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Healthcare resource use and cost burden of urinary incontinence to United States payers

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Abstract

Objective: To assess healthcare resource utilization and costs for female patients diagnosed with stress or mixed urinary incontinence (SUI/MUI) compared to a matched cohort of patients without SUI/MUI.

Methods: We conducted a retrospective matched cohort study of women using the IBM MarketScan research database. Women diagnosed with SUI/MUI between July 1, 2014 and June 30, 2016 were identified using International Classification of Diseases 9 and 10 codes for SUI or MUI with the date of first diagnosis as the index date from which 2-year postindex healthcare resource use and direct cost data were derived from claims, examined, and compared 1:1 with patients without a SUI/MUI diagnosis, matched by age and Charlson's Comorbidity Index.

Results: A total of 68 636 women with SUI/MUI were matched 1:1 with controls. In the 2-year postindex date, a significantly higher proportion of SUI/MUI patients had ≥1 inpatient visit and ≥1 outpatient visit compared to the control group (inpatient: 18.89% vs. 12.10%, $p < 0.0001$; outpatient: 88.44% vs. 73.23%, $p < 0.0001$). Mean primary care visits were significantly higher in SUI/MUI patients compared to controls (7.33 vs. 5.53; $p < 0.0001$) as were specialist visits (1.2 vs. 0.08; $p < 0.0001$). Mean all-cause outpatient costs were higher in SUI/MUI patients compared to controls ($7032.10 vs. $3348.50; $p < 0.0001$), as were inpatient costs ($3990.70 vs. $2313.70; $p < 0.0001$).

Conclusion: Women with SUI/MUI consume significantly higher medical resources and incur higher costs to payers, compared to women without SUI/MUI. While reasons for this are not fully understood, improved and standardized treatment for women with SUI/MUI may positively affect cost and outcomes.

KEYWORDS
healthcare resource utilization, mixed urinary incontinence, stress urinary incontinence, urinary incontinence, women

1 | INTRODUCTION

Urinary incontinence (UI) is the complaint of involuntary loss of urine and is characterized by three main subtypes: urgency urinary incontinence (UUI), stress urinary incontinence (SUI), and mixed urinary incontinence (MUI).[1] UUI is the complaint of involuntary loss of urine associated with urinary urgency, which is in turn defined as complaint of a sudden, compelling desire to pass urine which is difficult to defer. SUI is the complaint of involuntary loss of urine on effort or physical exertion, or on sneezing or coughing. MUI represents a combination of SUI and UUI symptoms.[1] UI can occur at any age, but is more common among women over 50 years.[2] Primary risk factors for UI in women include pregnancy, vaginal delivery, obesity, and age. Additional contributors to risk include smoking, constipation, and genetic factors.[3,4] UI affects over 60% of women in the United States with prevalence estimates varying based upon study population and UI measurement.[5,6]

UI is infrequently addressed during routine healthcare visits despite its high prevalence and associated symptoms,[7–9] and adverse impact on health and quality of life.[10,11] As a result, UI can impose a significant burden on patients' health and finances.[12] Although 70% of conservative management of SUI in women is believed to involve out-of-pocket expenses, overall costs of SUI management are $12 billion and rising, therefore payers may also incur substantial UI-related costs.[12] Recent estimated cost to society of total annual cost of UUI management and treatment of UUI is $66 billion (2007 US dollars), with a projected increase to $82.6 billion by 2020.[13,14]

An objective assessment of healthcare resource use and associated costs to payers is important to understand the incremental burden of UI and help inform coverage policies associated with treatments and interventions. The aim of this study was to assess the 2-year healthcare resource utilization and costs associated with patients diagnosed with SUI/MUI compared to a matched cohort of patients without SUI/MUI in the US population.

2 | MATERIALS AND METHODS

2.1 | Data source

This was a retrospective matched cohort analysis conducted on administrative pharmacy and medical claims data from the IBM MarketScan Commercial and Encounters database (Commercial), and Medicare Supplemental and Coordination of Benefits database (Medicare) from July 2013 to June 2018. The MarketScan Commercial database includes medical and pharmacy claims for approximately 65 million beneficiaries and their dependents. The Medicare Supplemental database covers records for approximately 5.3 million retired employees and spouses older than 65 years who are enrolled in supplemental Medicare insurance. These databases capture person-specific enrollment, including demographic and clinical information, inpatient and outpatient healthcare utilization data, and expenditures for over 350 payers comprised of large employers, health plans, and government and public organizations. Because this study used only deidentified patient records and did not involve the collection, use, or transmittal of individually identifiable data, institutional review board approval was not necessary.

