

MOST PATIENTS HAVE OUT-OF-POCKET COSTS FOR COLON PREPS ASSOCIATED WITH CRC SCREENING, CONTRARY TO THE ACA MANDATE: A REAL-WORLD ANALYSIS FROM A LARGE DATASET

Eric D. Shah, MD, MBA¹, Audrey H. Calderwood, MD, MS², and Daniel L. Halberg, PhD³

¹University of Michigan, Ann Arbor, MI, ²Dartmouth Geisel School of Medicine, Lebanon NH ³Braintree Laboratories, Inc., Braintree, MA

INTRODUCTION

- Colorectal Cancer (CRC) is the “most preventable yet least prevented” form of cancer.^{1,2} Changing epidemiology of CRC has led to the U.S. Preventive Services Task Force (USPSTF) to reduce the screening age to 45.³ CRC also presents a significant health equity issue.^{4,5}
- Colonoscopy is vital to preventing and reducing CRC, yet colonoscopies are often avoided because of unnecessary barriers, including “prep hesitancy” and out-of-pocket costs for bowel preparations.^{6,7} Additionally, the current threshold for prep adequacy is 85%.⁸ Not all prep regimens meet this standard, with unapproved over-the-counter regimens being the most used but least effective.⁹ Newer technology, low-volume preparations have demonstrated higher overall efficacy, tolerability, and palatability.^{10,11}
- In 2016, CMS issued an FAQ in accordance with the Affordable Care Act (ACA) stating that bowel preparation medications are integral to screening colonoscopy and should be provided without cost sharing.¹²
- The purpose of this study was to evaluate out-of-pocket costs (OPC) for colonoscopy preparations in patients undergoing screening colonoscopy.

METHODS

- This model was based on information licensed from IQVIA. Medical and Prescription claims were included for the period May 2022 – April 2023 reflecting estimates of real-world activity. Claims associated with ICD codes specific to screening colonoscopy for both commercial and Medicare plans were analyzed.
- Products included in the analysis were currently marketed branded and generic low-volume and high-volume colonoscopy preps. Claims were subdivided into payer type.
- Data are presented as percentages and medians. The “% Claims with \$0 OPC” were calculated for claims without cost-sharing. “Median non-zero” values were calculated for the remaining percentage of claims associated with cost-sharing.

RESULTS

- 2,593,079 total claims were evaluated. 52.9% of claims were commercial and 35.0% were Medicare Part D.
- 36% of claims were associated with a \$0 out-of-pocket. 47% of commercial claims were associated with \$0 out-of-pocket compared to 17% of Medicare Part D.
- For commercial plans, 65% of high-volume colon preps had \$0 out-of-pocket compared to 39% of low-volume colon preps. The median non-zero out-of-pocket costs for high-volume and low-volume preps were \$10 and \$60, respectively.
- For Medicare Part D, 25% of high-volume preps had a \$0 out-of-pocket versus 10% for low volume preps. The median non-zero out-of-pocket costs were \$8 and \$55.99, respectively.
- Out-of-pocket costs were highly variable among plans, with the top 25 plans having a range of 5% to 92% \$0 out-of-pocket.

Top 25 Plans: Percent of Claims with \$0 Out-of-Pocket for Colonoscopy Prep for Screening Colonoscopy

