DELAY IN INSURANCE APPROVAL OF BIOLOGIC THERAPY DOSE ESCALATION IS ASSOCIATED WITH INCREASED DISEASE ACTIVITY IN PATIENTS WITH INFLAMMATORY BOWEL DISEASE

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OBJECTIVE
To evaluate the impact of time to dose escalation insurance approval on disease activity in patients with IBD at a tertiary care center with an integrated specialty pharmacy.

METHODS
DESIGN
Single-center retrospective cohort analysis

INCLUSION
Adult patients prescribed dose escalation of adalimumab, ustekinumab, certolizumab or golimumab from January to December 2018

EXCLUSION
• Prior authorization (PA) process not completed by center’s specialty pharmacy
• Medication fulfilled through manufacturer or under medical benefit

PRIMARY OUTCOME
CRP measurement at follow-up, defined as the first measurement after 45 days following provider decision to escalate dose

SECONDARY OUTCOME
Patient-reported disease activity evaluated using Harvey Bradshaw Index (HBI)

COHORT CHARACTERISTICS
Table 1. Demographics (n=114)

- Age, years (mean ± standard deviation): 40 ± 14
- Gender, female: 60 (53%)
- Race
  - White: 109 (96)
  - Black or African American: 5 (4)
  - Crohn’s disease: 100 (88)
  - Insurance type, commercial: 95 (83)

Table 2. Biologic therapy dosing regimens

- Adalimumab:
  - 40 mg weekly: 42 (37)
  - 40 mg every 10 days: 1 (<1)
  - 40 mg or 80 mg alternating weekly: 1 (<1)
- Ustekinumab:
  - 90 mg every 6 weeks: 50 (44)
  - 90 mg every 4 weeks: 16 (14)
- Golimumab:
  - 100 mg every 2 weeks: 2 (2)
- Certolizumab:
  - 200 mg every 2 weeks: 1 (<1)

RESULTS

Figure 1. Insurance approval pathway

- Median time from provider decision to escalate dose of biologic therapy to insurance approval was 5 days (IQR 1 – 12).

Figure 2. Regression analysis of follow-up CRP as function of time from decision to treat to insurance approval

- Follow-up CRP was evaluated at a median of 92 days (IQR 72 – 119) and follow-up median HBI was evaluated at a median of 95 days (IQR 89 – 118) following dose escalation.

Figure 3. Change in CRP from baseline to follow-up

- Patients who experienced a delay in insurance approval (n=23, 20%) had higher follow-up CRP levels compared to patients with no delay (n=91, 80%).

Table 3. Baseline and follow-up CRP (n=114) and HBI (n=62) values

- Median CRP: 4.2 mg/dL (1.3 – 9.7)
- Median HBI: 3 (1 – 7)

CONCLUSIONS

- Our findings suggest that a longer time to secure insurance approval of dose-escalated biologic therapy is associated with worse CRP outcomes.
- This highlights that the complex dose escalation process of biologic therapy can negatively impact clinical outcomes and supports the benefit of having an integrated specialty pharmacy team to ensure timely completion of prior authorization appeals.