Executive Summary
Alopecia Areata: A Disease That Extends Beyond Physical Manifestations

Approximately 700,000 people in the United States (US) are diagnosed or affected by alopecia areata (AA), with just under half of these patients estimated to have complete scalp or total body baldness.1 AA is a serious, recurring autoimmune disease that affects all ages, both sexes, and all skin types.2 Although symptoms range from bald patches to total hair loss, this is not simply a cosmetic issue. The converging physical and mental impact of AA often carries a lifetime burden and has a substantial cost for payers and patients.

Unmet Medical Need—Recognizing This Is an Autoimmune Condition
There are currently no Food and Drug Administration (FDA)-approved treatments available for patients with AA—just several therapies used off-label to manage the condition. With the current lack of formal treatment guidelines, patients are prescribed a variety of therapeutics for AA.3 This makes it difficult for providers to serve patients with AA effectively. As a result, nearly 8 in 10 patients with AA are unsatisfied with the current treatment options.4

The Mental Health Impact of AA
AA is not just the loss of one’s hair, the disease can also have a devastating emotional impact. Patients with AA often experience a variety of mental health issues related to their hair loss, such as anxiety and depression.5 About 70% of patients reported that AA had a marked impact on their self-esteem, an impact that did not abate over time.6 Mortality risk associated with intentional self-harm and psychiatric diseases is shown to be increased in patients with AA compared to individuals without AA.7 Transitioning the view of AA is vital; thinking of AA as simply “hair loss” diminishes the suffering of many with the disease and lessens the importance of providing coverage for treatment. Much of the public continues to incorrectly regard AA as a cosmetic or communicable disease. Many patients with AA experience diminished health-related quality of life, but patients with AA often report feeling that their concerns are dismissed.6

The High Costs of AA for Patients
Beyond the physical and mental health impact of AA, patients with AA face significant out-of-pocket costs. These costs are from cost-sharing associated with medically covered services for AA and comorbid conditions as well as other interventions not covered by insurance. For example, many AA patients reported use of non-medical interventions such as wigs or camouflage (71%) and/or dietary changes or supplements (64%).8 All of this is potentially compounded by work productivity and activity impairment due to AA.9 Mitigating the high out-of-pocket costs faced by patients with AA is key to improving access to treatment.

Coverage Policies Must Ensure Access to FDA-Approved Treatments for AA
AA should not be overlooked as a cosmetic condition. There is an unmet need for an efficacious long-term treatment option. AA is unpredictable, with spontaneous regrowth of sections of hair occurring in 80% of patients within the first year followed by sudden relapse.

Over the next two years, US payers and policymakers need to drive coverage policies for new FDA-approved therapies currently in development to ensure appropriate patient access and affordability when innovation becomes available. Coverage of future FDA-approved treatments will bring patients with AA stability and improved quality of life.

Currently, a group of dermatologic conditions (acne, psoriasis, and rosacea) are specifically listed as non-cosmetic by the Centers for Medicare & Medicaid Services for the purposes of Medicare Part D coverage. As a result, FDA-approved treatments for these conditions are covered by Medicare. With several shared characteristics between AA and these non-cosmetic, Medicare-covered dermatologic conditions, there is no question that future FDA-approved treatments for AA should be covered by payers.
Changing the Path Forward for AA Patients

Innovative FDA-approved treatments for AA should be covered and deemed “medically necessary” by payers.

There are actions payers and policymakers can take to change the trajectory of this condition by improving access to effective treatment, reducing costs, and managing this major life impact:

01 Update the Medicare Part D Drug manual to include any future FDA-approved AA treatments as covered Part D drugs

02 Establish access and reimbursement for FDA-approved treatments for AA as medically necessary once they become available

03 Avoid utilization management tools such as step therapy and prior authorization that restrict patients’ access to preferred FDA-approved treatments

04 Recognize the long-term nature of AA (hair grows minimally every 2 months) and the potential for relapse when developing coverage and access guidelines

05 Ensure that cost-sharing is affordable for patients on a monthly and annual basis

06 Capture the medical and therapeutic advances for AA in physician-developed treatment guidelines

07 Support people with mental illness associated with AA in achieving access to affordable therapy to help manage the psychological impact of AA

08 Identify any health disparities based on race or ethnicity and ensure health equality by delivering personalized care through coverage and access to treatments for AA

09 Involve a diverse range of participants in AA clinical trials

References


Alopecia areata (AA) is a serious recurring autoimmune disease that affects all ages, both sexes, and all skin types. This is not simply a cosmetic issue. AA can also have a devastating physical and emotional impact. The converging physical and mental impact of AA often carries a lifetime burden, and when left untreated or undertreated, has a substantial cost for payers and patients.

