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Drug Pricing Stewardship from Mark Cuban's Cost Plus Generic Drug Program

Snigdha Gulati MBBS[1], Mohak Gupta MBBS[2], TingTing Yan AB[3], Sneha Yelamanchili AB[3], Lucy Qinghua Xu AB[3], Tina Bharani MD[4], Ali Naji MD PhD[5], Divyansh Agarwal MD PhD[6,7,ζ]

1 Department of General and Thoracic Surgery, Cleveland Clinic, Cleveland, OH 44195
2 Department of Internal Medicine, Cleveland Clinic, Cleveland, OH 44195
3 Faculty of Arts & Sciences, Harvard University, Cambridge, MA 02138
4 Department of Surgery, Thomas Jefferson University Hospital, Philadelphia, PA 19107
5 Department of Surgery, University of Pennsylvania Perelman School of Medicine, Philadelphia, PA 19104
6 Department of Surgery, Massachusetts General Hospital, Boston, MA 02114
7 Massachusetts Institute of Technology, Cambridge, MA 02139

[ζ] To whom correspondence may be addressed:

Divyansh Agarwal, MD PhD
Massachusetts General Hospital, Harvard Medical School
55 Fruit St., GRB 425,
Boston MA 02114
(267) 334-8324
dagarwal@mgh.harvard.edu
agarwald@mit.edu

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ABSTRACT

Importance: The exceedingly high U.S. spending per capita on prescription medications is mediated, at least in part, by the inefficiencies of existing generic pharmaceutical distribution and reimbursement systems. Yet, the extent of potential savings and areas for targeted interventions for generic drug prescribers remains underexplored.

Objective: To analyze the 2021 Medicare Part D spending on generic drugs in comparison with pricing of a low-cost generic drug program, Mark Cuban Cost Plus Drug Company (MCCPDC), to gauge the extent of achievable potential savings.

Design, Setting, and Participants: In this retrospective, observational study we performed a systematic analysis of potential Medicare Part D savings when using MCCPDC generic pricing. The 2023 MCCPDC data, as of August 2023, was obtained from the provider's publicly available database. The 2021 Medicare Part D data and prescriber datasets were obtained from the U.S. Centers for Medicare & Medicaid Services.

Main Outcomes and Measures: Outcomes included total prescription volume, proportion of drugs with savings, total U.S. dollar Medicare savings, and average weighted price reduction per unit drug. Results were stratified by medical and surgical subspecialties to identify areas for targeted interventions. Subspecialty-wise contribution to total savings versus contribution to total prescription volume was characterized.

Results: Total estimated Medicare Part D savings were $8.6 billion using 90-day MCCPDC pricing, with surgical drugs accounting for over $900 million. Nearly 80% of the examined drugs were more price effective through MCCPDC using 90-day supply. Commonly prescribed drugs in cardiology, psychiatry, neurology, transplant surgery, and urology demonstrated highest estimated absolute savings. The most disproportionate savings relative to prescription volume were observed for drugs in oncology, gynecology, infectious disease, transplant surgery, and colorectal surgery.

Conclusions and Relevance: This study underscores the significant potential for Medicare Part D savings through strategies that address the systemic overpayment for generic medications. We identified key areas for reform as well as specific medical and surgical subspecialties where targeted interventions could yield substantial savings.

Key points for decision makers:

1. By using the pricing of Mark Cuban Cost Plus Drug Company as a benchmark, this study identifies an opportunity for Medicare Part D to save up to $8.6 billion annually on generic drugs, with Medicare overpayment observed for nearly 80% of the examined drugs.

2. Efforts to optimize Medicare Part D spending may focus on a two-pronged approach – targeting both exorbitantly priced and high-volume generic medications, which could maximize overall Medicare Part D savings and also positively impact a large proportion of patient beneficiaries.

3. There is significant variation in savings potential across medical and surgical subspecialties, which allows for targeted interventions in surgical subspecialties to yield disproportionate savings.