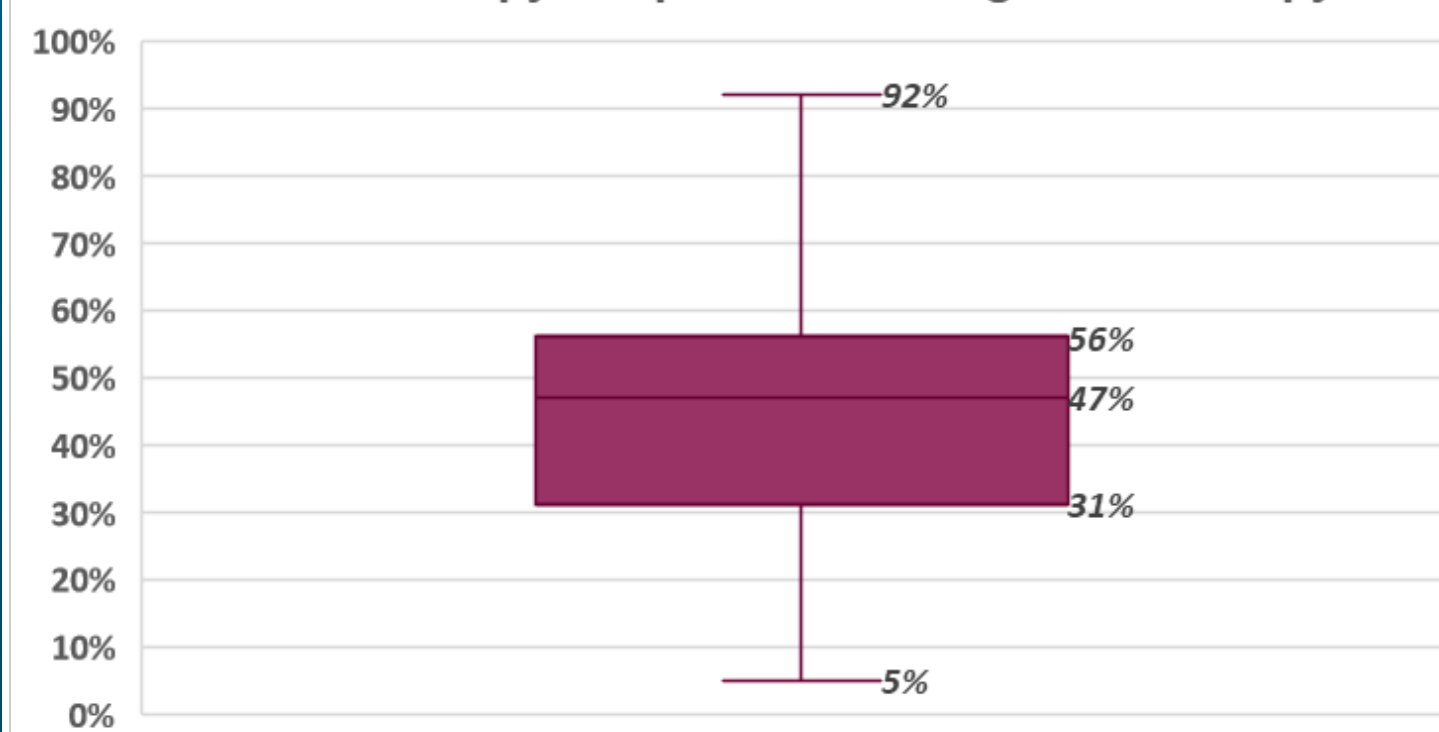


Table 1: Out-of-Pocket Costs for Colon Preps Associated with Screening Colonoscopy (Commercial vs. Medical Part D Plans)

Category	#Total Claims	% Claims with \$0.00 OPC	Median Non-Zero OPC
TOTAL	2,593,079	36%	\$ 40.00
Commercial	1,371,795	47%	\$ 50.00
High Volume	428,019	65%	10.00
- Branded	218,719	63%	10.00
- Generic	209,300	67%	10.00
Low Volume	943,776	39%	60.00
- Branded	744,738	31%	60.00
- Generic	199,038	68%	24.93
Medicare D	882,286	17%	\$ 20.49
High Volume	417,845	25%	8.00
- Branded	209,275	26%	8.00
- Generic	208,570	25%	8.00
Low Volume	464,441	10%	55.99
- Branded	374,197	9%	60.00
- Generic	90,244	14%	45.50

