



Canada's Drug Agency
L'Agence des médicaments du Canada

CDA-AMC REIMBURSEMENT REVIEW

Patient and Clinician Group Input

baricitinib (Olmiant)

(Eli Lilly Canada Inc.)

Indication: For the treatment of adult patients with severe alopecia areata.

March 19, 2024

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Patient Input

CADTH Reimbursement Review

Name of Drug: Olumiant (baricitinib)

Indication: Alopecia Areata

Name of Patient Group: Canadian Alopecia Areata Foundation (CANAAF)

Author of Submission: Carolynne Harrison with input from Anthony Gilding (former board member)

1. About Your Patient Group

The Canadian Alopecia Areata Foundation (CANAAF) supports those affected by Alopecia Areata, promotes awareness and education of this autoimmune disease, and raises funds for research. CANAAF's mission is to offer a supportive community where patients and families can connect, learn, and celebrate together to journey through their Alopecia with confidence. Our vision is to be a nationally recognized, locally-focused pillar in the overall support network for the alopecia community. CANAAF was founded in 2008 by 2 parents "on a bucket full of tears, a huge heart, and an incredible, unstoppable desire to assist and protect our children." The Canadian Alopecia Areata Foundation was registered as a charitable organization in 2010, the voice for all Canadian patients and families affected by alopecia areata. CANAAF is run by a volunteer, working board of directors.

2. Information Gathering

Data on the psychosocial and emotional impact of alopecia areata has been collected from the literature. One Canadian study on this topic exists and was conducted by Gilding et al. (2022). The rest of the studies are from other parts of the world. This does not diminish their value in any way as the patient experience with alopecia areata is universal, and this has been demonstrated. These studies have been published in a variety of renowned medical journals from the 1990s to the present. All of the studies included in this report have been peer-reviewed.

Patient perspectives on alopecia areata have also been received through patient reports and support sessions that CANAAF has run for many years. In these sessions, patients openly reflect on their experience with alopecia areata and what they are looking for in a treatment. Alopecia areata affects all sexes, ages, races and ethnicities equally, so the perspectives from CANAAF's support groups, as well as the literature are rich and diverse.

3. Disease Experience

The Canadian Dermatology Association describes Alopecia Areata as occurring in approximately 2% of the world population. Alopecia areata is incredibly burdensome on a patient's mental health and quality of life. From the time a patient wakes up, to the time they go to bed, alopecia areata is consistently interfering with their daily living. The disease causes disfiguring hair loss that occurs unexpectedly, and can progress rapidly. The patient's hair is falling out in front of them throughout the day, and is visible to those around them. This hair loss is not the typical shedding that occurs normally. With alopecia areata, hair falls out in clumps/bunches. As one can imagine, this is incredibly traumatizing and triggers a great deal of debilitating anxiety and depression in patients. This significant impact on patients' mental health is well documented in the literature (Baghestani, Zare & Seddigh, 2015; Gilding et al., 2022; Okhovat et al., 2023; Sellami et al., 2014).

It is extremely difficult dealing with shock and a loss of identity. The sudden change is reported to lead to feelings of confusion, grief, and shame. "I was not sure if my hair would grow back or if it would fall out completely, and I felt betrayed by my own body for exposing me. It is easy to take our hair for granted, but it protects us against the sun, heat loss, and debris. It is also a way to identify ourselves: our gender, sexuality, health, and style, amongst other notable societal factors". (Patient report).

The anxiety, depression, and other resultant psychological conditions are not minor in nature. They are often quite severe and require psychiatric evaluation and management (Altunisik, Ucuş & Turkmen, 2022). The unpredictable nature of shedding and regrowth (if any) also significantly impacts mental health.

