Impact of Social Determinants of Health on Biologic Utilization and Spending in Crohn's Disease

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Background

- Crohn's disease (CD) is a chronic condition characterized by persistent transmural inflammation with patchy distribution that can impact any part of the gastrointestinal tract. CD presents in adolescence or early adulthood and follows a relapsing-remitting course, significantly impacting quality of life.[1]
- Management of moderate-to-severe CD often relies on biologic therapies, which include anti-tumor necrosis factor (TNF) agents (e.g., infliximab, adalimumab), integrin receptor antagonists (e.g., vedolizumab), and interleukin inhibitors (e.g., risankizumab, ustekinumab). Patients typically initiate anti-TNF therapies and transition to other agents if they do not achieve disease control.[1]
- Biologic therapies are costly and vary in price across agents, with anti-TNF agents like Humira (adalimumab) generally being less expensive than interleukin agents like Skyrizi (risankizumab).[2]
- Risankizumab and other biologic therapies have additional administrative complexities, requiring patients to switch from intravenous to subcutaneous dosing, which necessitates a shift from the medical benefit to the pharmacy benefit.[1]
- Social determinants of health (SDOH)—the conditions in which people are born, live, learn, work, play, worship, and age—may limit access to biologic therapies, influencing CD outcomes and access to specialty care.[3,4] Prior research confirms that patients with worse SDOH are more likely to have increased disease severity and complications.[5]
- SDOH can be measured by the Social Deprivation Index (SDI), which combines SDOH factors from all 5 domains of Healthy People 2030's definition of SDOH—including economic stability, education access and quality, health care access and quality, neighborhood and build environment, transportation access, and social and community context—into a single score reflecting area-level deprivation.[4,6] Scores range from 0 to 100, with higher SDI scores indicating greater social disadvantage within a community.
- Although SDOH have been shown to influence CD outcomes, their impact on biologic therapy utilization remains largely unexplored.

Objective

Our objective is to explore the relationship between the SDI and biologic therapy utilization patterns and cost in members with CD.

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Methods

- All analyses were conducted using integrated (medical and pharmacy) claims from a nationally representative population of approximately 19 million commercial, Medicare, and Medicaid members.
- Figure 1 displays the study methods as outlined.

Identification of members newly initiating biologic therapy for CD

- Members' first CD biologic claim (index date is the service date of first biologic claim) was identified between January 1, 2024, and June 30, 2024, using Healthcare Common Procedure Coding System (HCPCS) and National Drug Code (NDC) codes corresponding to CD biologic medications (adalimumab, risankizumab, infliximab, certolizumab pegol, ustekinumab, vedolizumab, natalizumab, mirikizumab, and guselkumab).
- Members were required to be continuously enrolled for 180 days pre-index date and 365 days post-index date.
- Members were identified as newly initiating a biologic for CD if they had ≥1 medical claim with a primary or secondary CD diagnosis (ICD-10-CM: K50.0–K50.919) and no prior CD biologic claim during the 180-day pre-index period.

Inclusion criteria

- Age ≥18 years old

Exclusion criteria

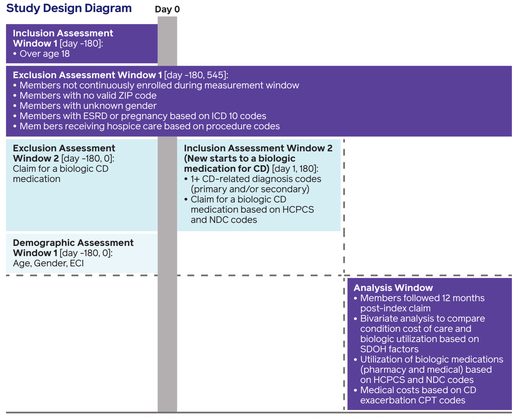
- Missing/Invalid ZIP code
- End-stage renal disease (ESRD) or pregnancy (ICD-10-CM codes)
- Unknown gender
- Hospice care based on procedure/revenue codes

Analysis

- SDI data from 2015–2019 were linked to member records using the ZIP code. Post-index (365-day) integrated claims were queried to identify biologic therapy use and associated plan-paid, member-paid, and total paid (plan + member) amounts. All costs reflect post-network discount payments and exclude manufacturer drug rebates.
- Medical-benefit paid amounts were based on biologic drug costs and exacerbation costs defined by CPT codes for CD-related surgeries.
- Pharmacy-benefit paid amounts were limited to the cost of the biologic drugs.
- Integrated paid amounts indicate pharmacy benefit and medical benefit total amounts paid.
- Integrated biologic paid amounts indicate pharmacy benefit and medical benefit total amounts paid on the following medications: adalimumab, certolizumab pegol, guselkumab, infliximab, mirikizumab, natalizumab, risankizumab, ustekinumab, and vedolizumab.
- Demographics (age, gender, Elixhauser Comorbidity Index [ECI]) were assessed for the study sample from July 1, 2023, to January 1, 2024.[7]
- Correlations were examined between SDI and demographic variables and all outcome variables.
- Bivariate linear regression analyses were used to assess the relationship between demographic variables and outcome measures using a significance threshold of 0.05.
- Subsequently, bivariate linear regression analyses were used to evaluate the relationship between SDI scores and each outcome (biologic therapy utilization and spend) where significant correlations existed. A statistical significance threshold of 0.05 was used for all analyses (α=0.05).
- Quartiles for SDI were calculated, and groups were compared to identify gaps in utilization for target CD medications. Members were excluded from this analysis if there were no claims for the target medications.

