



ISSN: 2578-3335 (Print) 2578-3343 (Online)

Volume 5 | Issue 1

Article 5

2023

A tale of two situations: a case report of the merger between dermatology outcomes and prescription drug access

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Recommended Citation

Ye, Kara; Amellal, Yasseen; Evans, Will; and Rohr-Kirchgraber, Theresa (2023) "A tale of two situations: a case report of the merger between dermatology outcomes and prescription drug access," *Cooper Rowan Medical Journal*: Vol. 5: Iss. 1, Article 5.

DOI: 10.31986/issn.2578.3343_vol5iss1.5

Available at: <https://rdw.rowan.edu/crjcsn/vol5/iss1/5>





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A tale of two situations: a case report of the merger between dermatology outcomes and prescription drug access

Case Reports and Case Series

A tale of two situations: a case report of the merger between dermatology outcomes and prescription drug access

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Keywords: Psoriasis, insurance, ixekizumab, cost, uninsured, patient assistance programs (PAPs), prior authorization

https://doi.org/10.31986/issn.2578.3343_vol5iss1.5

Cooper Rowan Medical Journal

This case report illustrates a case of guttate psoriasis in a young adult and the logistical role dermatologists can play in patients acquiring their prescriptions and improving the quality of their care.

CASE DESCRIPTION

A 23-year-old male of Black and Arab descent with Fitzpatrick type IV skin presented with a 2-week history of progressively worsening coin-shaped erythematous plaques on his trunk, upper, and lower extremities, encompassing 15% body surface area. A diagnosis of guttate psoriasis was made by a dermatologist. After failing a trial of two different topical corticosteroid creams over the course of 2 months, ixekizumab was recommended because of contraindications to methotrexate and phototherapy. The patient's health insurance company denied coverage of this medication due to a required 3-month trial of topical corticosteroids and methotrexate. Without insurance, ixekizumab's cost for 1 month of therapy was an unaffordable \$13,000. Over the next few days, the dermatologist and office staff collaborated with the patient to access the medication through ixekizumab's manufacturer's patient assistance program (PAP). With this program, the patient was able to obtain monthly deliveries of ixekizumab for \$25 per month for the next 12 months. Marked improvement with ixekizumab was noted with subsequent mild post-inflammatory hypopigmentation.

LEARNING OBJECTIVES

- Overview of guttate psoriasis, current treatment options, and prognosis.
- Discuss the role health insurance plays in medication coverage and barriers to coverage.
- Define patient assistance programs (PAPs) and identify pathways to utilize them.
- Discuss the role of PAPs in obtaining non-covered and/or costly medications.

INTRODUCTION

Many Americans rely on health insurance as protection from unpredictable and financially catastrophic events¹; however, what are the options for patients whose health insurance denies coverage of medications, testing, or procedures? The financial burden and cost of medicine remains one of the most significant barriers to patient compliance.^{2, 3} This delay or failure to initiate therapy leads to increased morbidity and mortality.

Psoriasis is a chronic inflammatory skin condition that manifests as sharply demarcated, erythematous, scaly plaques most commonly on the scalp and extensor surfaces of the knees and elbows; however, any area of the skin can be affected.⁴ Patients often experience psychological stress and embarrassment about the appearance of their skin, low employment rates, and decreased quality of life⁵⁻⁷ akin to other debilitating chronic health conditions, such as coronary heart disease, diabetes, and asthma.⁸ Therefore, prompt treatment is critical to reducing these burdens. The cost of long-term therapy with various immunomodulators may hinder patient compliance, and delays in obtaining affordable treatment can have negative impacts on the quality of care. This case illustrates the role of dermatologists coupled with PAPs as a powerful resource for medication access.

DISCUSSION

Guttate psoriasis, a less common variant of psoriasis, is characterized by the eruption of small, scaly papules over the upper trunk and proximal extremities. The condition occurs most commonly in children and young adults and is frequently preceded by a streptococcal throat infection.⁹ While the pathophysiology is not well understood, one proposed mechanism suggests a cross-reactivity between streptococcal M-proteins and structurally similar type I

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keratins in the epidermis that triggers a T-cell mediated autoimmune response.¹⁰ An autoimmune pathogenesis is supported by a strong association between individuals with the HLA-Cw6 allele and development of psoriasis.¹¹ Clinical examination is usually sufficient for diagnosis.

The clinical course of guttate psoriasis is variable. Some cases spontaneously remit within weeks to months, while others may have recurring symptoms or progress into chronic plaque psoriasis.¹² First-line therapies include phototherapy and topical corticosteroids; topical vitamin D analogs may also be used solely or in conjunction with corticosteroids.¹³ For refractory disease, systemic therapy with biologic or other immunomodulating therapies may be used. Among these agents is ixekizumab, an approved therapy for moderate-to-severe plaque psoriasis in adults that reduces inflammation by selectively inhibiting IL-17A.¹⁴ While some medications such as adalimumab and etanercept are covered by nearly all health insurance plans, more recently-approved biologics, such as ustekinumab, secukinumab and ixekizumab, are covered by only 70-80% of plans.¹⁵ Our patient was denied ixekizumab because he did not meet the criteria of completing a 3-month trial of methotrexate.¹⁶ Our patient was unwilling to initiate this medication secondary to concern of the side effect of hepatotoxicity. Young adults aged 19-34 years old face tremendous barriers to medication coverage as the highest underinsured and uninsured group compared to any other age demographic.¹⁷ In addition, health insurance companies may require additional documentation or justification for the use of specialty medications for any age group, which further delays or complicates the approval process. PAPs are orchestrated by prescription drug manufacturers to provide particularly needed specialty medications at little or no cost based on varying factors delineated by each program.

