Medication Use and Costs among U.S. Children and Adults with Inflammatory Bowel Disease

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Background

- Inflammatory bowel diseases (IBD) affect over 1 million Americans\(^1\)

- Substantial economic burden
  - Direct costs $6.3 billion per year\(^2\)
  - Outpatient medications account for nearly \(\frac{1}{4}\) of IBD costs\(^3,4\)

- Details regarding patterns of medication use and associated costs are unknown

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\(^1\)Loftus, Gastroenterology, 2004  
\(^2\)Kappelman, Gastroenterology, 2008  
\(^3\)Bassi, Gut, 2004  
\(^4\)Odes, Gastroenterology, 2006
Objectives

1. To describe the use and costs of outpatient medications by persons with Crohn's disease (CD) and ulcerative colitis (UC) in the U.S.

2. To determine whether patterns of medication use vary by patient age, gender, and geographic residence.
**Methods I**

**Study Design:** Cross-sectional study using claims data
- PharMetrics Patient Centric Database
- 87 health plans; 33 states
- Continuous enrollment between Jan 2003 and Dec 2004

**Patient selection:** Cases of CD and UC identified using a standard administrative definition
- 3 health-care contacts associated with an ICD-9 diagnosis code of 555.xx (CD) or 556.xx (UC) or
- ≥ 1 IBD claim and ≥ 1 pharmacy claim for 5-ASA, 6MP, AZA, infliximab, adalimumab, and budesonide
Methods II

Identification of medication utilization:

- National Drug Codes (NDC) for outpatient pharmacy dispensings
- # claims and paid costs per person-year for each of the following medication classes:
  - oral steroids, oral 5-ASA, rectal 5-ASA, thiopurines, methotrexate, ileal-release budesonide, and infliximab
- Costs based on paid amounts
Methods III

Statistical analysis:

• Descriptive statistics to report overall utilization and costs

• Logistic regression to compare the proportion of patients with $\geq 2$ claims/year for each medication class by age, gender, and U.S. census region (Northeast, South, Midwest, and West)
## Patient Demographics

<table>
<thead>
<tr>
<th></th>
<th>CD patients</th>
<th>UC patients</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>n</strong></td>
<td>9,056</td>
<td>10,364</td>
</tr>
<tr>
<td><strong>Mean age</strong></td>
<td>42</td>
<td>45</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>% Female</td>
<td>56</td>
<td>53</td>
</tr>
<tr>
<td>% Male</td>
<td>44</td>
<td>47</td>
</tr>
<tr>
<td><strong>Region</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>% Northeast</td>
<td>23</td>
<td>23</td>
</tr>
<tr>
<td>% Midwest</td>
<td>23</td>
<td>22</td>
</tr>
<tr>
<td>% West</td>
<td>21</td>
<td>23</td>
</tr>
<tr>
<td>% South</td>
<td>33</td>
<td>32</td>
</tr>
</tbody>
</table>
## Utilization of IBD Medications in the U.S.

<table>
<thead>
<tr>
<th>Medication category</th>
<th>CD</th>
<th>UC</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>% patients with ≥ 2 claims</td>
<td>% patients with ≥ 2 claims</td>
</tr>
<tr>
<td>Oral 5-ASA</td>
<td>39</td>
<td>43</td>
</tr>
<tr>
<td>Rectal 5-ASA</td>
<td>7</td>
<td>20</td>
</tr>
<tr>
<td>6MP/AZA</td>
<td>25</td>
<td>11</td>
</tr>
<tr>
<td>Oral steroids</td>
<td>14</td>
<td>12</td>
</tr>
<tr>
<td>Infliximab</td>
<td>10</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Ileal-release budesonide</td>
<td>5</td>
<td>1</td>
</tr>
</tbody>
</table>

* Use of other medication classes was < 5%
IBD Costs by Medication Class

Crohn’s disease

- Oral 5-ASA (21.5%)
- Rectal 5-ASA (1.2%)
- 6MP/AZA (8.4%)
- Oral steroids (0.2%)
- Infliximab (66%)
- Budesonide (1.8%)
- Other IBD Meds (0.9%)

