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JAMA Dermatology | Original Investigation

Medicare Part D Payments for Topical Steroids Rising Costs and Potential Savings

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IMPORTANCE Rising pharmaceutical costs in the United States are an increasing source of financial burden for payers and patients. Although topical steroids are among the most commonly prescribed medications in dermatology, there are limited data on steroid-related spending and utilization.

OBJECTIVE To characterize Medicare and patient out-of-pocket costs for topical steroids, and to model potential savings that could result from substitution of the cheapest topical steroid from the corresponding potency class.

DESIGN, SETTING, AND PARTICIPANTS This study was a retrospective cost analysis of the Medicare Part D Prescriber Public Use File, which details annual drug utilization and spending on both generic and branded drugs from 2011 to 2015 by Medicare Part D participants who filled prescriptions for topical steroids.

MAIN OUTCOMES AND MEASURES Total and potential Medicare and out-of-pocket patient spending. Costs were adjusted for inflation and reported in 2015 dollars.

RESULTS Medicare Part D expenditures on topical steroids between 2011 and 2015 were \$2.3 billion. Patients' out-of-pocket spending for topical steroids over the same period was \$333.7 million. The total annual spending increased from \$237.6 million to \$775.9 million, an increase of 226.5%. Patients' annual out-of-pocket spending increased from \$41.4 million to \$101.8 million, an increase of 145.9%. The total number of prescriptions were 7.7 million in 2011 and 10.6 million in 2015, an increase of 37.0%. Generic medication costs accounted for 97.8% of the total spending during this time period. The potential health care savings and out-of-pocket patient savings from substitution of the cheapest topical steroid within the corresponding potency class were \$944.8 million and \$66.6 million, respectively.

CONCLUSIONS AND RELEVANCE Most topical steroids prescribed were generic drugs. There has been a sharp increase in Medicare and out-of-pocket spending on topical steroids that is driven by higher costs for generics. Use of clinical decision support tools to enable substitution of the most affordable generic topical steroid from the corresponding potency class may reduce drug expenditures.

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ising pharmaceutical costs in the United States are a source of increasing financial burden for payers and patients. Increased pharmaceutical costs are often attributed to novel agents that require funding for development and testing. Although generic drugs are usually cheaper, a paradoxical phenomenon of increasingly prohibitive prices for many older generic drugs has emerged in recent years.

Costs associated with brand name and generic medications vary by payer, pharmacy, and state, which makes systematic analysis of national health care spending on any given drug class challenging. A recent analysis of 26 selected brandname and generic dermatologic medications at 4 pharmacies in Florida between 2009 and 2015 demonstrated mean price increases of 401% and 279%, respectively. ^{3,4} While the impact of increased drug prices on system-wide dermatology and patient expenditures has not been assessed, individual reports suggest that the increased prices are formidable barriers to medication adherence. ⁴⁻⁶

In this study, we examine drug utilization and costs for both generic and branded topical steroids within Medicare Part D from the perspective of the payer and patients and model the potential savings from identification and dispensing and/or prescribing the cheapest topical steroid within each potency class. Our analysis is based on the Medicare Part D Prescriber Public Use File, which was released by the Centers for Medicare and Medicaid Services in December 2016 and details annual drug utilization and spending on both generic and branded drugs between 2011 and 2015.⁷

We chose to focus on topical steroids because they are used to treat a broad range of dermatoses, are among the most commonly prescribed agents in dermatology, and often require a prescription, enabling us to capture drug utilization and expenditures via a prescription insurance database.^{8,9}

Methods

Data Set

We evaluated population-based claims data from the Medicare Part D Prescriber Public Use File, which provides prescription costs for approximately 70% of Medicare beneficiaries with a Medicare Part D prescription drug plan between 2011 and 2015. Information provided by the Medicare Part D Public Use File includes the brand name, generic name, claim count (including refills), unit count (total dosage units in grams or milliliters), average cost per unit, beneficiary count, average beneficiary cost share, total annual spending per user, and total spending by Medicare. This study was granted institutional review board exemption by Partners Healthcare.

