

**Purpose:** To assess the impact of age on annual costs of care and resource utilization for pts with UC using a medical claims database.

**Methods:** A retrospective analysis, using the PharMetrics database, of pts with a diagnosis of UC (ICD-9 code 556.x) from January 1, 2000 through June 30, 2005 was conducted. Pts had to be continuously enrolled for 6 months pre-and 12 months post-UC diagnosis, and have 2 distinct claims for UC. Mean per pt healthcare resource utilization and costs were calculated for pts in the yr following their initial UC diagnosis. Outcomes are presented for UC pts by age groups: pediatric ≤ 18 yrs of age; adults 18 to 64 yrs; and adults ≥ 65 yrs of age.

**Results:** The study cohort consisted of 15105 pts with UC. Almost 50% of the pts were males. Mean annual total cost for all UC pts in the study were \$13233. Pediatric UC pts incurred the highest mean cost (\$23113), followed by adults ≥ 65 yrs \$15811, and adults 18 to 64 yrs \$12693. Inpt hospitalization costs constituted the largest component (\$5771, 44%) of the mean annual total costs for all pts. The next highest cost components were prescription medications (\$2423, 18%), outpts (\$1310, 10%), physician office visits (\$899, 6.8%), and lab procedures (\$470, 3.6%). Resource utilization was highest in the adults ≥ 65 yrs followed by pediatric, and adults 18 to 64 yrs (Table).

**Conclusions:** UC in pediatric pts is associated with a high cost of care that is almost twice the cost for the adults UC pts. New therapies that can reduce hospitalizations have the potential to decrease overall cost of care for pts with UC.

Mean Healthcare Costs and Resource Utilization

	Pediatric (<18 yrs)	Adults (18–64yrs)	Adults 65 yrs≥	All pts
N (%)	589 (3.9)	13866 (92)	650 (4.3)	15,105
Age	13	44	75	44
Females	48	54	58	54
Deyo-Charlson Comorbidity Index Score	1.4	1.3	2.9	1.3
Total healthcare costs	\$23,113	\$12,693	\$15,811	\$13,233
Inpt	\$15,051	\$5,276	\$7,926	\$5,771
Outpt	\$1,413	\$1,276	\$1,941	\$1,310
ER	\$283	\$264	\$332	\$268
Physician	\$1,088	\$884	\$1,052	\$899
Lab	\$677	\$467	\$357	\$470
Prescription	\$2,207	\$2,469	\$1,641	\$2,423
Total healthcare visits	15	13	19	14
Inpt admissions (days)	0.6 (4.3)	0.3 (1.8)	0.8 (4.5)	0.4(2.0)
Outpt visits	2.5	2.0	3.3	2.0
ER visits	0.4	0.5	0.5	0.4
Physician visits	11	11	15	11
Lab visits	5.0	4.1	6.0	4.2
# of prescriptions	19	23	28	23

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**UC: Annual Costs of Care and Resource Utilization in Adult Pts 18 to 64 Years from a Payer Perspective**

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**Purpose:** To assess the annual cost of care & resource utilization for adult UC pts 18 to 64 yrs of age from a medical claims database.

**Methods:** A retrospective analysis, using the PharMetrics database, of adult pts 18 to 64 yrs with a dx of UC (ICD-9 code 556.x) from Jan. 1, 2000 through June 30, 2005 was conducted. Pts had to be continuously enrolled for 6 months pre-and 12 months post-UC dx, and have 2 distinct claims for

UC. Mean per pt healthcare resource utilization and costs were calculated for pts in the yr following their initial UC dx.

Outcomes are presented for UC pts by disease severity grps. Grp 1 required hospitalization for UC; Grp 2 required chronic aggressive pharmacotherapy (i.e. corticosteroids or immunosuppressants) for ≥4 months; and Grp 3 included remaining pts.

**Results:** The cohort had 13856 UC pts. Average pt age was 44 yrs & 56% were females. Mean annual total costs for all pts with UC were \$12693 vs \$3661 for non-UC pts. Grp 1 pts incurred the highest mean cost (\$36155), while Grps 2 & 3 incurred \$11401 & \$6493, respectively. Inpt hospitalization costs had the largest component (\$5276, 42%) of the mean annual total costs for all pts. The next highest cost components were prescription meds (\$2469, 20%), outpts (\$1276, 10%), physician office visits (\$884, 7.0%), and lab procedures (\$467, 3.7%). Resource utilization was also highest in Grp 1 (Table).

**Conclusions:** UC in adults 18 to 64 yrs is associated with a high cost of care that is almost 3-fold the cost for those without UC. Pts requiring hospitalization incurred the highest cost. New therapies that can reduce hospitalizations have the potential to decrease overall cost of care for UC pts.