2.2 | Study design and participant identification

Women diagnosed with SUI or MUI were identified using the specific International Classification of Disease—Clinical Modification (ICD-9-CM) and ICD-10-CM codes (ICD-9-CM [625.6, 788.33]; ICD-10-CM [N39.3, N39.46]) in any diagnosis field between July 1, 2014 and June 30, 2016. Women greater than 18 years of age as of July 1, 2013 were included in the study. Exclusion criteria included a record of pregnancy or continuous enrollment for less than 80% of the time during the entire study period (July 2013 to June 2018). The cases, women with SUI or MUI, were matched 1:1 with women without SUI, MUI, or other similar urinary conditions (overactive bladder [OAB], UUI, or fecal incontinence), using the same inclusion/exclusion criteria. Matching was based on age (±2 years) and Charlson's Comorbidity Index (CCI)[15] (exact match) in a ratio of 1:1 to control for variations in morbidity. The CCI was calculated in the preidentification period (July 1, 2013 to June 30, 2014) for cases and controls. It has been widely used for matching on health status in epidemiologic studies.[16] The first date of the first SUI or MUI diagnosis available in the databases for each case was identified as the index date and attributed to each corresponding matched control to ensure that healthcare resource utilization and associated costs were compared over the time period with similar clinical practices. Cases and controls were followed for 2-year postindex date to evaluate healthcare resource utilization and costs.

2.3 | Outcomes

Healthcare resource use calculated in the post-index period included all-cause inpatient hospital visits, all-cause outpatient visits, all-cause physician's office visits, and physical therapy evaluations. Inpatient and outpatient visits were identified from the Commercial and Medicare inpatient encounters files. The number of each type of encounter in the postindex period (2 years after the index date) was calculated and categorized as 0, 1, 2, 3, 4, and ≥5 encounters. Physician's office visits were identified from the Commercial and Medicare outpatient claims files as place of service codes 11 (office) or 49 (independent clinic). These were further categorized as primary care physician (PCP) visits using provider codes 204 (internal medicine) or 240 (family medicine) and specialist visits using provider codes 210 (urology) or 320 (obstetrics/gynecology). The mean number of physician office visits, pelvic floor muscle training (PFMT) visits, and physical therapy visits were calculated (CPT codes: 97535, 97014, 97032, E0740, G0238; Physical Therapy CPT codes: 97161–97164). All healthcare resource use variables evaluated were compared between groups.

In addition to medical resource use, prescription medication use was identified from the Medication Claims file. Specifically, anxiolytic, antidepressant, tricyclic antidepressant, and anticholinergic medication use was identified. Given the limited use of Beta-agonists, such as mirabegron, during the timeframe of claims considered, this class of medications was not included in the analysis. The number of prescriptions, number of patients who were prescribed, and prescription duration were compared between groups. Plan costs (plan paid amounts) for medical resources, including inpatient admissions, outpatient visits, and physician office visits as well as prescription medication costs were evaluated and compared between groups.

2.4 | Statistical analyses

Continuous variables were reported using means and standard deviations (*SD*). Categorical variables were reported using frequencies (*n*) and proportions (%). Healthcare resource use and costs were compared between cases and matched controls using paired *t* tests for continuous variables and chi square tests for categorical variables. All analyses were conducted using SAS 9.3.