Topical Steroid Inclusion and Exclusion Criteria

We identified all generic and branded cream, ointment, and lotion formulations of topical steroids. We excluded prescriptions for topical steroids with proprietary or noninterchangeable vehicles such as gels, foams, oils, body washes, and shampoos. We also excluded topical steroids that were combined

Key Points

Question What are the trends, drivers, and potential modifiers of Medicare spending on topical steroids?

Findings In this retrospective analysis of Medicare Part D claims data between 2011 and 2015, Medicare spent \$2.3 billion on topical steroids; spending increased 226.5%, while prescriptions increased 37.0%. If prescribers had written for the cheapest topical steroid within the same potency class, Medicare could have saved \$944.8 million.

Meaning Medicare spending on topical steroids continues to rise, largely owing to increased medication costs for generic drugs; encouraging physicians to prescribe the cheapest topical steroids within a given potency group may decrease health care expenditures without compromising patient outcomes.

with other active ingredients or pharmaceutical agents, such as combination topical steroid and antifungal agents. The database included 1008 pharmaceutical agents commonly prescribed by dermatologists, and 2 reviewers (A.A. and A.M.) narrowed the list to 102 agents containing topical steroids. Two reviewers (H.S. and A.M.) applied inclusion and exclusion criteria, resulting in 32 total topical steroids included in the study (eTable 1 in the Supplement).

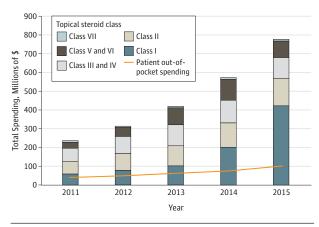
Classification of Topical Steroids

All topical steroids were classified by potency classes I through VII according to the US system. The Medicare Public Use File data for topical steroids were aggregated across all dosages and strengths, such that different strengths (eg, 0.25% vs 0.1%) of the same compound could not be distinguished. We grouped the topical steroids by potency into 5 main groups: class I, class II, classes III and IV, classes V and VI, and class VII (eTable 1 in the Supplement). When medications fell into multiple steroid classes owing to different drug delivery vehicles and/or prescription strengths, two reviewers (A.A. and A.M.) evaluated all associated classes to categorize the medication into 1 of the 5 groups. One reviewer (A.M.) evaluated the topical steroids within each of the 5 groups for interchangeability in clinical practice.

Cost Calculations

We calculated Medicare spending based on total spending data, and the potential health care system savings by modeling the total savings if each beneficiary incurred the average annual cost for the cheapest topical steroid within the same potency group. Total out-of-pocket patient spending was determined by analyzing beneficiary counts and average beneficiary cost shares, which reflect the amount that beneficiaries paid that was not reimbursed by a third party. Potential annual out-of-pocket patient savings were estimated by modeling the savings if all beneficiaries paid the average beneficiary cost share for the cheapest topical steroid within the potency group. All values were adjusted for inflation rates and reported in 2015 dollars (eTable 2 in the Supplement).¹⁰

Figure 1. Total Medicare Part D Spending on Topical Steroids by Potency Class, 2011 to 2015



Each bar represents total Medicare spending, and the orange line graph represents the proportion that is out-of-pocket costs for patients.

Results

Economic Spending on Topical Steroids

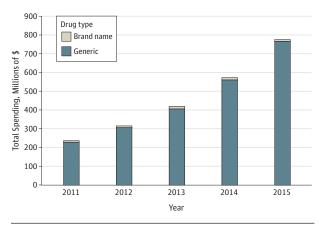
A total of \$2.3 billion (47.5 million prescriptions) was spent on topical steroids between 2011 and 2015 (**Figure 1**). The total annual spending increased from \$237.6 million (7.7 million prescriptions) to \$775.9 million (10.6 million prescriptions), an increase of 226.5%. Patients paid a total of \$333.7 million out-of-pocket for topical steroids between 2011 and 2015 (**Figure 1**). Patients' annual out-of-pocket spending increased from \$41.4 million to \$101.8 million, an increase of 145.9%. The annual number of prescriptions increased 37.0%. Generics accounted for 97.8% of the total spending between 2011 and 2015 (**Figure 2**). Costs associated with class VII steroids had the slowest rate of growth (22.5%), while costs of class I steroids had the highest (604.4%). Within class I steroids, the change in average user spending (605.3%) was highest for clobetasol propionate (eTable 3 in the Supplement).

