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

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

We conducted a retrospective review of our electronic medical record 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 that had been prescribed tofacitinib, the most well-studied JAKi for AA[2–4], over this period of time. Our query revealed 42 patients that met these criteria (Table I). One patient was initially authorized for prescription plan coverage of tofacitinib; this patient carried the diagnosis of RA for which tofacitinib is FDA-approved. Of patients that were initially denied coverage, five patients either did not start the appeal process or stopped the process prior to a final, definitive decision. Of patients that completed the appeal process, 20 of 36 patients (55.6%) were provided insurance plan coverage after the first appeal, and two patients (5.6%) 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 nine cases externally reviewed (66.7%) were approved for coverage. In total, 29 of 42 patients (69%) received some amount of coverage.

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We further examined cases that failed 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 that halted or did not start the appeal process, and patients with an FDA-approved indication, approximately 60% (3 out of 5) of patients with government-sponsored plans (Medicaid or Medicare) were denied coverage, while 7.1% (2 out of 28) of patients with private insurance were denied coverage (p=0.0165, Fisher 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 (https://data.mendeley.com/datasets/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 1.

Prescription plan coverage of tofactinib for alopecia areata.

	Private insurance plans (35)	Govt. sponsored insurance (7)	p-value
Age in years, average (st. dev)	35.4 (14.5)	58.4 (16.8)	0.0006
Male, n (%)	12 (34.3%)	3 (42.9%)	0.6858
Female, n (%)	23 (65.7%)	4 (57.1)	0.6858
Patients with patchy AA and >50% scalp involvement, n (%)	6 (17.1%)	0 (0%)	0.5668
Patients with severe (alopecia totalis or universalis), n (%)	15 (42.9%)	6 (85.7%)	0.0977
Patients with eyelash/eyebrow involvement, n (%)	21 (60%)	6 (85.7%)	0.3874
No. of appeals, average	1.5	1.3	0.4216
Topical Treatment Failure,* n (%)	33 (94.3%)	5 (71.4%)	0.2398
Intralesional Injection Failure, n (%)	30 (85.7%)	6 (85.7%)	0.5541
Systemic Medication Failure,† n (%)	19 (54.3%)	3 (42.9%)	0.6909
Initial approval, n (%)	1 (2.9%)	0 (0%)	1
Approved after 1st appeal, n (%)	18 (48.6%)	2 (28.6%)	0.4143
Approved after 2nd appeal, n (%)	2 (5.7%)	0 (0%)	1
Approved after External Review, n (%)	6 (17.1%)	0 (0%)	0.5668
Appeal response currently pending, n (%)	3 (8.6%)	0 (0%)	1
Voluntarily halted appeal process or chose not to appeal	3 (8.6%)	2 (28.6%)	0.1875
Final Approval Rate, n (%)	27 (77.1%)	2 (28.6%)	0.0213
Reasons for denial	Patient does not carry the diagnosis of RA, PsA, or UC; Patient does not have a condition approved by FDA for use of this medicine; Off Label use not supported by medical literature; Use of xeljanz for AA is considered experimental/investigational	Drugs considered for coverage under Medicare part D must be used for a medically-accepted indication; Medicare requires a FDA approved diagnosis for requested drug; Information not sufficient to support approval for medical necessity	

*Topical treatments included: topical steroids, minoxidil, squaric acid, diphenylcyprone, anthralin, bimatoprost. 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, infliximab; note that not all immunosuppressive/immunomodulatory medications were prescribed for AA