A significant unmet need exists to improve treatment strategies and the options available to people with AA. There are currently no Food and Drug Administration (FDA)-approved treatments available for patients with AA—just several therapies used off-label to manage the condition. This makes it difficult for healthcare providers to treat patients with AA effectively.

Nearly 8 in 10 patients with AA report being unsatisfied with the current treatment options. Patients are commonly prescribed off-label treatments with limited effectiveness and often face relapse after treatment. Additionally, despite advanced understanding of the autoimmune nature of the disease and the low quality of life (QoL) for patients, many insurers do not consider treatment for AA to be medically necessary. As a result, patients’ annual and lifetime out-of-pocket costs can be significant.

Expanding policymakers’ and payers’ view of AA is vital; thinking of AA as simply “hair loss” diminishes the suffering of many patients living with this disease and minimizes the importance of providing coverage for treatment. In fact, the FDA recognizes AA as a chronic autoimmune disease with a “debilitating emotional and psychological impact on patients which goes beyond the loss of hair.”

However, there are actions payers and policymakers can take to change the trajectory of this disease by improving access to effective treatment, reducing costs, and managing the major life impact AA has on patients.
This paper will make clear the need to treat AA as a serious autoimmune condition and to appreciate the impact of this disease on patients by highlighting significant data to support payer coverage.

• We begin by describing the characteristics of AA that make it a serious autoimmune disease.
• The paper then discusses the demographics of the AA patient population and reviews the types of AA. Using patients’ own words, the next section explains the mental and physical impact of AA, including out-of-pocket costs and current treatments.
• Finally, the paper concludes by highlighting policy and payer changes that could shift the access paradigm and put patients with AA front and center.

Given the burden of the illness and the FDA’s support for better treatment options, it is imperative that payers recognize and cover any FDA-approved treatment option(s).

Solutions to improve access to effective treatment:

01 Updating the Medicare Part D Drug manual to include any future FDA-approved AA treatments as covered Part D drugs

02 Establishing access and reimbursement for FDA-approved treatments for AA as medically necessary once they become available

03 Avoiding utilization management tools, such as step therapy and prior authorization, which restrict patients’ access to preferred FDA-approved treatments

04 Recognizing the long-term nature of AA (hair grows minimally every 2 months) and the potential for relapse when developing coverage and access guidelines

05 Ensuring that cost-sharing is affordable for patients on a monthly and annual basis

06 Capturing the medical and therapeutic advances for AA in physician-developed treatment guidelines

07 Supporting people with AA in accessing affordable treatment to help manage the psychological impact associated with the disease

08 Identifying any health disparities based on race or ethnicity and ensuring health equality by delivering personalized care through coverage and access to treatments for AA

09 Involving a diverse range of participants in AA clinical trials
There Is Pattern Baldness and Then There Is AA; One Is an Autoimmune Disease

AA is a serious autoimmune disease. Approximately 700,000 people in the United States (US) are diagnosed or affected by AA with just under half of these patients estimated to have complete scalp or total body baldness. This makes AA the second most common type of hair loss in the US, just behind pattern baldness, or a receding hair line. However, AA is distinctive from pattern baldness and age-related hair thinning. For example, unlike androgenetic alopecia (male pattern baldness), which is caused by hormones, AA occurs when the immune system attacks the hair follicles. Like other autoimmune conditions, there is no pattern or predictability to AA, and it can occur with other autoimmune conditions or after infections and/or inflammation.

It is important to understand that AA is a chronic disease that can be treated, but not cured. The disease has a strong association with several genes with immune functions. The entry of inflammatory cells into the hair follicle's immune privilege zone is thought to result in hair loss. Like other autoimmune diseases, AA can be treated if the immune signaling pathways are inhibited.