3 | RESULTS

3.1 | Baseline demographics

In total, 68 636 women with SUI/MUI were identified for the study along with an equal number of women without SUI/MUI (total sample = 137 272 women). Baseline demographics for the cases and matched controls are presented in Table 1. To confirm the success of the matching process, we determined the mean (*SD*) age of the cases was not significantly different from the control group (56.64 vs. 56.7 years) and the mean CCI score was the same in the two groups (mean CCI Score: 0.49). The

TABLE 1 Demographic characteristics for cohorts with and without SUI/MUI

Characteristic	SUI/MUI cohort (*n* = 68 636)	Matched controls (*n* = 68 636)
Age at index encounter, mean ± *SD*	56.64 ± 12.71	56.7 ± 12.70
Age categories, *n* (%)		
18–34	1685 (2.45%)	1638 (2.39%)
35–44	9329 (13.59%)	9288 (13.53%)
45–54	20 390 (29.71%)	20 446 (29.79%)
55–64	22 534 (32.83%)	22 135 (32.25%)
65+	14 698 (21.41%)	15 129 (22.04%)
CCI, mean ± *SD*	0.49 ± 0.96	0.49 ± 0.96
Region, *n* (%)		
Northeast	12 687 (18.48%)	12 879 (18.76%)
North central	16 320 (23.78%)	16 228 (23.64%)
South	29 379 (42.8%)	28 884 (42.08%)
West	10 077 (14.68%)	10 218 (14.89%)
Unknown	173 (0.25%)	427 (0.62%)

TABLE 1 (Continued)

Characteristic	SUI/MUI cohort ($n = 68\,636$)	Matched controls ($n = 68\,636$)
Employment status, *n* (%)		
Employed	40 599 (59.15%)	41 966 (61.14%)
Retired	16 833 (24.6%)	18 743 (27.31%)
COBRA continuee	146 (0.21%)	130 (0.19%)
Long-term disability	164 (0.24%)	107 (0.16%)
Surviving spouse/dependent	2477 (3.61%)	2844 (4.14%)
Unknown	8367 (12.19%)	4846 (7.06%)
Employee classification, *n* (%)		
Salary	14 903 (21.71%)	17 109 (24.92%)
Hourly	20 703 (30.17%)	25 267 (36.81%)
Non-union	12 083 (17.60%)	11 254 (16.40%)
Union	3615 (5.27%)	3121 (4.55%)
Unknown	17 332 (25.25%)	11 885 (17.32%)
Other confounders, *n* (%)		
Myocardial infarction	276 (0.40%)	286 (0.42%)
Congestive heart failure	1383 (2.01%)	1498 (2.18%)
Peripheral venous disease	2445 (3.56%)	2286 (3.33%)
Cardiovascular disease	3141 (4.58%)	2737 (3.99%)
Chronic obstructive pulmonary disease	8859 (12.91%)	7953 (11.59%)
Dementia	385 (0.56%)	559 (0.81%)
Paralysis	185 (0.27%)	173 (0.25%)
Diabetes	8277 (12.06%)	8968 (13.07%)
Diabetes complications	2467 (3.59%)	2447 (3.57%)
Renal disease	1573 (2.29%)	1804 (2.63%)
Mild liver disease	257 (0.37%)	325 (0.47%)
Moderate to severe liver disease	50 (0.07%)	76 (0.11%)
Ulcers	413 (0.60%)	351 (0.51%)
Rheumatic disease	1736 (2.53%)	1643 (2.39%)
Acquired immunodeficiency syndrome	39 (0.06%)	44 (0.06%)

Abbreviations: CCI, Charlson's comorbidity index; COBRA, Consolidated Omnibus Budget Reconciliation Act; MUI, mixed urinary incontinence; SD, standard deviation; SUI, stress urinary incontinence.

highest proportion of the cases (32.83%) were 55–64 years of age at index encounter. There were subtle but statistically significant differences in geographic region, employment status, employee classification, and some confounders between cases and controls, mainly due to the very large sample sizes ($p < 0.0001$) (Table 1). But the distribution of all these variables was relatively even across the two groups.

The mean number of inpatient visits per patient in the 2-year postindex date was significantly higher in cases compared to controls (0.28 vs. 0.18; $p < 0.0001$). A higher proportion of cases had ≥1 inpatient hospitalization in the 2-year postindex period compared to controls (18.89% vs. 12.10%; $p < 0.0001$) (Figure 1). The mean number of outpatient visits per patient in the 2-year postindex was significantly higher in cases compared to controls (7.79 vs. 4.83; $p < 0.0001$). A higher proportion of cases had ≥1 outpatient visit in the 2-year postindex period compared to controls (88.44% vs. 73.23%; $p < 0.0001$) (Figure 1).

