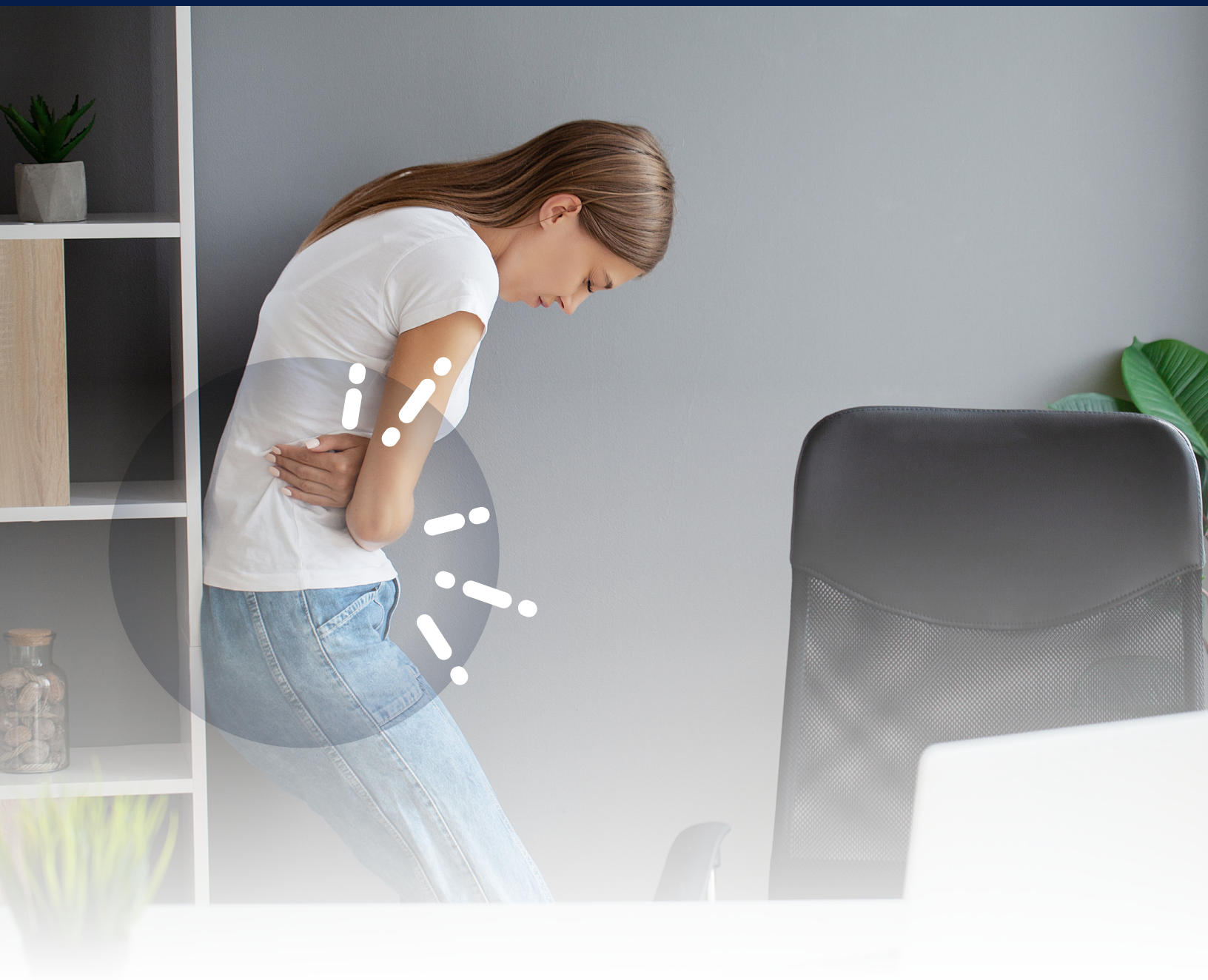


A DEEPER UNDERSTANDING OF INFLAMMATORY BOWEL DISEASE (IBD) AS A LIFELONG DISEASE

An Overview of the Burden of IBD and Its Impact on the Workforce

abbvie

IBD Is a Chronic Condition Affecting the Gastrointestinal (GI) Tract

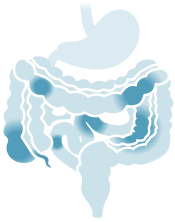
IBD is an inflammatory lifelong disease impacting ~3 million individuals in the US[1]

