Help Us Solve
The Cruel Mystery

LUPUS®

FOUNDATION OF AMERICA

FACTS ABOUT LUPUS:

Lupus is one of the cruelest, most mysterious diseases — an unpredictable and misunderstood autoimmune disease that ravages different parts of the body, causing the immune system to attack healthy tissue instead of fighting infections. It is difficult to diagnose, hard to live with, a challenge to treat and can be fatal.

COMMON SYMPTOMS OF LUPUS:

- Extreme fatigue
- Cognitive issues
- Painful or swollen joints
- Fever
- Anemia
- Butterfly-shaped rash on the face or other disfiguring rashes
- Photosensitivity
- Hair loss
- Abnormal blood clotting
- Mouth or nose ulcers
- Chest pain when breathing deeply
- Fingers turning white and/or blue when cold

What you need to know about lupus?

- Lupus symptoms can be severe, highly unpredictable, cause debilitating pain to many parts of the body, and can damage any organ or tissue, from the skin or joints to the kidneys, heart or lungs.
- There is no single test to diagnose lupus. On average, it takes nearly six years for people with lupus to be diagnosed, from the time they first notice their lupus symptoms.
- Lupus strikes without warning, affects each person differently, and has no known causes or cure.
- While lupus can be disabling and potentially fatal, in many cases its health effects can be managed through aggressive medical treatment and lifestyle changes.
- There are only three therapies developed specifically to treat lupus that are approved by the U.S. Food and Drug Administration.
- While lupus is a widespread disease, awareness of the disease lags behind many other illnesses. 63% of Americans surveyed have never heard of lupus or know little or nothing about this disease and its symptoms beyond the name.
- Despite the widespread prevalence of lupus, research on the disease has remained underfunded, relative to its scope and devastation.

Who has lupus?

- An estimated 1.5 million Americans have lupus.
- Ninety percent (90%) of the people living with lupus are women, however, men, children and teenagers develop lupus, too.
- Lupus can strike anyone at any time, but usually develops between ages 15 and 44, and lasts a lifetime.
- Lupus is two to three times more prevalent among African American, Hispanic/Latina, Asian American, Native American, Alaska Native, Native Hawaiian and other Pacific Islander women than among White women.

Lupus takes a significant toll, the burden on daily life can be devastating.

- **Lupus is ranked the fifth cause of death among Black and Hispanic women, ages 15-24,** and a leading cause of death among all young women.
- **55%** of people with lupus say they can no longer work full-time due to lupus complications.
- **76%** of lupus patients say fatigue caused by lupus has forced them to cut back on social activities.
- The average annual total costs for people with lupus (combining direct and indirect costs) can be as high as **$50,000**.
- People with lupus take on average nearly **eight prescription medications** to manage all their medical conditions caused by the disease.

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ABOUT THE LUPUS FOUNDATION OF AMERICA:

The Lupus Foundation of America is the largest national organization devoted to improving the quality of life for all people affected by lupus through programs of research, education, support and advocacy.

WE ARE FOCUSED ON THREE STRATEGIC OUTCOMES:

Reducing Time to Diagnosis

Ensuring People with Lupus Have an Arsenal of Safe and Effective Treatments

Expanding Direct Services and Increasing Access to Treatments and Care

Our vision is a life free of lupus and what we strive toward each and every day. We know we won't achieve it alone—that's why we need more people like you to get involved so together we can make the greatest impact in the fight against lupus.

VISIT LUPUS.ORG TO LEARN MORE ABOUT LUPUS AND HOW YOU CAN GET INVOLVED.

Lupus Foundation of America, Inc.
2121 K Street NW, Suite 200
Washington, DC 20037
email: info@lupus.org

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LUPUSORG

PROVIDING SUPPORT, RESOURCES AND RAISING AWARENESS

Living with lupus can be challenging and life-changing, but it does not have to be faced alone. We at the Lupus Foundation of America are here to listen, to provide caring support and answers through hundreds of trustworthy resources and tailored support services that cover every aspect of lupus. Our health education specialists and national network of regional offices, chapters and volunteers guide individuals and families through the complexities of lupus and host a range of support groups and education programs. And we work tirelessly to raise global awareness and increase the understanding of lupus and its impact among local communities and health care providers, helping reduce the time to diagnosis. **Learn more at: Lupus.org**

