

# Prevalence of Crohn's Disease (CD) and Ulcerative Colitis (UC), Biologic Therapy Use, and Total Medical and Pharmacy Claims Expense Associated with CD and UC in a Population of 15 Million Commercially Insured Members

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## Background

- Inflammatory bowel disease (IBD) is a set of chronic, immune-mediated disorders characterized by chronic inflammation of the gastrointestinal tract. Crohn's disease (CD) and ulcerative colitis (UC) are the two major types of IBD.
- Conventional therapies used for CD and UC include: aminosalicylates, immunomodulators, and corticosteroids. Aminosalicylates and immunomodulators may have limited benefit in CD and corticosteroids are recommended only as short-term therapy for either diagnosis.<sup>1,2,3</sup>
- Biologic therapy (BT) used for CD and UC includes:
  - ❖ Tumor necrosis factor-alpha antagonists (adalimumab and infliximab for both CD and UC, certolizumab pegol for CD, and golimumab for UC)
  - ❖ Anti-integrin monoclonal antibodies (natalizumab for CD and vedolizumab for both CD and UC)
  - ❖ Anti-interleukin (IL)-12/IL23 ustekinumab for CD
- In addition, the targeted synthetic agent tofacitinib was recently FDA-approved for UC.
- There is interest in current, real-world total prevalence of CD and UC, BT rates and total health care costs.
  - ❖ Use and cost of BT have been progressively increasing for years.<sup>4</sup>
  - ❖ Most published studies of IBD total cost of care reflect costs observed years ago.<sup>5,6</sup>

## Objectives

- To determine CD and UC: prevalence, percentage treated with biologic therapy, and total pharmacy and medical claims expense per member, incurred between July 2017 and June 2018 (12 months), compared with matched members without CD or UC.

## Results

- Among 4.12 million continuously eligible members: 8,652 (0.21 percent, mean age 44 years) were classified as CD, and 7,977 (0.19 percent, mean age 46 years) as UC. **Figure** graphs prevalence by age. Prevalence estimates are consistent with other reports from United States populations.<sup>8,9</sup>
- We selected 43,260 matched not-CD and 39,885 not-UC members. The difference in claims cost between the CD (UC) members and the matched comparison samples provides an estimate of the cost associated with CD (UC).
- Mean total cost of care for all study members was: \$50,514 for CD, \$33,691 for UC, \$7,916 for not-CD, and \$8,186 for not-UC; for an excess cost of \$42,598 for CD and \$25,505 for UC. **Table 1** shows costs by categories.
- Of the excess cost:
  - ❖ 68.2 percent of CD and 53.3 percent of UC was for BT to treat the conditions.
  - ❖ 6.7 percent of CD and 18.4 percent of UC was for other pharmacy claims, with leading cost categories aminosalicylates and enteric corticosteroids.
  - ❖ 14.9 percent of CD and 16.1 percent of UC was for other medical outpatient claims, with leading cost categories: lab tests, office visits, and endoscopy.
  - ❖ 10.2 percent of CD and 12.2 percent of UC was for inpatient claims.
- Table 2** shows cost for CD and UC members stratified by whether they had any claim for BT.
  - ❖ 4,258 (49.2 percent) of CD and 2,021 (25.3 percent) of UC members had a claim for BT between July 2017 and June 2018.
  - ❖ For these members with any claim for BT, mean total cost of care, BT cost, and all other cost was:
    - CD total: \$80,236; \$59,048 (73.6 percent) BT and \$21,187 (26.4 percent) all other
    - UC total: \$75,157; \$53,698 (71.4 percent) BT and \$21,459 (28.6 percent) all other
- During the 12 months, 448 (5.2 percent) of CD and 237 (3.0 percent) of UC members had a CD or UC hospitalization, respectively.
- Table 3** shows cost for CD and UC members stratified by whether member had a hospitalization with CD or UC as primary diagnosis. These members had a mean non-BT cost of \$75,239 for CD and \$90,845 for UC, and accounted for 18.2 percent of the total non-BT cost of CD and 13.4 percent of UC.

