

# Oral Mesalamine Use in Crohn's Disease After Implementation of the American College of Gastroenterology Guidelines: A TARGET-IBD Cohort Study



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## INTRODUCTION

- American College of Gastroenterology (ACG) guidelines for the management of adults with Crohn's disease (CD) from March, 2018 state that oral mesalamine, "should not be used...to treat CD."<sup>1</sup>

## OBJECTIVE

- This work estimates the prevalence of any use of mesalamine among patients with CD before and after the implementation of the guideline.
- It describes current utilization patterns of mesalamine in CD by disease phenotype, location and concomitant use of biologic agents.

## METHODS

### Cohort

- TARGET-IBD is an ongoing longitudinal, observational cohort beginning in July, 2017 of >3,400 patients with IBD managed according to local practice standards at 34 academic and community sites in the United States
- Redacted medical records (structured and unstructured) from consented patients were ascertained including:
  - Patient narratives, laboratory, endoscopic findings, pathology, and imaging data every six months
- Patient-reported outcome (PRO) measures were collected at enrollment and every 3 months
- Blood samples were collected at enrollment and annually

### Patient Population

1,236 patients enrolled between March, 2017 and September, 2019 with baseline data prior to the new recommendation were included in this analysis

### Medication Use

Medication use was captured as any use in the follow up period. Use of mesalamine was stratified into patients who were on mesalamine alone or patients on mesalamine and a biologic.

### Statistical Analysis

The proportion of patients on mesalamine was estimated in time windows after the policy change to discern penetration into usual practice. The odds and 95% confidence intervals of mesalamine use before and after the policy change were estimated by patient and provider characteristics.

## RESULTS

### Before the Policy Change

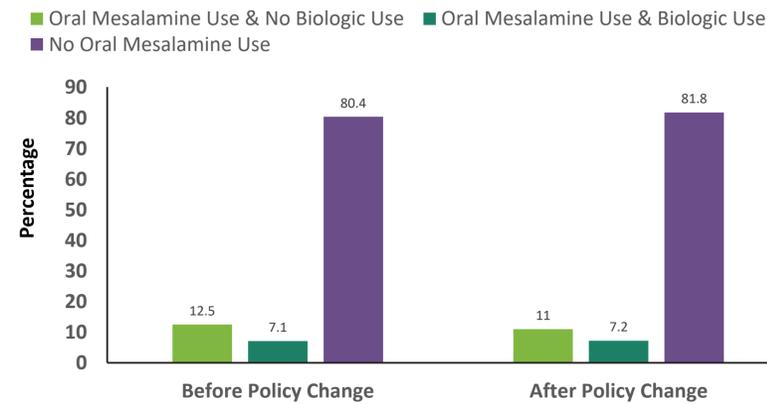
- 57% were female, 86% were white, 3% were Hispanic, and 55% of patients had Crohn's in the ileocolon, 78% had private insurance
- 67% received care in academic centers and the median duration of disease at enrollment was 12.0 years.
- 12.5% used mesalamine only, 7.1% used mesalamine + a biologic and 80.4% did not use mesalamine.
- Patients with private health insurance were 39% less likely to be users of mesalamine compared to patients who were not enrolled in a private health plan.
- Patients with Crohn's disease in the colon and with inflammatory presentation were more than twice (Colon vs ileum:OR:2.23, 95% CI: 1.40,3.58; Inflammatory vs Fistulizing: OR:3.00;95% CI: 1.99,4.54 ) as likely to be users of mesalamine than patients with disease in the ileum and with fistulizing presentation respectively.

### After the Policy Change

- The distribution of patient characteristics was similar after the policy change.
- The magnitude of predictors of mesalamine use was similar to prior to the policy change

