

Impact of a Pharmacist-Driven Appeals Process in an Inflammatory Bowel Disease Clinic



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Background

- Inflammatory bowel disease (IBD) is characterized by chronic and relapsing inflammation of the gastrointestinal (GI) tract.¹
- With a substantial portion of patients either not responding to initial biologic therapy or experiencing secondary loss of response, alternative approaches such as dose escalations may be warranted.
- Literature has shown that 30-41% of patients with Crohn's disease (CD) develop a loss of response to anti-TNF α biologics after one year and 40% of patients with CD or ulcerative colitis (UC) required a biologic dose escalation within 36 months of initial therapy.^{2,3}
- Off-label dose optimizations frequently lead to prior authorization (PA) denials warranting appeal submissions.
- Prolonged appeal processes can lead to delays in therapy.
- Time to medication approval was reduced by 78% with a clinic-embedded pharmacist in specialty clinics who were managing the appeals process.⁴

Objective

Evaluate the impact of a pharmacist-driven appeals process in an IBD clinic.

Methods

- Retrospective, single-center, IRB-approved review of adult patients with at least one self-administered biologic or oral small molecule prescription medication that required a PA at the AHWFB IBD Clinic between April 1st, 2018 and September 30th, 2019 and January 1st, 2020 to June 30th, 2021
- Primary Endpoint: time to appeal submission
- Secondary Endpoints: rate of submitted appeals; healthcare utilizations or new steroid initiation within 3 months of PA denial; rate of approved appeals; appeal approval rate based on denial reason; and time from PA denial to appeal determination