## Methods

- From 15 million commercially insured members, we identified individuals continuously eligible July 2014 to June 2018 (four years), and age less than 65 years.
- Based on published criteria, CD and UC were defined as all who had five or more medical claims and a majority of the 10 most recent coded claims with a diagnosis code for CD or UC.<sup>7</sup>
- We selected two random samples of members – not-CD and not-UC – from all members with no claims for CD or UC, matched 5 to 1 with CD and UC by sex, age, and plan.
- All pharmacy claims were categorized by National Drug Code (NDC), medical outpatient by Healthcare Common Procedure Coding System (HCPCS), and inpatient by primary diagnosis codes.
  - ❖ BT for UC was defined as pharmacy claims or medical outpatient claim lines for: adalimumab, golimumab (Simponi<sup>®</sup>), infliximab, vedolizumab.
  - ❖ Medical claims expense includes claim lines for administration of the drug.
- Claims cost is the sum of allowed amounts without adjustment for rebates or coupons.
- Hospitalization for CD or UC was defined as an inpatient facility claim with CD or UC as the primary diagnosis code.
- BT for CD was defined as pharmacy claims or medical outpatient claim lines for: adalimumab (Humira<sup>®</sup>), certolizumab (Cimzia<sup>®</sup>), infliximab (Remicade<sup>®</sup>, Inflectra<sup>®</sup>, Renflexis<sup>®</sup>), ustekinumab (Stelara<sup>®</sup>), vedolizumab (Entyvio<sup>®</sup>), or natalizumab (Tysabri<sup>®</sup>). Natalizumab claims only classified as CD treatment if from a medical claim with a diagnosis code for CD but not for multiple sclerosis.

**Table 1.** Crohn's Disease (CD) and Ulcerative Colitis (UC) Claims Cost Per Patient Per Year (PPPY): CD or UC Members Compared with Matched Members without CD or UC

Expense category	% of Members with Claim(s)				Mean Cost PPPY, July 2017 to June 2018			
	Members with Diagnosis		Matched Members		Members with Diagnosis		Matched Members	
	CD N=8,652	UC N=7,977	Not CD N=43,260	Not UC N=39,885	CD N=8,652	UC N=7,977	Not CD N=43,260	Not UC N=39,885
<b>Biologic Therapy (BT), pharmacy + medical benefits</b>	<b>49.2%</b>	<b>25.3%</b>	<b>0.0%</b>	<b>0.0%</b>	<b>\$ 29,060</b>	<b>\$ 13,605</b>	<b>\$ –</b>	<b>\$ –</b>
BT, pharmacy benefit	26.0%	10.1%	0.0%	0.0%	\$ 15,988	\$ 5,164	\$ –	\$ –
BT, medical benefit	27.1%	16.7%	0.0%	0.0%	\$ 13,072	\$ 8,441	\$ –	\$ –
<b>Pharmacy, excluding BT</b>	<b>96.3%</b>	<b>97.7%</b>	<b>86.6%</b>	<b>87.7%</b>	<b>\$ 4,575</b>	<b>\$ 6,568</b>	<b>\$ 1,726</b>	<b>\$ 1,879</b>
Oral aminosalicylates	25.8%	58.0%	0.1%	0.1%	\$ 1,276	\$ 2,874	\$ 1	\$ 1
Rectal aminosalicylates	2.1%	14.2%	0.0%	0.0%	\$ 60	\$ 402	\$ 0	\$ 0
Enteric corticosteroids	9.6%	7.8%	0.0%	0.1%	\$ 309	\$ 333	\$ 1	\$ 1
Azathioprine	13.7%	10.7%	0.1%	0.1%	\$ 49	\$ 41	\$ 0	\$ 0
Mercaptopurine	7.5%	5.4%	0.0%	0.0%	\$ 43	\$ 32	\$ 0	\$ –
Oral corticosteroids	31.6%	33.7%	17.2%	17.8%	\$ 11	\$ 14	\$ 4	\$ 4
Methotrexate	6.5%	2.8%	0.0%	0.5%	\$ 29	\$ 11	\$ 2	\$ 2
Rectal corticosteroids	2.3%	2.8%	0.6%	0.7%	\$ 6	\$ 8	\$ 1	\$ 1
Metronidazole	10.8%	8.5%	2.5%	2.6%	\$ 4	\$ 2	\$ 0	\$ 0
Ciprofloxacin	11.0%	9.1%	4.1%	4.6%	\$ 2	\$ 1	\$ 0	\$ 0
All other pharmacy					\$ 2,787	\$ 2,850	\$ 1,717	\$ 1,868
<b>Medical outpatient, excluding BT</b>	<b>99.9%</b>	<b>99.9%</b>	<b>99.1%</b>	<b>99.4%</b>	<b>\$ 10,917</b>	<b>\$ 8,736</b>	<b>\$ 4,561</b>	<b>\$ 4,633</b>
Lab tests	90.3%	86.9%	69.5%	70.1%	\$ 1,789	\$ 1,237	\$ 526	\$ 513
Office visits	98.4%	98.0%	92.0%	92.7%	\$ 1,014	\$ 891	\$ 506	\$ 521
Emergency room visits	23.6%	18.1%	14.1%	13.7%	\$ 440	\$ 300	\$ 185	\$ 178
Home visits	7.7%	5.4%	2.3%	2.4%	\$ 189	\$ 67	\$ 19	\$ 8
Colonoscopy	32.6%	37.0%	5.1%	6.0%	\$ 752	\$ 819	\$ 100	\$ 115
Upper endoscopy	12.4%	7.6%	2.4%	2.5%	\$ 259	\$ 171	\$ 46	\$ 46
Surgical pathology	38.6%	42.5%	11.5%	12.6%	\$ 381	\$ 388	\$ 48	\$ 49
Abdominal or pelvic CT/MRI	23.5%	12.7%	4.8%	5.3%	\$ 687	\$ 329	\$ 101	\$ 111
All other medical outpatient					\$ 5,405	\$ 4,534	\$ 3,030	\$ 3,091
<b>Medical inpatient</b>	<b>13.2%</b>	<b>10.0%</b>	<b>4.0%</b>	<b>4.3%</b>	<b>\$ 5,963</b>	<b>\$ 4,782</b>	<b>\$ 1,629</b>	<b>\$ 1,674</b>
<b>Total pharmacy + medical</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>\$ 50,514</b>	<b>\$ 33,691</b>	<b>\$ 7,916</b>	<b>\$ 8,186</b>
<b>Pharmacy + medical, excluding BT</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>\$ 21,454</b>	<b>\$ 20,086</b>	<b>\$ 7,916</b>	<b>\$ 8,186</b>