ATTACKING LUPUS FROM EVERY DIRECTION

We are tackling lupus from every direction. Through our research efforts we have funded more than 400 studies and 250 fellowships working to identify the causes of lupus, discover better ways to control symptoms, find pathways to new treatments and ultimately a cure. We not only drive research to deliver the most significant impact on peoples' lives in the shortest time possible, we work to address the root problems that interfere with scientific progress and set a course to solve them. We are also committed to addressing the factors that contribute to healthcare and health outcome disparities in populations living with the highest burden of lupus. Find out more about our research program at **Lupus.org/Research**

ADVOCATING FOR PEOPLE WITH LUPUS

Every day we fight to ensure the government is responsive to the needs of people with lupus. We work with elected officials in the House and Senate to support policies to improve the lives of people with lupus and ensure equitable access to care. We also work with federal agencies like the Food and Drug Administration to overcome regulatory hurdles and incorporate patient perspectives into the drug development and approval process, and with state health programs to provide compassionate care to the people who need it most. Our advocacy team is backed by tens of thousands of lupus advocates across the nation. Working with our advocates and congressional allies, we've generated more than $680 million in federal research funding for lupus in the last five years alone. The patient voice is one of the most powerful tools toward helping us continue to drive change. Find out more about becoming an advocate at **Lupus.org/Advocate**

S. 464/H.R. 2163, SAFE STEP ACT OF 2021

Senator Murkowski (R-AK), Senator Hassan (D-NH), Senator Cassidy (R-LA), Senator Rosen (D-NV)
Representative Ruiz (D-CA-36), Representative Wenstrup (R-OH-2), Representative McBath (D-GA-6),
Representative Miller-Meeks (R-IA-2)

Purpose: Improve step therapy protocols and ensure patients are able to safely and efficiently access the best treatment for them.

Background: Step therapy is a tool used by health plans to control spending on patient's medications. While step therapy can be an important tool to contain the costs of prescription drugs, in some circumstances, it has negative impacts on patients, including delayed access to the most effective treatment, severe side effects, and irreversible disease progression. Currently, when a physician prescribes a particular drug treatment for a patient, the patient's insurance company may require them to try different medications and treatments before they can access the drug originally prescribed by their physician. This protocol is known as "step therapy" or "fail first." Step therapy protocols may ignore a patient's unique circumstances and medical history. That means patients may have to use medications that previously failed to address their medical issue, or – due to their unique medical conditions – could have dangerous side effects.

The Safe Step Act of 2021: The Safe Step Act amends the Employee Retirement Income Security Act (ERISA) to require a group health plan provide an exception process for any medication step therapy protocol. The bill:

- **Establishes a clear exemption process:** The Safe Step Act requires insurers implement a clear and transparent process for a patient or physician to request an exception to a step therapy protocol.
- **Outlines 5 exceptions to fail first protocols.** Requires that a group health plan grant an exemption if an application clearly demonstrates any of the following situations:
    1. Patient already tried and failed on the required drug. A patient has already tried the medicine and failed before.
    2. Delayed treatment will cause irreversible consequences. The drug is reasonably expected to be ineffective, and a delay of effective treatment would leave to severe or irreversible consequences.
    3. Required drug will cause harm to the patient. The treatment is contraindicated or has caused/is likely to cause an adverse reaction.
    4. Required drug will prevent a patient from working or fulfilling Activities of Daily Living The treatment has or will prevent a participant from fulfilling their occupational responsibilities at work or performing Activities of Daily Living. Activities of daily living (ADLs) mean basic personal everyday activities such as eating, toileting, grooming, dressing, bathing, and transferring (42 CFR § 441.505).
    5. Patient is stable on their current medication. The patient is already stable on the prescription drug selected by his or her provider, and that drug has been covered by their previous or current insurance plan.
- **Requires a group health plan respond to an exemption request within 72 hours in all circumstances, and 24 hours if the patient's life is at risk.**

S. 464/H.R. 2163, Safe Step Act of 2021
Exception Examples

1. Patient already tried and failed on the required drug. Michael was eight years old when his parents noticed his foot turning in when he walked, prompting a series of doctor's appointments. Following numerous misdiagnoses, Michael was finally diagnosed with Psoriatic Arthritis at the age of 12. The search to find an effective treatment for Michael's disease proved to be a long, frustrating process. In Michael's case, the first two drugs failed, and the "fail first" process he endured took nearly ten months during which he received no treatment. The first drug he tried did nothing to abate his pain; the second caused him to develop lupus-like symptoms, resulting in more appointments and tests. The insurance company then wanted Michael to *try another remedy that was the same type he had already failed twice before covering his physician's recommended medication*. Finally, Michael's doctor was able get coverage approved for the medication he had initially prescribed. Despite the eventual success, this period of over a year without treatment caused Michael's disease to progress rapidly, resulting in Michael developing an additional chronic illness.