AA is believed to be multifactorial, which means that there are a variety of genetic and environmental factors that contribute to the development and progress of the disease. For example, studies have observed the impact of environmental factors, such as nutrient deficiencies (vitamin D, zinc, folate, etc). AA can also be inherited, with nearly 20% of patients with AA having a family history.

While autoimmune diseases can manifest differently across patients, common autoimmune diseases tend to cluster in the same individual. Unfortunately, patients with AA have a high comorbidity burden. A multi-year analysis of patients diagnosed with AA identified the most common comorbidities associated with AA as hyperlipidemia (22.4%), hypertension (21.8%), thyroid disorders (13.1%), contact dermatitis or eczema (10.8%), depression (9.5%), and anxiety (8.4%). Comorbid autoimmune diseases linked to AA included atopic dermatitis (2.8%), psoriasis (2.1%), chronic urticaria (1.5%), and rheumatoid arthritis (1.1%). The linking of these comorbid conditions can be devastating for patients, as they often have multiple serious conditions impacting their QoL. In addition, comorbid conditions can drive significant healthcare expenditures for patients and payers.

AA Can Occur at Any Age to Anyone

AA can occur at any age and presents at similar rates in males and females. Onset before the age of 40 occurs in the majority (70%–80%) of patients. Almost half of patients with AA show clinical signs before the age of 20, with the condition predominately severe when it appears in children. Cases of AA in children tend to lead into adulthood and are more severe than adult–onset cases.

While the conventional view is that AA does not differ by race, there are gaps in the findings that require further research. The limited research that exists identified African Americans as having slightly increased odds of AA diagnosis (odds ratio: 1.77) in the US. The authors of the study discussed the interplay between genetic and environmental factors as accounting for the racial differences, but did not reach a conclusion. A separate cross-sectional analysis found higher incidence of AA in African American and Hispanic women compared to White women.
## The Types of AA

There are several subtypes of AA based upon the location and extent of hair loss. AA most commonly causes scalp hair loss, but can also involve the face, including eyelashes, eyebrows, and beards. The clinical spectrum of AA ranges from patchy hair loss on the scalp to complete baldness across the entire body. AA is often classified into 3 broad categories based on the amount of hair loss: patchy alopecia areata, alopecia totalis, and alopecia universalis.

### Patchy alopecia areata:

Patchy alopecia areata is the most common type of AA. This type is characterized by 1 or more patches of hair loss on the scalp. The patchy subtype may remit quickly, be persistent over time, or progress to total scalp or body hair loss. As many as half of patchy AA patients spontaneously regrow hair. Relapse may occur at any time.

### Alopecia totalis (loss of all hair on the scalp):

Alopecia totalis occurs when the patient has 100% or near total hair loss on the scalp. It is estimated that 5% of patients with AA develop alopecia totalis. The median time between the presentation of AA and the development of alopecia totalis is thought to be 1 year. Spontaneous recovery occurs in less than 10%, and long-term complete recovery is about 9%. The totalis variant generally has a worse prognosis than patchy, up to nearly a quarter of alopecia totalis patients do not respond to therapy.

### Alopecia universalis (loss of hair across the body):

Approximately 9% of patients with AA have loss of all scalp and body hair, classified as alopecia universalis. Universalis means losing nasal hair, eyebrows, and eyelashes, which leads to physical challenges later (discussed herein). Alopecia universalis is more advanced than other types and is the most severe. Similar to alopecia totalis, only 9% of universalis patients achieve complete recovery.

Up to 25% of patients with AA progress to alopecia totalis or alopecia universalis, at which point, full recovery is rare. According to one study, without treatment, 55% of individuals with chronic AA, lasting over 12 months, will have persistent multifocal relapsing and remitting disease. Around 30% will develop alopecia totalis, and 15% will develop alopecia universalis.

The clinical course of AA may be characterized by complete remission, progression to alopecia totalis or alopecia universalis, or recurring over a long period of time. Patients may have several incidents of hair loss and subsequent regrowth throughout their lives. Hair loss may naturally remit, although the time frame for regrowth may be months to years.
A Significant Unmet Medical Need Exists for Patients With AA

Imagine being a teenager or a professional who has a new job and has an occurrence of AA. While hair can be changed and adopted into all sorts of styles, the absence of hair is not the same. Patients report a range of physical and psychological implications, as well as comorbidities associated with their AA. And, to add to the anxiety, AA is a relapsing-remitting disorder, so patients can feel like they are always waiting for their hair loss to potentially get worse.