Members with CD or UC diagnosis were identified among 4 million commercially insured members continuously eligible July 2014 to June 2018 (four years) who had >= five medical claims and majority of ten most recent coded claims with a diagnosis code for CD or UC, respectively. Matched members = randomly selected samples of continuously enrolled members matched 5:1 with CD or UC, respectively, by sex, age, and health plan. Office, emergency room, and home visits = claims lines for evaluation and management; CT/MRI = computerized tomography or magnetic resonance imaging. See Methods for BT drug list.

**Table 2.** Members Utilizing Biologic Therapy (BT) versus no BT with Crohn's Disease (CD) or Ulcerative Colitis (UC): Claims Cost Per Patient Per Year (PPPY)

Expense category	% of Members with Claim(s)				Mean Cost PPPY, July 2017 to June 2018			
	CD		UC		CD		UC	
	No BT N=4,394	Any BT N=4,258	No BT N=5,956	Any BT N=2,021	No BT N=4,394	Any BT N=4,258	No BT N=5,956	Any BT N=2,021
<b>Biologic Therapy (BT), pharmacy + medical benefits</b>	<b>0.0%</b>	<b>100.0%</b>	<b>0.0%</b>	<b>100.0%</b>	<b>\$ –</b>	<b>\$ 59,048</b>	<b>\$ –</b>	<b>\$ 53,698</b>
BT, pharmacy benefit	0.0%	52.9%	0.0%	40.0%	\$ –	\$ 32,487	\$ –	\$ 20,384
BT, medical benefit	0.0%	55.1%	0.0%	66.1%	\$ –	\$ 26,561	\$ –	\$ 33,314
<b>Pharmacy, excluding BT</b>	<b>96.3%</b>	<b>96.3%</b>	<b>97.9%</b>	<b>96.9%</b>	<b>\$ 5,441</b>	<b>\$ 3,681</b>	<b>\$ 6,738</b>	<b>\$ 6,068</b>
Oral aminosalicylates	35.5%	15.9%	62.6%	44.5%	\$ 1,836	\$ 697	\$ 3,067	\$ 2,307
Rectal aminosalicylates	1.9%	2.4%	14.9%	12.1%	\$ 57	\$ 63	\$ 446	\$ 270
Enteric corticosteroids	8.3%	11.0%	6.2%	12.6%	\$ 280	\$ 340	\$ 270	\$ 519
Azathioprine	13.1%	14.3%	9.1%	15.7%	\$ 49	\$ 49	\$ 37	\$ 52
Mercaptopurine	7.5%	7.5%	4.7%	7.5%	\$ 47	\$ 38	\$ 28	\$ 44
Oral corticosteroids	29.1%	34.2%	30.2%	44.1%	\$ 7	\$ 15	\$ 7	\$ 33
Methotrexate	2.9%	10.1%	1.3%	7.3%	\$ 17	\$ 41	\$ 5	\$ 28
Rectal corticosteroids	2.2%	2.3%	2.7%	3.3%	\$ 5	\$ 6	\$ 8	\$ 9
Metronidazole	7.8%	13.8%	7.8%	10.6%	\$ 3	\$ 5	\$ 2	\$ 2
Ciprofloxacin	9.9%	12.3%	9.4%	8.5%	\$ 1	\$ 3	\$ 1	\$ 1
All other pharmacy					\$ 3,139	\$ 2,423	\$ 2,866	\$ 2,803
<b>Medical outpatient, excluding BT</b>	<b>100.0%</b>	<b>99.9%</b>	<b>100.0%</b>	<b>99.8%</b>	<b>\$ 10,568</b>	<b>\$ 11,276</b>	<b>\$ 8,499</b>	<b>\$ 9,432</b>