2. Delayed treatment will cause severe or irreversible consequences. Jake, from Alaska, was diagnosed with Crohn's disease as a young child. A year later, he experienced a severe flare and the doctors insisted he immediately be put on an anti-TNF biologic. Jake was a primary non-responder to the anti-TNF, which meant that he would not respond to any anti-TNF. His doctors then tried to put him on an alternative biologic, however, his insurance company required him to prove failure on an additional anti-TNF biologic even though it was against the clinical evidence and guidelines. This process delayed Jake's access to appropriate treatment for several weeks. By the time Jake was granted coverage for the new biologic, his disease had progressed so much that the treatment was not as effective as it would have been if prescribed earlier. As a result, Jake lost his colon. Jake turned 13 this year.

3. Required drug will cause harm to the patient. Jenn, from California, was diagnosed with psoriasis and psoriatic arthritis, her doctor prescribed a treatment that would ease her arthritis pain and slow down joint degeneration. Unfortunately, Jenn's doctor-prescribed treatment was denied by the insurance company and required her to take an alternate medication, which would have led to life-threatening side-effects on the patient's liver. After three months of back-and-forth between the provider, patient, and the insurance company, and explaining that the insurance preferred medication would result in a "death sentence" – Jenn was asked to try a third medication which exacerbated her condition. Finally after nearly a year, Jenn was approved for her original doctor-prescribed treatment and began seeing improvements within three weeks.

4. Required drug will prevent a patient from working. Elliot, nicknamed Duffy, from Alaska, is an epilepsy patient and works as a ski instructor and heavy machine operator. The first medication he tried controlled his seizures, however the side-effects made him feel like he was inebriated and dizzy, making it unsafe and even dangerous to perform the tasks necessary for his jobs. Despite his inability to work on the treatment, his insurer would not cover alternative treatments, and he was faced with the option of losing his job or paying out right for a different treatment, which would cost him $700 a month. Duffy opted to pay for the new treatment with no coverage. The new medication controlled his seizures with less side effects so that he could perform his occupational duties.

5. Patient is stable on their current medication. Katie, a psoriatic arthritis patient, has been stable on her treatment for years. Her treatment was covered by her employer's private insurance until, in the middle of the plan year, her insurer sent her a letter stating that her current treatment would no longer be covered until she went through step therapy protocols. Within four weeks, Katie, who had been an active adult, was back in a wheelchair. Her step therapy journey lasted for ten months, leading to 14 surgeries, countless doctors' visits, missed time from work, and ultimately health care costs that far exceeded the price of her treatment.

S. 464/H.R. 2163, Safe Step Act of 2021
Endorsing Organizations

This bill has been endorsed by 207 organizations:

ADAP Advocacy Association
AIM at Melanoma
Aimed Alliance
Alamo Breast Cancer Foundation
Allergy & Asthma Network
Alliance for Balanced Pain Management
Alliance for Patient Access
Alpha-1 Foundation
American Academy of Dermatology Association
American Academy of Neurology
American Association of Clinical Urologists
American Cancer Society Cancer Action Network
American College of Gastroenterology
American College of Rheumatology
American Diabetes Association
American Gastroenterological Association
American Heart Association
American Liver Foundation
American Muslim Senior Society
American Partnership for Eosinophilic Disorders
American Society for Gastrointestinal Endoscopy
American Society of Hematology
American Urological Association
Arizona Peer and Family Coalition
Arizona Prostate Cancer Coalition, Inc.
Arizona Psychiatric Society
Arizona United Rheumatology Alliance
Arkansas State Rheumatology Association
Arthritis Foundation
Association for Clinical Oncology
Association of Black Cardiologists
Association of Community Cancer Centers (ACCC)
Association of Diabetes Care & Education Specialists
Association of Gastrointestinal Motility Disorders (AGMD)
Association of Women in Rheumatology
Asthma and Allergy Foundation of America
Autoimmune Association
Beyond Celiac
Brain Injury Alliance of Nebraska
Cancer Advocacy Group of Louisiana
Cancer Support Community
Caregiver Action Network
Celiac Disease Foundation
Child Neurology Foundation
Chronic Disease Coalition
Clinical Association of California Endocrinologists
Coalition of Hematology Oncology Practices
Coalition of Skin Diseases
Coalition of State Rheumatology Organizations
Coalition of Wisconsin Aging and Health Groups
Color of Crohn's & Chronic Illness
Community Access National Network (CANN)
Community Liver Alliance
Connecting to Cure Crohn's and Colitis
Crazy Creole Mommy Life
Crohn's & Colitis Foundation
CURE Epilepsy
Cure SMA
CURED Nfp
Danny Did Foundation
Depression and Bipolar Support Alliance
Derma Care Access Network
Dia de la Mujer Latina, Inc.
Digestive Disease National Coalition
Dup15q Alliance
Dystonia Advocacy Network
Dystonia Medical Research Foundation
Epilepsy Alliance America
Epilepsy Foundation
Epilepsy Services of New Jersey
Fabry Support & Information Group
Gastroparesis: Fighting for Change
GBS|CIDP Foundation International
Georgia Academy of Family Physicians
Georgia AIDS Coalition
Geriatric Medicine PAs
Gilda's Club South Florida
Gilda's Club South Florida
Global Healthy Living Foundation
Global Liver Institute
GO2 Foundation for Lung Cancer
Gut It Out Foundation
Hawai'i Parkinson Association
HealthyWomen
Heartland Endocrine Roundtable
Hemophilia Federation of America
HIV + Hepatitis Policy Institute
Hope Charities
IBDMoms
ICAN, International Cancer Advocacy Network
Illinois Association for Behavioral Health
Illinois Medical Oncology Society
Indiana Oncology Society
Infusion Access Foundation (IAF)
International Essential Tremor Foundation
International Foundation for Gastrointestinal Disorders (IFFGD)
International Myeloma Foundation
International Pain Foundation
International Topical Steroid Awareness Network
Iowa Oncology Society
Kentuckiana Rheumatology Alliance
Large Urology Group Practice Association (LUGPA)
Louisiana Dermatological Society
Louisiana Hemophilia Foundation
Louisiana Psychiatric Medical Association
Louisiana Urological Society