Healthcare Costs and Resource Utilization by Disease Severity

	Grp 1	Grp 2	Grp 3	All Pts
N (%)	2387 (17)	3088 (22)	8381 (61)	13,856
Age	43	43	45	44
Females%	55	53	54	54
Deyo-Charlson Comorbidity Index Score	2.5	1.2	0.9	1.3
Total Healthcare	\$36,155	\$11,401	\$6,493	\$12,693
Inpt	\$24,693	\$1,842	\$1,016	\$5,276
Outpt	\$1,981	\$1,383	\$1,036	\$1,276
ER	\$568	\$235	\$188	\$264
Physician	\$1,261	\$992	\$737	\$884
Lab	\$559	\$546	\$412	\$467
Prescription	\$3,502	\$4,283	\$1,508	\$2,469
Total healthcare visits	19	15	11	13
Inpt admissions (days)	1.5 (8.8)	0.1 (1.0)	0.1 (0.3)	0.3 (1.8)
Outpt visits	3.0	2.3	1.5	2.0
ER visits	0.8	0.4	0.3	0.5
Physician visits	14	12	9	11
Lab visits	6.0	4.8	3.4	4.1
# of prescriptions	32	33	17	23

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**The Prevalence and Costs To Treat GI Comorbidities in Persons with Constipation**

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**Purpose:** To compare the prevalence and costs associated with specific GI comorbidities among persons with or without constipation.

**Methods:** A retrospective analysis was conducted using the Human Capital Management Services Research database, which represents multiple US-based employers and contains employee data from 2001–2005. Prevalence and costs among persons with constipation (C) ICD-9 codes (564.0, 564.00, 564.01, and 564.09) were compared with a 24:1 propensity score-matched cohort of controls without constipation (NC). Comorbidities were examined over 1 year. The index date in the C cohort was defined as 3 months prior

to the date of first diagnosis during 2001 or later; the average C index date was used in the NC cohort. GI comorbidities were assessed using Agency for Healthcare Research and Quality specific GI categories. Costs were the sum of the insurance payments for each category. The prevalence of GI comorbidities was calculated for both cohorts. Satterthwaite *t*-tests were used to assess significance of cost differences, and *z*-scores of log odds ratios were used to assess prevalence differences between cohorts.

**Results:** Data were available for 1215 persons with C and 29160 propensity score-matched NC controls. Table 1 presents prevalence and costs per person for both cohorts. All prevalence comparisons were highly significant ( $P < 0.0001$ ). Most cost differences were significant ( $P \leq 0.03$ ).

Annual Prevalence and Costs for GI Comorbidity

Comorbidity	Prevalence* (%)		Costs per Person (\$)		
	Constipation	Control	Constipation	Control	<i>P</i> -Value
GI Hemorrhage	15.4	1.8	77.5	8.4	<0.0001
Hemorrhoids	15.2	1.5	68.6	6.3	<0.0001
Esophageal Disorders	14.4	3.9	66.7	14.0	0.0015
Diverticulosis/Diverticulitis	7.5	1.2	75.3	13.4	<0.0001
Anal and Rectal Conditions	5.8	0.6	73.2	2.5	0.0288
Stomach/Duodenum Disorders	5.2	0.7	15.0	3.0	0.0300
Intestinal Obstruction w/out Hernia	2.7	0.2	76.1	4.7	0.0158
Enteritis/Ulcerative Colitis	1.6	0.4	55.1	5.5	0.1738

\*all prevalence comparisons  $P < 0.0001$

**Conclusions:** Patients with constipation have significantly more GI comorbidities than patients without constipation. These comorbidities incur additional costs, suggesting a need for comprehensive patient management.

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**Cost of Illness for Constipation: Medical, Pharmacy, and Work Absence Costs in Employees with or without Constipation**

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**Purpose:** To assess the Annual Cost of Illness for constipation (C) among US-based employees.

**Methods:** A retrospective analysis was conducted using the Human Capital Management Services Research database, which represents multiple US-based employers and contains employee data from 2001–2005. Data fields included medical, pharmacy, payroll, work absence (where available), and demographics. ICD-9 Codes 564.0 (Constipation), 564.00 (Unspecified), 564.01 (Slow Transit), and 564.09 (Other) distinguished employees with C from employees with no claims for these codes (NC). Two-part regression modeling was used to determine the annual cost differences between C and NC employees while controlling for age, job tenure, gender, salary, region, and Charlson Comorbidity Index score. Direct medical (inpatient and outpatient visits), prescription drug, and work absence claims costs were analyzed.