Lab tests	86.8%	94.0%	84.6%	93.9%	\$ 1,668	\$ 1,913	\$ 1,074	\$ 1,719
Office visits	98.0%	98.7%	97.8%	98.8%	\$ 928	\$ 1,103	\$ 847	\$ 1,020
Emergency room visits	22.3%	24.8%	17.4%	20.1%	\$ 455	\$ 424	\$ 289	\$ 333
Home visits	4.8%	10.6%	4.0%	9.5%	\$ 228	\$ 149	\$ 47	\$ 125
Colonoscopy	26.4%	39.0%	33.3%	47.9%	\$ 581	\$ 929	\$ 721	\$ 1,108
Upper endoscopy	11.2%	13.6%	7.2%	8.7%	\$ 239	\$ 281	\$ 165	\$ 189
Surgical pathology	33.5%	44.0%	39.5%	51.6%	\$ 298	\$ 467	\$ 344	\$ 517
Abdominal or pelvic CT/MRI	19.3%	27.9%	12.1%	14.7%	\$ 526	\$ 853	\$ 306	\$ 398
All other medical outpatient					\$ 5,644	\$ 5,158	\$ 4,708	\$ 4,022
<b>Medical inpatient</b>	<b>11.9%</b>	<b>14.4%</b>	<b>9.2%</b>	<b>12.4%</b>	<b>\$ 5,703</b>	<b>\$ 6,230</b>	<b>\$ 4,383</b>	<b>\$ 5,960</b>
<b>Total pharmacy + medical</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>\$ 21,712</b>	<b>\$ 80,236</b>	<b>\$ 19,620</b>	<b>\$ 75,157</b>
<b>Pharmacy + medical, excluding BT</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>\$ 21,712</b>	<b>\$ 21,187</b>	<b>\$ 19,620</b>	<b>\$ 21,459</b>

Members with CD or UC diagnosis were identified among 4 million commercially insured members continuously eligible July 2014 to June 2018 (four years) who had >= five medical claims and majority of ten most recent coded claims with a diagnosis code for CD or UC, respectively. No BT = members with no BT claims between July 2017 and June 2018. Any BT = members with any BT claims between July 2017 and June 2018. See Methods for BT drug list.

## Conclusions

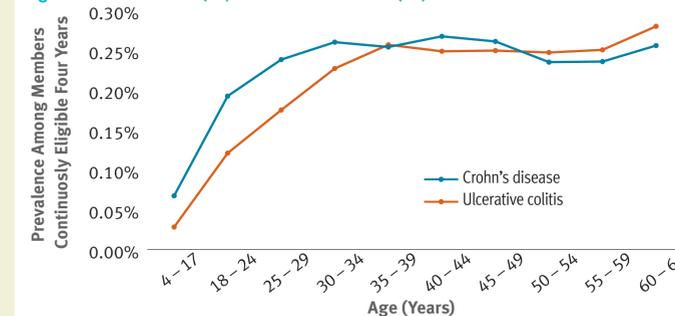
- Using real-world, integrated medical and pharmacy claims data, from a large commercial population, CD and UC each have a prevalence of 2 per 1000 members.
- Treatment with biologic therapy (BT) was twice as common among members with CD (49 percent) as among UC (25 percent).
- Members hospitalized for CD or UC account for a disproportionate share of non-BT cost.
- BT accounted for over 70 percent of the annual CD or UC total cost, therefore it is not possible to obtain a direct medical care offset return on investment.
- BT value needs to be assessed from a societal perspective and with a long time horizon.
- When BT is used to treat CD or UC, payer value-based contracting with manufacturer should be considered to ensure BT value to cost is obtained.