S. 464/H.R. 2163, Safe Step Act of 2021
Endorsing Organizations

Lupus and Allied Diseases Association, Inc.
Lupus Foundation of America
Mental Health America
METAvivor
Methodist Healthcare Ministries of South Texas, Inc.
Metro Maryland Ostomy Association
Mid-Atlantic Society of Endocrinology
Mississippi Arthritis and Rheumatism Society
Montana State Oncology Society
Movement Disorders Policy Coalition
Multiple Sclerosis Association of America
Multiple Sclerosis Foundation
NAMI Minnesota (National Alliance on Mental Illness)
NAMI Nevada
National Alliance on Mental Illness
National Alopecia Areata Foundation
National Ataxia Foundation
National Celiac Association
National Council for Mental Wellbeing
National Eczema Association
National Hemophilia Foundation
National Infusion Center Association (NICA)
National Multiple Sclerosis Society
National Organization for Rare Disorders
National Organization for Tardive Dyskinesia
National Organization of Rheumatology Management
National Pancreas Foundation
National Patient Advocate Foundation
National Psoriasis Foundation
Nebraska Academy of Eye Physicians and Surgeons
Nebraska Chapter - National Hemophilia Foundation
Nebraska Chapter of the American College of Cardiology
Nebraska Dermatology Society
Nebraska Neurological Society
Nebraska Nurse Practitioners
Nebraska Oncology Society
Nebraska Osteopathic Medical Society
Nebraska Pharmacists Association
Nebraska Rheumatology Society
Nevada Chronic Care Collaborative
Nevada Oncology Society
North American Society for Pediatric Gastroenterology, Hepatology and Nutrition
Ohio Association of Rheumatology
Oklahoma Chapter - American College of Physicians
Oklahoma Pharmacists Association
Oklahoma Society of Clinical Oncology
Pacific Northwest Bleeding Disorders
PACO Foundation
Parkinson's Foundation
Partnership to Advance Cardiovascular Health
Patient Services, Inc.
Patients Rising Now
Pennsylvania Society of Gastroenterology
Pennsylvania Society of Oncology & Hematology
Phaware Global Association
Pontchartrain Cancer Center
Project Sleep
Prostate Conditions Education Council
Pulmonary Hypertension Association
Rheumatology Alliance of Louisiana
Rheumatology Asoociation of Minnesota and the Dakotas
Rheumatology Association of Iowa
Rheumatology Nurses Society
Rheumatology Society of New Mexico
Scleroderma Foundation
Society for the Study of Male Reproduction
Society of Dermatology Physician Assistants
Society of Gastroenterology Nurses and Associates, Inc.
South Carolina Advocates For Epilepsy
Spondylitis Association of America
State of Texas Association of Rheumatologists
Susan G. Komen
Tennessee Rheumatology Society
Texas Endocrinology Association
The American Liver Foundation
The American Society for Parenteral and Enteral Nutrition
The American Society for Transplantation and Cellular Therapy
The Arc of Nebraska
The Arizona Clinical Oncology Society (TACOS)
The Leukemia & Lymphoma Society
The Life Raft Group
The Mended Hearts, Inc
The Michael J. Fox Foundation for Parkinson's Research
The Sturge-Weber Foundation
Tourette Association of America
Transplant Recipients International Organization (TRIO)
Transplant Support Organization (TSO)
TSC Alliance
U.S. Hereditary Angioedema Association
U.S. Pain Foundation
United for Charitable Assistance
United Ostomy Associations of America
Us TOO International
VHL Alliance
Virginia Association of Hematology & Oncology
Vivent Health
Western Endocrine Association
Wisconsin Association of Hematology & Oncology
Wound Ostomy Continence Nursing Certifiction Board
Wyoming State Oncology Society
ZERO - The End of Prostate Cancer