1. Introduction

Medicare accounts for over one-fifth of U.S. healthcare expenditures with a disproportionate spending on prescription drug coverage [1,2]. While drug protection patents, pharmacy benefit managers (PBMs), and lack of government-mediated regulation of drug prices are surmised to contribute to the high expenditure, recent initiatives such as the Inflation Reduction Act have sought to grant the Centers for Medicare & Medicaid Services (CMS) authority to negotiate prices for specific high-cost brand drugs without generic or biosimilar alternatives [3–5]. Although generic drugs have resulted in enormous savings for the U.S. healthcare system, inefficiencies in distribution and reimbursement persist, resulting in continued overpayment for these drugs [4,6–8]. An interplay of opaque pricing and complex intermediaries, including vertically integrated insurers and PBMs, lies at the core of generic drug overpayments [4–6]. Additionally, insurer practices such as profit-oriented formulary placements that favor high-profit brand drugs over low-cost generics, spread pricing, and copay clawbacks exemplify anti-competitive practices leading to high generic costs. To overcome these issues, low-cost generic drug programs (LCGPs) such as the MCCPDC have emerged.

MCCPDC is an online direct-to-consumer pharmacy serving all 50 U.S. states which bypasses the intermediaries and provides transparent pricing breakdown, and therefore, may potentially liberalize access to the uninsured and provide a benchmark for low drug prices achievable when systemic inefficiencies are minimized. While existing work comparing Medicare Part D prices to LCGPs has demonstrated alarmingly high Medicare spending for several generic drugs [6–9], the extent of these savings with continued expansion of LCGPs, and the potential variation of savings across medical and surgical subspecialties that could inform potential areas for targeted reform, remains underexplored.

In this study, we aimed to estimate potential Medicare savings if Part D plans utilized MCCPDC prices for drugs which were available at a lower price from MCCPDC. Medicare's spending on surgical care alone exceeds over $100 billion annually, accounting for a sizable proportion of program spending [10]. Given the substantial amount of healthcare spending on surgery and the high utilization of drugs involved in perioperative processes, we comprehensively evaluated potential cost reductions for surgical drugs in addition to a global analysis across all medical specialties. We performed a systematic analysis of potential Medicare Part D savings for drugs, categorized by surgical and medical subspecialties, to identify areas for targeted interventions that could yield significantly high savings relative to drug prescription volume.

2. Methods

2A. Medicare Part D Claims by All Providers

We used MCCPDC's drug formulary data as of August 20, 2023, which included information on drugs available from MCCPDC at that date, including drug name, dosage form, dosage strength, and price breakdown. We extracted pricing information for all unique drugs available in pill or capsule forms for both the minimum (30-count) and the maximum (90-count) quantities offered [11]. The highest dosage form, often the most expensive, for each drug was used in order to have conservative estimates of the calculated cost differences. The total price included a drug's manufacturing cost, a 15% markup, a $3 pharmacy fee, and a $5 shipping fee, based on MCCPDC's pricing model. Cost per unit was estimated by dividing the total price by the number of dosage units (30 or 90).

We then matched each drug in MCCPDC to the corresponding drug in the 2021 Medicare Part D Spending by Drug dataset [12]. This dataset presents information on spending for drugs prescribed to Medicare beneficiaries enrolled in Part D by physicians and other healthcare providers, and focuses on average spending per drug dosage unit. Seven MCCPDC generics that did not have a comparable generic in the Medicare dataset were excluded (Table S1). This was done to avoid unfair comparison of generic drug pricing to brand name drug pricing, which might falsely increase estimated savings. We extracted the total dosage units prescribed and the average cost per unit for each drug matched from the Medicare dataset. In instances where multiple formulations were found in the Medicare dataset corresponding to one drug in MCCPDC, we used the average cost per unit associated with the formulation with the highest prescription volume. The average cost per unit was estimated from the Medicare dataset by averaging the cost of various strengths and manufacturers for each generic drug weighted by the claims volume of each variant. Medicare Part D drug prices are negotiated between each Part D plan and the manufacturer, and therefore vary across Part D plans. Medicare Part D drug spending represented total spending for the prescription claim, including amounts paid by the Medicare Part D plan and beneficiary payments but did not include any manufacturers' rebates, as CMS is prohibited from publicly disclosing such information. To adjust for drug cost changes from 2021 to 2023, we adjusted Medicare prices by the percentage change in each drug's National Average Drug Acquisition Cost (NADAC) from June 30, 2021 to August 30, 2023 [13]. Thus, all prices are reported in 2023 U.S. dollars.

