

# Treatment Patterns and Economic Burden of Uterine Fibroids in a United States Managed Care Database

Bela Bapat,<sup>1</sup> Keith L Davis,<sup>1</sup> Kelly Bell,<sup>2</sup> Linda Deal,<sup>2</sup> Sandra Talbird<sup>1</sup>

<sup>1</sup>RTI Health Solutions, Research Triangle Park, NC, United States;

<sup>2</sup>Pfizer, Collegeville, PA, United States

## BACKGROUND

- 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,<sup>1</sup> and between 20% and 40% of all women will develop UF during their lifetime.<sup>2</sup>
- 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 symptom relief 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 33% to 40% of all hysterectomies performed.<sup>3,4</sup>
- Myomectomy (surgical removal of the fibroid only) is the most common treatment for women who want to preserve their reproductive capability.
- Despite the high incidence of UF and common use of costly surgical interventions with certain health risks, real-world treatment patterns and costs in UF have not been widely studied in large-scale observational cohorts.

## OBJECTIVE

- To document the surgical treatment patterns and total all-cause costs 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 75 health plans in all four US geographic regions, were analyzed.

- The database captured more than 40 million unique patients from 1997 to mid-2007.

- 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  $\geq 6$  months before and  $\geq 36$  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 score<sup>5</sup> evaluated over 6 months pre-index UF diagnosis

- UF-related surgeries (hysterectomy, myomectomy, UAE, and ablation), defined by CPT-4 and HCPCS procedure codes (code lists available upon request)
  - Surgery rates within 12, 24, and 36 months post-index UF diagnosis
  - Distribution of initial surgery type
  - Time to first surgery (among patients with surgery)
  - Age at first surgery (among patients with surgery)
- Rates of repeat surgery
- Total all-cause health care costs (adjusted to 2007 US dollars)
  - Per patient costs estimated for the 12-month period post-index UF diagnosis
  - Costs presented for the overall cohort and by procedure type among patients with a UF-related surgery during the 12-month period post-index UF diagnosis

### Statistical Analyses

- Analyses were carried out using SAS<sup>®</sup> (Version 9) statistical software
- Analyses were exploratory and descriptive in nature
  - Mean values, standard deviations (SDs), medians, and ranges of continuous variables
  - Frequency distributions for categorical variables

## RESULTS

### Patient Characteristics (Table 1)

- A total of 109,595 patients met the study inclusion criteria.
- Mean (SD) age at index UF diagnosis was 43 (6) years.
- Mean (SD) Charlson score was 0.3 (0.8).

Table 1. Characteristics of the Study Population

	n	%
All patients	109,595	100.00
Mean age (SD)	42.87 (5.97)	
<b>Age category (years)</b>		
15-20	257	0.23
21-30	3,936	3.59
31-40	29,076	26.53
41-45	33,200	30.29
46-51	43,126	39.35
Mean Charlson score (SD)	0.27 (0.84)	
<b>Geographic region</b>		
Northeast	27,671	25.25
Midwest	13,308	12.14
South	24,587	22.43
West	44,029	40.17
<b>Payer type</b>		
Medicare	107	0.10
Medicaid	2,019	1.84
Commercial	100,083	91.32
Other	7,386	6.74
<b>Insurance type</b>		
HMO	39,998	36.50
PPO	43,192	39.41
POS	19,064	17.39
Other	7,341	6.70

HMO = health maintenance organization; PPO = preferred provider organization; POS = point of service.

### 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 diagnosis; cumulative surgery rates for 24 and 36 months post-index diagnosis were 36% and 40%, respectively (Figure 1).
- Hysterectomy was observed in 25%, 28%, and 31% of patients within 12, 24, and 36 months post-index diagnosis, respectively, and accounted for approximately 80% of all surgical cases (Figure 1).
- Ablation was the next most common procedure, observed in 3%, 4%, and 5% 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 199 (283) days; by procedure type, mean time to first surgery was shortest for hysterectomy (189 days) and longest for UAE (362 days) (Table 2).

Figure 1. UF-Related Surgery Rates

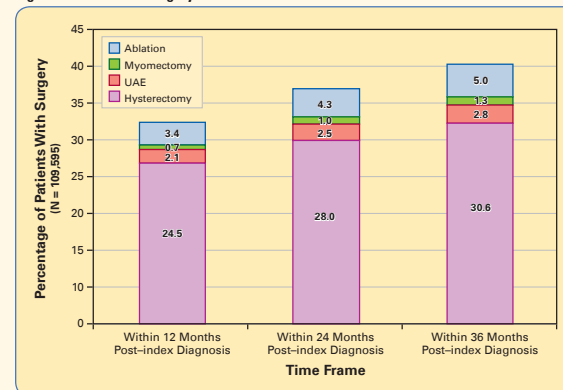


Figure 2. Distribution of Procedure Type for First Observed UF-Related Surgery Among All Surgical Cases

