

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

Nisha B. Shah, PharmD<sup>1</sup> | Josh DeClercq, MS<sup>2</sup> | Laura Cherry, PharmD<sup>3</sup> | Autumn D. Zuckerman, PharmD, BCPS, AAHIVP, CSP<sup>1</sup> | Praveen Vimathalas<sup>4</sup> | Leena Choi, PhD<sup>2</sup> | Charles Donoho, BSPHarm<sup>1</sup> | Baldeep S. Pabla, MD, MSCI<sup>5</sup> | Elizabeth A. Scoville, MD, MSCI<sup>5</sup> | Robin L. Dalal, MD<sup>5</sup> | Dawn B. Beaulieu, MD<sup>5</sup> | David A. Schwartz, MD<sup>5</sup> | Sara N. Horst, MD, MPH<sup>5</sup>

<sup>1</sup>Vanderbilt Specialty Pharmacy, Vanderbilt University Medical Center <sup>2</sup>Department of Biostatistics, Vanderbilt University Medical Center <sup>3</sup>Lipscomb University, <sup>4</sup>Vanderbilt University, <sup>5</sup>Vanderbilt Inflammatory Bowel Disease Clinic, Vanderbilt University Medical Center

## BACKGROUND

- A complex prior authorization process is usually required to secure insurance approval of alternate (non-Food and Drug Administration-approved) biologic dosing, often needed to manage inflammatory bowel disease (IBD). We previously reported a delay for some patients as a result.<sup>1</sup>
- C-reactive protein (CRP) is used as a biomarker of inflammation in patients with IBD and can help assess disease activity.