**Results:** Data were available for 298006 employees. C employees compared with NC controls were on average 42.7 vs. 40.1 years of age, 63.0% vs 42.0% Female, and 19.8% vs 17.2% Black, respectively (all  $P < 0.0001$ ). All annual cost of illness comparisons (Table 1) were statistically different ( $P < 0.03$ ), except for costs of workers' compensation. C was associated with an annual mean incremental cost versus controls totaling \$3545; direct medical costs accounted for 76.5%, prescription drug costs for 11.6%, and

work absence costs (sick leave, short- and long-term disability, and workers' compensation, where absentee data were available) for 11.9%.

Cost of Illness

Cost Category	Constipation		No Constipation		Difference (\$)	<i>P</i> -Value
	N	Adjusted Mean Cost (\$)	N	Adjusted Mean Cost (\$)		
Direct Medical	2,095	4,472	295,911	1,758	2,714	<0.0001
Prescription Drug	2,095	874	295,911	465	410	<0.0001
Sick Leave	920	475	143,287	355	120	<0.0001
Short-term Disability	1,074	465	149,066	288	178	0.0005
Long-Term Disability	1,710	78	224,745	19	60	0.0299
Workers' Compensation	1,907	790	272,024	726	64	0.3803
Total		7,155		3,610	3,545	

**Conclusions:** Constipation is associated with substantial costs; in this study, direct medical costs contributed the majority of total incremental costs.

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**Healthcare Cost Comparisons by Point of Service for Persons with or without Constipation**

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**Purpose:** To compare the costs of healthcare by point of service (POS) for persons with or without constipation.

**Methods:** A retrospective analysis of an employer database containing medical claims, payroll, and demographic data over the years 2001–2005 was accessed. Annual healthcare costs for employees with or without constipation were compared for care received in: doctor's office, inpatient hospital, outpatient hospital or clinic, emergency department (ED), laboratory, and other. ICD-9 Codes 564.0 (Constipation), 564.00 (Unspecified), 564.01 (Slow Transit), and 564.09 (Other) were used to distinguish employees with constipation (C) from the nonconstipation (NC) cohort (employees with no claims for these ICD-9 codes). The index date in the C cohort was defined as 3 months prior to the date of first diagnosis during 2001 or later; the average C index date was used in the NC cohort. Two-part regression models were used to compare each category of costs between cohorts. Age, gender, marital status, race, salary and other job-related variables, region of the US, and Charlson Comorbidity Index score were included in the models as independent variables to control for possible confounding factors.

**Results:** Data were available for 1138 persons with C and 113701 NC controls. Overall, the constipation cohort was 1.86 years younger, 12.7% more likely to be female, 6.6% less likely to be white, 3.3% more likely to be black, 1.5% more likely to work full-time, and compensated \$4966 less in annual salary per person (all  $P \leq 0.001$ ). The C cohort incurred \$3105 per person additional annual costs for all services. Costs by category for the C cohort versus NC cohort were: outpatient hospital or clinic (\$2135 vs. \$733), inpatient hospital (\$1645 vs. \$581), doctor's office (\$1064 vs. \$561), ED (\$141 vs. \$45), laboratory (\$27 vs. \$9), and other locations (\$51 vs. \$29). The incremental increase in cost (%) for C (vs. the NC cohort) by POS category were: outpatient hospital or clinic (45.2%), inpatient hospital (34.3%), doctor's office (16.2%), ED (3.1%), laboratory (0.6%), and other locations (0.7%). All POS category comparisons were significant ( $P \leq 0.0002$ ).

**Conclusions:** Patients with constipation have significantly higher costs of care throughout the healthcare system and at all POS locations.

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**Assessment of Work Absences Associated with Constipation**

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**Purpose:** To assess the annual work absence associated with constipation (C) in an employed population.

**Methods:** A retrospective analysis was conducted using the Human Capital Management Services Research Reference database, which represents multiple US-based employers and contains employee data from 2001–2005. Data fields analyzed included medical, payroll, work absence, and demographics. This analysis compared the annual absences for employees with and without C diagnoses. ICD-9 Codes 564.0 (Constipation), 564.00 (Unspecified), 564.01 (Slow Transit), and 564.09 (Other) were used to distinguish employees with C from the nonconstipation (NC) cohort (employees with no claims for these ICD-9 codes). The index date in the C cohort was defined as 3 months prior to the date of first diagnosis during 2001 or later; the average C index date was used in the NC cohort. Two-part regression modeling was used to determine the differences between the cohorts while controlling for age, job tenure, gender, salary, region, and Charlson Comorbidity Index score.

**Results:** Data were available for 273931 employees (Table 1). C was associated with 5.06 annual mean incremental absence days (compared with the NC cohort), of which long-term disability accounted for 62.1% (3.14 additional days,  $P = 0.0325$ ), short-term disability for 28.8% (1.46 additional days,  $P = 0.0012$ ), and Sick Leave 13.9% (0.71 additional days,  $P < 0.0001$ ).

