK’s BENLYSTA as the first medicine for adult patients with active lupus nephritis in the US. GSK Press Release Dec. 17, 2020
- XI – FDA approves first treatment for pediatric patients with lupus April 16, 2019.
- XII – Benlysta is now the first and only biologic approved for adults and children who have lupus or lupus nephritis. July 22, 2022.
- Xii - FDA Approves Aurinia Pharmaceuticals’ LUPKYNIS™ (voclosporin) for Adult Patients with Active Lupus Nephritis. January 21, 2021.
- xiv - Saphnelo (anifrolumab) approved in the US for moderate to severe systemic lupus erythematosus. August 2, 2021.