Drugs where Medicare cost per unit exceeded MCCPDC cost per unit were used to quantify the proportion of drugs with potential savings. For each medication with potential annual Medicare savings, we calculated the difference between Medicare and MCCPDC cost per unit and multiplied this value by the total dosage units dispensed to Medicare beneficiaries in 2021. Drugs were categorized into subgroups based on organ systems and medical specialties to augment real-world applicability. These groupings, as noted in Table S2, were based on based on consensus between three surgeon authors of the study. This study followed the Consolidated Health Economic Evaluation Reporting Standards 2022 guidelines from EQUATOR [14].

2B. Medicare Part D Prescriptions by Surgical Providers

We also matched each drug in MCCPDC to the corresponding drug in the 2021 Medicare Part D Prescribers by Drug and Provider dataset [15], filtered to include only prescriptions by surgical providers (Table S2) using the search term “surgery”. This dataset also provides information on prescription drugs prescribed to Medicare beneficiaries enrolled in Part D by physicians and other health care providers, and organizes data by prescribing provider and drug name. Seven MCCPDC generics that did not have a comparable generic in the 2021 Medicare dataset were excluded from downstream analyses as noted above. We extracted data for provider specialty type, drug generic name, total supply duration, and total drug cost. We estimated cost per unit by dividing the total drug cost by the total units supplied. The total units supplied were estimated by multiplying the total days supplied and typical daily doses for each drug. Typical daily dosing for each drug was determined based on consensus between three authors of the study, comprising of two general surgeons and an internist. Twenty-three medications commonly recommended on an “as needed” basis and without any fixed daily dosing were excluded. Cost was adjusted for inflation between 2021 and 2023 and compared to cost per unit from MCCPDC with and without pharmacy and shipping fees. For each drug with potential savings from MCCPDC, the cost difference per unit was multiplied by the total units supplied to estimate the total annual savings available through MCCPDC. This analysis was done for all surgical provider types listed in Table S2, as well as for each surgical subspecialty individually to capture savings profiles for specific subspecialty disciplines. We also calculated the average cost reduction per unit drug for each subspecialty, weighted by prescription volume. While drugs with potential losses when using MCCPDC were not included in estimating total savings as above, these were included when estimating the weighted average cost reduction to gain a more representative perspective of cost changes when switching to the MCCPDC pricing model.

2C. Sensitivity analysis

For the estimation of total savings, instead of only including drugs where MCCPDC pricing was cheaper relative to Medicare Part D, we conducted sensitivity analyses including all examined drugs. These estimates examine the effect of completely switching to MCCPDC for all available drugs irrespective of their cost through MCCPDC versus Medicare Part D.

3. Results

3A. Summary characteristics of the examined drug pricing data

A total of 301 unique drug formulations available through MCCPDC were included in the analysis. The highest number of drugs belonged to the cardiovascular (69), neurology (38), infectious disease (37), and psychiatry (32) categories. Medicare Part D prescription volume was the highest for cardiovascular drugs, followed by endocrine, psychiatry, and renal/urinary medications. Pulmonary, hematology, and obstetrics and gynecology (OBGYN) medications had the lowest prescription volumes (Figure S1). As compared to current Medicare spending, MCCPDC offered savings for 161 drugs (53.5%) using a 30-day supply and 241 drugs (80%) using a 90-day supply. With a 90-day supply, the proportion of drugs with savings was highest for oncology (8/8, 100%), followed by gastroenterology (17/18, 94%), infectious disease (34/37, 92%), renal/urinary (17/19, 90%), and psychiatry (28/32, 88%); lower proportions of analgesic (6/11, 54%), cardiovascular (48/69, 70%), and endocrine (17/24, 71%) medications also demonstrated potential savings through MCCPDC (Figure S1).

Examining surgical provider prescriptions, 248 drugs available from both MCCPDC and Medicare Part D were included in the analysis. Medicare Part D prescription volume was highest for providers in transplant surgery and urology, followed by critical care/acute care surgery (Figure S2). Out of 248 available drugs, 148 (60%) medications demonstrated potential savings using a 30-day supply from MCCPDC; this number rose to 210 (85%) based on 90-day supplies. Based on a 90-day prescription, the proportion of drugs with savings was highest for trauma/critical care (215/254, 88%), orthopedic surgery (168/194, 87%), and transplant surgery (207/241, 86%), and the lowest for hand surgery (32/46, 70%) (Figure S2).