Apart from the personal effects of alopecia areata, the disease also significantly impacts how patients interact with other people. The loss of hair, therefore, can create layers of stigma and misunderstandings. People may be mistaken for having cancer and undergoing chemotherapy. "Short hair or baldness may be associated with a preference for an 'edgy' look or having a certain sexuality, which may not be accurate. Those with this disease may feel less feminine or less masculine without hair. Children and teenagers may experience bullying. There is also the daunting pressure of explaining oneself to strangers, creating a sense of isolation". (Patient report). Given the disfiguring nature of the hair loss, patients are often reluctant to go out in public due to the fear of being stared at, or being the victim of bullying and harassment. Many, if not all patients at some point will experience very significant social anxiety as a result (Gilding et al., 2022; Mostaghimi et al., 2021; Russo et al., 2019). In many cases, patients have a valid concern regarding bullying, as it is unfortunately quite prevalent, particularly in children and adolescents (Christensen, Yang & Castelo-Soccio, 2017; Prendke et al., 2023). For adult patients, taking time off work and experiencing productivity loss as a result is quite common (Gandhi et al., 2023; Muntyanu et al., 2023).

This very significant impact on a patient's mental health, quality of life, and daily living warrants the financial coverage of Olumiant (baricitinib) as it has been shown to be incredibly effective at regrowing hair in patients with moderate-to-severe alopecia areata (Kwon et al., 2023) and has already been approved for use in the United States of America.

In addition, there is also a significant financial burden associated with alopecia areata.

Based on feedback from a CANAAF community alopecia patient focus group conducted in 2023:

- Financially speaking, the cost of AA in a given year averages about \$9,000, with a wide range from \$2,000 to \$20,000. The most significant cost item is a wig purchase and maintenance, which can cost over \$2,500 a year. A number of diverse "other" items averaged over \$1000 per year (including wig maintenance, eyebrows, make-up, tattoos and special shampoos).
- Some consultants experienced significant impacts on their ability to work. At least two quit their jobs, one being a caregiver of a young AA sufferer and the other who still lacks the confidence to return to work. One patient described an employment situation where her boss' comments about her lack of hair caused her so much anxiety, she had to leave her employment. Another explained that she initially had to take time off in order to access wig maintenance, which is not always readily available in all areas.

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4. Experiences With Currently Available Treatments

Topical corticosteroids are the first-line therapy for alopecia areata given their anti-inflammatory effects. It has been shown that they are barely effective and really only work for very limited alopecia areata (Das et al., 2010). Moreover, topical corticosteroids are often greasy or very drying depending on the formulation and can be quite irritating to the scalp (Nassar et al., 2022). Intralesional corticosteroids are effective at treating limited alopecia areata (Kubeyinje, 1994), meaning a few small patches of hair loss on the scalp. However, not all private insurance plans and government pharmacare plans cover the cost of the medication for alopecia. These injections are known to be quite painful as well. Oral corticosteroids have variable rates of success in treating extensive alopecia areata, though the effect only lasts as long as the patient is on the medication (Cowley & Dong, 2020). Apart from the high relapse rates (Cowley & Dong, 2020), they are not always covered by drug plans and come with a whole host of unfavourable side effects (Manson et al., 2009).

Minoxidil is a popular medication used to treat diffuse alopecias such as androgenetic alopecia. Given its efficacy in these conditions, it has been used in alopecia areata with variable results. Studies have shown that topical minoxidil can be effective in treating very mild alopecia areata, though the results tend to only last around 6 months (Freire et al., 2019). It should also be noted that minoxidil has unfavourable side effects such as excessive hair growth on other parts of the body such as the face - including the forehead and cheeks (Rai, 2017). Minoxidil can also be quite irritating to the scalp and can cause allergic contact dermatitis (Navarro-Triviño, Pegalajar-García & Ruiz-Villaverde, 2022). Lastly, topical minoxidil can only be purchased over the counter, and thus its expensive cost is not covered by drug plans. Minoxidil can also be used orally, though because it is an anti-hypertensive drug, it comes with a host of systemic side effects whose risks may outweigh the potential benefits (Beach et al., 2021). Oral minoxidil may not be covered by drug plans for alopecia.