Potential Savings on Topical Steroids Within Current System We calculated potential savings by determining the total health care and patient costs if all beneficiaries had received the cheapest generic topical steroid within their potency group. We identified total potential health care savings between 2011 and 2015 of \$944.8 million (Figure 3). Potential savings increased from \$82.1 million in 2011 to \$422.8 million in 2015. The total potential out-of-pocket patient savings were \$66.6 million, increasing from \$8.1 million in 2011 to \$25.5 million by 2015.

Prescribing Patterns

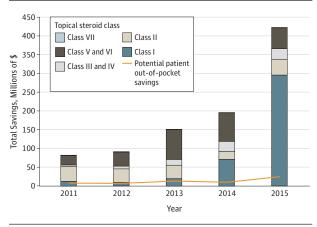
The proportion of prescriptions written for the cheapest topical steroid within each corresponding potency group varied by potency class and year (Table). Prescriptions for the cheapest topical steroid decreased from 78.5% to 10.5% for class I steroids, and decreased from 57.6% to 30.7% for class II steroids between 2011 and 2015. The prescriptions for the cheap-

Figure 2. Total Medicare Part D Spending on Brand and Generic Topical Steroids, 2011 to 2015



The blue portion represents total Medicare spending on generics, and the gray portion represents total Medicare spending on brand-name agents.

Figure 3. Total Medicare Part D Potential Cost Savings by Potency Class, 2011 to 2015



Each bar represents potential Medicare savings, and the orange line graph represents the proportion that could be out-of-pocket savings for patients.

est class V and VI steroids increased from 1.3% to 74.1%, once a less used and cheaper alternative, Beta-Val (betamethasone valerate), was no longer prescribed, and hydrocortisone, a more commonly prescribed agent, became the cheapest alternative in 2014. There was less fluctuation in the prescriptions of the most affordable agents in class III-IV (from 87.5% to 90.6%) and class VII (from 96.8% to 99.5%).

Discussion

The total cost for topical steroids in the Medicare Part D program between 2011 and 2015 was \$2.3 billion. The percentage increase in total Medicare and out-of-pocket patient spending was 226.5% (from \$237.6 million to \$775.9 million) and 145.9% (from \$41.4 million to \$101.8 million), respectively, despite only a 37.0% increase (from 7.7 million to 10.6 million)

Table. Prescription Claims for Topical Steroids, 2011 to 2015					
Year	2011	2012	2013	2014	2015
Total claims, No.	7 734 302	8 683 810	9 955 241	10 533 710	10 593 293
Claim increase compared with 2011, %		12.3	28.7	36.2	37.0
Cheapest claims within class, No.	5 198 602	5 939 899	6 940 162	6 820 451	6 646 131
Cheapest claims within class, %	67.2	68.4	69.7	64.8	62.7
Class I	78.5	80.4	82.5	10.3	10.5
Class II	57.6	59.3	59.4	59.8	30.7
Classes III and IV	87.5	88.0	88.8	89.5	90.6
Classes V and VI	1.3	0.1	0.01	67.8	74.1
Class VII	96.8	97.5	99.0	99.6	99.5

in total prescriptions. The disproportionate increase in aggregate drug spending compared with claims suggests that the increase in spending is likely largely due to rising drug prices. Both patients and the health care system bear the financial burden of these higher costs.

