T reatment Patterns and Economic Burden of Uterine Fibroids in a United States Managed Care Database

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• Uterine fibroids (UF) are benign tumors of the uterus.
• UF has an annual incidence of 9.2 per 1,000 women aged 25 to 44 years.1
• Associated symptoms (e.g., menstrual bleeding, uterine pain, fatigue) are usually managed with hormonal agents such as gonadotropin-releasing hormone agonists or oral contraceptives.
• More definitive treatment option is obtained by surgical removal of the fibroids via hysterectomy or myomectomy, or by destruction of the fibroids by uterine artery embolization (UAE) or ablation.
• UF is the dominant reason for hysterectomy/removal of the entire uterus in the United States (US), accounting for an estimated 35% to 40% of all hysterectomies performed.2,3
• Myomectomy (surgical removal of the fibroid only) is the most common treatment for women who want to preserve their reproductive capability.
• Despite the exposure of UF incidence and common use of robotic surgical interventions with certain health risks, real-world treatment patterns and costs to UF have not been widely studied in large-scale observational cohorts.

OBJECTIVE
To document the surgical treatment patterns and total cost of UF in a large real-world population of US managed care enrollees.

METHODS
Study Design
• Retrospective observational cohort study

Data Source
• Data from PharMetrics, a commercially available source of administrative insurance claims and enrollment information from 11 health plans in all 50 US geographic regions, were analyzed.
• The database captured more than 40 million unique patients from 1997 to mid-2003.
• The data include patients' entire continuum of care, including hospitalizations, outpatient and emergency services, procedures, and prescription medication use.

Inclusion Criteria
• Female
• Diagnosis of UF (ICD-9-CM code 218.xx) between January 1, 2000 and July 31, 2004
• Age 15 to 51 years (premenopausal) at first-observed (index) UF diagnosis
• Continuous health plan enrollment for a 6 months before and a 36 months after the index UF diagnosis

Study Measures
All outcomes were assessed over a 36 month period following patients' index UF diagnosis.
• Background patient characteristics
• Demographics
• Comorbidity burden, measured by Charlson score5 evaluated over 6 months pre-index UF diagnosis
• UF-related surgeries (hysterectomy, myomectomy, UAE, and ablation), defined by CPT® and HCPCS procedure codes (code lists available upon request)
• Surgery rates within 12, 24, and 36 months post–index UF diagnosis
• Associated symptoms (e.g., menstrual bleeding, uterine pain, fatigue) are usually managed with hormonal agents such as gonadotropin-releasing hormone agonists or oral contraceptives.
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RESULTS
Patient Characteristics (Table 1)
• A total of 158,000 patients met the study inclusion criteria.
• Mean (SD) age at index UF diagnosis was 43.1 (7.9) years.
• Mean (SD) Charlson score was 0.3 (0.9).

Table 1. Characteristics of the Study Population

<table>
<thead>
<tr>
<th>Variable</th>
<th>Mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>UF patients</td>
<td>158,000 (60,000)</td>
</tr>
<tr>
<td>Age group (yr)</td>
<td>42.87 (5.97)</td>
</tr>
<tr>
<td>POS = point of service.</td>
<td></td>
</tr>
<tr>
<td>Demographics</td>
<td></td>
</tr>
<tr>
<td>Race/ethnicity</td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>107,055 (60,055)</td>
</tr>
<tr>
<td>Black</td>
<td>11,105 (5,105)</td>
</tr>
<tr>
<td>Asian</td>
<td>9,659 (4,659)</td>
</tr>
<tr>
<td>Hispanic</td>
<td>7,091 (3,091)</td>
</tr>
<tr>
<td>Other</td>
<td>609 (309)</td>
</tr>
<tr>
<td>Year of first observed UF diagnosis</td>
<td>2000 (2000)</td>
</tr>
<tr>
<td>Comorbidity burden, measured by Charlson score</td>
<td>0.3 (0.9)</td>
</tr>
</tbody>
</table>

Surgical Treatment Patterns (Figures 1 and 2, Table 2)
• Overall, 31% of patients underwent a UF-related surgical procedure within 12 months following their index diagnostic cumulative surgery rates for 24 and 36 months post–index UF diagnosis were 35% and 40%, respectively (Figure 1).
• Hysterectomy was observed in 22%, 26%, and 31% of patients within 12, 24, and 36 months post–index UF diagnosis, respectively, and accounted for approximately 80% of all surgical cases (Figure 1).
• Ablation was the next most common procedure, observed in 3%, 6%, and 8% of patients over the respective follow-up periods and representing 11% to 13% of surgical cases depending on the follow-up period (Figure 1).
• Among patients undergoing surgery, hysterectomy was the first observed procedure in more than three-quarters of all cases (Figure 2).
• Among patients undergoing surgery, mean (SD) time to first surgery post–index UF diagnosis was 158 (280) days; by procedure type, mean time to first surgery was shortest for hysterectomy (139 days) and longest for UAE (462 days) (Table 2).

Figure 1. All-Related Surgical Rates

Table 2. 1-Year and 2-Year Age-Specific Surgery Rates Among Surgical Cases

<table>
<thead>
<tr>
<th>UF-related procedure</th>
<th>1-Year Age-Specific Surgery Rates</th>
<th>2-Year Age-Specific Surgery Rates</th>
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</thead>
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<tr>
<td>Hysterectomy</td>
<td>158 (280) days</td>
<td>139 (269) days</td>
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<tr>
<td>Myomectomy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ablation</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Figure 2. Distribution of Procedure Type for First Observed UF-Related Surgery Among All Surgical Cases

All-Cause Costs (Figure 3)
• Among all UF patients, regardless of receipt of surgery, mean (SD) all-cause costs of UF in a large real-world population of US managed care enrollees were $5,782 (2,460) per patient.

Figure 3. Mean and Median All-Cause Health Care Costs per Patient During 12 Months Post–Index UF Diagnosis

Table 3. Percentage of Surgical Cases With Repeat Surgery Within 12 Months Following the Initial Procedure

<table>
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<tr>
<th>UF-related procedure</th>
<th>Rate of Repeat Surgery</th>
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<tr>
<td>Hysterectomy</td>
<td>508 (1.56)</td>
</tr>
<tr>
<td>Myomectomy</td>
<td>5 (0.02)</td>
</tr>
<tr>
<td>Ablation</td>
<td>45 (0.34)</td>
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REFERENCES

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CONCLUSIONS
• Nearly one-third of UF patients undergo surgical treatment in the first year following diagnosis, and approximately 40% of patients receive surgical intervention by 3 years postdiagnosis.
• Hysterectomy is by far the most common surgery for UF both as an initial surgical approach and as a follow-up procedure to preserve sterility.
• Our findings confirm that UF-related surgeries received by younger women tend to involve less invasive, uterine-preserving procedures such as myomectomy. Age data on hysterectomy suggest that women generally wait for this procedure until after peak child-bearing years.
• UF is costly to payers, with mean all-cause costs of $5,782 per patient during the first 12 months after diagnosis. Among the large proportion of patients requiring downstream surgery, these costs are even higher, at nearly $15,000 per patient.
• Managed-care payors should consider these study findings when evaluating formulary access for new therapies for UF particularly nonsteroidal treatments.

This study was funded by Wyeth Research. Wyeth Research has been acquired by Pfizer, Inc.