Mean CD medication costs: $2,306/yr

Ulcerative colitis

- Oral 5-ASA (61.7%)
- Rectal 5-ASA (15.9%)
- 6MP/AZA (9.1%)
- Oral steroids (0.4%)
- Infliximab (10.1%)
- Budesonide (1.3%)
- Other IBD Meds (1.5%)

Mean UC medication costs: $912/yr
Use of IBD Medications in Children vs. Adults

- **Oral 5-ASA**
  - Children (CD): 50%
  - Adults (CD): 100%

- **Rectal 5-ASA**
  - Children (CD): 0%
  - Adults (CD): 50%

- **6MP/AZA**
  - Children (CD): 100%
  - Adults (CD): 0%

- **Oral steroids**
  - Children (CD): 0%
  - Adults (CD): 50%

- **Infliximab**
  - Children (CD): 0%
  - Adults (CD): 0%
Use of IBD Medications in Children vs. Adults

OR's adjusted for gender, region, and Medicaid status
**Summary**

- Oral 5-ASA are the most widely used medications for both CD and UC
  - largest proportion of medication costs in UC
- Infliximab used by ~10% of CD patients
  - accounts for the majority of CD medication costs
- Generally higher medication use among children compared to adults
### Strengths

- Large sample size (~ 20,000 patients with IBD)
- Diversity of the study population: range of health plans of varying size, type, and location
- Insurance claims allow accurate determination of medication dispensing and paid costs

### Limitations

- Use of claims data may result in diagnostic misclassification
- Unable to account for inpatient medication use, free samples, and out-of-pocket costs.
- Did not correct for multiple testing
Conclusions

- This study provides contemporary estimate of the patterns and costs of IBD medication use in the U.S.

- Biologics largest proportion of CD medication costs
  - Need for cost-effectiveness studies

- Age, region, and gender differences in medication utilization require further exploration
  - Disease characteristics (i.e. severity, time from dx)
  - Provider and/or health-system factors
Additional slides
Other associations

- ↑ Use of oral steroids in NE (CD and UC)
- ↑ Use of infliximab in S and W vs. NE and MW (CD)
- Females less likely to use oral and rectal 5-ASA (CD and UC)
- No gender differences in use of oral steroids, 6MP/AZA, and infliximab
## Assessment of Misclassification

<table>
<thead>
<tr>
<th>Claim Type</th>
<th>CD</th>
<th>UC</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥ 1 pharmacy claim</td>
<td>77%</td>
<td>80%</td>
</tr>
<tr>
<td>≥ 3 pharmacy claims</td>
<td>65%</td>
<td>64%</td>
</tr>
<tr>
<td>Hospitalization</td>
<td>24%</td>
<td>14%</td>
</tr>
</tbody>
</table>
## Independent effects of age on IBD Medication Use

<table>
<thead>
<tr>
<th>Medication category</th>
<th>CD Odds ratio (95%CI) children vs. adults</th>
<th>UC Odds ratio (95%CI) children vs. adults</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral 5-ASA</td>
<td>1.4 (1.2-1.7)</td>
<td>1.4 (1.1-1.7)</td>
</tr>
<tr>
<td>Rectal 5-ASA</td>
<td>0.6 (0.4-0.8)</td>
<td>0.8 (0.7-1.1)</td>
</tr>
<tr>
<td>6MP/AZA</td>
<td>1.8 (1.5-2.1)</td>
<td>2.4 (1.9-3.0)</td>
</tr>
<tr>
<td>Oral steroids</td>
<td>1.3 (1.1-1.6)</td>
<td>1.8 (1.5-2.3)</td>
</tr>
<tr>
<td>Infliximab</td>
<td>1.2 (1.0-1.6)</td>
<td>3.2 (1.5-6.8)</td>
</tr>
<tr>
<td>Ileal-release budesonide</td>
<td>1.3 (0.9-1.8)</td>
<td>1.8 (1.0-3.5)</td>
</tr>
</tbody>
</table>

* Adjusted for gender, region, and Medicaid status
Higher medication utilization in children versus adults warrants further exploration

- Higher proportion of incident cases
- Early onset IBD is a distinct phenotype (more extensive, increased severity)
- Differences in practice patterns between pediatric and adult gastroenterologists