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Absence Due To Constipation

Absence type	Employees with Constipation		Employees without Constipation		Difference	P-value
	N	Adjusted Mean Days	N	Adjusted Mean Days		
Sick Leave	920	3.02	143,287	2.31	0.71	<0.0001
Short-term Disability	1,074	4.24	149,066	2.78	1.46	0.0012
Long-term Disability	1,710	4.28	224,745	1.14	3.14	0.0325
Workers' Compensation	1,907	1.30	272,024	1.55	-0.25	0.2473
Total		12.84		7.78	5.06	

**Conclusions:** Persons with C incur more than 65% more annual paid work absence days than persons without C. These results likely underestimate the impact of C, as the analysis was limited to persons who sought medical treatment, were diagnosed, and received a C diagnosis on their medical claims. Further study of the impact of unreported C on work absences is needed.

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**Assessing Direct and Indirect Costs in Ulcerative Colitis: The Perspective of a Self-Insured Telecommunications Company**

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**Purpose:** To advance understanding of the cost drivers associated with UC and benchmark the impact on a large self-insured provider.

**Methods:** Claimant records for a retrospective cohort of pts with UC (ICD-9 code 556.x) from a database of a self-insured employer, consisting of approx. 500000 employees, retirees, or dependents from 2002 to 2004 were analyzed to determine costs attributed to direct utilization and short-term disability (STD). 18 months of continuous enrollment was required [6-month pre and 12 months post-index date]. A randomly selected, age and gender matched control group, of non-UC claimants was the comparator. Individual claimants (UC and Controls) with costs  $\geq 3$  SDs from the overall mean were excluded on a basis of outlier status ( $N = 13$ ,  $n = 50$ ). Multiple linear regression technique was used to determine the predictors of cost, adjusting for CMS-HCC scores. A disease severity stratification algorithm classified UC pts into 3 mutually exclusive cohorts, mild [untreated or treated with aminosylates or topical therapy]; moderate [additional therapies (e.g., oral corticosteroids, immunomodulators)]; or severe [requiring hospitalization for UC] cohort.

**Results:** Healthcare costs were evaluated for 1044 UC pts. Mean annual unadjusted total costs for all UC pts were \$12120 vs \$5128 for the non-UC group ( $N = 4178$ ). The regression model indicated UC was a predictor of higher costs vs the control group (coefficient = 5136.37,  $p < 0.005$ ). When stratified by disease severity, the severe UC cohort had 79.6% higher mean total costs vs the moderate group (\$21999 vs \$12248) and the moderate UC cohort had a 24.3% higher mean total costs vs the mild group (\$12248 vs \$9847). After adjustment for CMS-HCC scores in the regression analysis, the severe group was a significant predictor of increased cost, vs the mild and moderate pts (coefficient = 5847.84,  $p = 0.03$ ). Additionally indirect costs for 211 (19.96%) UC pts filed claims for disability dispensation, with a mean payment of \$2366.

**Conclusions:** Utilization expenditures for the UC cohort were over 2 times more costly vs pts without UC. Healthcare costs were highest for pts with severe UC. These results highlight the impact of UC healthcare expenditures on a self-insured employer. Increased awareness and attention to UC is warranted.

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**Steroid Sparing Results in Further Improvement in Quality of Life in UC Patients in Remission**

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**Purpose:** IFX has been shown to improve health related quality of life (HRQL) and achieve clinical remission while discontinuing steroids through 30 wks in pts with moderate-to-severe active UC. For pts in remission at wk 30, we compared the improvement in HRQL between those who discontinued steroid use, and those who had not.

**Methods:** 728 pts were randomized (1:1:1) to PBO, IFX 5, or 10 mg/kg with tx at baseline, wks 2, 6, and q 8 wks (ACT 1 & ACT 2). HRQL was assessed using the IBDQ and SF-36. Pts on steroids at baseline and in remission at wk 30 were categorized into 2 grps: those who discontinued steroids at wk 30, and those who had not. Remission was defined as a Mayo score  $\leq 2$  points, with no individual subscore  $> 1$ . Analysis of variance on van der Waerden scores was used to compare change from baseline in HRQL scores.

**Results:** Among 408 pts on steroids at baseline, 91 were in remission at wk 30. Of these 91 pts, 70 discontinued steroids at wk 30. Baseline scores of the IBDQ & physical and mental component summaries (PCS & MCS) of the SF-36 were similar between pts who discontinued steroids at wk 30 and those who had not. Pts who discontinued steroids at wk 30 had more improvement in the IBDQ and PCS vs those still on steroids. The difference was significant for PCS (Table).