3B. Total savings estimated based on the Cost Plus LCGP pricing model

Total potential Medicare Part D savings in 2023 were estimated at $5.2 billion using a 30-day supply (for 161 drugs with savings) and $8.6 billion using a 90-day supply (for 241 drugs with savings). The highest absolute savings were from drugs in the following categories:

cardiovascular ($2 billion), psychiatry ($1.5 billion), and neurology ($939 million), followed by nephrology ($788 million), gastroenterology ($784 million), oncology ($624 million), and infectious diseases ($525 million) (Figure S1). With respect to individual drugs, the top 10 drugs with highest absolute savings are shown in Table 1, totaling potential savings of ~$3 billion.

We observed that prescription volume did not always correlate well with the savings observed across various medical specialties (Fig. 1). Notably, cardiovascular medications comprised almost half of the total Medicare prescription volume in the study while only comprising ~24% of the total savings using a 90-day supply. Similarly, endocrine drugs comprised 16% of the total prescription volume but accounted for 6% of potential savings. In contrast, oncology and OBGYN medications offered the most disproportionate savings, with oncology drugs comprising 0.2% of prescription volume but accounting for 7% of total savings, and OBGYN drugs comprising 0.1% of volume but 5% of total savings. Similarly, neurology medications comprised 6% of volume but 11% of savings, psychiatric drugs comprised 9% of volume but 17% of savings, and infectious disease drugs comprised 2% of volume but 6% of the total savings.

3C. Medicare Part D analysis by surgical providers

Potential Medicare Part D savings in surgical contexts were estimated at $700 million using a 30-day supply (for 148 drugs with savings) and $902 million for a 90-day supply (for 210 drugs with savings). The highest absolute savings for a 90-day supply were observed in transplant surgery ($616 million), urology ($183 million), and trauma surgery/critical care ($44 million) (Figure S2). With respect to individual drugs, the top 10 drugs with highest absolute savings are shown in Table 2. Although overlapping surgical specialties may prescribe similar medications, the predominant surgical prescribers for these drugs were transplant surgeons and urologists, concordant with these subspecialties' relative contributions to the aggregate savings. Sevelamer alone, a drug used to manage hyperphosphatemia in patients with renal disease, offered over $152 million in potential savings with a 93% cost reduction per unit through MCCPDC. The highest average weighted price reduction per unit drug was estimated in colorectal ($1.3), transplant surgery ($0.57), and podiatry ($0.57) (Figure S2). The top saving drugs from each surgical subspecialty are summarized in Table S4.

We also noted discordance between prescription volume and potential savings for medications across surgical subspecialties (Fig. 2). For instance, while transplant surgery accounted for 51% of surgical prescription volume, it accounted for 68% of total savings. Similarly, disproportionately higher savings were present in podiatry (1.6% of volume and 2% of savings), and colorectal surgery (0.1% of volume and 0.3% of savings). In contrast, trauma and acute care surgery accounted for 9% of prescription volume with 5% of total savings.

3D. Sensitivity analysis

For the all-prescriber analysis using 90-day supply, when drugs were included irrespective of whether they were more expensive through MCCPDC compared to Part D, total net savings of $8.6 billion changed to net loss of $3.1 billion in the sensitivity analysis. Levothyroxine alone led to $3.8 billion loss as this medication was more expensive through MCCPDC. Similarly, incorporating potassium chloride and metformin ER medications resulted in losses of $2.9 billion and $1.9 billion, respectively in this scenario. For the analysis limited to surgical prescribers, including all drugs in the MCCPDC nonetheless resulted in persistent savings. Using 90-day supply, total net savings of $900 million reduced to $830 million in the sensitivity analysis.

4. Discussion

Our study leverages MCCPDC's pricing as a benchmark for the lowest attainable generic drug costs, with the goal of gauging the extent of achievable savings by mitigating systemic inefficiencies. We find a compelling potential for Medicare Part D savings, with total estimated savings of $8.6 billion when utilizing 90-day drug supplies. The majority of drugs assessed in this study could be procured more affordably through MCCPDC particularly when using 90-day MCCPDC supply, highlighting overpayment by Medicare for generic medications. Certain specialties like oncology, OBGYN, infectious diseases, transplant surgery, and colorectal surgery exhibited a higher ratio of savings to prescription volume and emerged as important targets for optimizing Medicare Part D expenditure.