Figure 1

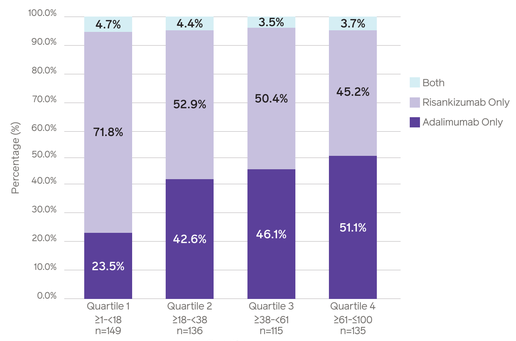
Study Design Diagram



ESRD = end-stage renal disease; CD = Crohn's disease; HCPCS = Healthcare Common Procedure Coding System; NDC = National Drug Code; ECI = Elixhauser Comorbidity Index; SDOH = social determinants of health
Index date is the service date of the first biologic medication claim. Biologic medications include: adalimumab, certolizumab pegol, guselkumab, infliximab, mirikizumab, natalizumab, risankizumab, ustekinumab, and vedolizumab. New start to biologic medication is defined as patients without claims from July 1, 2023, to January 1, 2024.

Figure 2

Adalimumab and Risankizumab Utilization Based on SDI Score Quartiles



SDI = Social Deprivation Index
SDI quartiles are grouped by patient counts. The sample was limited to utilization of adalimumab and risankizumab, and excludes other biologic medications used for Crohn's disease included in the analysis (certolizumab pegol, guselkumab, mirikizumab, natalizumab, ustekinumab, and vedolizumab).

Table 1

Cost Outcomes Bivariate Regression Analysis Results

Cost Outcomes	Coefficient	t value	*P* value	Correlation
Pharmacy Paid Amount				
n=1,245				
Member paid	7.13	1.45	0.147	0.04
Plan paid	-34.32	-0.52	0.602	-0.02
Total paid	-27.19	-0.40	0.689	-0.01
Medical Paid Amount (biologic drugs + CD-related surgeries and exacerbations)				
Member paid	4.12	0.52	0.600	0.02
Plan paid	-137.98	-2.35	0.019	-0.07
Total paid	-161.68	-2.66	0.008	-0.08
Integrated (Medical + Pharmacy) Paid Amount (biologic drugs + CD-related surgeries and exacerbations)				
Member paid	11.25	1.25	0.210	0.04
Plan paid	-172.30	-2.03	0.042	-0.06
Total paid	-188.87	-2.20	0.028	-0.06
Integrated Biologic Paid Amount				
Biologic member paid	1.08	0.16	0.873	0.01
Biologic plan paid	-126.16	-3.30	0.001	-0.09
Biologic total paid	-141.88	-3.53	<0.001	-0.10

CD = Crohn's disease
Biologics included: adalimumab, certolizumab pegol, guselkumab, infliximab, mirikizumab, natalizumab, risankizumab, ustekinumab, and vedolizumab. Covariates were excluded because they were insignificant.

Table 2

Biologic Medication Utilization Bivariate Regression Analysis Results

Medication Utilization	Coefficient	t value	*P* value	Correlation
Integrated (Medical + Pharmacy) Claims				
adalimumab (n=237)	0.013	2.88	0.004	0.08
risankizumab (n=320)	-0.010	-3.08	0.002	-0.09
infliximab (n=332)	0.003	-0.65	0.517	-0.02
ustekinumab (n=252)	0.003	1.27	0.205	0.04
vedolizumab (n=258)	-0.006	-1.84	0.066	-0.05
Medical Claims				
risankizumab (n=291)	-0.004	-3.18	0.002	-0.09
infliximab (n=331)	-0.003	-0.68	0.496	-0.19
ustekinumab (n=194)	0.001	0.64	0.522	0.02
vedolizumab (n=258)	-0.005	-1.66	0.097	-0.05
Pharmacy Claims				
adalimumab (n=237)	0.013	2.88	0.004	0.08
risankizumab (n=239)	-0.005	-2.57	0.010	-0.07
infliximab (n=3)	0.000	0.50	0.619	0.01
ustekinumab (n=184)	0.003	1.19	0.234	0.03
vedolizumab (n=16)	-0.001	-0.99	0.322	-0.03

Biologics included: adalimumab, certolizumab pegol, guselkumab, infliximab, mirikizumab, risankizumab, ustekinumab, and vedolizumab. Due to the low number of members utilizing certolizumab pegol, natalizumab, mirikizumab, and guselkumab, these drugs were excluded from this table. Adalimumab did not have medical claims. Covariates were excluded because they were insignificant. At least 1 biologic medication from each class was included in the table. For medications with statistically significant values, another drug from the class was included for comparison.

