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Changes in Health Care Resource Utilization Following Initiation of Ustekinumab in Members with Inflammatory Bowel Disease in a Medicaid Population

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INTRODUCTION

- Targeted immunomodulators (TIMs) are potentially more effective but significantly more costly compared to traditional disease-modifying antirheumatic drugs.[1]
- Improved control of inflammatory bowel disease (IBD) symptoms may reduce health care utilization and expenditures associated with disease management; however, further research is needed.[1,2]
- The Institute for Clinical and Economic Review (ICER) found that ustekinumab for ulcerative colitis (UC) had one of the highest incremental cost-effectiveness ratios among TIMs when compared to the placebo arms of clinical trials.[3]
- Studies examining whether ustekinumab reduces health care utilization and costs may help payers to manage the economic burden of IBD.

OBJECTIVE

To assess the real-world health care utilization and medical costs among Massachusetts Medicaid (MassHealth) members with IBD enrolled in the Fee-For-Service (FFS), Primary Care Clinician (PCC), and Primary Care Accountable Care Organization (ACO-B) plans before and after ustekinumab initiation.

METHODS

- This retrospective, pre-post analysis utilized prior authorization (PA) data, medical claims, pharmacy claims, and eligibility data.
  - ICD-10-CM codes for IBD-related diagnoses in the first two positions were used to identify IBD-related medical claims.
- **Inclusion criteria:**
  - Members with approved PAs for ustekinumab for Crohn's disease (CD) and/or UC from May 1, 2018 to July 31, 2020
  - Members ≥18 years of age at the time of the first fill for ustekinumab (index date)
  - Members with ≥2 paid pharmacy claims for ustekinumab during the post-index period
  - Members whose index date was between August 1, 2018 and July 31, 2020
- **Exclusion criteria:**
  - Members with subtherapeutic dosing for IBD (<90 mg every 8 weeks) if an approved PA was also for another indication
  - Members with paid pharmacy claim(s) for ustekinumab with third-party liability (TPL) coverage
- **Primary endpoint:** compared the mean annual IBD-related medical costs for inpatient hospitalizations, emergency department (ED) visits, and outpatient visits during the pre- and post-index periods
- **Secondary endpoint:** compared the mean total number of events comprising the primary endpoint during the pre- and post-index periods
- Subanalyses evaluated ustekinumab utilization and stratified the primary endpoint by gender, age, diagnosis, adherence (paid pharmacy claims), discontinuation (no paid pharmacy claim for ustekinumab ≥90 days after the final day of supply of the last ustekinumab claim), and high doses (>90 mg every 8 weeks).
- Paired t-tests and Wilcoxon signed-rank tests were used to analyze normally distributed and nonnormally distributed data, respectively.

REFERENCES

1 Park KT, Ehrlich OG, Allen JI, Meadows P, Szigethy EM, Henrichsen K, et al. The Cost of Inflammatory Bowel Disease: An Initiative From the Crohn's & Colitis Foundation. Inflamm Bowel Dis. 2020 Jan 1;26(1):1-10. PMID: 31112238.

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3 Ollendorf DA, Bloudek L, Carlson JJ, Pandey R, Fazioli K, Chapman R, et al. Targeted Immune Modulators for Ulcerative Colitis: Effectiveness and Value. Boston (MA): Institute for Clinical and Economic Review, 2020 Oct 16 [cited 2022 Feb 8]. Available from: https://icer-review.org/topic/ulcerative-colitis/.

RESULTS

FIGURE 1. Study Population

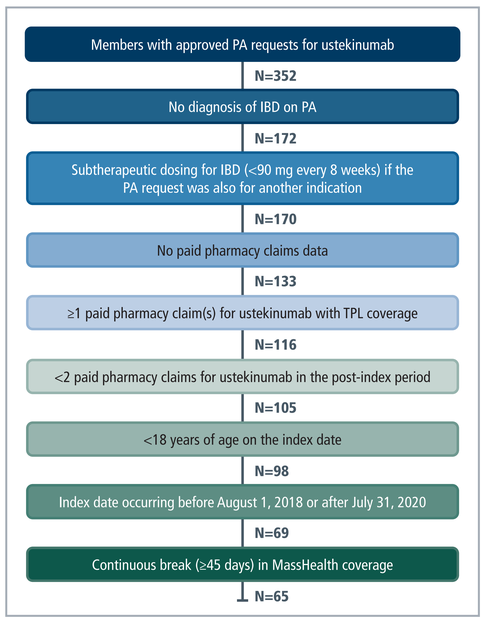


TABLE 1. Baseline Characteristics

Patient Population	N (%)
All members	**65**
Gender	
Males	28 (43.1%)
Females	37 (56.9%)
Age	
Aged 18 to 30 years	18 (27.7%)
Aged >30 to <50 years	33 (50.8%)
Aged ≥50 years	14 (21.5%)
Diagnosis*	
CD	59 (90.8%)
Adherence	
2 to 5 paid pharmacy claims	16 (24.6%)
≥6 paid pharmacy claims	49 (75.4%)
Discontinuation	
No	50 (76.9%)
Yes	15 (23.1%)
High-dose	15 (23.1%)