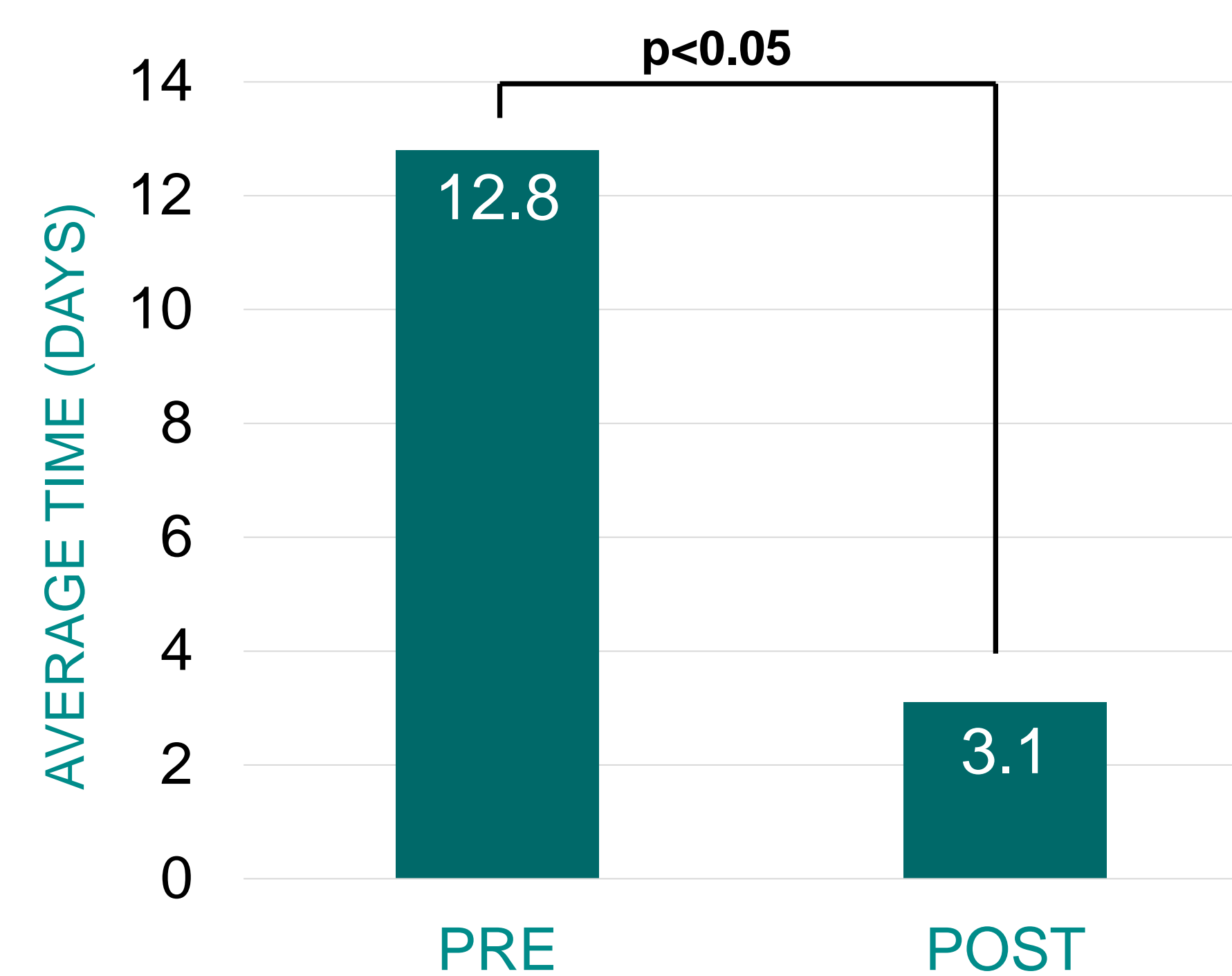
IBD Clinic Appeals Process Workflow

- Historically, a provider or nurse at the AHWFB IBD Clinic managed appeals for denied PAs concurrently with their primary clinic duties.
- A pharmacist began owning the appeals process in late 2019.
- Currently, all biologic specialty medications requiring a PA are routed first through the medication access specialist (MAS) for completion and submission of the PA on behalf of the provider team.
- If the PA is denied and an appeal is warranted, it is completed and submitted by the pharmacist.