To enhance the likelihood of hair regrowth, the first-line and most common treatment for AA is steroids. An assessment of treatment patterns and healthcare costs and utilization among patients with AA found that of patients receiving treatment, 80.3% received topical steroids and 30% received oral steroids for AA. Any sign of hair regrowth may be helpful for the psyche of patients with AA, although the reaction to steroids can be different for every patient. Like all current non-FDA-approved treatments for AA, steroids do not prevent new hair loss from developing.

Coping with AA is a daily challenge, one for which there are currently no FDA-approved treatments. Instead, patients with AA assume the cost of unsuccessful medical therapies and camouflage, such as wigs or microblading, often with limited to no coverage from insurance and lost income.

The FDA has publicly acknowledged the need for safe and effective treatments for AA. AA is one of only 24 disease-specific meetings hosted by the FDA, known as Patient-Focused Drug Development (PFDD) meetings. During the 2017 PFDD meeting, patients living with AA shared the day-to-day impact of the disease and described the ineffectiveness of current treatment options. Hundreds of patients with AA participated either in person, live webcast, or through written comments. After engaging with patients, the FDA recognized the “significant unmet medical need for treatments for patients with AA.”
The Physical Implications of AA

Hair—both on the head and on the body—serves as protection from the elements. The hair loss associated with AA leaves patients susceptible to sunburn, eye irritation, allergies, poor thermoregulation, and harmful airborne particles. A recent population-based study investigated the atopic comorbidities among patients with AA. The data revealed a higher prevalence of asthma (7.8%–6.5%), allergic rhinitis (16%–12.8%), and allergic conjunctivitis (23.5%–19.6%) as a result of hair loss. These are all considered long-standing respiratory conditions that impact QoL and productivity and can require pharmacologic treatment.

Dermatological Issues

Several dermatologic disorders are linked to AA. First, patients with AA have a significantly increased risk for atopic dermatitis (eczema), a chronic inflammatory skin disease that causes the skin to become inflamed and irritated, making it extremely itchy. A systematic review and meta-analysis found 9.4% of patients with AA had a previous and/or current history of atopic dermatitis compared to 1.9% of patients without AA. Alopecia totalis or universalis patients were associated with higher odds of atopic dermatitis.

In addition, there has long been a higher incidence of vitiligo in patients with AA. It is estimated that as high as 8% of patients with AA develop vitiligo. Vitiligo is a disease that causes loss of skin color in patches. The discolored areas usually get bigger with time. Vitiligo usually appears before age 20 and may affect nearly all skin surfaces. Patients with vitiligo are more likely to develop extensive AA.

Vitiligo is among a group of dermatologic conditions (acne, psoriasis, and rosacea) specifically listed as non-cosmetic by the Centers for Medicare & Medicaid Services (CMS) for the purposes of Medicare Part D coverage. As a result, FDA-approved treatments for these conditions are covered by Medicare. With several shared characteristics between AA and these non-cosmetic Medicare-covered dermatologic conditions, there is no question that future FDA-approved treatments for AA should be covered by payers.

Beyond the Physical, the Mental Health Impact of AA

Hair is an important component of identity and self-image. Patients with AA often experience a variety of mental health issues related to their hair loss, such as anxiety and depression.

Given the unpredictable clinical course of AA and the impact on appearance, it is not surprising that the disease carries a significant mental and emotional burden. Several systematic reviews connect the extent of the disease with the amount of psychological distress.
Patients with AA who participated at the FDA’s 2017 PFDD meeting candidly described their loss of hair as “traumatic.” Several patients referenced the emotional toll AA took on their life, which was oftentimes severe. Many said their hair was a core part of their identity while one patient remarked that she would, “give anything to get my hair back.” This patient made the remark after she was mistaken for a boy and asked if she was in the correct bathroom.

The effects of AA are far-reaching, not only for the patient, but for the patient’s family, coworkers, and friends. Patients with AA describe feeling ashamed, humiliated, and profoundly depressed as a result of hair loss. About 70% of patients reported that AA had a marked impact on their self-esteem an impact that did not abate over time. The course of AA is unpredictable, with spontaneous regrowth of sections of hair occurring in 80% of patients within the first year, followed by sudden relapse. The risk of relapse introduces a higher likelihood of paranoia and obsessive-compulsive traits.