With more than **+70,000 new cases in the US every year**, the prevalence of IBD is expected to rise exponentially over the next decade.[2,3]

- IBD is a complex, chronic condition that includes 2 major types: Crohn's disease (CD) and ulcerative colitis (UC)[2]
  - In IBD, parts of the GI tract become inflamed, which can cause bowel damage and increase risk for other serious diseases such as colorectal cancer[4-6]
  - This inflammation can lead **to abdominal pain, severe diarrhea**, fatigue, weight loss, and malnutrition[2]
- IBD often presents in an **inconsistent manner** with **nonspecific symptoms**, making accurate **diagnosis challenging**[2,7]

CD and UC Are the Two Most Common Forms of IBD[2]

2 major types



Crohn's disease
Can affect any part of the digestive tract

Ulcerative colitis
Affects the large intestine and rectum

- IBD occurs in men and women equally and may have an early onset, resulting in a **lifetime of necessary care**[8,9]
- A population-based analysis found that Caucasian individuals were **2×** more likely to be diagnosed with IBD than individuals of other races, with increasing rates in Hispanic and Asian individuals in recent years[8,10]
- IBD is most often diagnosed in adolescents and adults in their **20s and 30s**[8,9]

Your Members With IBD Often Experience Serious Symptoms and Complications, Even Outside of the GI Tract[11]

IBD is associated with serious complications that require specialized care and coordination

- Neurologic
- HEENT
- Pulmonary
- Cardiovascular
- Hematologic
- Musculoskeletal
- Hepatic
- Pancreatic
- Cutaneous
- Gastrointestinal
- Urogenital

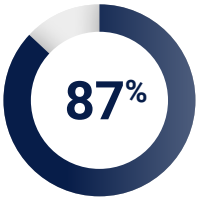
Many patients with IBD endure mental health disorders and burdensome emotional impacts that are compounded by their IBD.[12]

HEENT=head, eyes, ears, nose, and throat.

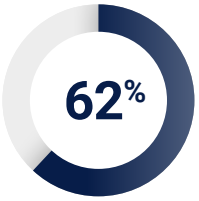
Pain and Bowel Frequency Are Some of the Most Common and Debilitating Symptoms of IBD

Abdominal pain is a common symptom of IBD[13]

In a pan-European study, patients with IBD reported feeling abdominal cramping pain at least once a week.*



during flares

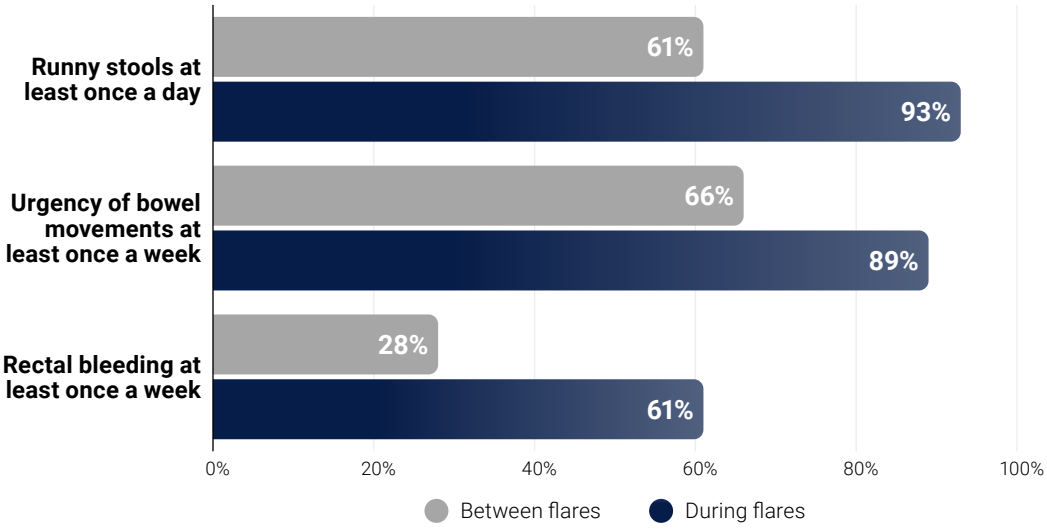


between flares

- It is possible for underlying inflammation to progress for several years with patients only experiencing classic symptoms such as abdominal pain and diarrhea[14]
- Up to one-sixth of **patients with IBD are chronically treated with opioids**,[15] despite research showing that opioids do not reduce pain for this patient population[16]

