Reply to: "Lack of a US Food and Drug Administration indication should not limit access to appropriate treatment"

To the Editor: We recently read with great interest Albrecht et al's commentary on how US Food and Drug Administration (FDA) indications limit treatment access.[1] Insurance companies frequently utilize FDA guidelines and drug compendia to dictate treatment coverage; however, these resources are frequently outdated and lacking in scope.[2] We agree that treatment coverage should not be restricted by FDA approval. To lend further credence to their declaration, herein we provide evidence of disparity in prior authorization (PA) rates between diseases with and without an FDA-indicated treatment.

We performed an IRB-approved, single-center retrospective review of PAs submitted at an academic center dermatology clinic over 6 months in 2017. PA data recorded included medication, dose, disease, PA decision, and post–PA-denial action. Prescriptions were excluded if PAs were unnecessary or no record of the PA decision was available. PA approval rate was calculated for all conditions seen in our dermatology department and stratified according to whether or not each disease had at least 1 FDA-indicated treatment.

Additionally, 4 diseases with an FDA-indicated treatment (acne vulgaris, atopic dermatitis, hidradenitis suppurativa [HS], and psoriasis) and 3 diseases without an FDA-indicated treatment (alopecia, contact dermatitis, and vitiligo) were selected for comparative analysis of PA approval rates. Further, for acne, atopic dermatitis, HS, and psoriasis, PA approval rates were compared between medications prescribed on-label and off-label in each disease. A chi-square test was utilized to determine statistical significance, set at $P < .05$ a priori.

A total of 722 PAs were included in this study. Overall approval rates for all dermatologic conditions seen in our clinic were significantly higher for diseases with an FDA-indicated treatment option compared with diseases without an FDA-indicated treatment (78.7% vs 57.1%) ($\chi^2 = 32.30$, $P < .0001$) (Table I). Additionally, a significantly higher approval rate was observed for acne, atopic dermatitis, psoriasis, and HS compared with that for contact dermatitis, vitiligo, and alopecia (81.6% vs 44.2%) ($\chi^2 = 31.86$, $P < .0001$) (Table I). Medications prescribed on-label for acne, atopic dermatitis, psoriasis, and HS were approved significantly more often than medications prescribed off-label (82.6% vs 68.4%) ($\chi^2 = 4.60$, $P = .032$) (Table II).

Our data illustrate that FDA indication impacts insurers' decisions on medication coverage. This is not unique to the United States; a study in Germany found a similar initial approval rate (56.8%) for off-label therapies.[3] Even in some diseases with an available FDA-indicated treatment, such as HS, approval rates were still low; in HS, for example, only 53.3% of PAs were initially approved. One limitation of our study is that our analyses did not detect scenarios in which a PA was submitted for an FDA-indicated treatment but was denied because the patient did not meet severity criteria to qualify for that medication. In summary, we advocate for development of more inclusive coverage algorithms to ensure that patients, particularly those with diseases for which there are no or few FDA-indicated medications, have access to efficacious treatments.

Table I. Prior authorization approval rates for diseases with at least 1 FDA-indicated treatment versus diseases without an FDA-indicated treatment, regardless of on- or off-label status of prescription

All prescriptions					
	Diseases with an FDA-indicated treatment available		Diseases without an FDA- indicated treatment available		Total
PA approved	425 (78.7)*		104 (57.1)		529 (73.3)
PA denied	115 (21.3)		78 (42.9)		193 (26.7)
Selected diseases with an FDA-indicated treatment					
	Acne	Atopic dermatitis	Hidradenitis suppurativa	Psoriasis	Total
PA approved	202 (91.4)	45 (66.2)	8 (53.3)	86 (75.4)	341 (81.6)
PA denied	19 (8.6)	2 (33.8)	7 (46.7)	28 (24.6)	77 (18.4)
Selected diseases without an FDA-indicated treatment					
	Alopecia	Contact dermatitis	Vitiligo		Total
PA approved	4 (36.4)	11 (61.1)	4 (28.6)		19 (44.2)
PA denied	7 (63.6)	7 (38.9)	10 (71.4)		24 (55.8)

FDA, US Food and Drug Administration; *PA*, prior authorization.
*Data are provided as n (%).

Table II. Prior authorizations for on-label and off-label prescriptions in selected diseases with a FDA-indicated treatment available

	Acne	Atopic dermatitis	Hidradenitis suppurativa	Psoriasis	Total
On-label prescriptions					
PA approved	196 (91.6)*	43 (67.2)	5 (62.5)	70 (74.5)	314 (82.6)
PA denied	18 (8.4)	21 (32.8)	3 (37.5)	24 (25.5)	66 (17.4)
Off-label prescriptions					
PA approved	6 (85.7)	2 (50.0)	3 (42.9)	15 (75.0)	26 (68.4)
PA denied	1 (14.3)	2 (50.0)	4 (57.1)	5 (25.0)	12 (31.6)

FDA, US Food and Drug Administration; *PA*, prior authorization.
*Data are provided as n (%).

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Conflicts of interest: Dr Flood receives fellowship funding from AbbVie, Janssen, and the National Psoriasis Foundation. Dr Kimball is a consultant and investigator for AbbVie, Bristol-Myers Squibb, Eli Lilly, Janssen, Novartis, Pfizer, and UCB. She receives fellowship funding from AbbVie and Janssen. Dr Porter is a consultant and investigator for AbbVie and Novartis. She is also an investigator for Bristol-Myers Squibb, Eli Lilly, Janssen, and UCB. She has previously received fellowship funding from AbbVie, Janssen and the National Psoriasis Foundation. Mr Savage, Ms Popatia, Ms Gobari, and Ms Salian have no conflicts of interest to declare.

Reprints not available from the authors.

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