When considering drugs prescribed in surgical contexts, LCGPs such as MCCPDC represent an underutilized opportunity for potential Medicare Part D savings, with total estimated savings exceeding $900 million based on a 90-day prescription supply. Substantial savings on individual medications appear to emerge from either a marked disparity in unit cost between MCCPDC and Medicare, or a more modest cost reduction amplified by high prescription volume (Tables 1 and 2). Considering that surgical costs represent a significant portion of Medicare spending, these results propose specific surgical disciplines whose Medicare spending could be significantly reduced through the wider use of MCCPDC. In addition to transplant surgery, trauma/critical care, colorectal surgery, and general surgery, common drugs employed in surgical oncology and orthopedics have important potential for cost savings. As the utilization and formulary list for LCGPs continue to grow, our findings suggest that efforts to optimize Medicare Part D spending should focus on a two-pronged approach – targeting both exorbitantly priced and high-volume generics, which could maximize overall Medicare Part D savings and positively impact a large proportion of beneficiaries [16]. While generics contribute to a relatively smaller fraction of total Medicare Part D spending, cost reduction in the generic space still has the potential to have a sizeable impact on patients given their prescription volume, particularly through systemic reforms to reduce generic prices, such as increased price transparency and competition, limitation of pharmacy and distribution costs, and curbing the adverse role of PBMs [17]. It is important to note that MCCPDC provides a limited subset of medications and thus, can service only a subset of patients and conditions. Additionally, utilizing MCCPDC as a Part D supplier may lead to unintended pharmaceutical market segmentation, which may drive up prices for brand name drugs in an effort to recuperate loss of revenue from increased generic competition.

We also observed that cardiovascular and endocrine drugs tended to offer lower savings relative to their volume; many of these drugs were either cheaper at Medicare prices (30% of cardiovascular and endocrine drugs) or had small cost reductions through MCCPDC. Notably, the most common therapeutic drug classes without savings were anti-hypertensives and anti-hyperglycemic medications. These categories had the largest number of available drugs, which results in intra-class competition, lower prices, and lower savings potential, thus explaining some of the variation between therapeutic classes and medical subspecialties. Additionally, MCCPDC's fixed shipping and pharmacy fee accounts for approximately $0.27 per unit with 30-day supply and $0.09 per unit with 90-day supply, thus putting drugs with an already low unit cost (such as long-standing generics) at a relative disadvantage in our analysis when comparing them with Medicare Part D prices. Furthermore, drugs commonly prescribed in transplant surgery, colorectal surgery, and podiatry, appeared to have the highest savings-to-volume ratio and the highest average weighted price reduction per unit drug (Fig. 2); the most disproportionate savings were observed in medications for inflammatory bowel disease (Table S4). Collectively, our analysis reveals significant opportunities for savings in the generic sector, both in terms of relative cost reductions and absolute dollar savings. While existing legislative priorities, such as those implicated in the Inflation Reduction Act, address brand-name drugs that make up a substantial part of Medicare spending, prior data shows that 90% of dispensed prescriptions and nearly 20% of total spending can be linked to generics [18].

Medicare Part D data did not include any manufacturers' rebates as CMS is prohibited from publicly disclosing such information. Pharmaceutical manufacturers do not pay rebates to PBMs or plans for generic drugs, in contrast to brand name drugs [4]. Thus, lack of data on rebates does not impact our findings regarding generic drugs, that made up a significant portion of this analysis. The only brand name drugs available from MCCPDC and included in this analysis – Invokana (Canagliflozin), Invokamet (Canagliflozin-Metformin HCl), Invokamet XR (Canagliflozin-Metformin HCl), Premarin, Premphase, Prempro, and Tirosint – may result in overestimated savings as manufacturer rebates were not accounted for these. Total savings, when excluding these brand name drugs, were still estimated to exceed $8.1 billion, which can be attributed in large part to the generic price differences between MCCPDC and Medicare Part D.

