Appendix C. Stakeholder Partnership Council (SPC) Recommendations for Protocol

SPC RECOMMENDATIONS	QuintilesIMS RESPONSE
Duration of Follow-up	
Extend the duration of follow-up from 1 year to a minimum of 2 years.	IMPLEMENTED: Patients were required to have a minimum of 2 years of follow-up. In addition, time-to-event analyses were conducted to use full follow-up on all patients.
Inclusion/Exclusion Criteria	
Exclude individuals with a diagnosis of gynecologic cancers, including the following: a. Ovarian cancer b. Uterine cancer c. Cervical cancer	IMPLEMENTED: Women with a diagnosis of gynecologic cancers, as noted by the committee, were excluded from analysis.
Exclude individuals with a diagnosis of uterine fibroids that occurred after the index date, with the exception of those who were treated with endometrial ablation.	NOT IMPLEMENTED: There was a lack of a consensus among the committee on this item and the results varied across the SPC meetings. However, the related recommendation immediately below was followed.
Extend the period of the index date from 2 weeks to 4 weeks for individuals who have an endometrial ablation.	IMPLEMENTED: The period beyond the index date was extended from 2 to 4 weeks for a dx of UF for women receiving EA (and also women undergoing a hysterectomy).
Patient Characteristics	
Include the use of the following medications as part of the patient characteristics collected: a. GnRH agonists b. Levonorgestrel-releasing intrauterine system (brand name Mirena) c. Tranexamic acid (brand name Lysteda) d. Leuprolide acetate (brand name Lupron) e. Medroxyprogesterone acetate (brand name Depo Provera) f. Other therapies to prevent pregnancy	IMPLEMENTED: The medications collected were expanded to include those recommended by the committee.

Include information about the following insurance characteristics for the COMPASS data: a. Whether insured b. Primary insurance type (commercial, Medicare, Medicaid) c. High cost-sharing	IMPLEMENTED: Note, however, that after further discussion with the COMPASS networks and review of available data, we were able to capture only insurance status (yes/no) and type.
Include the variables of height and weight (to calculate BMI) as part of the patient characteristics collected.	IMPLEMENTED: We collected data on obesity and included obesity status in the multivariable analyses.
Include information on posttreatment pregnancy as part of the patient characteristics collected.	NOT IMPLEMENTED: Pregnancy and pregnancy-related outcomes were not consistently available and were not analyzed in this study.
Collect information about the specialty for the health care provider.	IMPLEMENTED: Health care provider specialty was collected; however, limitations about completeness were discussed.
Collect information about the following health system characteristics for the index procedure from COMPASS data: a. Type of practice or hospital b. Geographic location c. Salary versus procedure-based forms of payment d. Degree of integration	IMPLEMENTED: Characteristics about the health system from the COMPASS data were included; however, we were able to capture only the type of practice and geographic location (Northeast, Midwest, West, Southeast).
Include the following control variables as proxies for severity of disease: a. Size and number of fibroids from pathology report b. Socioeconomic factors (zip code/census tract, income, education level, race) c. High-cost sharing insurance plan d. Number of fibroid-related visits prior to index procedure	NOT IMPLEMENTED: After exploration, it was felt that this suggestion is not feasible/well aligned within the scope, budget, and/or design of the study. To clarify, pathology reports would require a manual review and would significantly add to the time and expense of this analysis. Second, we did not have quality information on high-cost sharing for insurance plans. Third, SES factors, although available to us, would be a weak surrogate for severity of disease, without yielding further information. And last, the number of visits would be influenced by many factors beyond disease severity (e.g., insurance type, copays/cost sharing) and would be better assessed in a prospective study using incident cases.

Comparators	
Distinguish between the following types of surgeries: a. Robotic b. Open c. Hysteroscopic	IMPLEMENTED: These data were collected as available in procedures codes.
Analyze "watchful waiting" as a comparator using a cluster of visits related to fibroid symptoms to identify index date.	NOT IMPLEMENTED: Given the retrospective nature of the study, the committee decided that it i could not reliably assess "watchful waiting."
Outcomes	
Include the following symptoms as part of the outcomes that are measured: a. Dysuria b. Anemia c. Leukorrhea d. Pelvic pain e. Leg pain or deep vein thrombosis f. Urinary retention g. Menorrhagia h. Hydronephrosis i. Shortness of breath	IMPLEMENTED: The symptoms were included in the analysis.
Subgroup Analyses	
Conduct subgroup analysis for the variable of obesity and pregnancy.	NOT IMPLEMENTED: We adjusted for obesity in the regression models but did not specifically perform subgroup analyses based on obesity status.