The HELP Copays Act Eliminates Harmful Health Plan Pricing Schemes and Protects Vulnerable Patients from Soaring Out-of-Pocket Costs

The sickest and most vulnerable patients—those who live with serious, complex chronic illness—are being targeted by health plan programs that undermine the benefits of copay assistance for medicines. The bipartisan Help Ensure Lower Patient (HELP) Copays Act eliminates barriers to treatment for patients ensuring that they can afford the necessary and life-saving medications prescribed by their doctors. The legislation requires health plans to count the value of copay assistance toward patient cost-sharing requirements. This would bring much-needed relief to vulnerable patients by ensuring that all payments—whether they come directly out of a patient's pocket or with the help of copay assistance—counts towards their out-of-pocket costs.

BACKGROUND

Patients are being asked to pay more. People living with serious, chronic health conditions often face multiple barriers to the therapies they need to treat their conditions, such as administrative hurdles like prior authorization and step therapy that limit access to specialty medications. And once approved, patients face skyrocketing deductibles and steep cost-sharing. With no other options to afford the medicine they need, many patients turn to charitable or manufacturer copay assistance to afford their drugs.

Copay accumulator adjustment programs (CAAPs) cut a critical lifeline for patients and leave them exposed. Under CAAPs, insurers have disallowed copay assistance from counting towards a patient's annual deductible or out-of-pocket maximum. As a result, many are faced with unexpected costs of thousands of dollars to get the medicines they need.

- The overwhelming share of medicines that are subject to programs like these (95%, according to the National Hemophilia Foundation analysis of the SaveOn SP Formulary) have no generic or biosimilar equivalents, leaving patients without a less expensive alternative.
- These programs disproportionately impact the most vulnerable patients who rely on certain medicines. A recent survey found that 69% of those who depend on such assistance make less than $40,000 a year, leaving them at risk of losing access to necessary health care.

The EHB loophole allows big companies to avoid paying for critical care for patients who most need help. A loophole under the Affordable Care Act (ACA) allows many employer health plans to deem certain categories of prescription drugs as "non-essential," even when they are life-saving or necessary for people with serious pre-existing and chronic conditions. When a covered drug is deemed "non-essential," the insurer will not count any cost-sharing toward the patient's deductible and out-of-pocket maximum. This loophole also allows employers to simply not cover drugs that treat expensive health conditions. By falling into the EHB loophole, patients in these plans often must pay hundreds or thousands of dollars in out-of-pocket costs for life-saving medicines and never hit their out-of-pocket maximum.

Together, these practices undermine coverage for pre-existing conditions, hurt patient access to medicines, decrease drug adherence, and likely cost our health care system even more money.

ABOUT The HELP Copays Act

The HELP Copays Act is a two-part solution that

- Clarifies the ACA definition of cost sharing to ensure payments made "by or on behalf of" patients count towards their deductible and/or out-of-pocket maximum.
- Closes the EHB loophole to ensure that any item or service covered by a health plan is considered part of their EHB package and thus cost sharing for these must be counted towards patients' annual cost sharing limits.

Congressional action is needed to protect patients. The bipartisan **HELP Copays Act** can help end these harmful pricing schemes and bring much-needed cost savings to vulnerable patients.

