National
Alopecia Areata
Foundation

The National Alopecia Areata Foundation continues to encourage community members to engage with their members of the House and Senate to advance key priorities. Similar to last year, we have prepared materials that will aid in all advocacy outreach.

Take action:

- Email your two Senators and your Member of the House of Representatives to share your experience with alopecia areata and to ask them to help us (information on the ask to be provided)

- Call the offices of your two Senators and your Member of the House of Representatives to share your experience with alopecia areata and ask them to help us (information on the ask to be provided)

Making virtual visits

To find and contact your U.S. Senator:

1. Visit the Senate website www.senate.gov

2. Conduct a search using the **Find Your Senators** pull-down menu in the upper right corner (select your state and click Go).

3. On the results page is a link to the Senators' website, contact information, and links to an online contact form (forms vary by Senator).

To find and contact your U.S. Representative:

1. Visit the House of Representatives website www.house.gov

2. Conduct a search using the **Find Your Representative** zip code search box in the upper right corner (enter your zip code and click Go).

3. On the results page is a photo of your Representative(s), links to the Representative's personal website and online contact form, and a local map.

4. In the event your zip code overlaps with multiple congressional districts, the results page will include boxes for you to enter your zip code+4 or mailing address to find the correct Representative.

Legislative Agenda
117th Congress, 2nd Session

About the Foundation

The National Alopecia Areata Foundation (NAAF) supports research to find a cure or acceptable therapy for alopecia areata, supports those with the disease, and educates the public about alopecia areata. NAAF is governed by a volunteer Board of Directors and a prestigious Scientific Advisory Council. Founded in 1981, NAAF is widely regarded as the largest, most influential and most representative foundation associated with alopecia areata. NAAF initiated an Alopecia Areata Treatment Development Program dedicated to advancing research and identifying innovative treatment options.

About Alopecia Areata

Alopecia areata is an autoimmune skin disease resulting in the loss of hair on the scalp and elsewhere on the body. It usually starts with one or more small, round, smooth patches on the head and can progress to total scalp hair loss (alopecia totalis) or complete body hair loss (alopecia universalis). Alopecia areata tends to strike children and 6.9 million Americans have been, are, or will be affected by the condition. This common skin disease is highly unpredictable and cyclical. Hair can grow back in or fall out again at any time, and the disease course is different for each person.

Patient Story

"There is a chance you could lose all your hair." That was the last thing anyone ever wants to hear. I will never forget standing in the shower in November 2015 with my hands full of hair and in complete disbelief. Was this really happening to me? I felt as though my identity was being ripped away from me as every strand of hair fell out of my head. My hair was my identity. Who would I be without it? How was I going to live like this for the rest of my life?

I lost all of my hair on my entire body including eyebrows and eyelashes within four weeks and I was diagnosed with the autoimmune disease called alopecia areata. For the next year, I did everything in my power to grow my hair back from every topical cream to medicines that compromised my immune system to weekly steroid injections into my scalp. This was the worst pain I had ever experienced in my life but I would do anything to grow my hair back.

Nothing was working. I had to stop as my mind, body, and soul couldn't take it anymore.

I don't know what was worse, the treatments or the stares I would receive out in public as everyone thought I was going through treatment for cancer. I wanted to blend in with society so badly, but wigs were so expensive. I refused to look at myself in the mirror because I hated the reflection. I wore a hat everywhere I went even to bed until the lights were turned off to take it off and I wouldn't take any pictures, especially during the holidays because I was ashamed of my appearance. I wanted my life back so I could be a good mom to my daughters and just enjoy life.

Alopecia areata is not just cosmetic, it takes an emotional toll as it caused severe anxiety and depression that I continue to deal with years later. I was very fortunate to have the unconditional support of my parents who helped me to purchase wigs so I could feel somewhat normal again; however, there are too many people with alopecia areata who do not have the luxury of support that I was blessed with. Your support would impact people's lives immensely.