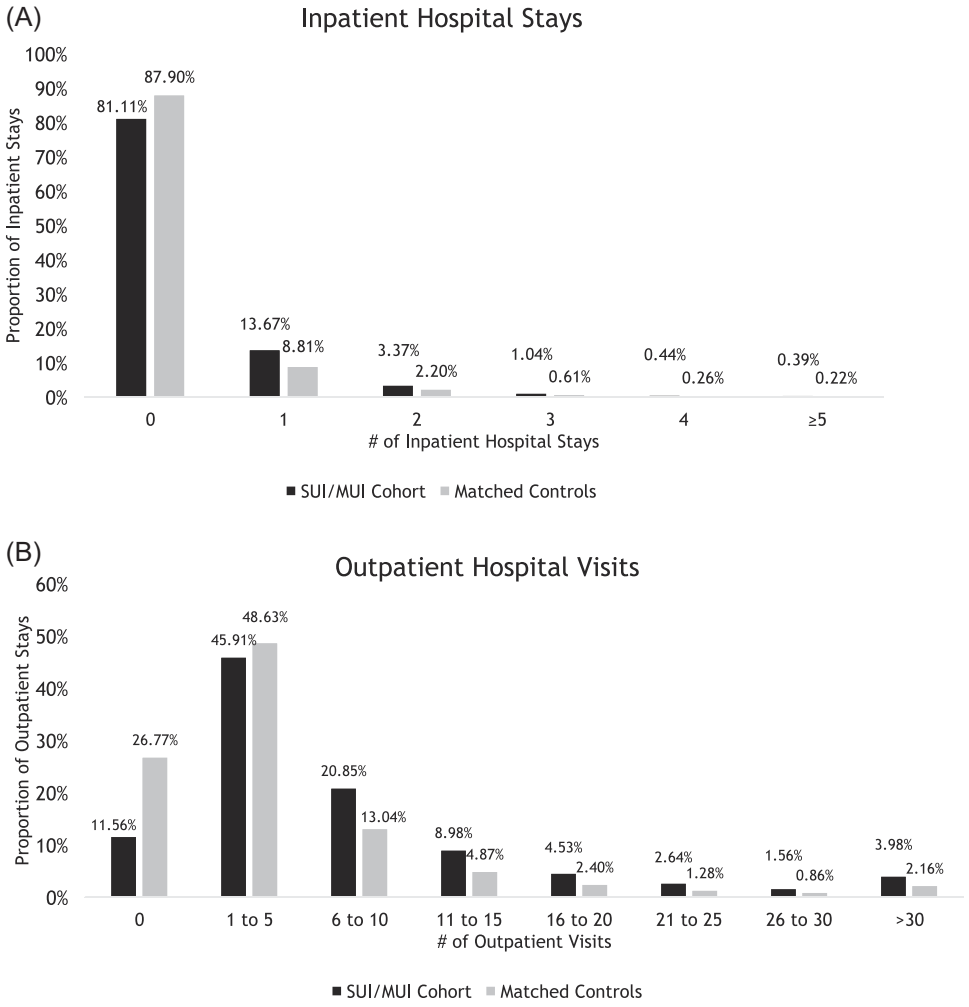

FIGURE 1 Comparison between the SUI/MUI cohort and the matched controls; Overall inpatient and outpatient visits in the postindex period, including index encounter. (A) Proportion of patients by inpatient stays; (B) Proportion of patients by outpatient visits. (A) Comparison of the proportion of inpatient visits between the Stress/Mixed Urinary Incontinence (SUI/MUI) cohort and matched controls in the postindex period. The highest proportion of patients had 0 inpatient visits in the 2-year postindex period. The proportion of patients in the SUI/MUI cohort who had 0 inpatient visits (81.11%) was lower than those in the matched controls cohort (87.90%). (B) Comparison of the proportion of outpatient visits between the SUI/MUI cohort and matched controls in the postindex period. The highest proportion of patients had 1–5 outpatient visits in the 2-year postindex period. The proportion of patients in the SUI/MUI cohort who had 0 outpatient visits (11.56%) was lower than those in the matched controls cohort (26.77%)

