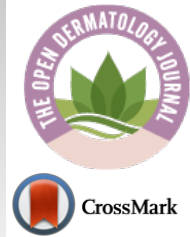




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RESEARCH ARTICLE

Sequelae from Financial Toxicity of Biologics and JAK Inhibitors in the United States: Health Insurance Companies May Eliminate Dermatology from the List of Specialists in their Physician Panels

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Dear Editor,

The cost of health care is escalating at alarming rates in the United States. There are real issues regarding affordability and access under the system today. US health care is unsustainable in its present course, and changes are imminent. Insurance companies are forced to consider various methods to rein in these costs. It seems evident that some of these innovative measures might restrict access to non-life-threatening diseases. With these concerns, I wish to sound the alarm to my specialty of dermatology as we, and specifically the prescriptions we write, might just be pricing ourselves out of future affordable health insurance plans. I pray I am merely following the famous finger-wagger Thomas Malthus, who said that the world population would grow so large that we won't be able to feed ourselves anymore.

In the US, the expenditure for health care is five times the amount we spend on defense and three times more than education. Health insurance premiums are ridiculously high and are due to get significantly higher. The average costs that U.S. employers pay for their employees' health care will increase 6.5 percent to more than \$13,800 per employee in 2023, up from \$13,020 per employee in 2022 [1]. If health insurance premiums continue to outpace national wage increases, the average cost of a family health insurance premium will surpass the average household income by the year 2033 [2]. Rising healthcare costs are wiping out almost all income growth. Obviously, the status quo in terms of health insurance coverage is not practical or possible [3].

End payers struggle to cope with health care costs and have had to shift the cost to employees. This has led to high-deductible health plans, coinsurance, increasing employee cost

sharing, and optimizing provider networks. Consumers on average face an annual cost of \$8000 to \$12000 [3]. This strains their usable income and has led to rising debt due to medical bills. Consumers' satisfaction with employer-sponsored healthcare coverage is lower than with Medicare, Medicaid, or individual health insurance exchange coverage [3]. Pharmaceutical costs have also increased, causing more out-of-pocket costs many cannot afford.

In the past, the healthcare industry was rigid and non-malleable. However, under recent stresses, changes happen more quickly. Examples include the growth of telehealth office visits during COVID and the sudden absence of abortions in some states, occurring almost overnight. In short, alterations in a healthcare coverage policy could transpire quickly if necessitated by dire financial concerns.

To survive, health insurance are left with some options, including more effective care delivery, and more effective deployment of advanced AI. However, the main area would be waste reduction (for example, elimination of common low-value procedures or treatments) [4]. Some items are already absent from some plans, including fertility testing, sleep disorders, dental procedures, obesity, and abortion. All insurances will continue to offer "essential" health benefits coverage, and they will not charge the insured or refuse to pay for such conditions. However, the "essential health benefits" list can be altered yearly when insurers outline their new coverage plans.

All of the medical specialties might go outside essential medical services at times, but this editorial will only examine my specialty, dermatology.

Cosmetic goods and procedures are not covered by health care insurances, and so is outside our concerns of insurance costs. But it might reflect on how our specialty appears to the healthcare industry. Cosmesis would include endogenous

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growth factors or endogenous blood-derived products, platelet-rich plasma, medical microneedling for traumatic/acne/surgical scars, striae distensae, enlarged pores, and rhytides. Most dermatologists sell expensive skin care products, which makes some people remember George Constanza's comment in the Slicer episode of Seinfeld when he discussed a female dermatologist by stating, "Saving lives? She's one step above working at the Clinique counter." This emphasis on cosmesis could be an image problem for dermatology to insurance who concentrate on essential health services.

Dermatology is not an inexpensive specialty. The national average of a first office visit at \$124 is higher than other specialties. The cost of supplies and equipment used in dermatology might be a factor for this high price. Office visits to dermatologists are more often associated with more out-of-pocket expenses than other specialties. Some dermatologists perform expensive procedures such as laser surgery, skin grafts, Mohs surgery, scar revision, and radiation therapy. In 2014, a New York Times article entitled "Paying till it hurts: Patients costs skyrocketed and spending income soars", [5] highlighted that a few Mohs surgeons overcharge and overtreat. Charges were over \$25,000 for the removal of small basal cell carcinomas. Such articles affect the image of our specialty but are not the primary cause for potential insurance limitations.

The most significant cost seen by insurance companies is dermatologists' frequent use of newer, extremely expensive, highly advertised medications. In this category would include biologics and JAK inhibitors. The skyrocketing drug prices of these agents can easily exceed \$100,000 per product per year per patient. These agents are used for skin conditions such as psoriasis, vitiligo, alopecia areata, prurigo nodularis, and atopic dermatitis. Reports indicate these treatments will soon expand to include hand dermatitis, seborrheic dermatitis, and skin itch [6]. These treatments tend to be improvements over present treatments, but they do not cure conditions. These diseases are chronic and these expenses continue to be incurred annually. Some patients fail to respond to these treatments, and some are placed on combinations of these agents. They do not improve health (as defined by most insurance companies) or extend life. These agents routinely have black box warnings suggesting risks of major adverse cardiovascular events, venothrombotic events, malignancy, and infections. Not to downplay the frustration and anxiety associated with any of these diseases, but insurance companies have to assess these costs *versus* treating heart disease, COVID, breast cancer surgery, and pneumonias. Insurance companies have to assess the use of all exorbitantly priced pharmaceuticals in times of limited finances.