FY2022 Funding Recommendations

Medical Research

- **Please provide the National Institutes of Health (NIH) with $49 billion for Fiscal Year 2023.** The National Institutes of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) at NIH coordinates a modest, but meaningful, alopecia areata research portfolio. Alopecia areata research is tremendously valuable as the skin and disease process are easily studied, and the results of scientific investigation have potential applications for other autoimmune diseases.

Education and Awareness

- **Please provide $6 million for the Chronic Diseases Education and Awareness Program at the Centers for Disease Control and Prevention (CDC).** This program seeks to provide collaborative opportunities for chronic disease communities that lack dedicated funding from ongoing CDC activities. Such a mechanism allows public health experts at the CDC to review project proposals on an annual basis and direct resources to high impact efforts in a flexible fashion.

Patient Access Issues

- **Please cosponsor H.R. 5430 legislation to provide coverage for wigs as durable medical equipment under the Medicare Program.** This legislation makes a simple change to the Social Security Act to ensure that cranial prosthetics are considered durable medical equipment for treatment purposes moving forward. To cosponsor this important legislation please contact Maddie Trice from Congresswoman Pressley's office at 5-5111 or maddie.trice@mail.house.gov. A Senate version is in the process of being re-introduced.

- **Please work to advance the Safe Step Act (S. 464/H.R. 2163).** Step Therapy practices require patients to try and fail one or more treatments before the insurer will cover the treatment originally prescribed. Too often, this leads to delays in proper treatment, worsened health outcomes, and contributes to higher healthcare costs. The Safe Step Act legislation has been reintroduced in Senate as S. 464 and the House as H.R. 2163 and would require insurers to implement a clear and transparent process for a patient or healthcare provider to request an exception to a step therapy protocol and requires group health plans to grant exceptions if certain protocol is met.

- **Please also be aware of NAAF's** support for access legislation intended to amend title XVIII of the Social Security Act to require PDP sponsors of a prescription drug plan under part D of the Medicare program that use a formulary to include certain generic drugs and biosimilar biological products on such formulary, and for other purposes.

RESEARCH!AMERICA
DISCOVERY. INNOVATION. HEALTH.

LASKER FOUNDATION

If you think research is expensive, try disease.

INVESTMENT IN RESEARCH SAVES LIVES AND MONEY

Alopecia Areata

Alopecia areata is an autoimmune skin disease that causes hair loss on the scalp, face, and sometimes other areas of the body. The hair loss tends to be unpredictable: hair may regrow, and it can fall out again—or it may not. This cycle can continue for years.[1,2] In addition to hair loss, those with alopecia areata sometimes have nail changes, but they are usually otherwise in good health. However, hair loss causes changes in a person's appearance that can affect his or her quality of life and self-esteem, potentially leading to depression, anxiety, and other emotional or psychological issues.[3] Currently, no cure or FDA-approved drug treatments for alopecia areata are available.[1,4]

TODAY

6.8 million people in the U.S. have had alopecia areata in their lifetime.[1]

147 million people worldwide are affected by alopecia areata.[1]

People in the U.S. have a **2.1%** lifetime risk of developing alopecia areata.[1]

COST

$1,384*:

Average out-of-pocket costs to treat and live with alopecia areata per year.[4]

*Based on a survey of 675 alopecia areata patients in the U.S.

$50,000:

Annual cost of tofacitinib, an arthritis medication that is also effective for regrowing hair for some patients with alopecia areata.[5,6]

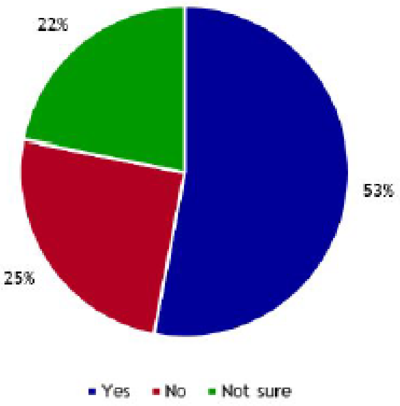
Research Delivers Solutions

Genetic studies have found that cellular molecular pathways involving **Janus kinase (JAK)** enzymes are often disrupted in patients with alopecia areata. Several case series and clinical trials have shown that drugs called JAK inhibitors can successfully reverse the effects of alopecia areata. These results show immense promise for the development of oral JAK inhibitor drugs for future treatment; large clinical trials are ongoing.[7]