Social Stigmatization

Patients with AA are often misunderstood and mischaracterized. Much of the public continues to incorrectly regard AA as a cosmetic or communicable disease. Stigmatization and cultural perception of hair loss drive cumulative life course impairment for patients with AA. This stigma leads to a significant reduction in patients’ QoL.

The diagnosis of AA has been described as “emotionally devastating.” The stigmatization associated with AA often presents in the form of bullying or being misunderstood by coworkers and the public. Patients with AA at the FDA’s 2017 PFDD meeting described being bullied at school, having wigs and hats snatched off, and being insulted or mocked by classmates. The bullying was described as carrying a lifelong burden of anxiety and depression. One woman at the FDA meeting stated she lived in constant fear of “being discovered as a bald woman, fearing being thought of as sick, bizarre, ugly, or worse.” Others avoided social gatherings altogether. A group of patients remarked that the depression and emotional toll of AA brought suicidal ideation, while some stated that they had already previously attempted suicide.

Patients with AA have similar stories to patients with psoriasis or acne. Like AA, psoriasis, which has 20+ FDA-approved and covered drugs, is a highly stigmatized autoimmune dermatologic condition. It is perceived as a contagious disease and a result of poor personal hygiene. As a result, patients with psoriasis are more likely to experience depression and lower QoL. Similarly, acne, recognized by CMS as non-cosmetic, is associated with greater stigmatization. In many instances, acne sufferers, like patients with AA reported bullying, teasing, and social exclusion.

Relationships (Romantic)

Having AA continues to be an impediment to developing new relationships. In a recent study, participants with AA found dating difficult or avoided it entirely due to low confidence and fear of judgment or rejection due to their AA. Patients reported not knowing how to speak to new partners about AA and worried that potential partners would find them unattractive. Individuals affected by AA have also reported problems within their existing romantic relationships, citing feelings of insecurity about appearance, which was often related to decreased intimacy. This anxiety can further increase feelings of isolation and depression.

This social impact to relationships is similar for conditions like vitiligo or acne—both of which have reimbursed covered treatments. An assessment of the psychological impact of vitiligo found the condition negatively affected personal relationships and even marriage potential for over half of patients with the condition. The stigmatization of acne had been found to impact romantic relationships for acne patients as well. Non-sufferers commonly perceived those with acne as unattractive.

The course of AA is unpredictable, with spontaneous regrowth of sections of hair occurring in 80% of patients within the first year, followed by sudden relapse.

Patients with AA reported significantly higher disease burden, both emotionally and physically.
Depression/Anxiety/Impact on Overall QoL

A recent study showed a higher likelihood of depression for patients with AA. The incidence of major depression in patients with AA was reported as 8.8% compared with 1.3% to 1.5% in the general population. A connection exists between AA and depression regardless of which disease occurs first. For example, patients with a major depressive disorder were at a 90% increased risk of developing AA. Patients with AA had a 34% increased risk of developing a major depressive disorder.

Patients with AA often exhibit considerable anxiety from the general uncertainty surrounding disease progression; many patients endure emotional and psychological distress on a daily basis. A generalized anxiety disorder has been reported in 18.2% of patients with AA compared with 2.5% of the general population.

Analysis of cross-sectional patient survey data indicated that with increasing severity, patients with AA reported significantly higher disease burden, both emotionally and physically: emotions (mild 39.6±26.3 vs moderate 56.6±29.8 vs severe 63.1±31.9, P<0.0001), symptoms (10.1±17.9 vs 18.2±22.5 vs 20.8±26.2, P=0.0265) and functioning (17.0±23.7 vs 28.8±29.3 vs 36.4±33.1, P=0.0018). Work and activity impairment due to AA also increased with disease severity: overall work impairment (4.9%±11.7% in mild AA vs 12.5%±17.2% in moderate AA and 18.4%±20.2% in severe AA, P=0.0013) and activity impairment (7.1%±14.0% in mild AA vs 12.3%±16.0% in moderate AA and 19.7%±23.5% in severe AA, P=0.0007), as measured by the Work Productivity and Activity Impairment questionnaire.