Even between flares, IBD symptoms pose a substantial burden[13]

Symptoms During and Between Flares: Results From a Pan-European Survey



67% of patients with IBD consider toilet availability when planning to attend an event.[17]

*Patients with IBD (N=4,670) from 25 European countries completed an online survey from November 2010 through August 2011. Respondents had CD (62%) or UC (33%), and the rest another form of IBD or an unconfirmed diagnosis. Many of the questions were sourced from validated, published, and peer-reviewed academic surveys or from national IBD association surveys conducted in the past.[13]

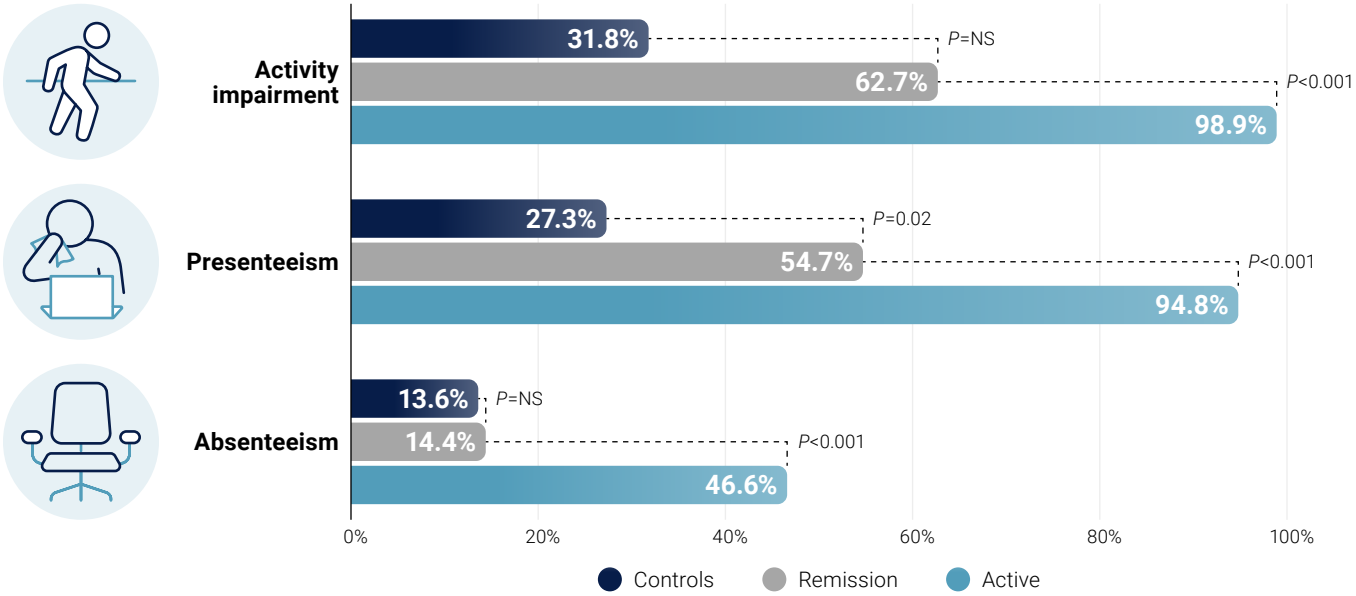
Magnitude of Work Impairment and Productivity Loss in IBD

Patients with IBD may experience reduced productivity at work[17]

EFCCA Patient Survey (N=4,670)

- **60%** of patients with IBD felt **stressed or pressured** about taking sick leave from work
- **56%** of patients felt IBD **negatively impacts** their career path
- According to US data from the Medical Expenditure Panel Survey, 1996–2012:[18]
  - **18%** of the CD vs 10% of the non-CD population were **unemployed** during the year due to illness
  - **57%** of the CD vs 67% of the non-CD population were **unemployed** at least part of the year

Prevalence of Absenteeism, Presenteeism, and Activity Impairment in Patients With Active IBD, Patients With IBD in Remission, and Controls[19]*



A 1996 to 2006 retrospective study sought to estimate the indirect costs associated with IBD, compared with individuals without IBD:[20]

- More IBD patients **missed time from work** due to illness: **71.5%** (143/200) vs **58%** (52,257/89,846) (*P*<0.0001)
- IBD patients **lost more work days** annually: **13.38 days** vs **9.89 days** (*P*=0.044)

Create access to gastroenterology care to drive evaluation of members who are experiencing IBD or symptoms of IBD to assess how their disease is impacting their QoL and level of work productivity.