Gene expression profiling of tissue samples from patients with alopecia areata has demonstrated that increased activation of key immune pathways may play a role in driving inflammation and the disease process. Treatment with dupilumab, a drug targeting one of these pathways, has led to hair regrowth in patients with alopecia areata who also had eczema. Ongoing and future clinical studies examining narrowly targeted therapeutics may help uncover the role of specific immune pathways in the development of alopecia areata and pave the way for additional clinical approaches to treating patients.[8]

Studies analyzing the microbiome in mice with alopecia areata have found imbalances in gut microbiota described as dysbiosis, suggesting that the gut microbiome may play a role in disease development. Case studies have reported hair regrowth in patients with alopecia areata who have undergone fecal microbiota transplants (FMT). These findings have led to the initiation of a clinical study to assess FMT as a potential treatment for patients with alopecia areata.[9,10]

Would you be willing to pay $1 per week more in taxes if you were certain that all of the money would be spent on additional medical research?



Source: A Research!America poll of U.S. adults conducted in partnership with Zogby Analytics in January 2020

Alopecia Areata

Then. Now. Imagine.

THEN

Before the 1930s, the cause of alopecia areata was unknown and many physicians believed it was a sign of parasites, emotional stress, or a nutritional deficiency in the blood.[9]

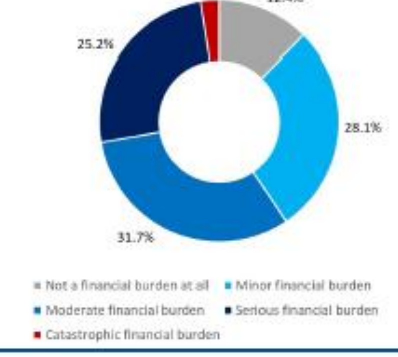
NOW

Scientists know alopecia areata is an autoimmune disease, and genome-wide studies have potentially identified the genes responsible for alopecia areata.[9]

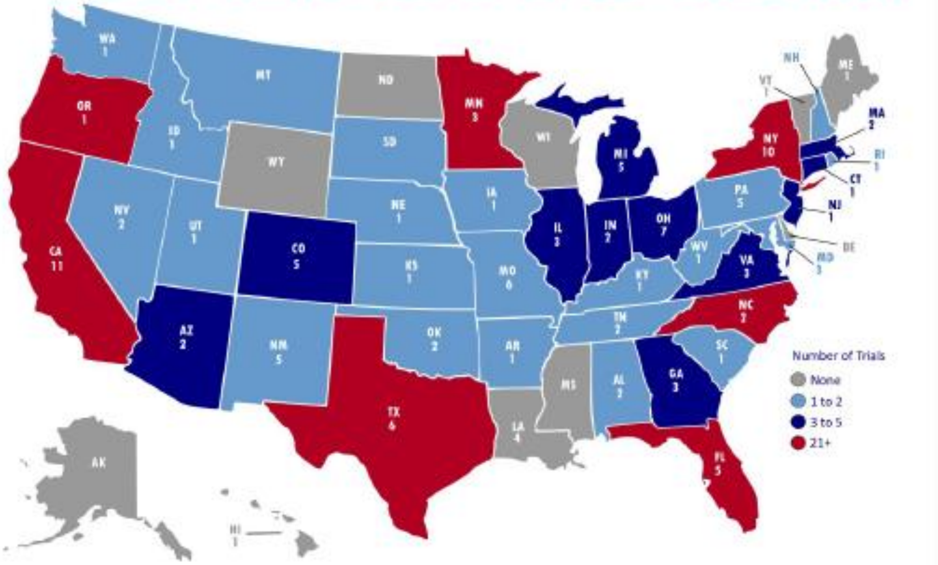
IMAGINE

A cure.

Reported Financial Burden of Alopecia Areata: Survey of 675 Patients[4]



Number of Clinical Trials for Alopecia Areata by State



SOURCE: NIH Clinical Trials. N.d.

