

Treatment of Pain Due to Endometriosis in a Large United States Administrative Claims Dataset

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Introduction

- Endometriosis (EM) is a condition characterized by the presence of endometrial tissue outside of the uterine cavity.^{1,2}
- EM is primarily diagnosed by laparoscopic inspection and is associated with dysmenorrhea, dyspareunia, infertility, and non-menstrual pain, affecting approximately 10% of women of reproductive age in the United States.^{1,2}
- While there is no cure for EM, a wide range of treatment options exist for pain management; this includes pharmacologic management with analgesics (eg, non-steroidal anti-inflammatory agents [NSAIDs] and opioids), and hormone therapy, as well as surgical treatments.³
- It is important to understand the journey of patients with EM, including treatment patterns, healthcare resource utilization (HCRU), and costs.
- As new medications become available,^{2,4} a retrospective review of analgesic prescribing patterns for the treatment of pain due to EM is warranted.

Objective

- Identify and describe the real-world demographic and clinical characteristics of US women with EM and characterize the patient journey, including pain management treatment patterns, HCRU, and costs between October 1, 2012 and July 31, 2022.

Methods

- Using IQVIA's PharMetrics® Plus database, this retrospective, longitudinal analysis identified women with newly diagnosed EM between October 1, 2015 and July 31, 2019 (selection window).
- To be included, women were required to be ≥15 years of age and to have ≥1 EM diagnosis code on a confirmatory claim during the selection window, as well as ≥36 months of continuous enrollment pre- and post-index.
 - The first EM claim was termed the “index date.”
- Table 1 summarizes selection criteria and patient attrition.
- Outcomes of interest were clinical characteristics, treatment patterns, all-cause HCRU and costs.
 - Data were collected in the 36-month pre- and post-index periods; costs were reported at 12, 24 and 36 months (shown) post-index as mean-per-patient using 2022 \$USD.
- Post-index adherence and persistence were assessed for hormonal therapy use.
 - Adherence was measured as proportion of days covered (PDC), with PDC ≥ 0.8 considered adherent.
 - Persistence was based on the time from the first treatment claim until discontinuation or study end, whichever occurred first.
- Outcomes were reported using descriptive statistics, with Chi-square tests for categorical variables and independent sample t-tests (mean) or Wilcoxon rank-sum tests (median) for continuous variables.

Results

Table 1. Patient Selection Criteria, Attrition

Criteria	N (%)
≥1 confirmatory claim for EM between October 2015 to July 2019	371,241 (100.0)
≥36 months of continuous pre-index enrollment	81,885 (22.1)
≥36 months of continuous post-index enrollment	37,504 (10.1)
Female sex	37,465 (10.1)
Age ≥15 at index date	37,440 (10.1)
No evidence of EM during the 36 months pre-index or EM-related procedures from 36 months pre-index to 1 month pre-index	28,147 (7.6)
No cancer (except non-melanoma skin cancer) during the study	24,970 (6.7)
Records without data quality issues (invalid birth year, sex, or health plan enrollment dates)	24,834 (6.7)
Final cohort	24,834

EM = endometriosis

Demographic and Clinical Characteristics

- A total of 24,834 eligible patients were identified; the majority (61.8%) had commercial insurance.