Accordingly, patients with AA report impaired health-related quality of life (HRQoL). In studies of HRQoL in AA, patients responded to validated questionnaires about how AA impacts their life (eg, symptoms and feelings, daily activities, relationships, physical functioning, social functioning, and bodily pain). The most frequently used measures were the Dermatology Life Quality Index (DLQI) and Short Form–36 (SF–36) for general health; and the Alopecia Areata Symptom Impact Scale, the Alopecia Areata Quality of Life Index, and the Alopecia Areata Quality of Life for hair-specific QoL measures.

A summary of multiple studies of patients completing the DLQI found that almost 80% of patients with AA reported impaired HRQoL. Studies that included SF–36 scores for patients, as well as a matched control group for the purpose of comparison, showed patients with AA had lower HRQoL in mental health, vitality, and role–emotional domain, suggesting diminished energy levels and reduced social functioning. Studies implementing hair-specific QoL measures indicated that HRQoL can be affected by many factors, including more severe hair loss and concomitant depression.

A lower HRQoL was observed in the pediatric population as well, based on the Pediatric Quality of Life Inventory compared with controls. The overall HRQoL for parents of children with AA was also found to be poor. Additionally, children with AA may have a higher incidence of anxiety and depression, further reducing their QoL.

Many patients with AA experience diminished QoL, but patients with AA often report feeling that their concerns related to the psychological and social impact of the disease are dismissed. The poor HRQoL in patients with AA may play a role in the development of psychiatric comorbidities such as depression, anxiety, and obsessive–compulsive disorder.

Risk of Death Associated With AA

Mortality risk associated with intentional self-harm and psychiatric diseases is shown to be increased in patients with AA compared to individuals without AA. Participants at the FDA meeting described the connection between their depression from AA and thoughts and attempts of suicide. Patients with alopecia totalis or universalis saw their risk associated with self-harm significantly increase. AA tends to be associated with more self-isolation, and an inability to describe the feeling of hair loss to others—known as alexithymia. The prevalence of alexithymia was reported to be 23% to 50% in patients with AA compared to 5% to 14% for the general public. Relatedly, an increased risk of mortality due to any cause has been found in patients with similar dermatologic conditions atopic dermatitis and psoriasis—both of which have covered treatments.
The High Costs of AA for Patients

Beyond the physical and mental health impact of AA, patients with AA face significant out-of-pocket costs. These costs are from cost-sharing associated with medically covered services for AA and comorbid conditions, as well as other interventions not covered by insurance. For example, many AA patients reported using non-medical interventions, such as wigs, other types of camouflage (71%), and/or dietary changes or supplements (64%). The out-of-pocket costs are potentially compounded by work and productivity losses.

AA Treatment Patterns

Mitigating the high out-of-pocket costs faced by patients with AA is key to improving access to treatment. Out-of-pocket costs were $1,175.20 for all-causes and $104.19 for AA. AA-related expenses likely extend well beyond those reported in claims data because much of AA treatment occurs outside of the health plan.

Currently there are no FDA-approved treatments for AA; however, with the current diversity in expert opinion and lack of formal treatment guidelines, patients are prescribed a variety of therapeutics for AA. This starts with topical steroids. Based on recently released research, mean total healthcare costs were $11,241.21 for all causes and $419.12 for treating AA.

Treatments prescribed to patients with AA within 12 months of diagnosis

<table>
<thead>
<tr>
<th>Treatment class</th>
<th>Index treatment</th>
<th>Follow-up treatment</th>
</tr>
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<tbody>
<tr>
<td>Topical steroidal</td>
<td>14,804 (86.8%)</td>
<td>30,526 (80.3%)</td>
</tr>
<tr>
<td>Oral steroids</td>
<td>801 (4.7%)</td>
<td>11,394 (30.0%)</td>
</tr>
<tr>
<td>Systematic antihistamines</td>
<td>309 (1.8%)</td>
<td>2,346 (6.2%)</td>
</tr>
<tr>
<td>Topical nonsteroidalb</td>
<td>701 (4.1%)</td>
<td>2,172 (5.7%)</td>
</tr>
<tr>
<td>Finasteride</td>
<td>723 (4.2%)</td>
<td>1,432 (3.8%)</td>
</tr>
<tr>
<td>Immunomodulatorc</td>
<td>116 (0.7%)</td>
<td>1,367 (3.6%)</td>
</tr>
<tr>
<td>Acupuncture</td>
<td>100 (0.6%)</td>
<td>630 (1.7%)</td>
</tr>
<tr>
<td>Phototherapy</td>
<td>129 (0.8%)</td>
<td>295 (0.8%)</td>
</tr>
<tr>
<td>Systemic nonsteroidal</td>
<td>37 (0.2%)</td>
<td>127 (0.3%)</td>
</tr>
<tr>
<td>Intralesional triamcinolone</td>
<td>9 (0.1%)</td>
<td>32 (0.1%)</td>
</tr>
<tr>
<td>Platelet-rich plasma</td>
<td>0 (0.0%)</td>
<td>6 (0.0%)</td>
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Some patients received ≥2 treatment types.

