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[Date]

To Whom It May Concern:

has alopecia areata, a common autoimmune disease that causes loss of hair on the scalp and elsewhere on the body. It usually starts with one or more small, round, smooth patches on the scalp and can progress to total scalp hair loss (alopecia totalis) or complete body hair loss (alopecia universalis).

Alopecia areata is associated with serious comorbidities that are debilitating for patients and contribute to a significant healthcare burden [1,2,3]. Patients experience higher rates of depression, anxiety, and suicidal ideation [4]. The sudden onset, recurrent episodes, and unpredictable course of hair loss can lead to difficulties at work, at school and in relationships [5].

A report from the U.S. Food and Drug Administration's Patient Focused Drug Development Initiative concluded that: alopecia areata places significant burden on daily life and has a severe impact on how patients feel and function; and symptoms can have considerable detrimental effects on a patient's quality of emotional well-being, social interactions and ability to lead a normal life [6]. The profound and psychologically devastating impacts of alopecia areata make it necessary and reasonable that patients with the disease seek treatment [7,8].

In June 2022, the U.S. Food and Drug Administration approved baricitinib (Olumiant) for the treatment of alopecia areata, marking the first approved treatment for the disease [9]. Baricitinib and other drugs in the Janus kinase (JAK) inhibitor class have been shown to be effective treatments for alopecia areata [10,11]. These treatments are immunomodulating agents that stimulate hair regrowth and their use must be continued to maintain their effect.

It is entirely reasonable and necessary for the cost of these treatments to be reimbursed. I would be happy to provide any additional information.

Sincerely,

Lisa Anderson, PhD  
Research Director

65 Mitchell Blvd., Suite 200B | San Rafael, CA 94903  
415-472-3780 | info@naaf.org | www.naaf.org



## References:

- 1 Singam V, Patel KR, Lee HH, et al. Association of alopecia areata with hospitalization for mental health disorders in US adults. *J Am Acad Dermatol*. 2018 Aug 6. pii: S0190-9622(18)32346-6.
- 2 Chu SY, Chen YJ, Tseng WC, et al. Comorbidity profiles among patients with alopecia areata: the importance of onset age, a nationwide population-based study. *J Am Acad Dermatol*. 2011 Nov;65(5):949-56.
- 3 Villasante Fricke AC, Miteva M. Epidemiology and burden of alopecia areata: a systematic review. *Clin Cosmet Investig Dermatol*. 2015;8:397-403. doi:10.2147/CCID.S53985
- 4 Koo JY, Shellow WV, Hallman CP, et al. Alopecia areata and increased prevalence of psychiatric disorders. *Int J Dermatol*. 1994 Dec;33(12):849-50.
- 5 Burns LJ, Mesinkovska N, Kranz D, Ellison A, Senna MM. Cumulative Life Course Impairment of Alopecia Areata. *Int J Trichology*. 2020 Sep-Oct 2020;12(5):197-204. doi:10.4103/ijt.ijt\_99\_20
- 6 U.S. Food and Drug Administration. The Voice of the Patient: Alopecia Areata. Fed Regist 82 FR 28665. Public Meeting: September 11 2017; Report Date: 3/2018.  
<https://www.fda.gov/media/136516/download>
- 7 Korta DZ, Christiano AM, Bergfeld W, et al. Alopecia areata is a medical disease. *J Am Acad Dermatol*. 2018 Apr;78(4):832-834.
- 8 Liu, LY, King BA, Craiglow BG. Health-related quality of life (HRQoL) among patients with alopecia areata (AA): A systematic review. *J Am Acad Dermatol*, 2016 Oct; 75(4):806-12.
- 9 FDA Approves First Systemic Treatment for Alopecia Areata, June 13,2022,  
<https://www.fda.gov/news-events/press-announcements/fda-approves-first-systemic-treatment-alopecia-areata>
- 10 King B, Ohyama M, Kwon O, et al. Two Phase 3 Trials of Baricitinib for Alopecia Areata. *N Engl J Med*. Mar 26 2022;doi:10.1056/NEJMoa2110343
- 11 Dillon KL. A Comprehensive Literature Review of JAK Inhibitors in Treatment of Alopecia Areata. *Clin Cosmet Investig Dermatol*. 2021;14:691-714. doi:10.2147/CCID.S309215

Sample Appeal Letter  
For Janus Kinase Inhibitor

**[Date]**

**[Address for Claims Review Department of Insurance Company]**

**Name of Insured: [insert]**

**Patient's Date of Birth: [insert]**

**Medical Policy #: [insert]**

Dear [Name or Claims Review Department]:

I am writing to appeal insurance denial of coverage for **Olumiant (baricitinib)** for my patient, **[name of patient]**, a **[age]** year old **[man or woman]** with **[alopecia areata or alopecia totalis or alopecia universalis]** who has been under my care since **[month and year]**. **[Describe clinically relevant aspects of patient's alopecia areata]**.

Alopecia areata is a disfiguring autoimmune disease that causes patches of hair loss on the scalp and can progress to total scalp hair loss (alopecia totalis) or complete loss of eyebrows, eyelashes, facial and other body hair (alopecia universalis). Alopecia areata is psychologically devastating and the medical literature details clinical depression and anxiety associated with it (reference below).

**[Name of patient]** has failed common and uncommon treatments of alopecia universalis including **[e.g. prednisone, methotrexate, intralesional kenalog, photochemotherapy, squaric acid, topical steroids]**.