Published comments by "leading dermatology experts" in the use of these new drugs are insightful. "If someone came in with mild atopic dermatitis that did not immediately clear up within two days of using a topical steroid, I would put them on a systemic (agent). Cost is really the only thing that is preventing me from using systemics almost universally." [7] "We are now looking at \$100,000 a year (per patient) for eczema treatment." [7] These "experts" universally suggest disregarding any FDA black box warnings for these drugs and avow they are mere "FDA guidelines." [8] On the other hand, if any agent gets FDA approval, then a green light is given, allowing extensive prescribing with no regard to costs. "We

have FDA-approved drugs that insurance now can cover." [9] They suggest that such agents are not just for recalcitrant cases, but for any case "with uncontrolled disease" even including itch without any visible skin lesions [8]. They further suggest that as physicians, we strive for patients to be clear or almost totally clear of all rashes as well as totally itch-free [8]. Patients, in their eyes are often undertreated. They also have little respect for the cost, as noted by "you get these high school dropouts who are running insurance panels which tell us, oh yeah, they should have this much X a month." [9] In terms of combination treatments, the panel stated, "there's no atopic dermatitis patient on the planet who is going to use only one agent." [8] Combination therapies include having a patient on JAK inhibitor as well as a biologic. They acknowledge that even with these expensive agents, there are failures. "I have several patients who failed on biologics, then failed with a JAK inhibitor, and then I tried putting them on both, together, and I have not seen it to be a real additive effect." [7].

There is a natural tendency to associate more advanced technology and newer procedures with better care, even if there's little to no evidence to prove that they're more effective. This assumption leads both patients and doctors to demand the newest, and often most expensive, treatments and technology available. Sometimes physicians as a group might not be able to temper the use of such agents with costs that the system can tolerate. This leads to healthcare insurance having to put limitations and exclusions on usage. Limitations are conditions or procedures covered under a policy but at a benefit level lower than the norm. Exclusions, on the other hand, are conditions or procedures that are completely omitted from coverage. Given the increasing rise of healthcare costs, one can assume the list of limitations and exclusions would increase. The specialty of dermatology could be part of a new set of limitations and exclusions are given the excessive and outrageously expensive systemic and topical treatments of non-essential non-life-threatening conditions. Hopefully, these restrictions will be limited to these new agents and not to the practice of medical and surgical dermatology.

A major issue is also direct-to-patient advertising. Despite some intent to educate, drug prescription ads are inherently complicated by financial incentives [10, 11]. In many cases, pharmaceutical spending on advertising exceeds spending on research and development. These advertisements empower patients and improve their conversations about medications. In fact, declining a prescription request threatens the doctor-patient relationship [10, 11]. The clinician must use sound clinical judgment when approached with a prescription request. The FDA oversees all prescription advertising, but it is a cumbersome and overextended entity that is asked to monitor too many products without the tools, funding, manpower, or time to complete tasks [12]. Also drug ads do not need to be approved for compliance prior to being released to the public. The World Health Organization has advocated that drug pricing be considered to minimize inappropriate prescribing. Presently, the FDA requires that all products claim prescription drug ads (the typical, specific medication advertisement):

1. Give at least one approved use of the drug.
2. Provide the generic name of the drug.
3. Share all adverse effects listed in the drug's "prescribing information."

4. Adding a fourth requirement, the full, exact pricing to uninsured individuals would be helpful as the public ultimately has to decide where our limited resources in health care should go, and what costs are reasonable. If Big Pharma is embarrassed by its pricing, then they can lower it.

It is preposterous to imagine that dermatology would be excluded from an insurance panel. However, it is even more preposterous that Big Pharma (by way of direct-patient advertising as well as by recruiting services of some leaders in dermatology) is dispensing medications costing \$100,000 per year for even mild cases of atopic dermatitis, seborrheic dermatitis, hand dermatitis, alopecia areata, vitiligo, psoriasis, hidradenitis, prurigo nodularis, and even itchy skin. These are not life or limb-threatening sets of problems. Let's not forget that we have 30 million in America with no health coverage at all. This allocation of major yearly dollar amounts to individual cases of a chronic skin rash is part of a whole system that cries out for public oversight. From some vantage points, this is nefarious. Forces are present to challenge affordability and access in dermatology and threaten the specialties' economic viability.

CONCLUSION

If the standard watchdogs (FDA, Academy of Dermatology, and leading dermatologists) are obtaining financial benefits from allowing Big Pharma to continue their ways, and the public is disillusioned by pharmaceutical advertising, who is left to lead our specialty to reasonable financial accountability?

AVAILABILITY OF DATA AND MATERIALS

The authors confirm that the data supporting the findings of this study are available within the article.

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CONFLICT OF INTEREST

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