Platelet-Rich Plasma (PRP) has been purported to produce hair regrowth in a variety of alopecias including alopecia areata. However, studies have shown that it produces very little benefit in very limited alopecia areata (Kapoor et al., 2020). It is not an effective treatment for extensive alopecia areata. It is a very expensive treatment not covered by insurance plans or government pharmacare plans, and the injections can be quite painful.

Topical calcineurin inhibitors pimecrolimus and tacrolimus have been used in an attempt to treat alopecia areata given their effect on T cell activity. However, multiple studies have shown that tacrolimus fails to treat extensive alopecia areata (Feldmann et al., 2002; Price, Willey & Chen, 2005). The same results have been reported for pimecrolimus (Rigopoulos et al., 2007).

It should also be noted that tacrolimus and pimecrolimus ointments are incredibly greasy which presents a difficulty for people who want to use it on their scalp or face.

The topical vitamin D analogue calcipotriol/calcipotriene has been studied as a potential treatment for alopecia areata. It is known that vitamin D receptors live in the hair follicle. We also know that vitamin D has immunomodulatory effects. Thus, calcipotriol/calcipotriene has been used in an attempt to treat alopecia areata. Unfortunately, it seems to really only work for patients who are vitamin D deficient (Narang, Daroach & Kumaran, 2017). Moreover, in the cases where it has proven effective, these patients had very mild alopecia areata (Molinelli et al., 2020). Topical vitamin D analogues do not appear to be effective for more severe alopecia areata (Berth-Jones & Hutchinson, 1991). As with other treatments, this medication isn't always covered by drug plans for alopecia.

Diphencyprone/Diphenylcyclopropenone (DCP/DPCP) is a form of topical immunotherapy that has been proposed to treat alopecia areata by distracting the immune system from attacking the hair follicles. The treatment works by inducing irritant contact dermatitis, to which the immune system will respond. The hope is that the immune system will switch from attacking the hair follicles, to responding to the contact dermatitis. Studies have shown that response to DCP/DPCP is highly variable, with most people experiencing only a modest amount of hair growth (Gordon et al., 1996; Lamb, Young & Holmes, 2016). DCP/DPCP is incredibly irritating to the scalp and often causes very significant allergic reactions in the person administering the treatment, and the person receiving it. DCP/DPCP has also been reported to trigger vitiligo, another cutaneous autoimmune disease (Pires et al., 2010). This is extremely problematic as vitiligo is an equally burdensome disease. This treatment can be quite expensive and often isn't covered by drug plans.

Methotrexate is a disease modifying anti-rheumatic drug (DMARD) that was initially designed to treat rheumatoid arthritis. Given its immunosuppressive pharmacology, it has been used to treat severe cases of alopecia areata. Results of studies have shown that methotrexate has a modest effect on hair regrowth (Lai & Sinclair, 2020; Phan, Ramachandran & Sebaratnam, 2019). Methotrexate can have quite a significant impact on quality of life as it causes fatigue for a couple of days after taking it and puts people at risk for organ system toxicity, infection, and malignancy (Gaies et al., 2012; Inose et al., 2020; Zachariae, 1990). As with any drug, the cost of this medication may not be covered for the treatment of alopecia areata.

Other systemic immunosuppressants like cyclosporine, sulfasalazine, azathioprine and mycophenolate have been used to treat alopecia areata. Cyclosporine has not shown the greatest response rates and often requires the concomitant use of oral corticosteroids before any response is seen (Lai & Sinclair, 2020). Similarly, sulfasalazine has not shown great response rates and has high rates of side effects (Misery et al., 2007; Rashidi & Mahd, 2008). Azathioprine has shown very modest responses and as with cyclosporine, requires the concomitant use of oral corticosteroids before any acceptable response is seen (Lai & Sinclair, 2020). No effect has been seen with the use of mycophenolate in alopecia areata (Köse et al., 2004). As with methotrexate, all of these immunosuppressants put patients at risk for organ toxicity, infection, and malignancy. Thus, in many cases, the risks outweigh the modest benefits. Lastly, the cost of these immunosuppressants is not often covered for alopecia areata.