PAPs sometimes may be used in addition to private insurance, Medicare, and Medicaid. Each company varies in the qualifications and amount of information required in the PAP application, with some programs requesting detailed medical and financial information. Most PAP applications have a portion for the physician to complete, and all programs require physician approval/signature. PAP enrollment periods are usually 12 months in length, and patients usually reapply at the end of the enrollment period, as illustrated by this case.

Even though there are an estimated 475 different PAPs across the country that provide over \$13 billion worth of medication to patients in need,¹⁸ many physicians and pharmacists find these programs tedious and difficult to navigate.¹⁹ PAP requirements are often updated by drug manufacturers, therefore the best place to find the most recent up-to-date information on PAPs is through social workers, pharmaceutical representatives, clinical pharmacists and web-based searches by the prescriber and/or clinical team. Useful sources include [NeedyMeds.org](https://www.NeedyMeds.org), which provides reliable, up-to-date information about PAPs as well as copies of applications. The cost of searching for a PAP and completing the forms is uncompensated time on the part of the physician and practice.

In our case, the patient met the requirements for the ixekizumab PAP which supports US citizens or legal permanent residents, patients with no insurance coverage for the medication or Medicare Part D, and patients with household annual adjusted gross income <500% the federal poverty guideline (<\$72,900 per 1 person household).²⁰ With the PAP, the patient was able to obtain ixekizumab for \$25 per month versus a list price of \$13,172 per month. The process for applying was straightforward in this case, as the patient was able to complete and submit the application at the physician's office. The first shipment of ixekizumab arrived a few weeks later, and the patient's symptoms significantly improved soon after.

CONCLUSION

Health insurance denial for medication coverage negatively impacts a patient's ability to obtain medication in a timely manner leading to possible disease progression and poorer outcomes. Moreover, prompt management can prevent comorbid health conditions particularly in psoriasis, such as depression and anxiety.²¹ Psoriasis is associated with negative self-image and increased psychological distress,² therefore, appropriate and expedient therapy can positively impact mood and outlook. Physicians and other healthcare providers are powerful resources as they can reach out to drug manufacturers, aid patients in submitting PAPs, and consult allied professionals like social workers and clinical pharmacists to provide patients necessary prescriptions and timely disease management and hopeful resolution.

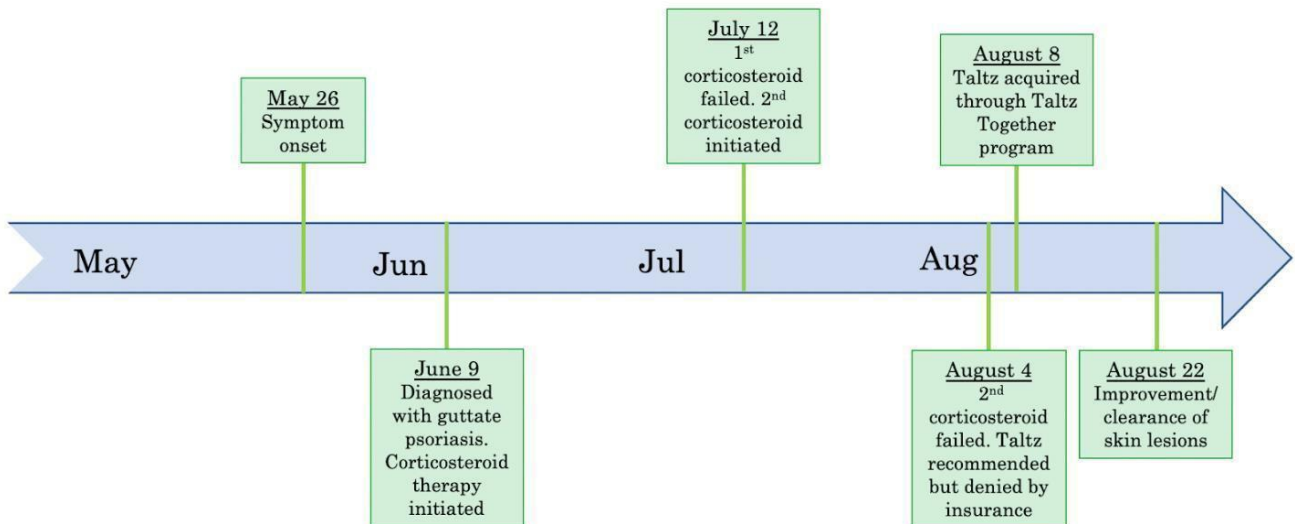


Figure 1. Timeline of events

- **May 26:** Patient noticed small “spots” appearing on his forearm.
- **June 4:** Patient scheduled an appointment at a health clinic as the spots had progressed to new areas of the body.
- **June 5:** Patient was referred to a dermatologist for suspected guttate psoriasis.
- **June 9:** Diagnosis of guttate psoriasis was confirmed by the dermatologist, and daily a super-potent corticosteroid cream (Halobetasol propionate 0.01%) was prescribed.
- **July 12:** Patient had slight symptomatic improvement but reported side effects such as skin atrophy on arms and increased appetite. Additionally, mental health drastically deteriorated for the patient, who stated “I wasn’t able to get out of bed most days.” Patient was switched to moderate strength corticosteroid cream (Triamcinolone acetonide 0.01%) BID due to these side effects.
- **August 4:** With only minimal improvement on the corticosteroid creams, the patient was consulted on use of the biologic medication ixekizumab.
- **August 6:** The patient’s health insurance denied coverage for ixekizumab. Patient applied to the PAP per his dermatologist’s recommendation.
- **August 8:** Taltz Together was approved within 3 days.
- **Current and Future:** This PAP requires reapplication every year, and currently covers up to 36 months of medication. The PAP applies to patients with active insurance who get denied coverage of ixekizumab. Patients with no insurance would pay around the list price \$13,000 per month.



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