**Table 3.** Crohn's Disease (CD) or Ulcerative Colitis (UC) members with a Hospitalization versus those with no Hospitalization: Claims Cost Per Patient Per Year (PPPY)

Expense category	% of Members with Claim(s)				Mean Cost PPPY, July 2017 to June 2018			
	CD		UC		CD		UC	
	No CD N=8,204	Inpatient N=448	No UC N=7,740	Inpatient N=237	No CD N=8,204	Inpatient N=448	No UC N=7,740	Inpatient N=237
<b>Biologic Therapy (BT), pharmacy + medical benefits</b>	<b>48.0%</b>	<b>70.8%</b>	<b>24.6%</b>	<b>48.1%</b>	<b>\$ 28,315</b>	<b>\$ 42,698</b>	<b>\$ 13,363</b>	<b>\$ 21,495</b>
BT, pharmacy benefit	25.2%	41.1%	9.8%	20.3%	\$ 15,518	\$ 24,608	\$ 5,127	\$ 6,387
BT, medical benefit	26.2%	44.9%	16.2%	34.6%	\$ 12,798	\$ 18,089	\$ 8,237	\$ 15,108
<b>Pharmacy, excluding BT</b>	<b>96.1%</b>	<b>98.9%</b>	<b>97.6%</b>	<b>100.0%</b>	<b>\$ 4,578</b>	<b>\$ 4,517</b>	<b>\$ 6,546</b>	<b>\$ 7,274</b>
<b>Medical outpatient, excluding BT</b>	<b>99.9%</b>	<b>99.8%</b>	<b>99.9%</b>	<b>99.6%</b>	<b>\$ 10,285</b>	<b>\$ 22,494</b>	<b>\$ 8,356</b>	<b>\$ 21,132</b>
Lab tests	89.9%	98.0%	86.7%	95.4%	\$ 1,718	\$ 3,080	\$ 1,142	\$ 4,339
Office visits	98.3%	98.9%	98.0%	99.2%	\$ 986	\$ 1,527	\$ 872	\$ 1,524
Emergency room visits	21.7%	57.4%	17.1%	48.5%	\$ 385	\$ 1,444	\$ 262	\$ 1,533
Home visits	7.3%	15.0%	5.2%	12.2%	\$ 161	\$ 695	\$ 52	\$ 549
Colonoscopy	32.0%	43.1%	36.6%	51.9%	\$ 737	\$ 1,030	\$ 801	\$ 1,422
Upper endoscopy	12.0%	19.6%	7.4%	14.3%	\$ 251	\$ 421	\$ 168	\$ 277
Surgical pathology	38.1%	48.0%	42.3%	51.1%	\$ 369	\$ 609	\$ 380	\$ 647
Abdominal or pelvic CT/MRI	21.5%	61.8%	11.8%	43.0%	\$ 607	\$ 2,158	\$ 288	\$ 1,662
All other medical outpatient					\$ 4,919	\$ 10,885	\$ 4,272	\$ 8,967
<b>Medical inpatient</b>	<b>8.4%</b>	<b>100.0%</b>	<b>7.3%</b>	<b>100.0%</b>	<b>\$ 3,654</b>	<b>\$ 48,228</b>	<b>\$ 3,017</b>	<b>\$ 62,439</b>
<b>Total pharmacy + medical</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>\$ 46,832</b>	<b>\$ 117,936</b>	<b>\$ 31,283</b>	<b>\$ 112,339</b>
<b>Pharmacy + medical, excluding BT</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>100.0%</b>	<b>\$ 18,517</b>	<b>\$ 75,239</b>	<b>\$ 17,919</b>	<b>\$ 90,845</b>

Members with CD or UC diagnosis were identified among 4 million commercially insured members continuously eligible July 2014 to June 2018 (four years) who had >= five medical claims and majority of ten most recent coded claims with a diagnosis code for CD or UC, respectively. See Methods for BT drug list and for inpatient identification methods.

**Figure.** Crohn's Disease (CD) and Ulcerative Colitis (UC) Prevalence



Prevalence = percentage of members with diagnosis among 4 million commercially insured members, continuously eligible July 2014 to June 2018 (four years). Members with diagnosis = members who had five or more medical claims and majority of the ten most recent coded claims with a diagnosis code for Crohn's disease or ulcerative colitis, respectively.

## Limitations

- This study uses only information from administrative claims to determine which members have CD or UC. Some study members may be misclassified.
- IBD frequently has a relapsing and remitting course, so limiting the