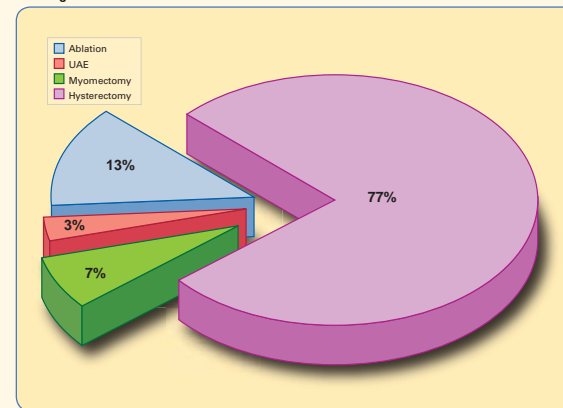


Table 2. Time to and Age at First Surgery Among all Surgical Cases

	Any Surgery	Hysterectomy	Myomectomy	UAE	Ablation
<b>Time to first surgery (days)</b>					
Mean (SD)	199.41 (283.29)	188.62 (277.87)	239.96 (290.53)	362.32 (319.26)	275.45 (325.24)
Median	59	53	104	265	98.5
Range	(0, 1,095)	(0, 1,095)	(0, 1,094)	(0, 1,093)	(0, 1,094)
<b>Age at first surgery</b>					
Mean (SD)	43.75 (5.25)	44.16 (4.92)	38.17 (6.17)	44.45 (4.91)	44.15 (4.96)
Median	44	45	38	45	45
Range	(15, 54)	(15, 54)	(18, 54)	(25, 54)	(24, 54)

### Repeat Surgeries (Table 3)

- Among patients receiving a UF-related surgery, 3% received a subsequent follow-up surgery within 12 months after the initial procedure.
- By initial surgery type, rates of follow-up surgery were 1.6% for hysterectomy, 4.6% for myomectomy, 10.5% for UAE, and 9.8% for ablation.
- The most common follow-up surgery was hysterectomy, which represented over 95% of all follow-up procedures performed.

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

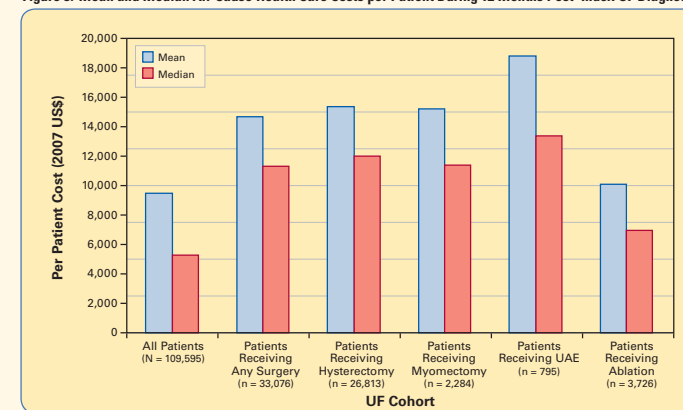
	First Observed UF-Related Surgery							
	Hysterectomy (N = 32,471)		Myomectomy (N = 2,982)		UAE (N = 1,285)		Ablation (N = 5,335)	
	n	%	n	%	n	%	n	%
Received subsequent surgery of any type	532	1.64	136	4.56	135	10.51	524	9.82
Received subsequent hysterectomy	508	1.56	85	2.85	78	6.07	409	7.67
Received subsequent myomectomy	5	0.02	48	1.61	5	0.39	4	0.07
Received subsequent UAE	22	0.07	7	0.23	44	3.42	18	0.34
Received subsequent ablation	7	0.02	5	0.17	14	1.09	104	1.95

Row categories for each surgery type are not mutually exclusive (i.e., patients may have received multiple subsequent surgeries of different types). Therefore, the total N for subsequent surgery of any type may not equal the sum of the individual surgery types.

### All-Cause Costs (Figure 3)

- Among all UF patients, regardless of receipt of surgery, mean (SD) all-cause costs during the 12-month postdiagnosis period were \$9,608 (\$16,720)
- Among patients undergoing surgery within 12 months post-index UF diagnosis, mean (SD) 12-month post-index diagnosis costs were highest among patients whose initial procedure was UAE, at \$19,009 (\$35,098) per patient, and lowest among patients whose initial procedure was ablation, at \$10,196 (\$13,905) per patient.

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



## 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 previous surgeries.
- 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 nearly \$10,000 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 payers should consider these study findings when evaluating formulary access for new therapies for UF, particularly nonsurgical treatments.

## ACKNOWLEDGMENTS

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## CONTACT INFORMATION

Keith L Davis, MA  
Senior Director, Health Economics  
RTI Health Solutions  
200 Park Offices Drive  
Research Triangle Park, NC 27709  
Phone: +1.919.541.1273  
Fax: +1.919.541.7222  
E-mail: kldavis@rti.org

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