The mean number of physician office visits in the 2-year postindex, was significantly higher in women with SUI/MUI compared to women without SUI/MUI (30.43 vs. 18.42; $p < 0.0001$) (Table 2), including specialist visits in fields of interest for UI care. On average, SUI/MUI patients had more PCP, urologist and gynecologist (including Female Pelvic Medicine and Reconstructive Surgery) visits (7.33 vs. 5.53, 1.20 vs. 0.08, and 2.12 vs. 0.85, respectively; $p < 0.0001$). Only 174 SUI/MUI patients (0.25%) had one or more physical therapy visits, and 3184 SUI/MUI patients (4.64%) had one or more PFMT visits in the 2-year postindex period.

The total mean costs incurred by payers in the 2 years after index for cases were 61% higher compared to controls ($27 446.50 vs. $17 035.90; $p < 0.0001$) (Figure 2). When evaluated by setting of care, the mean cost per patient, over the 2-year postindex, was significantly higher in cases compared to controls for outpatient visits ($7032.10 vs. $3348.50; $p < 0.0001$), physician office visits ($3523.70 vs. $2017.40; $p < 0.0001$), and inpatient visits ($3990.70 vs. $2313.70; $p < 0.0001$).

Rates of filled prescriptions for anxiolytic, antidepressant, tricyclic antidepressant, and anticholinergic medications were significantly higher in cases compared to controls (14.67% vs. 9.63%, 42.87% vs. 28.62% and 53.24% vs. 31.23%, respectively; $p < 0.0001$) (Table 3). The duration of medication use (in days) over the 2-year period amongst patients who filled prescriptions was

TABLE 2 Resource use and encounters (2-year postindex): SUI/MUI cohort versus matched control group

Resource use	SUI/MUI cohort ($n = 68\,636$)	Without SUI/MUI ($n = 68\,636$)	p value
Number of physician office visits, mean ± *SD*	30.43 ± 26.65	18.42 ± 19.94	<0.0001
Patients who had a PCP visit, *n* (%)	59 332 (86.44%)	53 642 (78.15%)	<0.0001
Number of PCP visits, mean ± *SD*	7.33 ± 8.95	5.53 ± 7.93	<0.0001
Number of urologist visits, mean ± *SD*	1.20 ± 2.6	0.08 ± 0.60	<0.0001
Number of gynecologist visits, mean ± *SD*	2.12 ± 3.10	0.85 ± 1.95	<0.0001

Abbreviations: MUI, mixed urinary incontinence; PCP, primary care physician; *SD*, standard deviation; SUI, stress urinary incontinence.

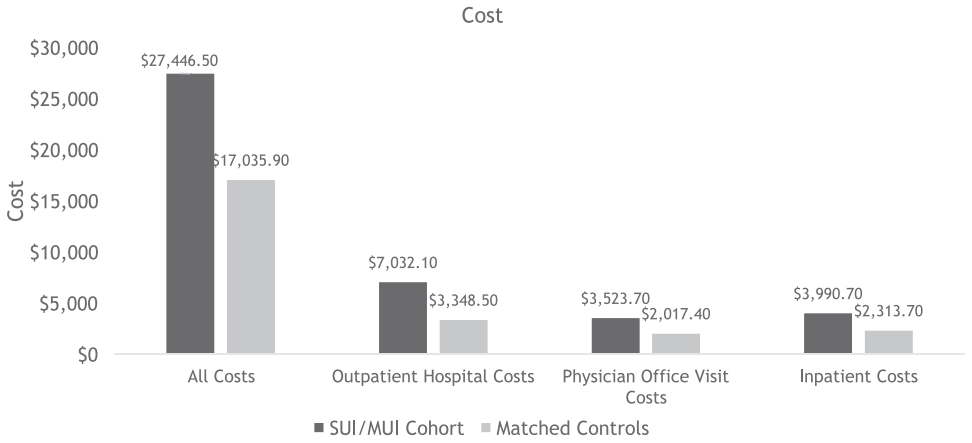

FIGURE 2 Costs of encounters (2-year postindex, including index encounter): SUI/MUI cohort versus matched controls. All costs, outpatient costs, physician office visit costs, and inpatient costs for the SUI/MUI cohort compared to the matched controls. All categories of costs as well as total costs were higher in the SUI/MUI cohort compared to matched controls