ALL COPAYS COUNT COALITION

March 15, 2022

The Honorable Nancy Pelosi
Speaker
United States House of Representatives
Washington, DC 20515

The Honorable Charles Schumer
Majority Leader
United States Senate
Washington, DC 20510

The Honorable Kevin McCarthy
Minority Leader
United States House of Representatives
Washington, DC 20515

The Honorable Mitch McConnell
Minority Leader
United States Senate
Washington, DC 20510

Dear Speaker Pelosi, Majority Leader Schumer, Minority Leader McCarthy and Minority Leader McConnell:

The undersigned patient advocacy organizations urge you to take action to address the high out-of-pocket costs in the Medicare Part D program, a significant barrier for seniors and individuals with a disability who cannot afford their prescription medications. Capping the unlimited financial liability for those enrolled in Medicare Part D has strong bipartisan support in Congress and among the public.

Beneficiaries with Medicare Part D program have seen significant increases in their out-of-pocket costs over the last decade. Between 2010 and 2019, the number of beneficiaries who had a single prescription associated with out-of-pocket costs high enough to reach the Part D benefit's "catastrophic phase"

soared from 33,000 to 483,000.[1] Although extensive research demonstrates the favorable impact of Medicare Part D on access to prescription medications, a combination of factors--increased drug list prices, the Part D benefit design, plan placement of certain drugs on specialty tiers subject to coinsurance, and negotiated discounts that are not accompanied by beneficiary rebates--have created insurmountable barriers for millions of Medicare beneficiaries trying to access needed treatments.

Without Congressional action, older adults and individuals with a disability will continue to face higher costs each year. The number of Medicare beneficiaries facing high out-of-pocket (OOP) costs for prescription drugs is increasing. 2019 saw the largest ever increase (33%) in the number of beneficiaries without the Low-Income Subsidy reaching the catastrophic phase. As a result, the number of beneficiaries reaching the catastrophic phase grew to 4.3 million beneficiaries.[2] This increase in the number of beneficiaries facing catastrophic costs has occurred even though the OOP spend required to reach the catastrophic phase grew substantially over the last decade ($4,700 in 2012 versus $7,050 in 2022).[3,4]

Millions of Medicare beneficiaries cannot afford their medication due to high cost-sharing requirements, and millions more will not be able to afford their medicines in the future unless Congress acts now to modernize the Part D benefit design. We respectfully request adoption of the following recommendations to help the sickest and most vulnerable Part D patients better afford their prescribed medications.

Cap out-of-pocket costs for prescription medications by instituting an annual limit for Medicare beneficiaries. Medicare beneficiaries are the only group of insured people in the U.S. not protected by a cap on annual out-of-pocket costs, forcing many to make difficult trade-offs or to forgo treatment altogether. Patients report affordability concerns when monthly OOP costs exceed $200,[5] which extrapolates to $2,400 annually. Therefore, we encourage Congress to set an annual OOP cap of $2,000 or lower to provide meaningful relief for beneficiaries.

Allow all Medicare beneficiaries to spread Part D out-of-pocket costs more evenly throughout the benefit year without an arbitrary threshold to qualify. The structure of Medicare Part D prescription drug plans front loads OOP medication costs early in the benefit year. Many patients cannot afford large out-of-pocket expenses all at once but could afford the total expenditure if spread out over time. Modifying the structure of Medicare plans so that OOP costs for prescription medications are spread more evenly over the course of the year – in combination with an OOP cap – will improve access and help patients remain on the treatments they need.

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[1] Medicare Payment Advisory Commission. Report to the Congress. March 2021. Available at: https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/mar21_medpac_report_to_the_congress_sec.pdf.

[2] Ibid.

[3] Kaiser Family Foundation. *The Medicare Part D Prescription Drug Benefit*. Oct 2017. https://files.kff.org/attachment/Fact-Sheet-The-Medicare-Part-D-Prescription-Drug-Benefit

[4] Centers for Medicare and Medicaid Services. *Announcement of Calendar Year (CY) 2022 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies. Table V-2.* 15 Jan 2021. https://www.cms.gov/files/document/2022-announcement.pdf

[5] PAN Foundation. Snapshot of 2020 Healthcare Costs. Accessed 20 Aug 2021. Jan 2021. https://www.panfoundation.org/app/uploads/2021/01/PAN-Foundation_MC_January-2021-Survey.pdf

The ability to smooth OOP expenses should be available to all beneficiaries at any time during the benefit year, regardless of a beneficiary's level of OOP spending. Further, Congress should instruct CMS to create baseline patient eligibility protections, including a payment grace period and hardship exceptions. We also encourage Congress to establish smoothing as the default position rather than requiring Medicare beneficiaries to opt-in or otherwise enroll.

Congress must act now to address the unsustainable OOP burden faced by Medicare Part D beneficiaries. **We call on you to enact these Part D reforms this year.**

We appreciate your leadership in seeking solutions to increase access to and affordability of health care for more Americans. If you would like further information or have questions, please contact Amy Niles, Executive Vice President at aniles@panfoundation.org.

