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Factors associated with insurance coverage of tofacitinib for alopecia areata: A retrospective review from an academic institution

To the Editor: It has become increasingly recognized that JAK inhibitors (JAKis) have substantial efficacy in the treatment of alopecia areata (AA).[1] JAKis approved by the US Food and Drug Administration (FDA) are currently under patent in the United States and can be expensive. The high cost of medication is a significant obstacle for patients, and, in the United States, the vast majority rely on insurance coverage to defray costs. AA is an off-label indication for JAKis, often complicating prescription plan coverage. We were interested in investigating the initial and postappeal rates of insurance plan coverage of JAKis for AA at our academic specialty hair clinic.

We conducted a retrospective review of our electronic medical records for patients seen with AA between 2017 through the end of 2019 in the Hair Disorders Clinic in the Department of Dermatology at the University of Iowa who had been prescribed tofacitinib, the most well-studied JAKi for AA,[2-4] over this period of time. Our query showed 42 patients who met these criteria (Table I). One patient was initially authorized for prescription plan coverage of tofacitinib; this patient carried the diagnosis of rheumatoid arthritis, for which tofacitinib is FDA approved. Of patients who were initially denied coverage, 5 patients either did not start the appeal process or stopped the process before a final, definitive decision. Of patients who completed the appeal process, 20 of 36 (55.6%) patients were provided insurance plan coverage after the first appeal, and 2 (5.6%) patients were provided insurance plan coverage after the second appeal. An external review/appeal by an independent physician was offered to those denied coverage after a first or second appeal. Six of the 9 cases externally reviewed (66.7%) were approved for coverage. In total, 29 of 42 patients (69%) received some amount of coverage.

We further examined cases in which patients were unable to obtain insurance coverage. We found that government-sponsored plans were associated with an increased final denial rate (Table I). It is noteworthy that an external review was not available for our patients with Medicaid plans. Excluding patients with pending coverage, patients who halted or did not start the appeal process, and patients with an FDA-approved indication, 60% (3 out of 5) of patients with government-sponsored plans (Medicaid or Medicare) were denied coverage, whereas 7.1% (2/28) of patients with private insurance were denied coverage ($P = .0165$, Fisher's exact test).

Overall, we report here that most private insurance companies will agree to provide some amount of coverage when presented with the growing amount of efficacy data and the risk/benefit profile for tofacitinib for AA if the appeal process options are pursued. A template for our appeal letters is provided in the supplemental materials (available via Mendeley at https://doi.org/10.17632/27dfnj844b.1). Limitations of our study include the focus on a single academic specialty clinic supervised by a sole provider and the limited number of patients. Of note, baricitinib, a JAKi that had previously been reported as a treatment for AA,[5] was recently granted breakthrough status by the FDA and may therefore benefit from an accelerated time frame for an AA indication and, possibly, lower prescription plan denial rates.

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Table I. Prescription plan coverage of tofacitinib for alopecia areata

	Private insurance plans (n = 35)	Government-sponsored insurance (n = 7)	*P* value
Age, y, mean (SD)	35.4 (14.5)	58.4 (16.8)	.0006
Male, n (%)	12 (34.3)	3 (42.9)	.6858
Female, n (%)	23 (65.7)	4 (57.1)	.6858
Patients with patchy AA and >50% scalp involvement, n (%)	6 (17.1)	0 (0)	.5668
Patients with severe (alopecia totalis or universalis), n (%)	15 (42.9)	6 (85.7)	.0977
Patients with eyelash/eyebrow involvement, n (%)	21 (60)	6 (85.7)	.3874
Number of appeals, average	1.5	1.3	.4216
Topical treatment failure,* n (%)	33 (94.3)	5 (71.4)	.2398
Intralesional injection failure, n (%)	30 (85.7)	6 (85.7)	.5541
Systemic medication failure,† n (%)	19 (54.3)	3 (42.9)	.6909
Initial approval, n (%)	1 (2.9)	0 (0)	>.99
Approved after first appeal, n (%)	18 (48.6)	2 (28.6)	.4143
Approved after second appeal, n (%)	2 (5.7)	0 (0)	>.99
Approved after external review, n (%)	6 (17.1)	0 (0)	.5668
Appeal response currently pending, n (%)	3 (8.6)	0 (0)	>.99
Voluntarily halted appeal process or chose not to appeal	3 (8.6)	2 (28.6)	.1875
Final approval rate, n (%)	27 (77.1)	2 (28.6)	.0213
Reasons for denial	Patient does not carry the diagnosis of RA, PsA, or UC Patient does not have a condition approved by the FDA for use of this medicine Off-label use not supported by medical literature Use of tofacitinib for AA is considered experimental/investigational	Drugs considered for coverage under Medicare Part D must be used for a medically accepted indication Medicare requires an FDA-approved diagnosis for the requested drug Information not sufficient to support approval for medical necessity	

AA, Alopecia areata; *FDA*, US Food and Drug Administration; *PsA*, psoriatic arthritis; *RA*, rheumatoid arthritis; *SD*, standard deviation; *UC*, ulcerative colitis.

*Topical treatments included topical steroids, minoxidil, squaric acid, diphencyprone, anthralin, bimatoprost, and topical tofacitinib.

†Systemic medications included prednisone 5-80 mg daily or every other day, methotrexate 15-25 mg weekly, mycophenolate mofetil 1000 mg twice daily, azathioprine, etanercept, and infliximab; note that not all immunosuppressive/immunomodulatory medications were prescribed for AA.

Reprints not available from the authors.

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