doi:10.36849/JDD.8853e







# Disparities in Alopecia Areata and Vitiligo FDA-Approved Therapies in Medicaid Formularies

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## INTRODUCTION

Vitiligo and alopecia areata (AA) are two common, autoimmune dermatologic diseases that significantly impact quality of life.[1,2] Oral and topical JAK inhibitors are innovative, emerging treatments. The FDA has approved ritlecitinib (Litfulo), baricitinib (Olumiant), and in the last month, deuruxolitinib (Leqselvi) for AA and ruxolitinib (Opzelura), monobenzyl ether of hydroquinone (Benoquin), tacrolimus (Protopic), and pimecrolimus (Elidel) for vitiligo.[3] The Centers for Medicare & Medicaid Services (CMS) has a mandate to determine if FDA-approved drugs are reasonable and necessary for the 73,793,274 Medicaid beneficiaries.[4] Patients without the financial means to pay out-of-pocket are unable to access treatments that are not covered by CMS. This study aimed to identify whether formulary coverage acts as a barrier to treatment for patients with vitiligo and alopecia areata.

## MATERIALS AND METHODS

Current Medicaid formularies for all fifty states and Washington, D.C. were accessed via state websites. The search terms included both brand and generic names. Medication coverage was categorized as specified, unspecified general (disease state not mentioned), requiring prior authorization (PA), not covered, or absence of published information. Preferred drugs were considered to be covered. The data from each state was reviewed by two study personnel.

## RESULTS

All states except Hawaii had publicly available Medicaid formularies. There was no direct coverage for any AA treatment in any state, with the exception of baricitinib in California. For AA, Ritlecitinib was not listed on the formulary in the majority of states (31, 60.78%), while 5 (9.80%) denied coverage and 14 (27.45%) required PA (Table 1). Baricitinib required PA for approval in 30 states (58.82%), the majority of which specified coverage for other conditions and specifically did not include AA (Table 1). Similarly, there was no direct coverage for vitiligo, with monobenzyl ether of hydroquinone often not listed on the formulary and the vast majority of states without coverage for other treatments: ruxolitinib (33, 64.71%), tacrolimus (30, 58.82%), and pimecrolimus (30, 58.82%; Table 1).

**TABLE 1.**

**Vitiligo and Alopecia Areata Medication Coverage on Medicaid in the US**

| Medication | # of States w/ Specified Coverage | # of States w/ Unspecified General Coverage | # of States w/ PA Required | # of States w/o Coverage (4) | # of States w/ Drug Not on Formulary | # of States w/o Public Formulary |
|---|---|---|---|---|---|---|
| Ritlectinib (Litfulo) | 0 (0.00%) | 0 (0.00%) | 14 (27.45%) | 5 (9.80%) | 31 (60.78%) | 1 (1.96%) |
| Baricitinib (Olumiant) | 1 (1.96%) | 0 (0.00%) | 30 (58.82%) | 14 (27.45%) | 5 (9.80%) | 1 (1.96%) |
| Ruxolitinib (Opzelura) | 0 (0.00%) | 1 (1.96%) | 9 (17.65%) | 33 (64.71%) | 7 (13.73%) | 1 (1.96%) |
| Benoquin (Hydroquinone) | 0 (0.00%) | 0 (0.00%) | 0 (0.00%) | 3 (5.88%) | 47 (92.16%) | 1 (1.96%) |
| Protopic (Tacrolimus) | 0 (0.00%) | 11 (21.57%) | 8 (15.69%) | 30 (58.82%) | 1 (1.96%) | 1 (1.96%) |
| Elidel (Pimecrolimus) | 0 (0.00%) | 10 (19.61%) | 8 (15.69%) | 30 (58.82%) | 2 (3.92%) | 1 (1.96%) |

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## DISCUSSION

Alopecia areata and vitiligo are not cosmetic diseases, but rather, they profoundly impact quality of life, mental health, and impose economic burdens on patients.[1,2] The FDA has approved safe and effective JAK inhibitors for treatment, but CMS has failed to determine these treatments as reasonable and necessary. Resulting prior authorizations and complex formularies inherently limit a dermatologist's ability to utilize guideline-directed medical therapy. Failing to provide coverage for these effective therapies disproportionately and inhumanely impacts low socioeconomic populations that constitute the majority of Medicaid beneficiaries that exhibit substantial price sensitivity.[5] These individuals do not have the means to pay for medications not covered in these formularies and federal regulations prevent them from using standard pharmaceutical-sponsored patient assistance programs that are readily available to commercially insured patients. Ritlecitinib, baricitinib, ruxolitinib, monobenzyl ether of hydroquinone, tacrolimus, and pimecrolimus are medications that must be covered in every state in the nation to rectify this healthcare inequity. This letter serves as a call to action to CMS and our respective state healthcare departments to recognize their oversight of these important treatments and to provide coverage for these essential medications.

## DISCLOSURES

There were no sources of funding for this study. Apoorva Mehta is Chief of Staff at SkinCheck. Nikhita Perry and Iain Encarnacion have no conflicts of interest to disclose. Dr Nicholas Mollanazar serves as an advisory board member for Boehringer Ingelheim, Janssen, Novartis, Regeneron Pharmaceuticals Inc., Sanofi, Trevi Therapeutics, Menlo Therapeutics Inc., Galderma, Leo Pharma, AbbVie, Pfizer, and Beiersdorf; as an investigator for Sanofi, Regeneron Pharmaceuticals Inc., and Genzyme; and acts as a consultant for Novartis, Regeneron Pharmaceuticals Inc., Sanofi, Janssen, and AbbVie. Dr Susan Taylor: Reports service as an investigator for Concert Pharmaceuticals, Croma-Pharma, Eli Lilly, and Pfizer. Dr Taylor has received salaries, fees, honoraria, and stock options as a consultant, advisor, board member, and speaker for Mercer Strategies, AbbVie, Arcutis Biotherapeutics, Armis Scientific, Beiersdorf, Biorez, Cara Therapeutics, EPI Pharma, Evolus, Galderma Laboratories, Glo Getter, Hugel America, Janssen, Johnson &, L'Oreal, Medscape/WebMD, MJH Life Sciences, Piction Health, Regeneron, Scientis US, UCB, and Vichy Laboratories.

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