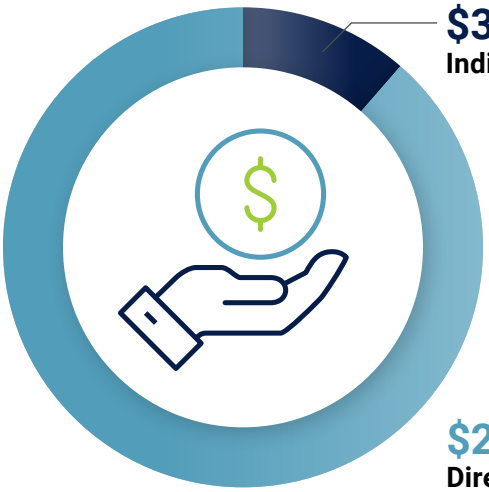
EFCCA=European Federation of Crohn's and Ulcerative Colitis Associations; NS=not significant.

*Prospective study of 440 adult patients with IBD and 22 controls (adults without IBD) to assess work productivity, work-related problems and adjustments, quality of life (QoL), and disease activity at an IBD center in California from March 2013 to February 2014. Remission of IBD was defined as a Harvey-Bradshaw index score of ≤4 for CD and a Partial Mayo score ≤2 for UC, with higher scores indicating active disease. Absenteeism was calculated based on the numbers of hours missed from work due to disease as a percentage of the total number of hours worked in a week. Presenteeism and activity impairment were assessed on an 11-point Likert scale, where 0 was no effect of the disease and 10 was full impairment due to disease.[19]

Economic Impacts of IBD Are High for Members, Employers, and Payers

IBD is associated with substantial healthcare costs

Up to $31.6 Billion in Annual Costs for IBD[2]*



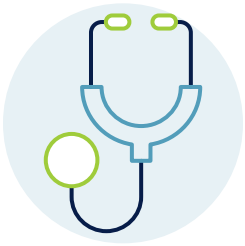
$3.6 Billion
Indirect Costs[2]†

$28 Billion
Direct Costs[2]*

Patients with IBD incurred more than 3× higher annual total direct costs than patients without IBD[21]‡
$22,987 vs $6,956

The estimated annual cost burden of IBD is $14.6 billion to $31.6 billion, with an estimated $11 billion to $28 billion in direct healthcare costs and an estimated $3.6 billion in indirect costs (based on extrapolation of 1999–2005 costs)[2]*†

Members with IBD have increased and often unplanned healthcare utilization[22]



In a retrospective claims database analysis, comparing patients with moderate to severe UC (n=4,314) vs matched non-IBD controls (n=4,314), UC patients had:[23]

- **~4×** the mean number of annual **hospital days** (1.2 vs 0.3; *P*<0.0001)
- **~2×** the mean number of annual **emergency department** (ED) visits (0.5 vs 0.3; *P*<0.001)
- **~2×** the mean number of **outpatient visits** (15 vs 7.5; *P*<0.0001)

IBD patients have more ED visits per year vs patients without IBD[24]§
In a study that compared healthcare utilization in populations of patients with and without IBD, patients with:

- **CD** had **20.1 additional ED annual visits** per 100 patients (36.0 vs 15.1 per 100 patients; *P*<0.001)
- **UC** had **10.3 additional ED annual visits** per 100 patients (26.2 vs 15.7 per 100 patients; *P*<0.001)

*A population-based study in Olmstead County, Minnesota, examined the number of new cases per year from 1940 to 2011. The incident (new) cases of IBD each year were 10.7 per 100,000 people and 12.2 per 100,000 people for CD and UC, respectively. These incidence data were used to estimate the number of cases of UC and CD based on the population of the US in 2014, yielding 780,000 and 907,000 cases, respectively. The annual direct costs of CD and UC were estimated based on 2003–2004 US insurance claims and 1999–2005 MarketScan data. Direct costs included inpatient, outpatient, ED, and prescription drug costs. The direct cost of CD was estimated to be between $8,265 and $18,963 per patient, while the estimated direct cost of UC was between $5,066 and $15,020 per patient. These cost data were combined with the estimated prevalence of CD and UC in 2014 to estimate the annual total cost burden.