Our study has important limitations. Patients with Part D coverage only pay low-cost sharing for generic drugs, not the full price of the drug, while patients filling drugs via MCCPDC pay the full price out-of-pocket with no coverage, suggesting that patients might prefer Part D compared to MCCPDC if they have the choice [19]. Thus, our findings are not directly applicable to beneficiary out-of-pocket spending on drugs from Medicare Part D plan versus an LCGP. Medicare spending data provides only the average cost per unit, which is a weighted combination of all strengths, dosage forms, and manufacturers for a particular generic drug. However, considerable heterogeneity may exist in pricing across these levels, which could not be accounted for in our analysis due to inherent limitations in available data. We adjusted the Medicare prices based on NADAC to account for changes in drug costs over time, which represents pharmacy acquisition costs based on a survey that is focused primarily on community pharmacies. Medicare plan sponsors tend to pay based on average wholesale price and do not pay for drugs based on NADAC, therefore our adjustment only represents an estimate. Further, the drugs studied in this analysis are limited to those available from MCCPDC as of August 2023, and therefore, it is not feasible to make broader inferences for generic drugs outside the scope of this study. For the sub-analysis focused on surgical prescriptions, the typically used dosing frequency for each drug was determined based on practitioner consensus, however, some drugs may be utilized in dosing frequencies different from the determined typical regimen. Lastly, our analysis does not account for direct and indirect remuneration (DIR) from pharmacies. DIR includes fees, payments, or payment adjustments made after the point-of-sale that change the cost of Part D covered drugs for Part D sponsors. DIR results from payment arrangements negotiated between Part D sponsors, PBMs, pharmacies, drug manufacturers, and other parties involved in the administration of the Part D benefit. CMS recently issued rulemaking requiring Part D plans to account for anticipated DIR in pharmacy cost-sharing calculations beginning 2024, which is helping to reduce up-front pharmacy reimbursement. This confounds the comparison between Part D and MCCPDC prices, and is unable to be accounted for in the current analysis.

5. Conclusion

Medicare Part D plans could potentially save up to $8.6 billion annually on generic drugs if the systemic overpayment for generic medications is addressed. The expansion of MCCPDC's formulary amplifies these potential savings, emphasizing the importance of a dual strategy that encompasses both negotiation for high-cost brand-name drugs and systemic reforms to lower generic drug prices. We found significant variation in savings potential across medical and surgical subspecialties, and identified areas where targeted interventions could yield disproportionate savings. This inquiry bears significance not only for policymakers and physicians but importantly for taxpayers and the 49 million current beneficiaries enrolled in Medicare Part D.

Figure Legends:

Figure 1. Contribution to total estimated savings as compared to total prescription volume stratified by primary subspecialty for drugs, for drugs prescribed by all providers.

Figure 2. Contribution to total estimated savings as compared to total prescription volume stratified by subspecialty of prescriber, for drugs prescribed by surgical providers.

Tables:

Table 1. Top 10 drugs prescribed by all providers with maximum absolute savings through MCCPDC compared to Medicare prices. Extended list is provided in table S3 .

Drug name	System or Specialty	Estimated Medicare annual savings, million US$	Number of units dispensed under Medicare Part D 2021, million	Reduction in cost per unit using MCCPDC prices, %
Icosapent Ethyl	Cardiovascular	482	284	57.8
Abiraterone Acetate	Oncology	473	21	95.3
Aripiprazole	Psychiatry	376	134	92.1
Rosuvastatin	Cardiovascular	316	1322	60.0
Invokana (Canagliflozin)	Endocrine	297	25	59.0
Duloxetine Delayed Release	Psychiatry	227	719	66.5
Pantoprazole Delayed Release	Gastrointestinal	223	1422	53.0
Medroxyprogesterone Acetate	OBGYN	219	17	98.5
Metoprolol Extended Release	Cardiovascular	209	2018	35.4
Sevelamer Carbonate	Renal & Urinary	184	200	79.4

Table 2. Top 10 drugs prescribed by surgical providers with maximum absolute savings through MCCPDC compared to Medicare prices. Specialty-specific breakdown is provided in table S4 .

Drug name	**Predominant surgical prescriber**	**Estimated Medicare annual savings, million US$**	**Number of units dispensed under Medicare Part D 2021, million**	**Reduction in cost per unit using MCCPDC prices, %**
Sevelamer Carbonate	Transplant	152	55	93.2
Mesalamine	Transplant	88	43	74.8
Abiraterone Acetate	Urology	50	0.5	99.2
Tolvaptan	Transplant	40	0.1	86.9
Budesonide	Transplant	29	5	94.5
Tamsulosin Hydrochloride	Urology	29	271	43.0
Ursodiol	Transplant	27	14	82.8
Finasteride	Urology	26	153	50.9
Pantoprazole Sodium	Transplant	24	134	54.5
Oxybutynin Chloride	Urology	24	48	79.4