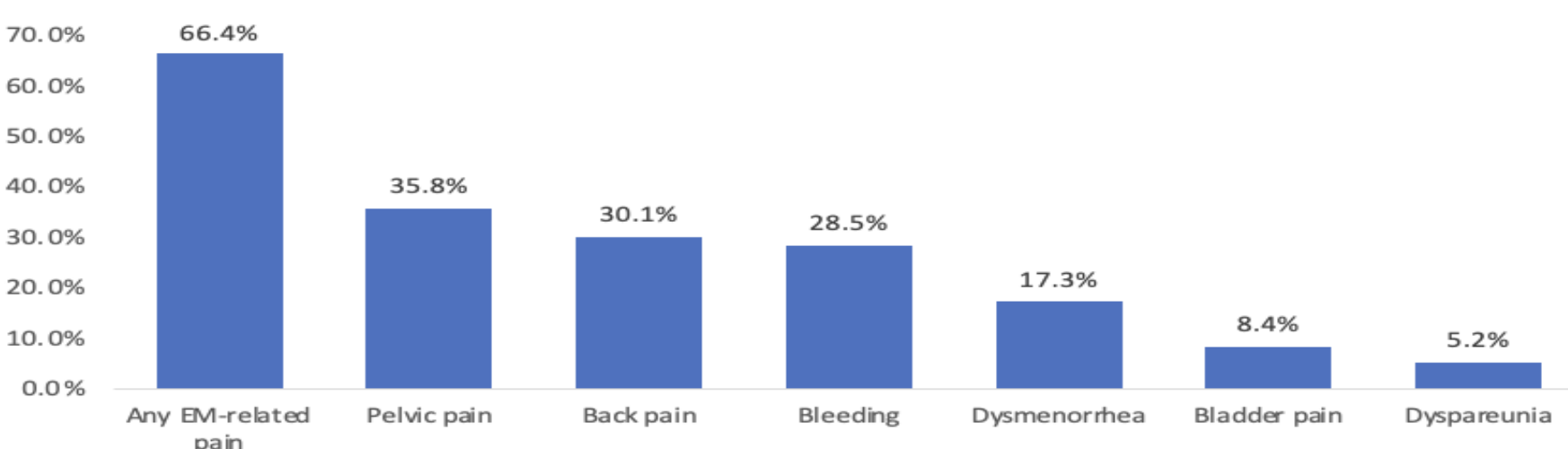
Table 2. Baseline Characteristics

Characteristics	Mean or %
Mean age at index, years	42.8
Comorbidities, %	
Anxiety	22.4
Hypertension	17.9
Dyslipidemia	17.0
Thyroid disease	16.9
Depression	15.2

- Table 2 shows baseline age and comorbidities for the full study cohort.
- Mean patient age was 42.8 years; the mean time from symptom onset to diagnosis was 200 days.
- Figure 1 shows the proportion of patients with EM-related pain and symptoms in the 12 months prior to EM diagnosis.

- Key symptoms associated with EM were pelvic pain (35.8%), back pain (30.1%), and bleeding (28.5%).

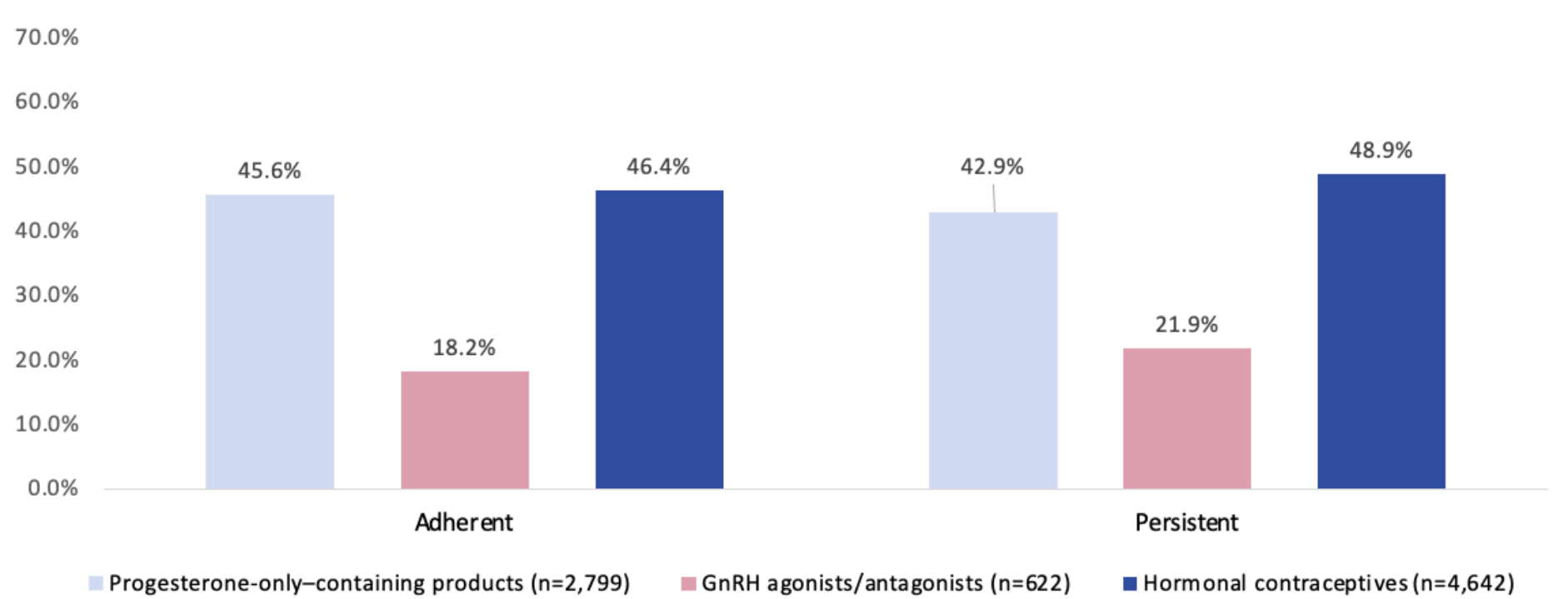
Figure 1. Proportion of Patients With EM-Related Pain/Symptoms in the 12 Months Pre-Index