†Indirect costs based on reports of being out of the workforce in a 1-year period in 1999 from symptomatic patients with IBD.

‡Study objective was to quantify healthcare costs of patients living with IBD (n= 52,782 [29,062 UC; 23,720 CD]) vs matched control patients without IBD (n= 52,782) using Optum Research database paid commercial and Medicare Advantage claims from 2007 to 2016. Costs were adjusted using the annual medical care component of the Consumer Price Index.

§Cross-sectional claims analysis of inpatient, office-based, emergency, and endoscopy services occurring between 2003 and 2004 in 9,056 patients with CD, 10,364 patients with UC, and 52,989 controls matched for age, gender, and region from 87 different health plans in 33 states.

Members with IBD may be driving up your medical spend

In 2010, the CDC/NCHS reported there were 294,000 hospitalizations specifically for IBD[2]

- **187,000** for CD
- **107,000** for UC

In one study, among 94,732 patients with IBD, 9% (8,211) were readmitted with IBD as their primary diagnosis and 19% (17,579) were readmitted for any diagnosis within 30 days[25]*

- Mean 30-day readmission costs were **$1,980 higher** than the initial hospital stay (mean cost per hospital stay=$10,639; mean readmission hospital cost=$12,619)

In another study of 52,498 patients with IBD, 24% were readmitted within 90 days[26†]

- Total charges attributed to 90-day readmissions were **$576.7 million** (2013)
- Anxiety, depression, and chronic pain were associated with a significant increase in the odds of readmission

Diarrhea alone may increase healthcare burden

In 2014, over 800,000 ED visits were directly related to diarrhea. Among GI-related symptoms, diarrhea was the:[27-29]

- **3rd** most common reason for **ED visits**[27]
- **6th** most common **hospital discharge diagnosis** (2009)[28]
- **6th** most common reason for **outpatient visits**[29]

Review your annual utilization data, including codes for IBD conditions, to understand the burden of IBD within your member population, including use of the ED for care.

- Consult with your healthcare plan advisors to strategize how best to improve care
- Review your provider network and prior authorization process to ensure your members have timely access to an IBD treating specialist

CDC=Centers for Disease Control and Prevention; NCHS=National Center for Health Statistics.

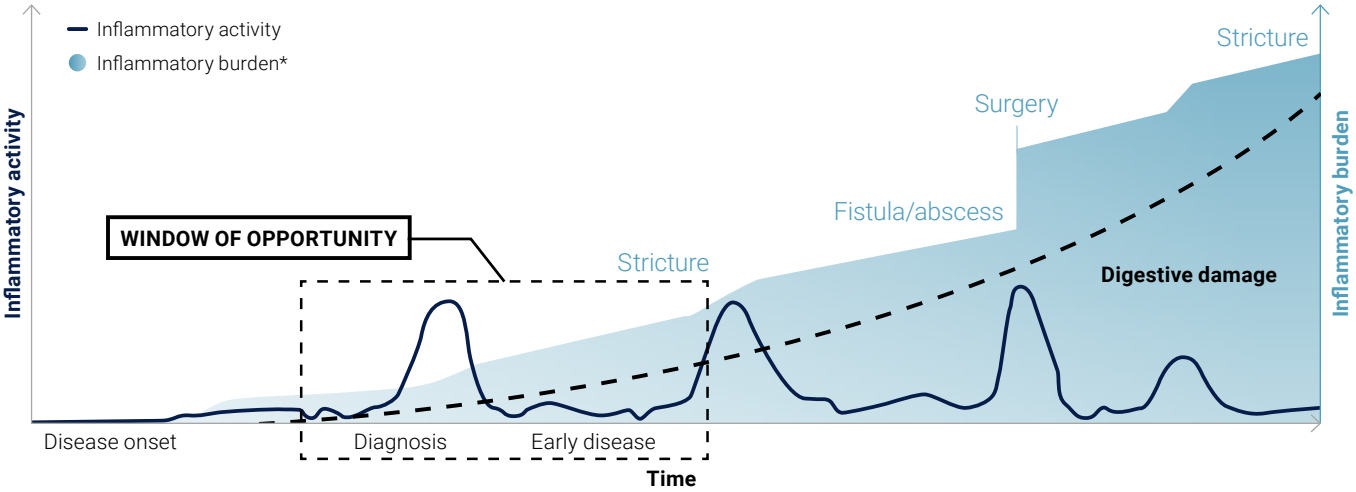
*Retrospective analysis of 2010 data examining prevalence and costs of readmission in the 30 days following discharge related to IBD from the Nationwide Inpatient Sample database, which includes ~8 million hospitalizations. Patients hospitalized for regional enteritis and UC were included.