*Less than 11 members had diagnoses of UC or UC and CD and related complimentary data fields have been omitted to protect confidentiality

FIGURE 2. Mean Annual IBD-Related Medical Costs Per Member (N=65)

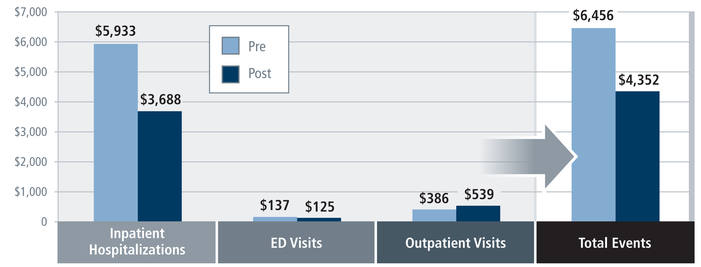


FIGURE 3. Mean Annual IBD-Related Events Per Member (N=65)

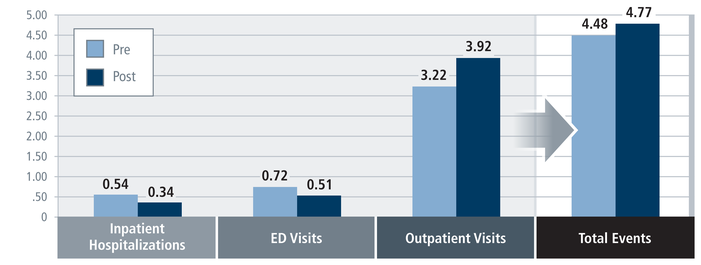
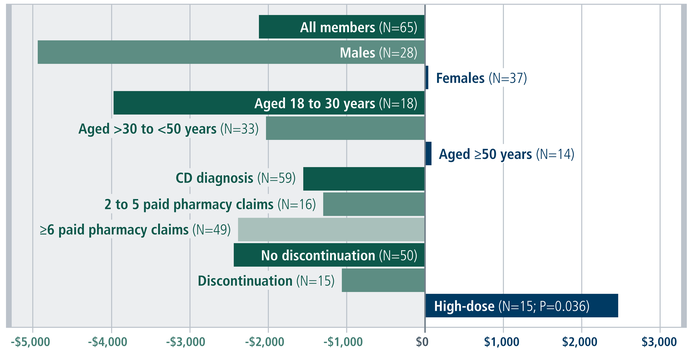


TABLE 2. Ustekinumab Utilization (N=65)

Utilization Per Member	Mean (SD, range)
Paid pharmacy claims	6.60 (2.41; 2 to 13)
Ustekinumab (130 mg/mL) vial; volume in mL	11.60 (29.44; 0 to 104)
Ustekinumab (90 mg/mL) syringe; units	6.78 (3.48; 2 to 26)

FIGURE 4. Mean Annual Change in Total IBD-Related Medical Costs by Subgroup



DISCUSSION

- Mean annual IBD-related medical costs decreased by $2,104 per member (P=0.32), which was driven by a reduction in inpatient hospitalization costs ($2,245) after ustekinumab initiation.
- In contrast to the decrease in mean annual IBD-related medical costs, the total number of mean annual IBD-related events increased by 0.29 events per member (P=0.71), which was driven by an increase in outpatient visits (0.70).
  - The overall uptake in outpatient visits may represent maintenance care or less severe disease episodes.
  - Visit types that may signal acute exacerbations and/or severe disease (e.g., inpatient hospitalizations, ED visits) declined.
- Analyses of subgroups did not yield statistically significant results (P>0.05) with the exception of members receiving ustekinumab at high doses, for which mean annual IBD-related medical costs increased ($2,459, P=0.036).
  - In the high-dose cohort, the increase in mean annual IBD-related medical costs was driven by inpatient hospitalization costs ($1,935), which may suggest that increased dosing is associated with increased and/or advancing disease activity.
- The reduction in mean annual IBD-related medical costs for members with suboptimal adherence, defined as 2 to 5 paid pharmacy claims ($1,288), was approximately half that of members with ≥6 paid pharmacy claims ($2,371); however, neither decrease was statistically significant.

LIMITATIONS

- Pharmacy costs are a driver of the cost of care for patients with IBD; however, these costs were excluded given that they may not accurately represent drug-related costs to MassHealth.[1]
- Individual patient comorbidities were not accounted for, which has been shown to affect health care resource utilization in IBD.[1]
- The study period occurred during the COVID-19 pandemic, which may have affected the rate of IBD-related events and potential utilization of health care resources.
- Other limitations of this study include small sample size, reliance on claims data, the retrospective nature of this analysis, and the absence of comparator groups and indirect costs.

CONCLUSIONS

- Initiation of treatment with ustekinumab was not associated with statistically significant changes in mean annual IBD-related medical costs or events overall; however, increased medical costs were observed in patients receiving high doses.
- Payers may consider management strategies for patients receiving high doses of ustekinumab to optimize health care costs and clinical outcomes.

FUTURE STUDIES

- Future studies should investigate indirect medical costs, pharmacy costs associated with ustekinumab treatment, and/or compare IBD-related health care utilization and costs to other TIMs.

DISCLOSURES/ACKNOWLEDGMENTS

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