1. "What you need to know about alopecia areata." NAAF. N.d.
2. "Alopecia areata: Overview." AAD. N.d.
3. "Alopecia areata." NLM. 2020.
4. Li et al. "Association of out-of-pocket health care costs and financial burden for patients with alopecia areata." JAMA Dermatol. 2019;155(4):493-494.
5. Crispin et al. "Safety and efficacy of the JAK inhibitor tofacitinib citrate in patients with alopecia areata." JCI. 2016;1(15):e89776.
6. "The Price They Pay." NYTimes. 2018.
7. Pratt et al. "Alopecia areata." Nat Rev Dis Primers. 2017;3:17011.
8. Renert-Yuval et al. "The Changing Landscape of Alopecia Areata: The Therapeutic Paradigm". Adv Ther. 2017;34(7):1594–1609.
9. Nair et al. "649 Gut microbiota plays a role in the development of alopecia areata". J Investig Dermatol. 2017;137(5): S112.
10. Rebello et al. "Hair Growth in Two Alopecia Patients after Fecal Microbiota Transplant". ACG Case Rep J. 2017;4:e107.

Research!America 241 18th St S, Arlington, VA 22202 | 703.739.2577
www.researchamerica.org | info@researchamerica.org

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R!A4.20

Issue Brief
Advance Medical Research
(Of particular interest to members of the House and Senate Appropriations Committees)

Background

The National Institutes of Health (NIH) forms the cornerstone of this nation's biotechnology industry. NIH supports basic, translational, and clinical research into various diseases and disorders, including alopecia areata and related autoimmune disorders. This federally funded research often serves as a catalyst with industry turning medical breakthroughs and scientific advancements into innovative therapies and cutting-edge diagnostic tools.

For the past few fiscal years, Congress has provided NIH with notable increases, and these increases (along with good science) have allowed the alopecia areata portfolio to expand and advance. Recently, NIH was supporting only a few alopecia areata grants at less than $1 million annually, but now the portfolio supports many grants, but more needs to be done.

NIH research has been woefully under-funded for years and the recent funding increases have reversed many of the challenges in the research community. These increases need to continue moving forward, and the entire research community is asking Congress to provide NIH with $49 billion for FY 2023.

Important Points

- The National Institutes of Health supports research into alopecia areata and related conditions, primarily through the National Institutes of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) and the National Institute of Allergy and Infectious Disease (NIAID) due to the condition's autoimmune component.
- Our community would like to thank Congress for providing $44.6 billion, NIH in FY 2022, but know that more research activities are needed to continue emerging opportunities to advance our scientific of alopecia areata.
- Our overarching concerns are that without meaningful financial support the development of treatment options will be delayed, and we may lose the next generation of talented young investigators to foreign competition and other fields.

To fully capitalize on innovative research projects investigating alopecia areata and related conditions, please work with your colleagues to provide NIH with at least $49 billion in FY 2023.

Issue Brief
Please support legislation that would re-classify cranial prosthetics as durable medical equipment

Background

Currently, the Social Security Act determines which products are considered "durable medical equipment" for the purposes of Medicare coverage. This definition includes things like crutches and oxygen tanks as well as prosthetics. However, the definition of a "prosthetic" does not specifically include cranial prosthetics, which can lead to coverage challenges. It is important to note that private insurance and other payers often base their coverage policies and standards off of Medicare.

Congresswoman Ayanna Pressley, Congressman James P. McGovern and Congressman Mike Quigley have introduced H.R. 5430 and Senator Richard Blumenthal (D-CT) is preparing to introduce a Senate companion that provides coverage for wigs as durable medical equipment under the Medicare Program. Many patients living with medical hair loss suffer from a variety of diseases, including cancer. With no known cause or cure, alopecia areata is an autoimmune skin disease affecting approximately 6.9 million Americans, many of whom are children.