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5. Improved Outcomes

Patients with alopecia areata are looking for a practical, yet extremely effective treatment option that will result in full and sustained hair growth. Olumiant offers this solution. It is a simple treatment option that involves taking a small pill once a day. Olumiant is a drug that is targeted specifically for alopecia areata. It inhibits the immune response proteins that are directly involved in the pathogenesis of alopecia areata, compared to the other treatment options that have been used historically which were not meant for alopecia areata. Olumiant does not require the application of irritating topical agents, or painful injections into the scalp or face. Olumiant has a better safety profile than the other immunosuppressants that have been used in the past for alopecia areata. With Olumiant, patients no longer have to put themselves at risk for unfavourable side effects and poor success rates just for the small chance of regrowing hair.

As mentioned earlier, alopecia areata causes significant anxiety and depression. These psychological comorbidities of alopecia areata affect all aspects of a patient's life and are caused directly by the hair loss seen in alopecia areata. These resultant psychological disorders are not mild by any stretch of the imagination. They have been reported to be so severe that patients have an increased risk of suicidal ideation (Gupta & Gupta, 1998; Jagtiani et al., 2017; Wang et al., 2023). Devastatingly, there have been reports of people with alopecia areata committing suicide (Sinclair, 2014). Given the serious nature of this psychological impact of alopecia areata, an effective treatment must be made available, and most importantly accessible to all patients. It is not an exaggeration to say that covering the cost of Olumiant for patients with alopecia areata in Canada will save lives.

Covering the cost of Olumiant in Canada will allow patients to access the drug and receive treatment. We can expect to see patients return back to their lives as they did before they developed alopecia areata. Patients will no longer be extremely self-conscious about their appearance, nor will they continue to avoid social situations because of their alopecia areata. They will no longer have to spend hundreds to thousands of dollars on camouflaging options such as wigs and hair pieces, eyebrow microblading, and scarves (Gilding et al., 2022). Patients will be able to return to work and/or school, as well as any other responsibilities they may have. This not only will benefit the patients, but it will also benefit workplaces and governments as we can expect to see the rates of

absenteeism and social assistance decrease since people will be returning to work. Children can go back to school and be free of ridicule and bullying because of their appearance. Most importantly, they can be children again.

It is difficult to fully express just how incredibly important it will be to cover the cost of Olumiant for patients with alopecia areata. To reiterate, making Olumiant accessible to Canadians with alopecia areata will allow them to live their lives to the fullest again. Alopecia areata stops patients' lives in a very dramatic manner. With Olumiant, patients can press play on their lives.

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6. Experience With Drug Under Review

The only way that patients were able to access Olumiant was to participate in a clinical trial or to pay out of pocket. The latter was not an option for most people as JAK inhibitors like Olumiant cost upwards of \$2,000 CAD per month. Compared to previous therapies used, Olumiant is much more effective as it is a targeted treatment designed specifically for alopecia areata. The major disadvantage of Olumiant is the cost, which is why we are advocating for it to be covered by private drug plans and eventually government drug plans. The benefits most certainly outweigh the disadvantages in this situation. The improvement in patients' lives while on Olumiant was astronomical. While on the drug, most patients regrew all of their hair and thus felt that they were able to live their lives to the fullest again.

The side effect profile of Olumiant is much more favourable compared to historical treatments. The most common side effects observed with this drug are a slightly increased risk of upper respiratory tract infections, headache, and nasopharyngitis (Jorgensen et al., 2020). Other side effects observed with Olumiant include changes in blood tests. These include decreases in white blood cell counts (which is to be expected considering it is an immunosuppressive medication), decreases in hemoglobin, small increases in creatinine, increases in lipid parameters, elevations in liver enzymes and bilirubin, and increases in creatine phosphokinase (Fragoulis, McInnes & Siebert, 2019; US Food and Drug Administration, 1997). In most cases, these changes in blood test values are benign and simply need to be monitored for any drastic changes. It has been demonstrated that Olumiant is safe and well-tolerated in people with moderate to severe alopecia areata (King et al., 2021).