†Retrospective analysis of 2013 data from the Nationwide Readmissions Database, a resource of the Healthcare Cost and Utilization Project State Inpatient Databases that includes data on >14 million hospitalizations. Patients aged ≥18 years with ICD-9 diagnostic codes for CD (555.xx) and UC (556.xx) were included. Patients coded with both were excluded.

The Importance of Early Intervention and Management in IBD

Lifelong, progressive, and inflammatory states of the bowel occur in a relapsing and remitting pattern

Cumulative Bowel Damage Due to Inflammation[5,6,30]
in a theoretical patient with CD



Disease activity is a cross-sectional snapshot of one moment in time. Inflammatory burden includes longitudinal and historical factors of disease severity, providing a more complete picture of disease course.[6]

Diagnostic delay and **prolonged use of ineffective treatment** for patients with IBD is associated with an increase in:[7]

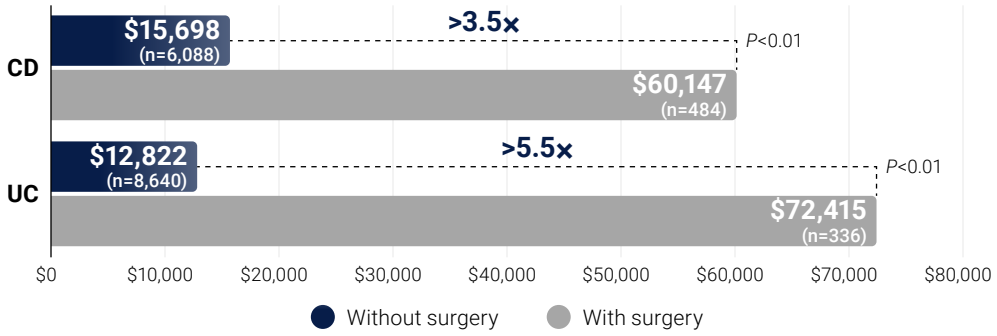
- Surgery rate
- Bowel stenosis (narrowing of the intestine)
- Perianal disease
- Overall complications

Long diagnostic delay has also been associated with shorter time to surgery.

Surgery can drive costs for members with IBD

If not closely managed, up to **75%** of patients with **CD** and **23% to 45%** with **UC** will eventually require surgery.[31]

12-Month Expenditure per Patient With CD and UC With and Without Surgery[32]*



Patients with IBD who require surgery have significantly higher medical expenditures than those who don't require surgery.

Early disease intervention and routine assessments may lead to improved management of members with IBD.

Work with your pharmacy benefit advisors to evaluate your current treatment formulary to ensure member access to available treatment for optimized IBD care.