There is a sizable medical literature supporting the use of Janus kinase (JAK) inhibitors in severe alopecia areata (select references below). Baricitinib (Olumiant) is a JAK inhibitor that was recently approved by the U.S. Food and Drug Administration for the treatment of alopecia areata, marking the first approved treatment for the disease.

Please approve this medicine for **[name of patient]** so that **[he/she]** may experience that which the rest of us take for granted: looking and therefore feeling normal. Please contact me if you need any further information.

Sincerely,

**[Physician's Name]**

**[Physician's Office Address and Phone Number]**

## References:

Liu, LY, King BA, Craiglow BG. Health-related quality of life (HRQoL) among patients with alopecia areata (AA): A systematic review. *J Am Acad Dermatol*, 2016 Oct; 75(4):806-12.

Xing L, Dai Z, Jabbari A, et al. Alopecia areata is driven by cytotoxic T lymphocytes and is reversed by JAK inhibition. *Nature medicine* 2014;20:1043-9.

Craiglow BG, King BA. Killing Two Birds with One Stone: Oral Tofacitinib Reverses Alopecia Universalis in a Patient with Plaque Psoriasis. *J Invest Dermatol*. 2014 Dec;134(12):2988-90.

Gupta AK, Carviel JL, Abramovits W. Efficacy of tofacitinib in treatment of alopecia universalis in two patients. *J Eur Acad Dermatol Venereol* 2016.

Jabbari A, Nguyen N, Cerise JE, et al. Treatment of an alopecia areata patient with tofacitinib results in regrowth of hair and changes in serum and skin biomarkers. *Exp Dermatol* 2016.

Lucy LY, Craiglow BG, Feng D, et al. Tofacitinib for the treatment of severe alopecia areata and variants: A study of 90 patients. *J Am Acad Dermatol*. 2017 Jan;76(1):22-28.

Liu LY, King BA. Tofacitinib for the Treatment of Severe Alopecia Areata in Adults and Adolescents. *J Investig Dermatol Symp Proc*. 2018 Jan;19(1):S18-S20.

Guo L, Feng S, Sun B, Jiang X, Liu Y. Benefit and risk profile of tofacitinib for the treatment of alopecia areata: a systemic review and meta-analysis. *J Eur Acad Dermatol Venereol*. 2020 Jan;34(1):192-201.

Dillon KA. A Comprehensive literature review of JAK Inhibitors in treatment of alopecia areata. *Clinical, Cosmetic and Investigational Dermatology*. 2021;14:691.

Pieri L, Guglielmelli P, Vannucchi AM. Ruxolitinib-induced reversal of alopecia universalis in a patient with essential thrombocythemia. *Am J Hematol* 2015;90:82-3.

Jabbari A, Dai Z, Xing L, et al. Reversal of Alopecia Areata Following Treatment With the JAK1/2 Inhibitor Baricitinib. *EBioMedicine* 2015;2:351-5.

Ismail FF, Sinclair R. JAK inhibition in the treatment of alopecia areata—a promising new dawn?. *Expert review of clinical pharmacology*. 2020 Jan 2;13(1):43-51.

Kibbie J, Kines K, Norris D, Dunnick CA. Oral tofacitinib for the treatment of alopecia areata in pediatric patients. *Pediatric Dermatology*. 2022 Jan;39(1):31-4.

Benton S, Farah R, Freese R, Hordinsky M. Tofacitinib as a pragmatic treatment choice for alopecia areata: A retrospective review. *Dermatologic Therapy*. 2022 Jan 8:e15310.

Almutairi, Nawaf, Tarek M. Nour, and Nasser Haji Hussain. "Janus kinase inhibitors for the treatment of severe alopecia areata: an open-label comparative study." *Dermatology* 235.2 (2019): 130-136.

Wambier CG, Craiglow BG, King BA. Combination tofacitinib and oral minoxidil treatment for severe alopecia areata. *Journal of the American Academy of Dermatology*. 2021 Sep 1;85(3):743-5.

Cheng MW, Kehl A, Worswick S, Goh C. Successful Treatment of Severe Alopecia Areata With Oral or Topical Tofacitinib. *Journal of Drugs in Dermatology: JDD*. 2018 Jul 1;17(7):800-3.

Phan K, Sebaratnam DF. JAK inhibitors for alopecia areata: a systematic review and meta-analysis. *Journal of the European Academy of Dermatology and Venereology*. 2019 May;33(5):850-6.

Liu LY, King BA. Tofacitinib for the treatment of severe alopecia areata in adults and adolescents. In *Journal of Investigative Dermatology Symposium Proceedings* 2018 Jan 1 (Vol. 19, No. 1, pp. S18-S20). Elsevier.

Craiglow BG, Liu LY, King BA. Tofacitinib for the treatment of alopecia areata and variants in adolescents. *Journal of the American Academy of Dermatology*. 2017 Jan 1;76(1):29-32.

Liu LY, Craiglow BG, Dai F, King BA. Tofacitinib for the treatment of severe alopecia areata and variants: a study of 90 patients. *Journal of the American Academy of Dermatology*. 2017 Jan 1;76(1):22-8.

King B, Ohyama M, Kwon O, et al. Two Phase 3 Trials of Baricitinib for Alopecia Areata. *N Engl J Med*. Mar 26 2022;doi:10.1056/NEJMoa2110343

FDA Approves First Systemic Treatment for Alopecia Areata, June 13,2022, retrieved from <https://www.fda.gov/news-events/press-announcements/fda-approves-first-systemic-treatment-alopecia-areata>