Sincerely,

Alliance for Aging Research
American Cancer Society Cancer Action Network
American Lung Association
Arthritis Foundation
Epilepsy Foundation
Leukemia and Lymphoma Society
Lupus Foundation of America
Multiple Sclerosis Association of America
National Council on Aging
National Health Council
National Organization of Rare Disorders
Parkinson's Foundation
Patient Access Network (PAN) Foundation
The Michael J. Fox Foundation

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FY 2023 BUDGET PRIORITIES

LUPUS AT A GLANCE

An estimated 1.5 million Americans are living with lupus

Lupus annually costs the U.S. $31.4 billion in direct and indirect expenditures

90% of people with lupus are women, but it can impact men and children

Women of color are 2-3 times more likely to develop lupus

On average, it takes 6 years to be diagnosed with lupus

Lupus is an unpredictable and misunderstood autoimmune disease that can ravage any organ in the body, from the skin and joints to the heart and kidneys. It is difficult to diagnose, hard to live with, and a challenge to treat. Common lupus symptoms include extreme fatigue, pain or swelling in the joints, fever, anemia, hair loss, light sensitivity and abnormal blood clotting. Lupus has no known cause and there is currently no cure for the disease. **Lupus is debilitating, destructive, and can be fatal.**

➢ $12 million for the National Lupus Patient Registry at the CDC

Researching the natural history, burden of disease, and treatment of lupus in the U.S.

Fiscal year 2022 funding: $9.5 million

Continued and increased funding for the National Lupus Patient Registry will:

- Raise awareness and accelerate time to diagnosis, leading to improved care and outcomes for people with lupus and a reduction in health disparities;
- Identify how lupus affects those living with it and ways to improve its treatments;
- Examine the impact of lupus on children and teenagers;
- Continue the development of lupus disease management programs for patients.

➢ $15 million for the Lupus Research Program at the Dept. of Defense

Funding high-impact research into the cause and treatment of lupus

Fiscal year 2022 funding: $10 million

Continued and increased funding for the Lupus Research Program will:

- Determine why military personnel are at high risk of developing lupus;
- Further study the links between factors common to military service also known to be lupus triggers like vaccines, chemicals, toxins, and ultraviolet light;
- Fund a higher percentage of the high-quality proposals the Dept. of Defense receives each year – in the program's first four years, only 48 of 402 proposals received funding (less than 12 percent).

➢ $2 million for the National Lupus Training, Outreach and Clinical Trial Education Program at the Office of Minority Health

Promoting lupus awareness and minority participation in lupus clinical trials

Fiscal year 2022 funding: $64.8 million for the Office of Minority Health

Continued and increased funding for the Office of Minority Health will:

- Identify barriers inhibiting minorities from enrolling in lupus clinical trials;
- Enable the Office of Minority Health to implement action plans to increase minority participation in clinical trials and facilitate their enrollment;
- Educate physicians about lupus and decrease the time to diagnosis.

➢ $49 billion for the National Institutes of Health

Providing more funds for lupus research than any other public source

Fiscal year 2022 funding: $45 billion

Continued and increased funding for the National Institutes of Health will:

- Support and bolster basic, clinical, and translational research across the country;
- Improve our understanding of the causes of lupus;
- Accelerate the discovery of genes associated with lupus and aid in the development of safe, effective treatments for the disease.

The Importance of Funding
Lupus Research and Education

Congressional support is critical to improving access to care and the development of new treatments for lupus.

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$12 million for the National Lupus Patient Registry at the Centers for Disease Control and Prevention

Advancing our understanding of who gets lupus and how it affects those living with the disease

It is because of Registry-funded research that we have confirmed that women of color are 2 to 3 times more likely to develop lupus and are beginning to better understand the burden of the disease over the long term.

Reducing the time to diagnosis and raising awareness of the disease among medical professionals and the public

On average, it takes 6 years for a person to receive an accurate lupus diagnosis. Delayed diagnosis leads to increased hospitalizations and costs, both to the patient and the system, and the longer a person is not receiving proper care for lupus, the more likely irreversible damage to the body becomes.

Conducting first-of-its-kind research into the impacts of lupus on children and teenagers

CDC-funded research is learning more about childhood lupus, including a study following more than 1,000 pediatric lupus patients for at least 10 years. The federal government has never before funded this type of research, and is able to do so because of increased congressional support for the program.

Improving the quality of life for people living with lupus

The Registry supports the development of lupus disease management programs that help people with lupus better track and manage their symptoms, leading to improved outcomes and quality of life.