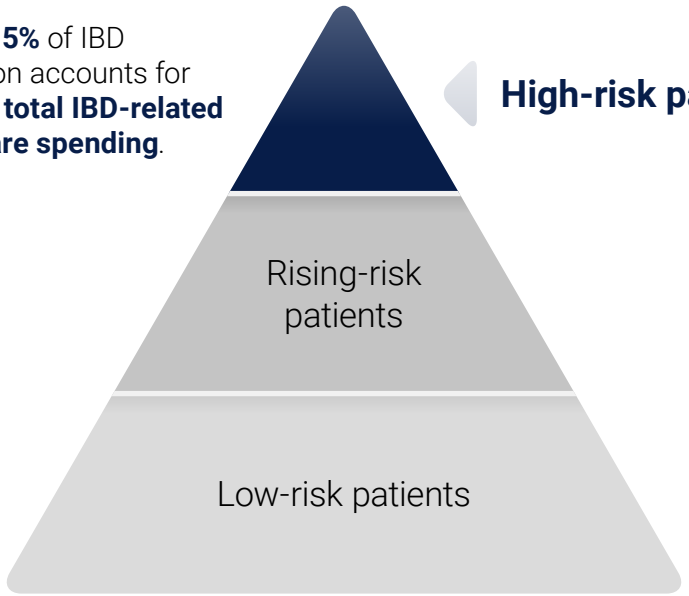
*Patients with CD (N=6,569) and patients with UC (N=8,970) were selected from 1999 to 2005 MarketScan databases representing up to 17 million commercially insured US employees and their dependents. Expenditures were summed for 12 months before and 12 months after the diagnosis of IBD and included the following: inpatient visit, ED visit, outpatient office visits, and prescription costs. Costs were adjusted to 2005 dollars.

Treatment Strategies to Help Reduce the Economic Burden of IBD

Tracking and monitoring patient progress against treat to target (T2T) treatment targets may enable better identification of members with IBD who are at the highest risk of an ED visit or hospitalization and may provide improved preventive care management

Healthcare Spending Is Concentrated Among a Small Subset of High-Risk Patients[33,34*†]

Riskiest 5% of IBD population accounts for **~44% of total IBD-related healthcare spending**.



Consistently practicing a T2T approach may give members with IBD the best chance of achieving:[35]

- Symptomatic remission and normalization of CRP
- Endoscopic healing
- A normalized QoL, free from disability

Delayed diagnosis of an underlying GI disease may lead to increased healthcare resource utilization and inadequate management

- Patients with chronic GI symptoms should be **referred to a gastroenterologist** to reduce time to diagnosis and improve care management[36]
- Up to **one-sixth** of patients with IBD are **chronically treated with opioids** despite research showing that opioids do not reduce pain in this patient population[15,16]

Review your provider network and prior authorization process to ensure your members have access to specialists and primary care providers knowledgeable and experienced with treating IBD. Furthermore, make sure that IBD treatments are covered and available with limited restriction.

CRP=C-reactive protein.

*A 2012 Medical Expenditure Panel Survey defined high-risk patients as those with the costliest medical conditions including heart disease, trauma-related disorders, cancer, mental disorders, and chronic obstructive pulmonary disease/asthma. Expenditures included all sources of inpatient care, ambulatory care, EDs, home health care, and prescribed prescriptions.[33]

†A 2009 to 2013 prospective observational study found that the riskiest 5% of patients with IBD who had the highest medical charges accounted for almost ~44% of total direct IBD healthcare costs (N=2,078).[34]

Raising Awareness and Improving the Care and Access to Treatment for Members With IBD

STEP 1

Raise Awareness of the Prevalence of IBD and the Burden of Disease

- Include GI screening and QoL questionnaires on your organization's resource site to encourage assessment of risk factors and possibly improve timely connection to care and treatment

STEP 2

Enhance Access to Comprehensive Care

- Optimize network adequacy ratios (e.g., members per IBD provider) to minimize time to treatment
- Eliminate barriers to appropriate IBD care by minimizing authorization requirements
- Review your formulary coverage for IBD treatments and, if necessary, redesign to include additional treatment options to allow for individualized treatment approaches

STEP 3

Utilize Care Management Programs for Continued Support

- Stay up to date on the current treatment options for IBD and ensure your members have unrestricted access

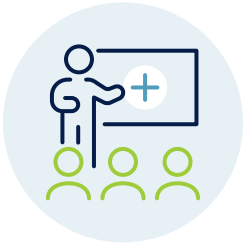
AbbVie's Employer Strategies Focus on Improving Workforce Health and Productivity by Addressing:

Disease State Awareness

Raising awareness of the burden and impact of disease

Access to Treatment

Establishing and expanding access to treatment through benefit design



Engagement and Educational Support

Developing connections to promote engagement and educational support

For additional information and support, contact your AbbVie Account Executive.

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