Olumiant is a much easier treatment option for patients as it only requires that they take one small pill, once a day. This is in comparison to other treatments that must be applied topically, injected, (often by a health care professional) or taken orally more than once a day. Olumiant is particularly effective for people with moderate to severe alopecia areata ($\geq 50\%$ scalp hair loss). It is not indicated for mild alopecia areata. With respect to treatment sequence, patients will typically start with topical corticosteroids, then progress to intralesional corticosteroids if those don't work. From there, they may be placed on an alternative topical treatment. If these fail, the next step is oral immunosuppressants like methotrexate +/- oral corticosteroids. In many cases, this sequence will end with sub-optimal hair growth. This is why we need a Janus Kinase (JAK) inhibitor like Olumiant as it has been proven to be significantly superior to the aforementioned treatments.

The values that are important to patients for Olumiant are safety, availability, accessibility, affordability, and efficacy.

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7. Companion Diagnostic Test

Not applicable for alopecia areata.

8. Anything Else?

It is imperative to re-emphasize that despite the common misconception, alopecia areata is definitely not just a cosmetic condition. It is an autoimmune disease that has profound implications for the patient, affecting their quality of life, mental health and psychosocial well-being. It is not just hair - it is so much more than that. Alopecia areata affects the whole family. The stigma associated with unpredictable hair loss cannot be understated.

The Canadian Alopecia Areata Foundation and the alopecia community are thrilled by the groundbreaking announcement of a new treatment for alopecia areata. This development offers a ray of hope to our community members who suffer from the devastating mental health impacts associated with alopecia areata. We eagerly await access to Olumiant and look forward to improved quality of life and empowered futures for individuals and their families with alopecia areata.

Treating alopecia areata with Olumiant will improve, and save lives. There are a plethora of research studies demonstrating the significant burden of this disease. Moreover, pathophysiologically, alopecia areata is an autoimmune disease. It is not simply the shedding of hair. There is an underlying pathology that deserves to be treated. It is CANAAF's sincere hope that CADTH will truly understand the importance of covering the cost of Olumiant for Canadians with alopecia areata.

Appendix: Patient Group Conflict of Interest Declaration

To maintain the objectivity and credibility of the CADTH reimbursement review process, all participants in the drug review processes must disclose any real, potential, or perceived conflicts of interest. This Patient Group Conflict of Interest Declaration is required for participation. Declarations made do not negate or preclude the use of the patient group input. CADTH may contact your group with further questions, as needed.

1. Did you receive help from outside your patient group to complete this submission? If yes, please detail the help and who provided it.

N/A

2. Did you receive help from outside your patient group to collect or analyze data used in this submission? If yes, please detail the help and who provided it.

N/A

3. List any companies or organizations that have provided your group with financial payment over the past 2 years AND who may have direct or indirect interest in the drug under review. Table 1: Financial Disclosures

Check Appropriate Dollar Range With an X. Add additional rows if necessary.

Company	\$0 to 5,000	\$5,001 to 10,000	\$10,001 to 50,000	In Excess of \$50,000
Eli Lilly			X	
Pfizer			X	

I hereby certify that I have the authority to disclose all relevant information with respect to any matter involving this patient group with a company, organization, or entity that may place this patient group in a real, potential, or perceived conflict of interest situation.

Name: Carolynne Harrison with input from Anthony J. Gilding (former CANAAF Board Member)

Position: President

Patient Group: Canadian Alopecia Areata Foundation (CANAAF) **Date:** March 15, 2024.

Clinician Group Input

No Clinician Group Input was received for this review.