significantly greater for antidepressant/tricyclic antidepressant, and anticholinergic usage (77.03 vs. 72.38 days, 31.14 vs. 18.50 days respectively; $p < 0.0001$) in cases compared to controls as calculated based on the numbers of refills and doses. The average cost of prescriptions over 2 years incurred by payers among patients who were prescribed anxiolytic, antidepressant/tricyclic antidepressant, and anticholinergic prescriptions was higher in cases compared to matched controls ($18.68 vs. $10.57, $179.70 vs. $92.72, $278.40 vs. $45.40, respectively; $p < 0.0001$).

4 | DISCUSSION

This study using administrative claims data from the IBM MarketScan Database documented that SUI/MUI is associated with a significant incremental burden on payers owing to higher healthcare resource use and costs. Payers consistently incurred significantly greater medical and pharmacy resource use and associated costs for women with SUI/MUI compared to women without SUI/MUI. Prior studies have demonstrated significant costs associated with UI and that population-based costs of UI management are substantial. Similarly our findings demonstrate an association between UI and increased total healthcare resource utilization and costs.[12,17]

Prior research shows that over $12 billion are spent annually among U.S. patients with SUI, an amount that continues to grow.[12] About 30% of all UI costs are estimated to be borne by payers, which remains substantial for a health condition such as UI, which has a high prevalence and population-based expenditure.[12] A prior 2014 US-based study reported that healthcare resource use, including surgery, medication use, physician's office visits, and hospitalizations, was significantly higher among patients with OAB and UI than among those without UI.[18] Findings from our study are consistent with this research, suggesting the need for effective management strategies that reduce the burden of this disease on patients, payers, and society. Our study adds to the existing body of knowledge by underscoring the burden associated with UI specifically on US payers.

TABLE 3 Medication use and cost (2-year postindex, including index encounter): SUI/MUI cohort versus matched control group

Variable	SUI/MUI cohort ($n = 68\,636$)	Matched controls ($n = 68\,636$)	p value
Average number of prescriptions over 2-years among all patients in the cohort, mean ± *SD*			
Anxiolytic	1.00 ± 3.75	0.65 ± 3.07	<0.0001
Antidepressants	5.11 ± 8.94	3.16 ± 7.24	<0.0001
Tricyclic antidepressants	0.41 ± 2.27	0.22 ± 1.73	<0.0001
Anticholinergics	3.24 ± 6.25	1.30 ± 3.90	<0.0001
Proportion of patients who were prescribed, *n* (%)			
Anxiolytic	10 069 (14.67%)	6609 (9.63%)	<0.0001
Antidepressants	29 427 (42.87%)	19 645 (28.62%)	<0.0001
Tricyclic antidepressants	4301 (6.27%)	2269 (3.31%)	<0.0001
Anticholinergics	36 539 (53.24%)	21 438 (31.23%)	<0.0001
Average number of prescriptions over 2 years among patients who were prescribed, mean ± *SD*			
Anxiolytic	6.80 ± 7.52	6.75 ± 7.55	0.68
Antidepressants	11.93 ± 10.25	11.03 ± 9.81	<0.0001
Tricyclic antidepressants	6.48 ± 6.55	6.76 ± 6.83	0.10
Anticholinergics	6.09 ± 7.48	4.16 ± 6.07	<0.0001
Duration of medication use (days) over the 2-year period among patients who were prescribed, mean ± *SD*			
Anxiolytic	31.31 ± 35.72	31.33 ± 35.88	0.96
Antidepressants	77.03 ± 56.76	72.38 ± 53.54	<0.0001
Tricyclic antidepressants	39.64 ± 38.27	42.88 ± 39.72	0.001
Anticholinergics	31.14 ± 42.41	18.50 ± 33.52	<0.0001
Average cost of prescriptions over 2 years among patients who were prescribed, mean ± *SD*			
Anxiolytic	$18.68 ± $213.20	$10.57 ± $206.70	<0.0001
Antidepressant	$179.70 ± $1,043.90	$92.72 ± $775.50	<0.0001
Tricyclic antidepressants	$8.44 ± $223.50	$5.66 ± $231.80	0.023
Anticholinergic	$278.40 ± $988.40	$45.50 ± $445.30	<0.0001

Abbreviations: MUI, mixed urinary incontinence; SD, standard deviation; SUI, stress urinary incontinence.