## 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)

	n (%)
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

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

## RESULTS

Figure 1. Insurance approval pathway

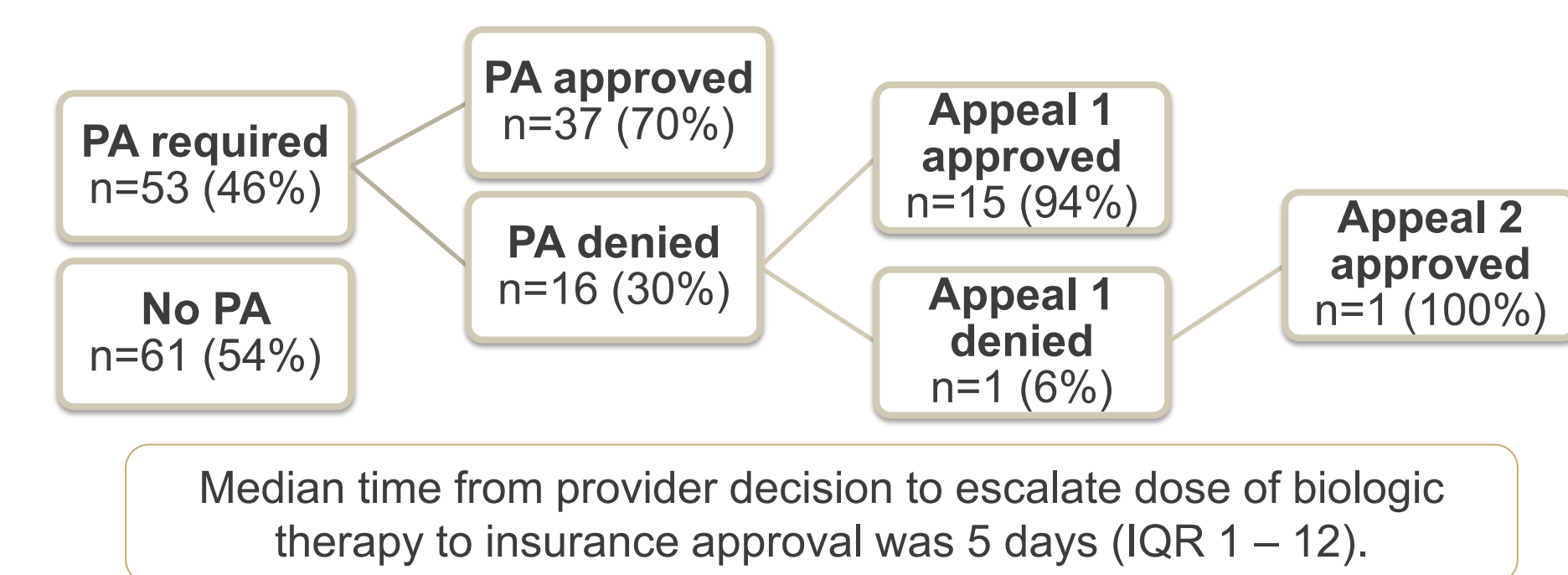
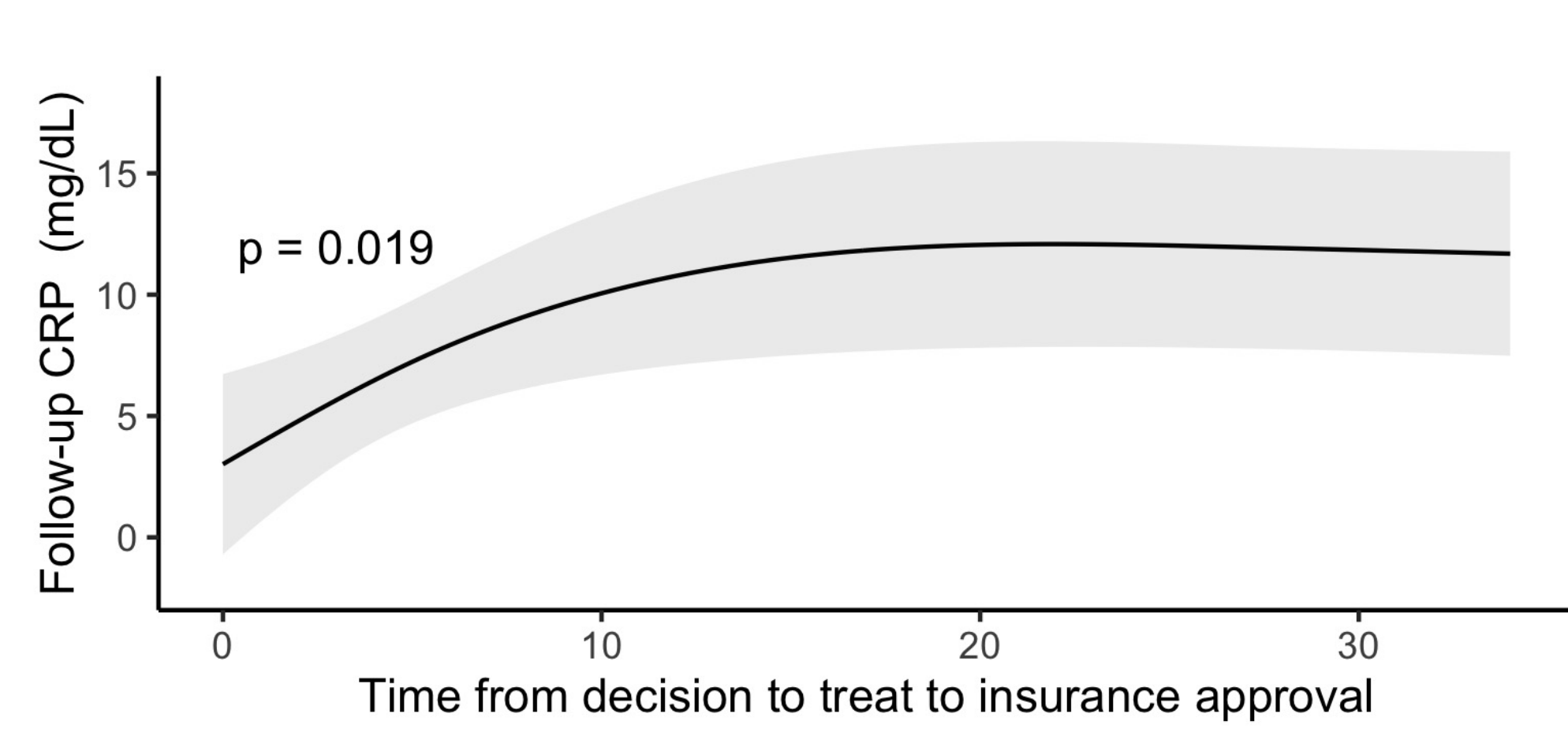


Table 3. Baseline and follow-up CRP (n=114) and HBI (n=62) values

	Median [interquartile range (IQR)]
Baseline CRP	4.2 mg/dL (1.3 – 9.7)
Follow-up CRP	4.5 mg/dL (1.4 – 9.8)
Baseline HBI	3 (1 – 7)
Follow-up HBI	4 (2 – 6)

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



In this cohort, 20% (n=23) of patients experienced a delay of greater than 14 days in securing insurance approval.