Important Points

- Many individuals affected by alopecia areata utilize cranial prosthetics as there are currently few other effective treatment options.
- Cranial prosthetics can represent a significant out-of-pocket burden for low- or fixed-income Americans, particularly individuals in Medicare.
- We are working on the reintroduction of bipartisan legislation in the House and Senate to ensure cranial prosthetics are considered durable medical equipment, which would benefit many patient communities affected by a variety of medical conditions that cause hair loss.
- This new benefit is not a give-away, but only becomes available when a physician certifies such a treatment to be medically necessary.
- To cosponsor this important legislation please contact Maddie Trice from Congresswoman Pressley's office at 5-5111 or maddie.trice@mail.house.gov. A Senate version is in the process of being re-introduced.

Issue Brief
Support Increased Prevention and Awareness

Background

Poor professional and public awareness remain serious barriers to early and effective treatment. CDC leads public awareness campaigns on health issues, conducts surveillance and epidemiology studies, and tracks emerging and established public health threats. Last year the CDC's Chronic Disease Education and Awareness Program was created and is currently funded at $3 million. This program seeks to provide collaborative opportunities for chronic disease communities that lack dedicated funding from ongoing CDC activities. Such a mechanism allows public health experts at the CDC to review project proposals on an annual basis and direct resources to high impact efforts in a flexible fashion.

Through its National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), the CDC supports several programs that work to improve chronic disease education and awareness. These programs work to:

- Find out how these diseases affect populations in the United States
- Study interventions to find out what works best to prevent and control these diseases
- Share information to help Americans understand risk factors and how to reduce prevalence

Talking Points

- The CDC's National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) supports several programs that work to increase public awareness and improve professional education.
- It is our hope that additional funding will enable CDC to support more proposals in subsequent years. In the interest of growing the program, supporting timely public health efforts, and ensuring the viability and effectiveness of emerging opportunities, please provide this new program with $6 million for FY 2023.

SAMPLE CALL/EMAIL SCRIPT

Good Morning/Afternoon,

My name is ______ and I live in ______.

I am an advocate with the National Alopecia Areata Foundation (NAAF). NAAF supports research to find a cure or acceptable therapy for alopecia areata, supports those with the disease, and educates the public about alopecia areata. NAAF is widely regarded as the largest, most influential and most representative foundation associated with alopecia areata. NAAF initiated an Alopecia Areata Treatment Development Program dedicated to advancing research and identifying innovative treatment options.

Alopecia areata is an autoimmune skin disease resulting in the loss of hair on the scalp and elsewhere on the body. It usually starts with one or more small, round, smooth patches on the head and can progress to total scalp hair loss (alopecia totalis) or complete body hair loss (alopecia universalis). Alopecia areata tends to strike children and 6.9 million Americans have been, are, or will be affected by the condition. This common skin disease is highly unpredictable and cyclical. Hair can grow back in or fall out again at any time, and the disease course is different for each person.

{Share your alopecia experience. Be concise but let them know how alopecia has affected your life.}

I am calling today to ask for _________ (Name of Senator or Representative)'s help.

Research remains critical to ultimately improving the health of individuals suffering from alopecia. We urge you to support a funding level of $49 billion for NIH in the FY 2023 Labor-HHS-Education Appropriations bill. We also ask that you support $6 million for the CDC Chronic Disease Education and Awareness Program. This program seeks to provide collaborative opportunities for chronic disease communities that lack dedicated funding from ongoing CDC activities. Such a mechanism allows public health experts at the CDC to review project proposals on an annual basis and direct resources to high impact efforts in a flexible fashion.

H.R. 5430 has been introduced to provide coverage for wigs as durable medical equipment under the Medicare Program. This legislation makes a simple change to the Social Security Act to ensure that cranial prosthetics are considered durable medical equipment for treatment purposes moving forward. Many patients living with medical hair loss suffer from a variety of diseases, including cancer. With no known cause or cure, alopecia areata is an autoimmune skin disease affecting approximately 6.9 million Americans, many of whom are children. To cosponsor this important legislation please contact Maddie Trice from Congresswoman Pressley's office at 5-5111 or maddie.trice@mail.house.gov. A Senate version is in the process of being re-introduced.

Please consider me a resource for you and your office about any health related and patient issues.

Sincerely,