A claims analysis of the US managed care population found total average 12-month all-cause costs for patients with AA were higher compared to non-AA patients ($8,853 vs $5,548). Higher average costs among patients with AA were driven primarily by differences in ambulatory ($4,138 vs $2,266) and pharmacy costs ($2,422 vs $1,372)—without an FDA-approved treatment for AA. Not surprisingly, among patients with AA, those with alopecia totalis and universalis forms have significantly higher costs. As previously described, AA is often coupled with other autoimmune diseases. The onset of multiple autoimmune diseases may require significant expenditures for diagnostics and treatment management. Diagnosis of certain autoimmune diseases may be challenging, as the symptoms and issues presented by the patient may resemble several autoimmune conditions. This can lead to a delay in diagnosis or patients being misdiagnosed entirely. Some autoimmune diseases are well known, and others are rare and difficult to diagnose. Many of the autoimmune conditions associated with AA are best treated through innovative systemic therapies that often have significant out-of-pocket costs for patients—and that is once they get past any utilization management hurdles. On average, patients take 3 medications to treat 1 autoimmune condition.
**Mental Health Treatment**

As might be expected, patients with AA utilize mental health treatments—outside of the contemporary AA treatments—to aid in management of their disease. A cross-sectional survey found patients with AA consulted many healthcare professionals to manage different aspects of their AA, including dermatologists (89%), primary care physicians (61%), psychological or behavioral health specialists (23%), hair loss specialists (22%), rheumatologists (13%), and pharmacists (12%). In one longitudinal cohort study, the ratio of patients visiting a psychiatric clinic was approximately 1.6 times higher in patients with AA than the control group. The highest average cost for patients was for counseling or therapy at $1,961 per year.

A sample of US hospitalization data revealed that patients with AA had higher proportions of mental health diagnoses. These mental health diagnoses included anxiety, mood, attention-deficit/hyperactivity and conduct, and psychotic disorders. The average primary hospitalization and cost for a mental health disorder in patients with AA was 6 days and $11,907.

Despite the high demand for mental health treatment, barriers to mental health coverage and access still exist. These perceived and actual barriers start with high out-of-pocket costs for patients due to lack of access to in-network providers and lack of coverage by both public and private payers for mental health services. Mental health providers have some of the lowest participation rates of all specialties, in both government-sponsored and private health plans. Only 62% of psychiatrists were found to accept Medicare or private insurance. As a result, patients in need of mental healthcare are left to navigate narrow networks to find a physician who will accept their plan or use out-of-network care, which leads to more out-of-pocket costs.

In a recent study, enrollees with mental health conditions were found to have significantly higher out-of-pocket costs than those with chronic physical conditions. Specifically, individuals with mental health conditions had cost-sharing payments for out-of-network care $341 higher than those with diabetes and no mental health condition.

**Concealment Not Covered**

Society puts an inordinate amount of pressure on beauty and attractiveness. While it may be more socially acceptable for a man to be bald, as some choose to shave their head regardless of thinning or lost hair, there is limited societal acceptance of a bald woman. Women often rely on wigs and cosmetic devices which are often uncomfortable and expensive.