Findings from our study indicate that healthcare resource use in SUI/MUI patients is driven by physician office visits, especially PCP visits, and hospital outpatient visits. This finding is in alignment with the current disease management and treatment paradigm wherein PCPs, including Obstetricians and Gynecologists who provide Well-Woman care and serve as primary care providers of choice, are ideally positioned to screen for and manage SUI/MUI patients.[19,20] A study assessing referral patterns to a urogynecology practice reported that most referrals for SUI, MUI, and UUI to their practice were made by PCPs or gynecologists,[21] which is consistent with our findings that PCPs and gynecologists care for a majority of SUI/MUI patients. Most UI procedures and surgeries including detrusor chemodenervation, sub-urethral slings, and colposuspensions are conducted in the outpatient setting.[22] This may contribute to the relatively low mean inpatient hospital visits among SUI/MUI patients reported in our study.

Our study adds to the existing body of literature by evaluating the use of UI-specific treatments including PFMT and physical therapy evaluations in patients with SUI/MUI. We observed that the proportion of SUI/MUI patients using PFMT or receiving physical therapy evaluations is very low. National and international clinical practice guidelines recommend supervised PFMT as a first-line treatment option for SUI in women (Level of evidence A).[23] The limited number of PFMT visits reported in our study suggests that guideline adherence may be low in patients with SUI/MUI, findings evaluated to a greater degree in a companion manuscript.[24] Future studies should

evaluate adherence to management and treatment guidelines for SUI/MUI patients and quantify its impact on healthcare resource use and costs.

Our study found significantly higher use of anxiolytic, antidepressant, tricyclic antidepressant, and anticholinergic medications in SUI/MUI patients compared to the control group. These findings are consistent with prior research demonstrating the association of anxiety and depression with SUI/MUI. A 2017 study reported that women with UI had significantly higher odds (odds ratio: 1.45; 95% confidence interval: 1.23–1.72) of having anxiety and depression compared to women without UI.[25] An additional pharmacologic consideration is that women with SUI-only comprised part of our cohort, and as of this writing, there are no FDA-approved medications for SUI, highlighting prescribing patterns for anticholinergics that may be off-label and with unclear efficacy. A 2013 study using MarketScan data found that of women with SUI who had no comorbid urinary conditions, 18.2% were prescribed an anticholinergic medication. This percentage rose to 26.2% when looking at women with SUI who underwent SUI-related surgery.[26] Given the substantial cost differential of these treatments (anxiolytic, antidepressant, and anticholinergic medications) in patients with and without SUI/MUI, these comorbid conditions may add further to the medical and pharmaceutical healthcare burden imposed by UI and require effective management along with other symptoms of UI.

Our study found a significantly higher medical cost burden to payers associated with SUI/MUI patients compared to controls. The incremental mean medical cost associated with SUI/MUI patients, incurred by payers, was over $10 000 in the 2-year postindex period, which was primarily driven by outpatient costs (~$7000). Surgeries for UI, which now are mostly conducted in the outpatient setting, have a high-cost burden, and may contribute to the high outpatient hospital costs in SUI/MUI patients in our study. Additionally, specialist visits were significantly higher in the group with SUI/MUI, and this may be an additional driver of differences in medical cost between groups. While prior cost studies in UI are conducted from a condition-specific and societal perspective, our study adds to the existing body of literature by reporting total medical costs in cohorts with and without UI that are otherwise age- and comorbidity-matched. This is an interesting finding and warrants investigation in future studies to better elucidate the contributors, UI-related and non-UI related, to this cost difference. Enhanced attention to evaluation and treatment of UI by payers and health systems may present an opportunity to decrease overall medical costs and improve health among women with UI.