Our findings support and expand on the literature on the impact of rising pharmaceutical costs for payers and patients. Although increased spending is often attributed to novel agents, our findings demonstrate that both Medicare cost increases and spending on topical steroids are primarily associated with generic pricing. The increase and variability in pricing of generic topical steroids within any given potency class challenge clinicians' ability to practice cost-effective medicine.⁴ These findings are anathema to an emerging culture focused on identifying and promoting value in dermatologic care.^{3,4,11-13}

The US Senate Special Committee on Aging recently released a report ¹⁴ on Medicare Part D spending that delineates how pharmaceutical companies have acquired previously affordable, generic medications, and dramatically increased prices. The rate of price increases of dermatologic agents outpaces those of inflation and national health care expenditure. ^{3,4} Our study demonstrates the impact of increased pharmaceutical costs of dermatologic agents at the national and patient level. Pharmaceutical costs especially have an impact on the care of elderly subscribers of Medicare, who are vulnerable to cost-related medication nonadherence. ¹⁵⁻¹⁷

While broad health-policy approaches to improve unpredictable drug market dynamics are needed, clinicians can moderate total health care spending within the current system. The percentage of claims for the most affordable agent within class I decreased from 78.5% to 10.5% between 2011 and 2015 as clinicians continued to prescribe clobetasol propionate despite its 6-fold increase in cost. The simple substitution of betamethasone dipropionate for all class I steroid prescriptions would have led to Medicare savings of \$295.6 million in 2015 alone. Some physicians may be indifferent to increasing drug costs, but others may be unaware or have higher clinical inertia. This data source could not identify characteristics of prescribers, including prescriber specialty, but it is possible that nondermatologist prescribers may also be less familiar with the interchangeability within topical steroid potency classes.

All clinicians, including dermatologists, could potentially benefit from electronic medical record resources that provide up-to-date information on the most affordable

agents.¹⁸ Active clinician support at the time of prescribing would need to account for a variety of factors, including market dynamics, geographical variation, and pharmaceutical coverage to determine the cheapest agent within a desired steroid class, and prompt physicians to prescribe this agent when they consider dispensing a more expensive agent from the same class.

Limitations

Our results must be considered within the context of this study design. This data set does not take drug manufacturer rebates into account, as the law prohibits disclosure of this information. The patient population in this study may not be generalizable. Clinical practice patterns and spending figures may be different in other non-Medicare populations. Physicians may also prefer certain drugs within the same therapeutic class for specific clinical reasons, although agents within the same potency class are often interchangeable. Future studies are needed to determine the generalizability of our findings and to evaluate our proposals for reducing costs.

Despite these limitations, our analysis most likely underestimates the true cost of topical steroids in this patient population. The data were limited to medications included in the Part D program, and patients may obtain similar drugs through supplemental coverage. It is also possible that patients paid out-of-pocket for their prescriptions if cheaper than their copay. While we focused on pharmaceutical costs, we could not quantify clinician and/or payer administrative costs or patient-related opportunity costs associated with switching prescriptions owing to expense. Significant costs may also be associated with newer or combination formulations that were excluded from this analysis.

Conclusions

There is tremendous health care spending on topical steroids. It is imperative that health policies emerge that regulate pharmaceutical company practices and improve transparency surrounding drug costs. ¹⁴ Until that time, interventions such as electronic medical record-based clinician support may allow clinicians to prescribe the most affordable topical steroids available on the market, ensuring efficacy while minimizing costs. Without these efforts, routine medications may become prohibitive in cost for our patients.

ARTICLE INFORMATION

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Author Contributions: Drs Adamson and Mostaghimi had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. Ms Song and Dr Adamson contributed equally to this work. Study concept and design: Adamson, Mostaghimi. Acquisition, analysis, or interpretation of data: All authors.

Drafting of the manuscript: Song, Mostaghimi. Critical revision of the manuscript for important intellectual content: All authors.

Statistical analysis: Song, Mostaghimi. Administrative, technical, or material support: All authors.

Study supervision: Adamson, Mostaghimi.

Conflict of Interest Disclosures: None reported.

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