Increased funding for the National Lupus Patient Registry is critical to advancing our understanding of the disease, accelerating the diagnostic process, and improving the quality of life for people with lupus.

$15 million for the Lupus Research Program at the Department of Defense

Advancing our understanding of why our military personnel may be at increased risk of developing lupus

Research has shown that post-traumatic stress disorder doubles the risk of autoimmune disease, including lupus. Other factors common to military service – including vaccines, chemical and toxin exposures, UV light, and infectious agents – have also been associated with the development of lupus. As the prototypical autoimmune disease, lupus is a key to understanding the link between autoimmunity and the military.

Funding high-risk, high-reward research not being conducted by other government agencies

Through their intensive review process and participation in the National Institutes of Health's Lupus Federal Working Group, the Department of Defense ensures that the research they fund does not duplicate the efforts of other government agencies, but rather builds on their efforts to maximize every dollar.

Becoming more relevant and important each year as the military continues to become more diverse

In 2018, women represented 16.5% of all active duty members, an increase of more than 7% since 2015. Of those more than 215,000 active duty women, greater than 56% are of color. As the military becomes more diverse in gender and ethnicity, the number of their personnel affected by lupus will increase.

Leaving the vast majority of high-quality proposals they receive unfunded

In its first 4 years, the Lupus Research Program has only been able to fund 48 of the 402 proposals submitted – less than 12%. More congressional support will leave fewer potential breakthroughs on the shelf.

Congress recognized the connection between lupus and the military by establishing the Lupus Research Program in 2017, and continued support means more high-quality research into every aspect of lupus.

$2 million for the Lupus Program at the Office of Minority Health

Addressing health disparities through clinical research

Evidence suggests that the lack of minority participation in lupus clinical trials exacerbates health disparities by creating confusion among providers about which lupus treatments are appropriate for minority patients. Representative trials will create more data and clarity around a treatment's effects for all people with lupus, potentially expanding coverage.

Identifying barriers to minority enrollment in lupus clinical trials

Despite being disproportionately affected by lupus, minority populations have been historically under-represented in lupus clinical trials. A recent study found that in randomized controlled trials for lupus between 1997 and 2017, African Americans made up only 14% of enrollees despite making up a significantly larger percentage of people with lupus.

Educating and empowering physicians to promote clinical trials to people with lupus

While only 1% of the U.S. population participates in clinical trials, a 2013 study found that 72% believed they would participate in a trial if their doctor recommended it. The Lupus Program at the Office of Minority Health teaches primary care providers about lupus clinical research and how to speak to their patients about the benefits of participating.

Developing innovative ways to reach minority communities with information about lupus clinical trials

Beyond their doctor, there are many people and institutions that play a role in the health of a person with lupus. The Office of Minority Health's Lupus Program is working with national lupus patient and community organizations to develop culturally competent materials and peer-to-peer education programs to facilitate enrollment in lupus trials.

Increased funding for the lupus program at the Office of Minority Health will promote minority enrollment in lupus clinical research from all angles and address existing health disparities in lupus.

$49 billion for the National Institutes of Health

Funding more lupus research than any public source in the world

In the last five years for which we have data, the National Institutes of Health have committed $584 million to lupus research. Their research has advanced our understanding of the causes of lupus and provided valuable insights for researchers both inside and outside of the federal government to build on.

Conducting research into every aspect of lupus

Congressional support for the National Institutes of Health supports their vast portfolio of basic, clinical, and translational research across the country. This research is identifying new potential targets and genes associated with lupus to aid in the development of safe and effective treatments for the disease.

Involving the entire agency to better understand lupus and its effects

At least 16 different Institutes within the National Institutes of Health have funded lupus research recently, demonstrating the devastating and expansive scope of the disease.

Evaluating mesenchymal stem cells as a potential treatment for lupus

The National Institute of Allergy and Infectious Diseases has made a five-year commitment to co-fund a major phase II study into the use of mesenchymal stem cells to treat lupus. The study is currently ongoing and enrolling patients.

Robust funding for the National Institutes of Health is critical to advancing our understanding of the causes of lupus and supports the entire pipeline of lupus research, including drug development.

General lupus talking points

Lupus is a leading cause of death in women

A recent study found that lupus is the 10th leading cause of death for women ages 15–24.

Living with lupus is very expensive

According to a recent study, mean total costs for people with lupus can be as high as $50,000 annually.

Nationally, lupus awareness is extremely low and likely contributes to delays in diagnosis

63% of Americans surveyed have never heard of lupus or know little or nothing about the disease and its symptoms.