A longer time to insurance approval significantly decreased the likelihood of CRP improvement (p = .019).

Delays in recommended change of biologic dosing because of insurance barriers can impact clinical outcomes.

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

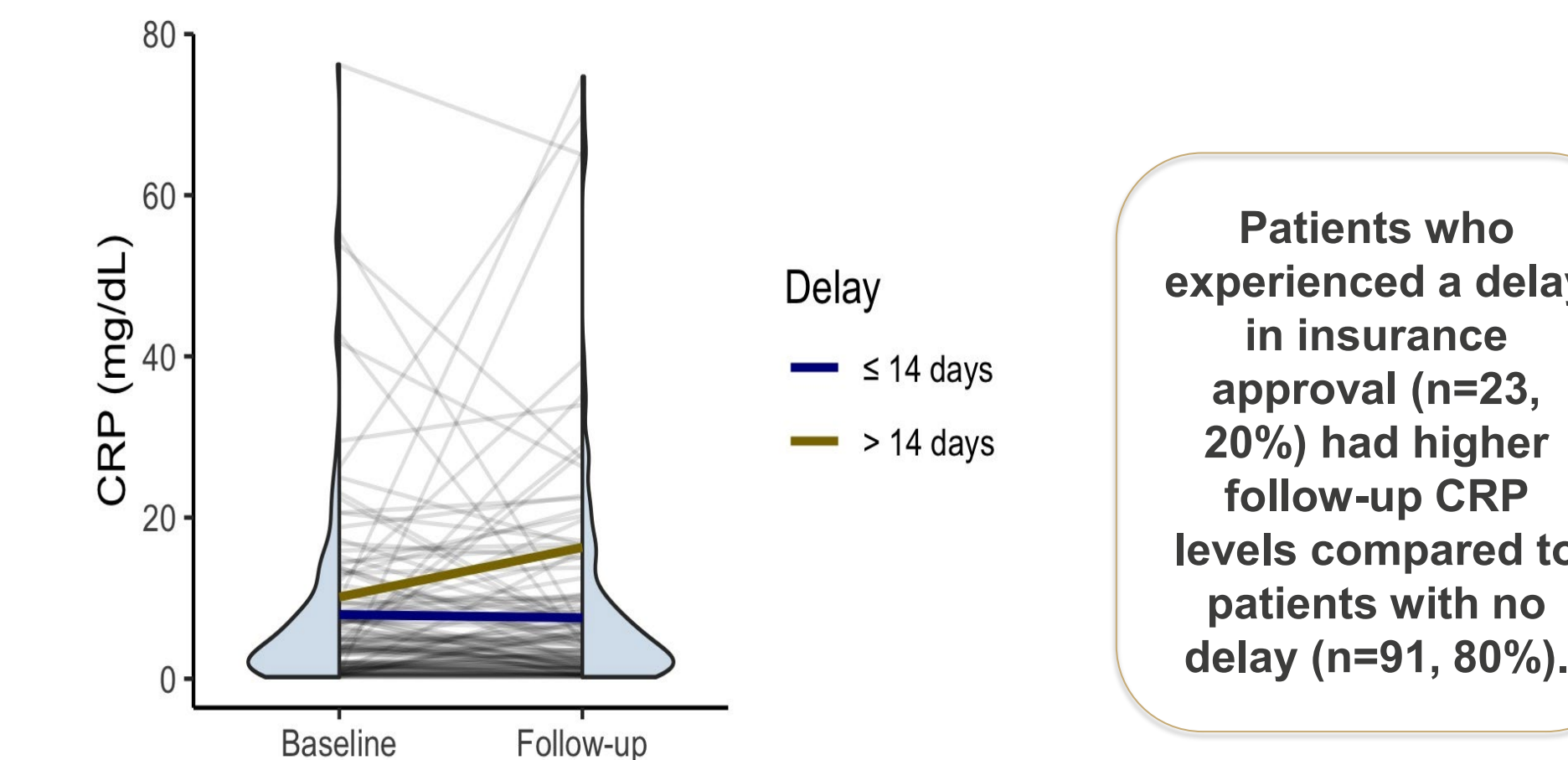
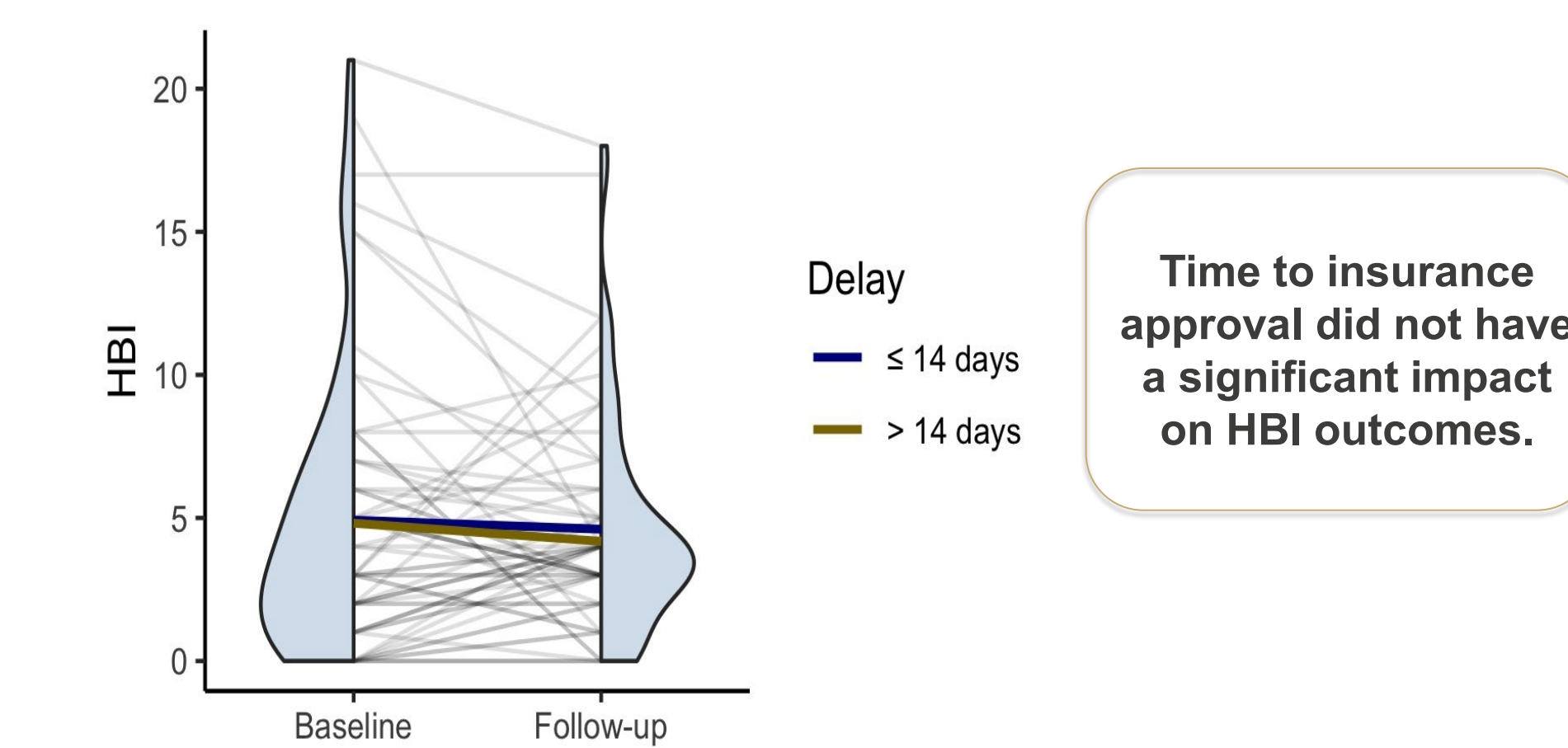


Figure 4. Change in HBI from baseline to follow-up



## 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.

1. Coe C, Cherry L, Shah N, et al. Alternative subcutaneous biologic dosing in inflammatory bowel disease is delayed depending on insurance approval requirements. American J Gastroenterol 2020;115:S45