Data Source: IQVIA

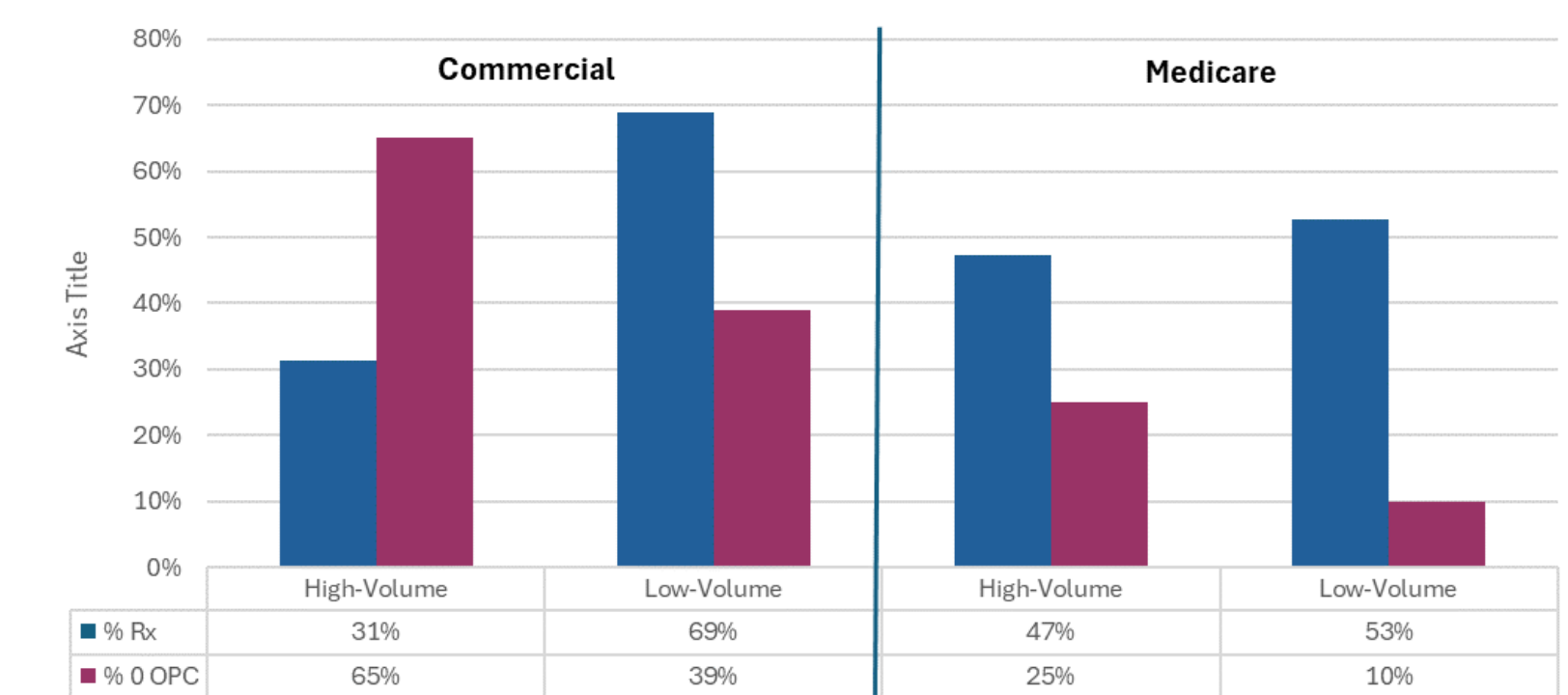
Table 2: Top 25 Payers Sorted by % of Claims with \$0 Out-of-Pocket for Colon Preps

Payers	# Claims	% of claims with \$0 OPC for prep
BCBS #3	10,464	92%
National Payer #6	31,852	85%
National Payer #4	47,718	72%
National Payer #7	25,086	63%
National Payer #8	9,115	59%
National PBM #4	19,432	57%
National PBM #2	206,152	55%
National Payer #2	67,690	54%
National PBM #1	238,806	50%
BCBS #2	14,405	49%
National Payer #3	54,210	48%
National PBM #5	9,926	48%
Regional Payer #1	16,645	47%
Regional Payer #2	7,717	46%
Large State Plan	8,713	43%
National PBM #3	119,176	39%
BCBS #5	8,219	38%
Government Plan	8,609	37%
Naitonal Payer #9	55,371	31%
BCBS #1	19,116	31%
National Payer #1	107,284	30%
BCBS #7	7,138	27%
BCBS #6	7,513	20%
BCBS #4	9,909	19%
National Payer #5	47,344	5%

Data Source: IQVIA

RESULTS

Percentage of Patients Receiving High Volume vs Low Volume Preps Compared to the Percentage Paying \$0 Out-of-Pocket



SUMMARY & CONCLUSIONS

- Most prescribed colonoscopy preps for CRC screening are subject to cost sharing, contrary to the ACA mandate.
- Low-volume preps were less frequently provided at \$0 OPC despite evidence positive efficacy and tolerability profiles. Commercial plans outperform Medicare Part D plans on this metric.
- Previous analysis of this dataset demonstrated that 51% of patients are cost-shifted to an OTC bowel prep regimen.¹³
- A weighted average assessment suggests that about 83% of patients are subject to cost sharing for bowel preparations related to screening colonoscopy (i.e., only about 17% pay zero overall).
- Eliminating the barrier of cost sharing for FDA approved bowel preparations may improve screening rates for CRC.

REFERENCES:

- Itkowitz, J Natl Cancer Inst. (2009)
- Brenner, Br J Cancer. (2018)
- US Preventive Services Task Force. JAMA (2021)
- Siegel, CA Cancer J Clin. (2023)
- McLeod, Hematoi Oncol Clin North Am. (2022)
- Sharma, Endosc Int Open. (2020)
- Vemulapalli, J Clin Gastroenterol. (2023)
- ASGE Standards of Practice Committee. Gastrointest Endosc. (2015)
- Millien & Mansour. Curr Gastroenterology Reports. (2020)
- Di Palma. Am J Gastroenterol. (2021)
- Bhandari, J Clin Gastroenterol. (2023)
- McLeod, Hematoi Oncol Clin North Am. (2022)
- Sharma, Endosc Int Open. (2020)
- Calderwood, Am J Gastroenterol. (2023)