Contributing to the strength of our study, data are collected from the MarketScan databases when all claims have been paid, eliminating the need for completion factors and improving the reliability and accuracy of the data. Additional enhancements during database creation include cross-checking of codes and verification that both claims and eligible enrollees exist for all sets of data contributed. These factors make this HIPAA compliant database extremely robust.[27]

There are some limitations to our study. First, this study was conducted using healthcare claims from the IBM MarketScan data. Therefore, the assessment may be susceptible to variability in coding and billing practices, and prescription fills may not reflect actual medication usage. With the use of claims data, there is also the potential for unobserved confounding, and generalizability being limited to the population under study. Because the IBM MarketScan data have high accuracy and robustness, and the data include country-wide Commercial and Medicare Supplemental insurance claims, these biases are minimized. As our primary interest was total healthcare resource use, we used the CCI to match groups as an indicator of overall health. Some well-known risk factors for UI, such as parity and obesity, are not included in the CCI and were not available in database for additional comparison. In keeping with the study objectives, we did not include resources pertaining to UI that are available over the counter and do not need a prescription (e.g., incontinence pads and skin care products). The healthcare resource use and cost burden of these over-the-counter resource options on patients and the society is substantial. Additionally, we were unable to control for race or ethnicity in our analysis, as these variables are not available in the IBM MarketScan database. Racial disparities have been documented in the prevalence of UI subtypes, with SUI being more prevalent among white women and UUI more prevalent among black women. Some evidence indicates that black women may be more likely to discuss their symptoms with their healthcare providers and that they are more bothered by their UI symptoms.[28,29] Although present, these differences are not expected to change the directionality of our results, as the study is sufficiently powered due to the large sample size. We required patients to be continuously enrolled for at least 80% of the study period (July 2013 to June 2018). Any claims incurred in the period that a patient was not continuously enrolled are not captured in this study. We expect the impact of these claims to be minimal, given that no one with less than 80% continuous enrollment was included in the study. Lastly, the analysis was conducted on the entire cohort without segmenting it by insurance type. Caution should be

exercised when generalizing our results to the commercial only or Medicare fee-for-service only population.

5 | CONCLUSIONS

Our study contributes to the current body of evidence in the field of SUI/MUI. It not only brings to light the substantial incremental healthcare resource use and cost burden associated with SUI/MUI, but also does so from the perspective of payers, which has been a significant gap in prior studies published in this area. These insights should motivate payers to prioritize review of UI screening, evaluation, and treatment paradigms to optimize care and healthcare resource utilization, exploring programs and processes that would more reliably direct patients to treatment consistent with published guidance. Such changes may optimize healthcare resource utilization and ultimately lead to a better quality of life for patients living with this disease.

AUTHOR CONTRIBUTIONS

Samantha Pulliam and Jessica McKinney: participated in the concept and design of the study in addition to publication development. However, they did not participate in acquisition of the data, analysis, or interpretation, which was conducted by Boston Healthcare Associates, a Veranex company. The Renovia Inc. authors had access to relevant aggregated study data, and other information (such as study protocol, analytic plan and report, validated data table, and clinical study report) required to understand and report research findings. All authors take responsibility for the presentation and publication of the research findings, have been fully involved at all stages of publication and presentation development, and are willing to take public responsibility for all aspects of the work. All individuals included as authors and contributors who made substantial intellectual contributions to the research, data analysis, and publication or presentation development are listed appropriately.

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CONFLICTS OF INTEREST

Manasi Datar, Li-Chen Pan and Thomas Goss are employees of Boston Healthcare Associates which received consulting fees from Renovia Inc. Jessica McKinney and Samantha Pulliam are employees of Renovia Inc.

ETHICS STATEMENT

All database records are statistically deidentified and certified by IBM/Marketscan to be fully compliant with US patient confidentiality requirements set forth in the Health Insurance Portability and Accountability Act of 1996. Because this study used only deidentified patient records and did not involve the collection, use, or transmittal of individually identifiable data, Institutional Review Board approval to conduct this study was not necessary.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from IBM Marketscan. Restrictions apply to the availability of these data, which were used under license for this study. Data are available from the author(s) with the permission of IBM Marketscan.

Data supporting the findings of this study are not publicly available because they are under license from IBM. Aggregate datasets generated and analyzed during the current study are available from the corresponding author on reasonable request, upon consultation with the sponsor.

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