Treatment Patterns

- In the 12 months pre-index:
 - Hormonal therapies were the least frequently used drugs (19.6% oral contraceptives; 11.5% progestins, 1.0% gonadotropin-releasing hormone (GnRH) antagonists/agonists).
 - Corticosteroids (38.7%), opioids (38.1%), and NSAIDs (34.5%) were the most frequently used drugs.
- Disease-specific drug use in the 12 months post-index:
 - Hormonal therapy use was 11.7% oral contraceptives; 11.3% progestins, 2.5% GnRH; corticosteroids (31.5%), and opioids (39.7%).
 - Patient adherence was poorest to gonadotropin GnRH agonists/antagonists (18.2%), while adherence to progesterone-only-containing products (45.6%) and hormonal contraceptives (46.4%) were similar.
 - Persistence was poorest with GnRH agonists/antagonists (21.9%), while persistence with hormonal contraceptives (48.9%) was slightly higher than with progesterone-only-containing products (42.9%).

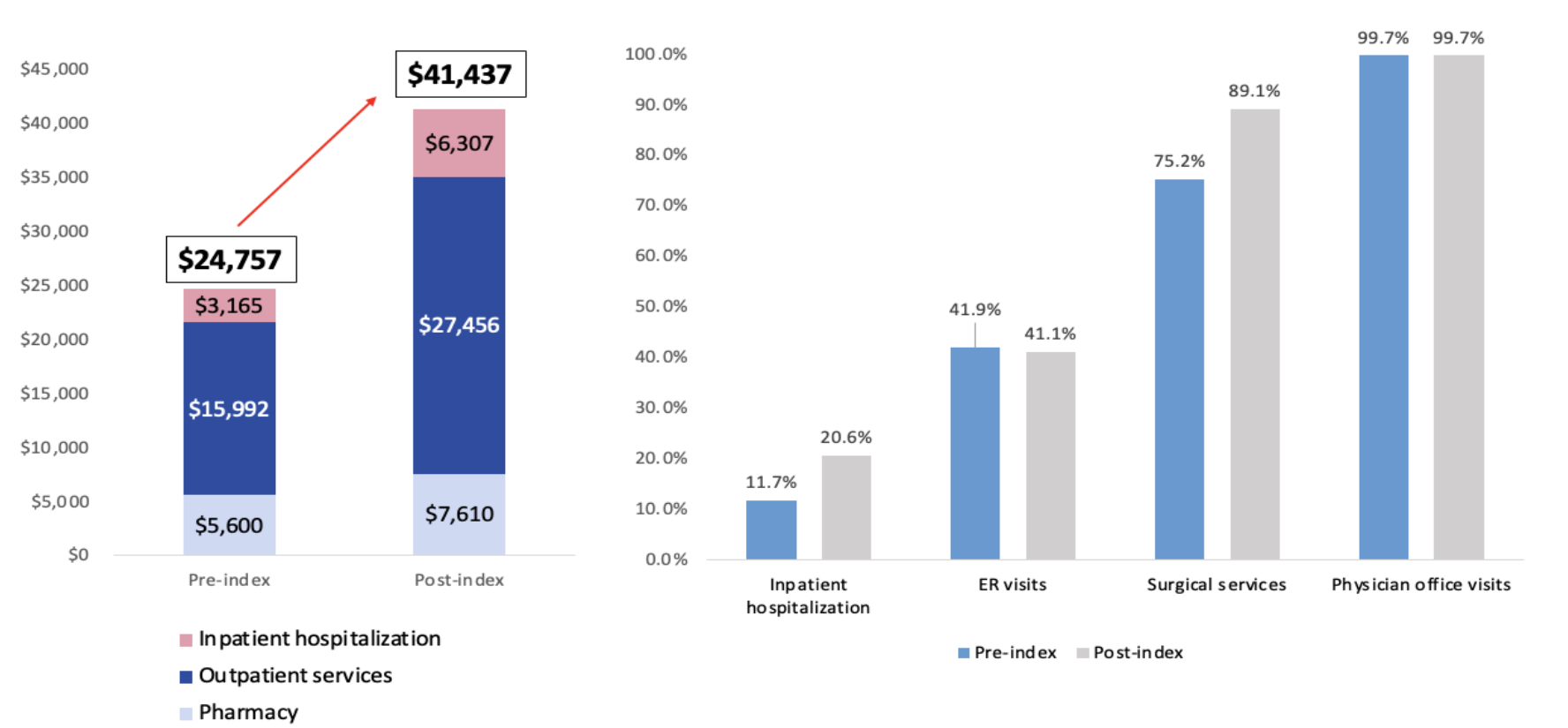
Figure 2. Post-Index Adherence and Persistence to GnRH Agonists/Antagonists, Progesterone-only-containing Products, and Hormonal Contraceptives



HCRU and Costs

- Figure 3 shows all-cause healthcare costs and HCRU in the 36-month pre- and post-index periods;
- From pre- to post-index, total healthcare costs increased, from \$24,757 to \$41,437.
- Inpatient hospitalization and pharmacy costs also increased from pre- to post-index, from \$3,165 to \$6,307, and \$5,600 to \$7,610, respectively.
- Post-index, increased outpatient costs were driven by surgical services; utilization of other outpatient HCRU categories (ie, physician office visits, lab/pathology visits, radiology exams, and ancillary services) remained >90% and relatively consistent across both periods.

Figure 3. All-Cause Healthcare Costs and Resource Utilization in the 36 Months Pre- and Post-Index



Limitations

- This study was observational and descriptive, which limits conclusions beyond the age and time constraints applied to participants.
- Claims data may be subject to coding errors.
- National Drug Code claims are not associated with a diagnosis; therefore, drugs may have been administered for reasons other than EM or pain, resulting in an overestimation of the drug treatment rate.
- Over-the-counter (OTC) drug use was not captured in this dataset.

Conclusion

- Pre- and post-index, hormonal therapy was not commonly used in this EM cohort, and adherence and persistence were low for all hormonal therapies.
- Pre- and post-index, patient opioid use remained constant, and corticosteroid use decreased.
 - Corticosteroids were commonly used in this cohort; further analysis is required to understand why.
- Both before and after EM diagnosis, outpatient care was the primary driver of patient healthcare costs.
- Post-index patient healthcare costs increased, driven by surgical services, hospitalizations, and pharmacy costs.
- These findings emphasize the need to evaluate treatments for pain related to EM and ensure that patient needs are being met.
- With new oral agents, including new hormonal treatments, approved for moderate to severe pain due to EM, this is an area of continued focus with the goal of improving patient adherence and persistence.

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