Results

- Between January 2024 and June 2024, 1,245 members newly initiated a biologic drug for CD treatment and met all analytic criteria.
  - 237 (19.04%) adalimumab
  - 15 (1.20%) certolizumab pegol
  - 4 (0.32%) guselkumab
  - 332 (26.67%) infliximab
  - 3 (0.24%) mirikizumab
  - 2 (0.16%) natalizumab
  - 320 (25.70%) risankizumab
  - 252 (20.24%) ustekinumab
  - 258 (20.72%) vedolizumab
- Of the 1,245 members, 1,064 (85.46%) had commercial insurance, 92 (7.39%) had Medicare, 37 (2.97%) had Medicaid, and 52 (4.18%) had unknown coverage.
- Of the 1,245 members, 56.2% were female, the average age was 44 years (SD=15.5), the average ECI was 2.8 (SD=2.5), and the average SDI score was 40.7 (SD=26.5).
- There were no statistically significant relationships between the demographic variables and the outcome measures based on regression results, thus all demographic variables were excluded from subsequent regression analyses.
- Among the CD biologic drugs assessed, adalimumab and risankizumab costs were associated with changes in SDI, while certolizumab pegol, guselkumab, infliximab, mirikizumab, natalizumab, ustekinumab, and vedolizumab were not associated with statistically significant outcomes. Table 1 and Table 2 display regression analysis results for biologic medication cost outcomes and utilization, respectively. Table 2 excludes certolizumab pegol, guselkumab, mirikizumab, and natalizumab due to low utilization.
  - The bivariate regression analysis results for cost outcomes found that, for every unit increase in SDI score, the integrated plan paid amount on biologic therapies decreased significantly—on average, by $126.16 ($P$=0.001)—and for every unit increase in SDI score, total biologic spend decreased significantly—on average, by $141.88 ($P$<0.001).
- Figure 2 displays adalimumab and risankizumab utilization by SDI score quartile; other biologic medications are not shown in the figure to clearly display the statistically significant relationships. Table 2 displays the bivariate regression analysis results for biologic medication utilization. For every unit increase in SDI score, utilization of adalimumab increased significantly—on average, by 0.01 claims (P=0.004)—while utilization of risankizumab decreased significantly—on average, by 0.001 claims (P=0.002).
  - To identify utilization gaps specific to risankizumab, SDI quartiles (Q1 – SDI ≥1-<18 and Q4 – SDI ≥61-≤100) were compared to examine the likelihood of transitioning to risankizumab. Results indicate that members in the lowest SDI quartile (experiencing the least social deprivation) were 1.94 times more likely (34.9%, n=327) to be prescribed risankizumab compared to the highest quartile (21.6%, n=305) (χ^2=12.9, P=0.0003).
- There were no statistically significant associations between SDI and other CD biologic therapies or member out-of-pocket amounts.

Limitations

- Results are based on exploratory bivariate unadjusted analyses. Further research is needed to examine identified relationships and conduct more in-depth analysis, controlling for pertinent covariates.
- Members' SDI scores reflect ZIP-code-based area-level deprivation, which might not directly relate to their individual SDI status.
- Results are correlational not causational.
- The study sample consisted primarily of commercially insured members and may not relate to other populations or disease states other than CD that utilize biologic medications.
- Analysis is based on real-world claims data; utilization not billed through insurance is not captured. Undetectable data-quality issues may exist that are common to all claims-data sources, such as submitting a valid code but not the code that was intended.

Conclusions

- This exploratory analysis of over 1,200 members newly starting Crohn's disease (CD) biologic therapy and their social determinants of health (SDOH) Social Deprivation Index (SDI) score associations with biologic costs and utilization found a statistically significant, yet numerically small, associated adalimumab-use increase and risankizumab-use decrease with rising SDI, alongside lower total biologic spend in higher SDI groups. These findings may reflect underlying differences in treatment cost and complexity, requiring further exploration.
- The SDI and adalimumab associations found in this study may be due to adalimumab's lower cost, self-administration, and pharmacy benefit coverage posing fewer barriers; whereas, risankizumab's initiation of therapy through medical administration—and billing and shifting to the pharmacy benefit—could add administrative and payment complexities potentially disproportionately impacting socially disadvantaged members.
- These findings may illustrate a need for managed care professionals to create solutions to address SDOH barriers. For example, transportation may be a barrier to members initiating risankizumab or attending follow-up appointments. Initiatives like member outreach, member assistance programs, or other innovative solutions could improve CD outcomes and increase medication access.
- Further research is needed to examine social factors that influence disparities in biologic therapy access and utilization in CD.

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