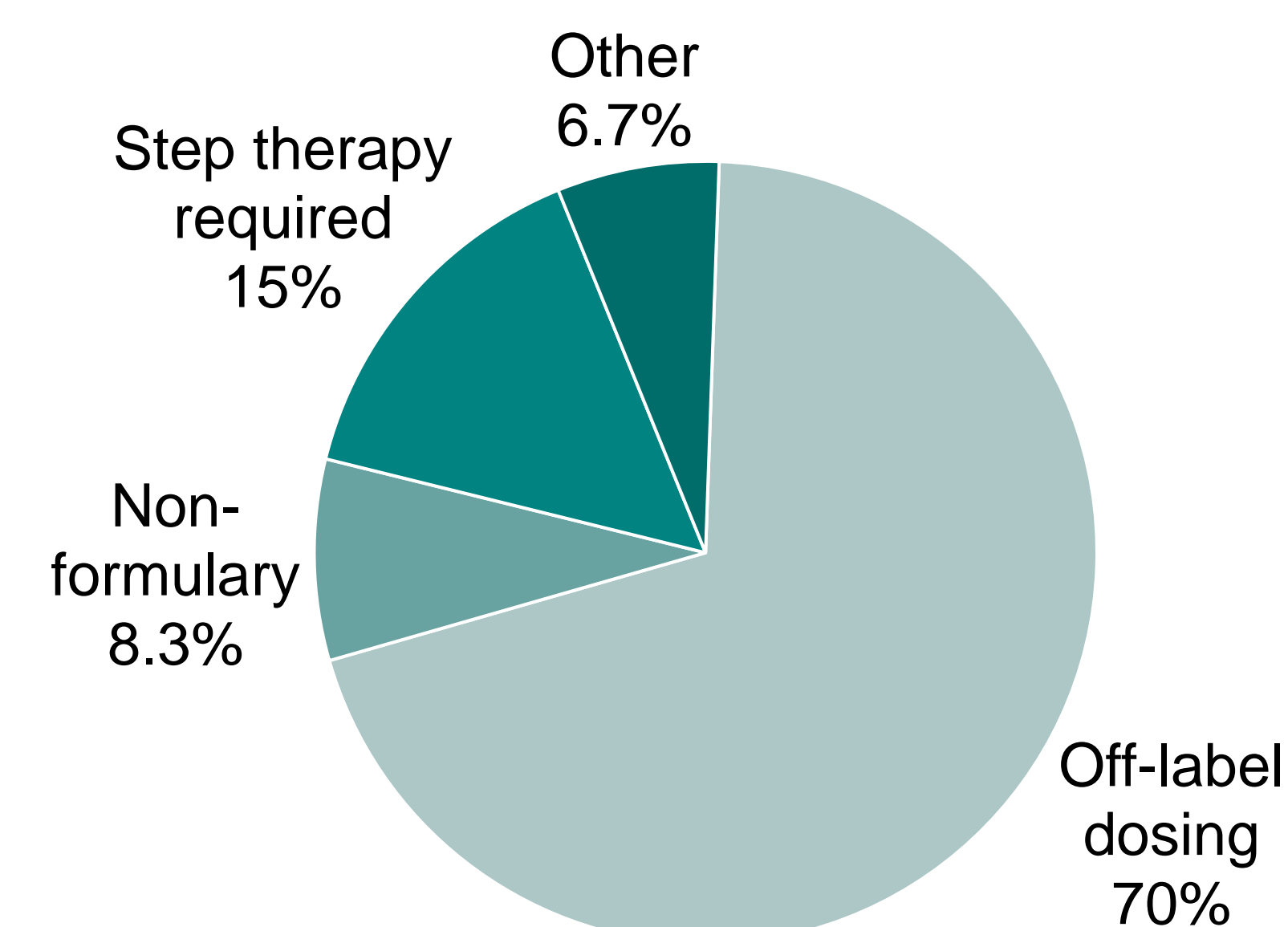


Results

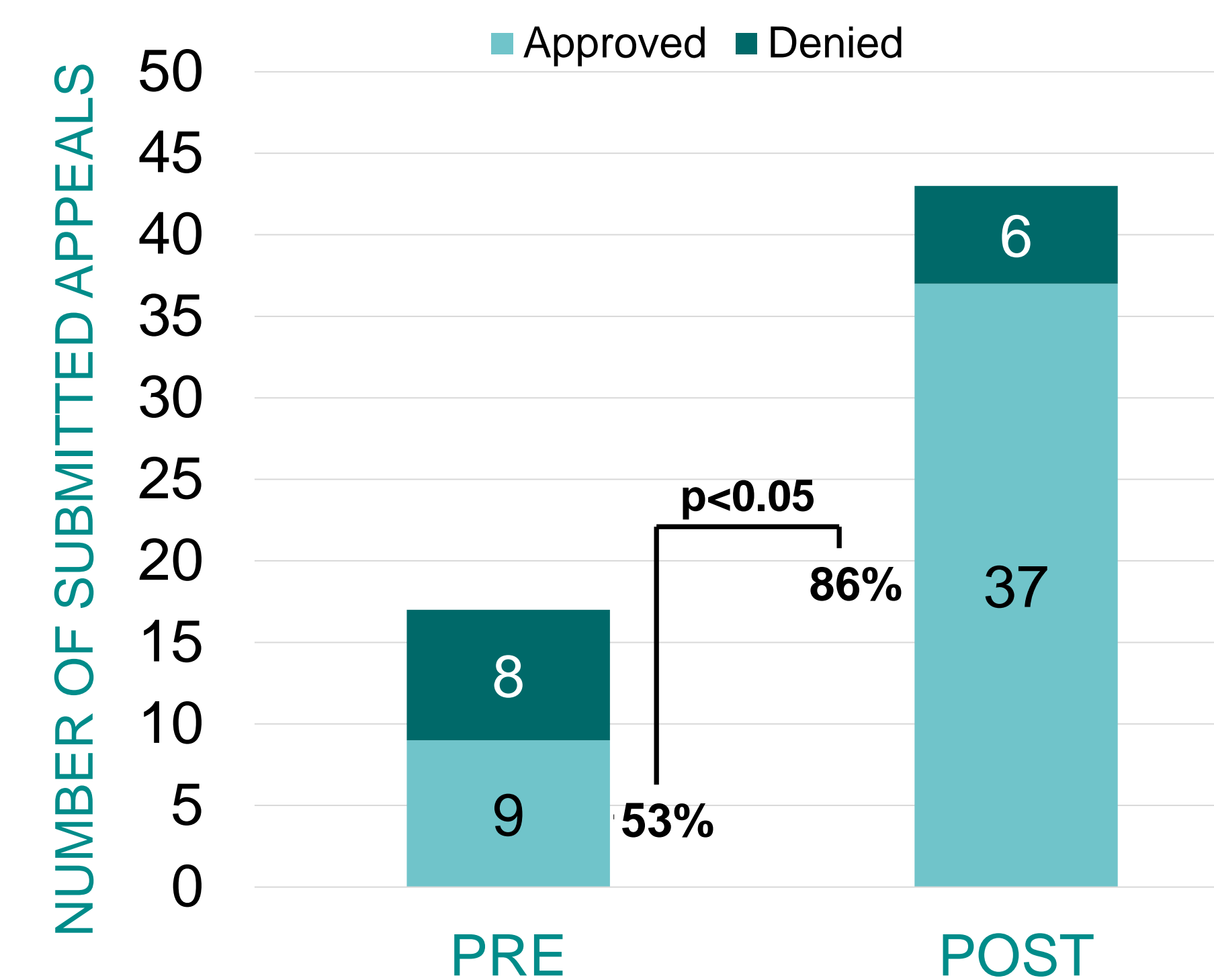
TIME TO APPEAL SUBMISSION



REASONS FOR APPEAL SUBMISSIONS



APPEAL OUTCOMES



ADDITIONAL OUTCOMES

- The total time from PA denial to appeal determination decreased by 9.9 days post-intervention (16.8 days vs 6.9 days; p < 0.05).
- The rate of submitted appeals increased post-intervention (76.2% vs 93.3%; p < 0.05).
- There was no statistically significant difference in the rate of steroid initiation (9.3% vs. 11.8%; p > 0.05) and healthcare utilizations (17.6% vs. 16.3%; p > 0.05) between groups.

Discussion

- PAs are commonly denied due to payor policies' discordance with national clinical guidelines.
- Of the approved appeals in both the pre- and post-intervention groups, the most common PA denial reason was off-label dosing. While biologic dose optimizations are well-supported by available guidelines and primary literature, this practice is not reflected in FDA-approved labeling, leading to payor rejections.
- For denied appeals, further access options exist such as pursuing a higher level of appeal, enrollment in manufacturer assistance programs, or following formulary alternatives as appropriate.
- There was no statistically significant difference in healthcare utilization and steroid initiation between pre- and post-intervention groups as appeal submission was overall timely in both groups.

Conclusions

- Ownership of the appeals process by a clinic-embedded pharmacist in an IBD clinic positively impacted appeal outcomes.
- Pharmacists can use their clinical and medication access knowledge to effectively and efficiently manage the appeals process.

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