Compliance with Ethical Standards

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Drafting of the manuscript: All authors.
Critical review of the manuscript for important intellectual content: Naji, Agarwal.
Statistical analysis: Gulati, Gupta
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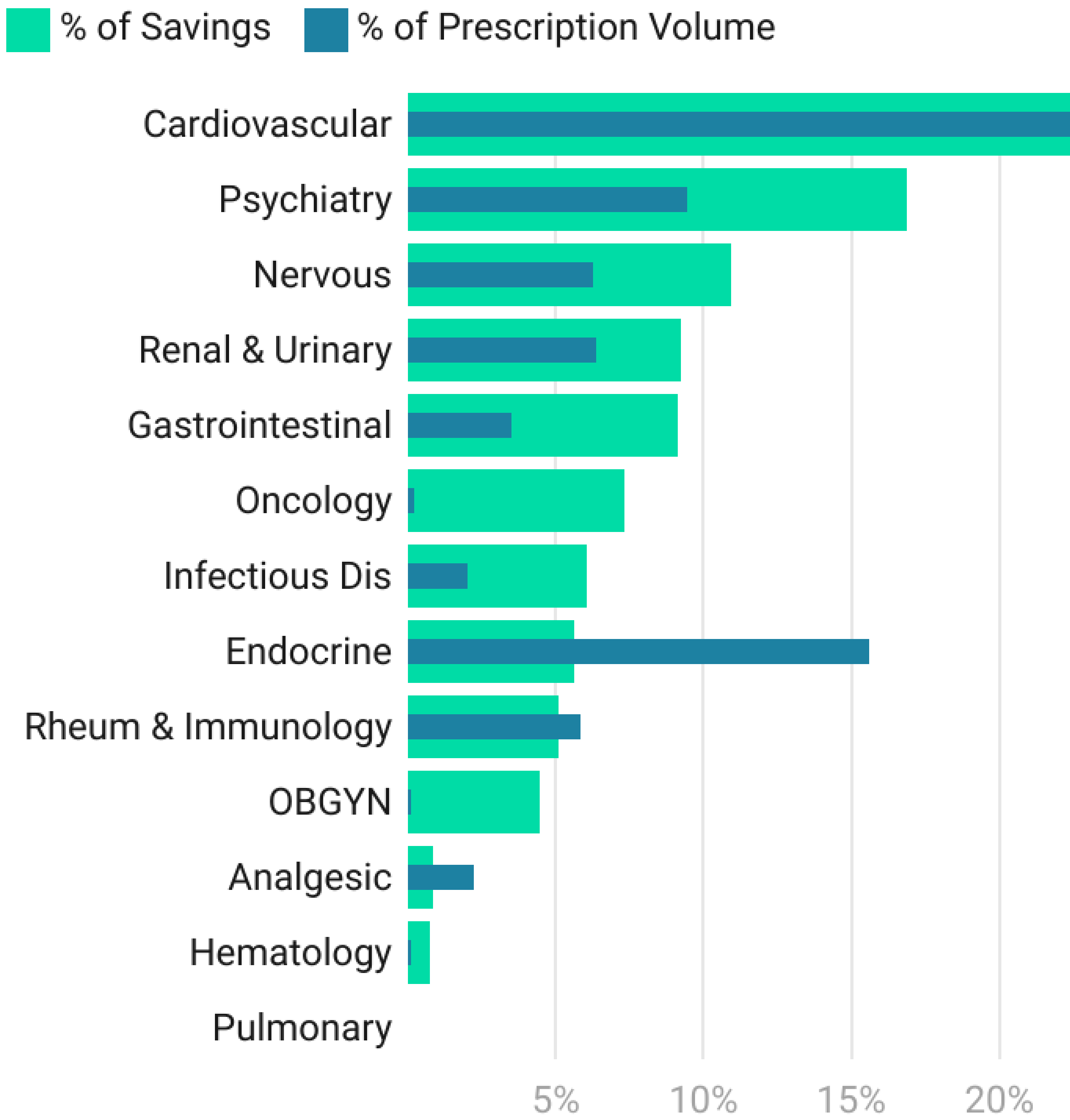
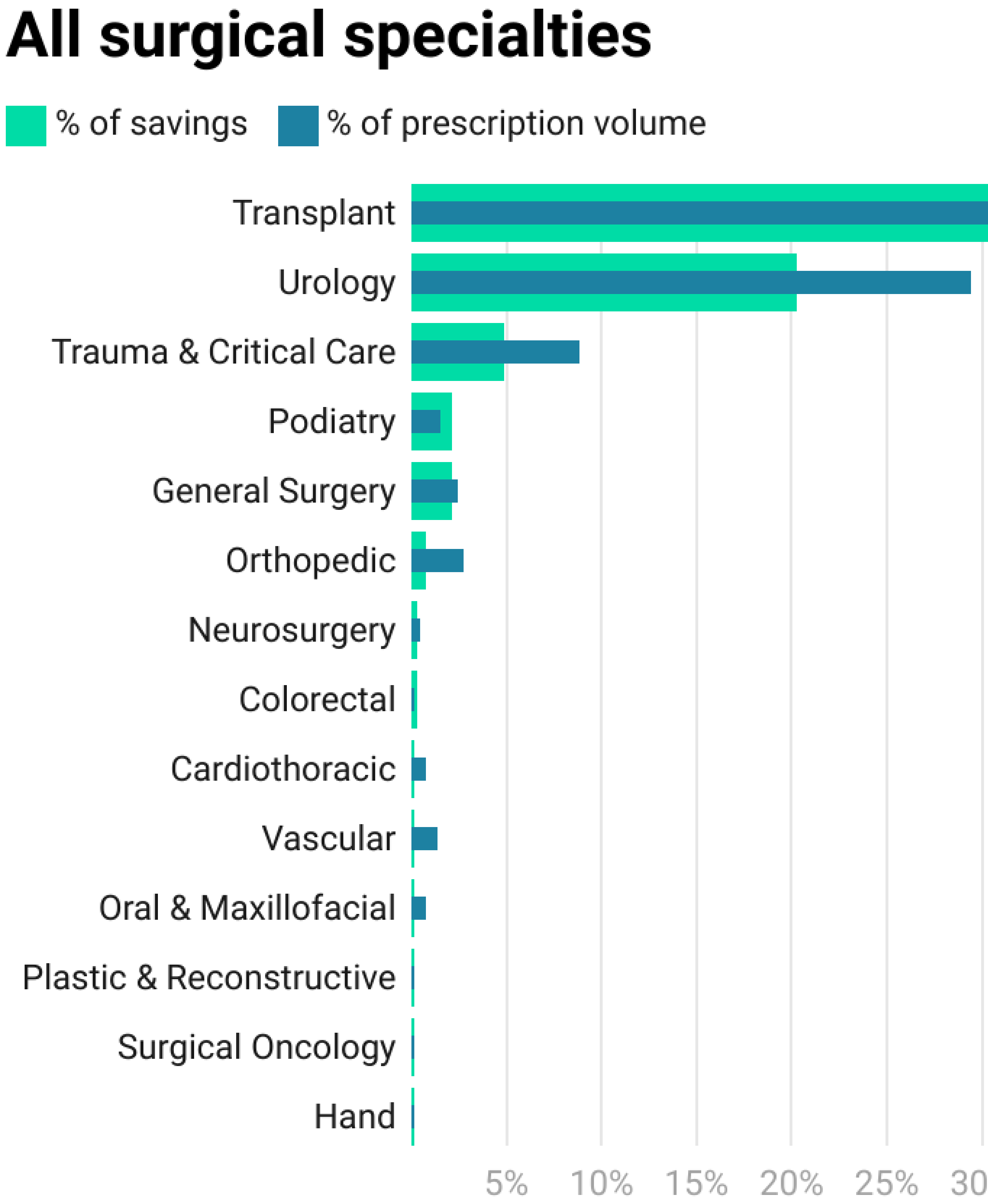

% of Savings
% of Prescription Volume
Cardiovascular
Psychiatry
Nervous
Renal & Urinary
Gastrointestinal
Oncology
Infectious Dis
Endocrine
Rheum & Immunology
OBGYN
Analgesic
Hematology
Pulmonary
5%
10%
15%
20%


All surgical specialties
% of savings
% of prescription volume
Transplant
Urology
Trauma & Critical Care
Podiatry
General Surgery
Orthopedic
Neurosurgery
Colorectal
Cardiothoracic
Vascular
Oral & Maxillofacial
Plastic & Reconstructive
Surgical Oncology
Hand
5%
10%
15%
20%
25%
30