Even though a wig is critical to help with the emotional burden of AA, Medicare does not consider wigs necessary and reasonable. In the commercial market, coverage for wigs is generally excluded unless specifically listed by the payer as a covered healthcare service. Medicare Advantage plans (Medicare Part C) may offer wigs as a supplemental benefit for hair loss that is a result of chemotherapy. However, wigs are not offered as a supplemental benefit for any other purpose, such as for hair loss from AA. Meanwhile, a small number of states mandate payer coverage for wigs that are worn for hair loss caused by AA. While a few additional states mandate coverage for wigs worn for hair loss caused by cancer treatment. Coverage is often subject to dollar or frequency limits, as specified by the payer.

The average estimated cost of one human hair wig or hairpiece is around $2,211 per year. These types of wigs can last 3 to 4 years. But even synthetic wigs, worn daily, can cost several hundred dollars and need to be replaced every few months. This added financial burden is another source of stress for patients with AA.
Alleviating the Burden of AA on Patients

There is a clear need to rethink how AA is framed among payers and policymakers. Given the burden of the illness, and the FDA’s support for better treatment options, plans must recognize the need to cover treatment option(s) approved by the FDA. That is just one of the steps that is needed; other potential ways of alleviating the burden of AA through improved access to treatments include:

1. **Officially classifying future FDA-approved treatments for AA as covered Medicare Part D drugs.** Today, the CMS Part D prescription drug manual lists conditions, which, while often perceived as cosmetic, are typically treated as dermatology disorders and thus covered (eg, acne, psoriasis, rosacea, vitiligo). CMS specifically classified FDA-approved drugs for the treatment of these dermatology conditions as covered under the Part D benefit. This list should be updated to include AA so that any FDA-approved treatment option(s) are more accessible to patients living with the disease.

2. **Ensuring payer coverage of FDA-approved treatments used for a medically accepted labeled indication, whether in addition to or in place of being medically necessary.** This will minimize or eliminate the time between FDA-approval and CMS coverage determination based on medical necessity. This will also differentiate FDA-approved treatments from experimental and investigational off-label therapies currently available for AA. Coverage of FDA-approved treatments for AA would allow healthcare practitioners and dermatologists to prescribe the most effective long-term treatment option.

3. **Recognizing the long-term nature of AA and the potential for relapse in benefit plan design;** in addition to the burden of comorbid conditions and ensuring that cost-sharing is affordable for patients on a monthly and annual basis.

4. **Removing access hurdles.** Patients with AA are often managing multiple comorbidities, and access to treatment should not be another burden. Appropriate access would help with the downstream costs associated with the burden from the comorbid conditions faced by the AA population. Patients subjected to utilization management experience delays in treatment, increased out-of-pocket expenses, added stress, and poorer health outcomes. Furthermore, patients should have access to the formulation and dosage of any future, FDA-approved treatments as prescribed by a healthcare practitioner in accordance with the medically accepted label without additional payer restrictions, ensuring that cost-sharing is affordable for patients on a monthly and annual basis. Finally, in preparation for future FDA-approved treatments for AA, payers who currently have coverage policies prohibiting coverage for hair loss should rescind or modify those guidelines so that they do not present access challenges for patients.

5. **Covering mental health treatment linked to the disease.**

6. **Recognizing the need to not exacerbate health disparities and to promote health equality by ensuring access to innovative treatments for patients—regardless of income.**

7. **Achieving diverse representation in clinical trials** to ensure AA medicines are as effective as possible for patients who use them.

8. **Serving all communities and patient populations with innovative, new treatments, regardless of income or geography.**

9. **Capturing future medical advances in formal treatment guidelines to improve patient access to effective care.** Patient preference for an effective long-term treatment is clear, as evidenced by a willingness to endure high out-of-pocket costs for current ineffective therapies and wigs.
Conclusion

AA is an autoimmune disease with a significant and costly burden of illness. The burden manifests as physical implications, as well as significant QoL and productivity impact-related issues from hair loss. AA should not be overlooked as cosmetic. There is an unmet need for an efficacious long-term treatment option. Coverage of future FDA-approved treatments will bring patients with AA stability and improved QoL.

Over the next 2 years, US payers and policymakers need to develop coverage policies for new FDA-approved treatments currently in development to ensure appropriate patient access and affordability when innovation becomes available. Coverage and reimbursement policies for FDA-approved treatments should meet the high physical and emotional burden faced by patients with AA. These policies will play a pivotal role to help patients with AA avoid the long-term suffering and overwhelming burdens associated with this disease.
References