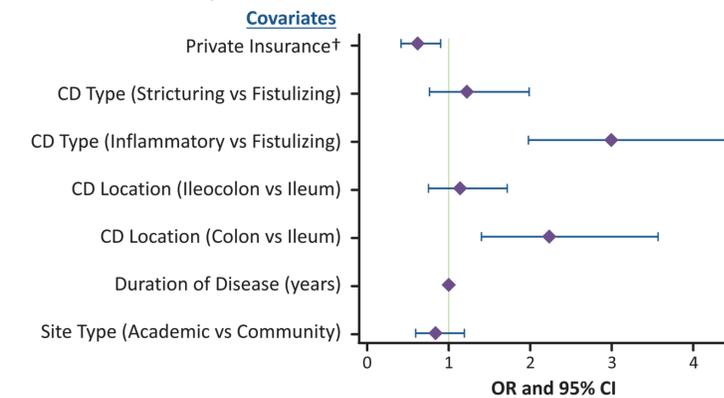
## RESULTS

Figure 1: Prevalence of Mesalamine Before and 6 months after Policy Change\*



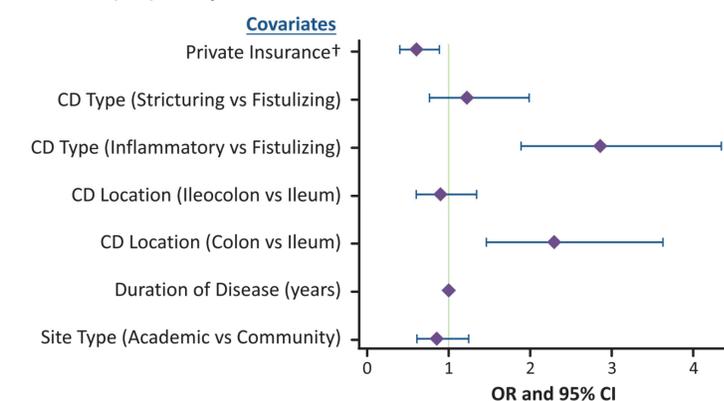
\*Prevalence of use 3 and 9 months after the policy change were similar.

Figure 2: Predictors of Oral 5-ASA Use Prior to Change in Guidelines (1/1/2017 – 12/31/2017)



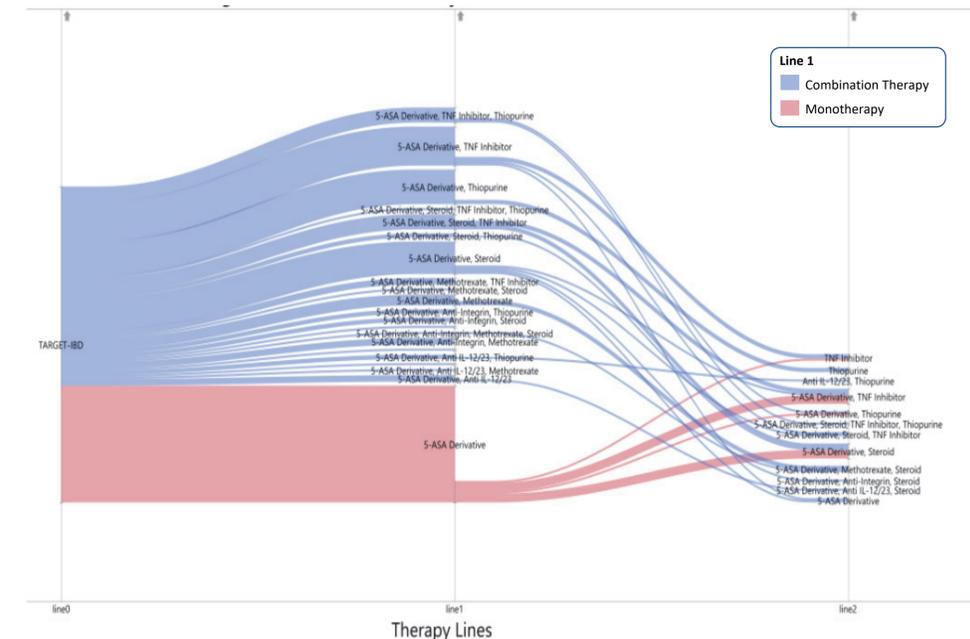
†The reference group for private health insurance is no private health insurance

Figure 3: Predictors of Oral 5-ASA Use After Change in Guidelines (4/1/2018 – 12/31/2018)



†The reference group for private health insurance is no private health insurance

Figure 4. Sequencing of Second Line Therapy Among Patients with Crohn's Disease Who Were Users of Mesalamine



- Among patients who were users of mesalamine, patients with data on second line therapy frequently stayed on mesalamine in combination with a second therapeutic agent

## CONCLUSIONS

- Mesalamine use remained stable in the TARGET-IBD CD population, despite the release of the ACG guideline.
- Individuals with colonic, inflammatory disease were more likely to receive mesalamine; participants with private health insurance were less likely.
- There was little difference between academic and community practice in prevalence of mesalamine use (before or after the guidelines).
- Given that the guidelines are relatively new, it is important to follow these participants over a longer period and monitor practice differences and ways to reinforce the practice recommendations to improve quality and cost of care.

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**References:** 1. Lichtenstein GR, Loftus EV Jr, Isaacs KL et al. ACG Clinical Guideline: Management of Crohn's Disease in Adults. *Am J Gastroenterol* 2018; 113:481-517; doi:10.1038/ajg.2018.27; accepted 11 January 2018.