Medicare beneficiaries initiating mirabegron versus anti-muscarinic treatment for overactive bladder: patient reported adherence and claims based adherence rates

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Background

Older age patients are more adherent to chronic medications for hypertension, diabetes, and hyperlipidemia then younger patients.[1] Successful treatment of OAB depends on persistence with the prescribed medication, and efficacy and tolerability are key influencers of persistence.[2] Antimuscarinics (AM) and mirabegron (MR) are pharmacotherapy options for overactive bladder (OAB). MR is a first in class beta-3 agonist for treatment of OAB that may have better adherence compared to AMs. This study examined adherence during the first 90 days for Medicare members initiating MR or AM and member characteristics associated with adherence.

Methods

This prospective observational study used real-time prescription (Rx) claims from the Humana Research Database to identify members with a new Rx for MR or AM within 1 week of first Rx and consented into the study. Subjects were required to meet the following criteria:

- Medicare Advantage (MAPD) or Medicare Prescription Drug Plan (PDP) member age ≥ 65 years of age.
- First Rx claim for MR or AM medication for treatment of OAB with no Rx claim for that specific index medication in previous six months.
- Continuous health plan enrollment for six months pre-index, and current health plan enrollment at time of identification.

Health plan members in long-term care facilities at time of identification were excluded.

All MR initiators and a comparably sized random sample of AM initiators were identified on a weekly basis and recruited to participate in a longitudinal series of 3 telephone surveys over 90 days. Morisky Medication Adherence Scale (MMAS-4)[3] and Patient Perception of Bladder Control (PPBC) Score[4] were collected in surveys. Claims based measures were: patient demographics, clinical characteristics, days' supply and proportion of days covered (PDC). Adherence was defined as PDC ≥ 0.80. Descriptive and inferential statistical analyses were performed.

Results

- 1,007 MR and 1,311 AM patients were identified and contacted to be recruited into the study; 146 MR and 186 AM patients completed all 3 surveys, had continuous enrollment for at least 90 days, and a confirmatory Rx claim for the index medication, and self-reported OAB diagnosis.
- Self-report and claims-based adherence at 90 days was similar between MR and AM initiators (MMAS-4: 3.7 vs 3.6; PDC=0.8 vs 0.8). The correlation between MMAS-4 and PDC was not significant (Table 1).
- More AM non-adherent resided in the South compared to AM adherent (61% vs 43%, p=0.024) and were less likely to have previously tried an OAB therapy based on claims data (5% vs 16%, p=0.039) but not self-report (25% vs 37%, p=0.092) (Table 2).
- Compared to non-adherent members, adherent members more frequently reported having previously tried an OAB therapy (self-report: 45% vs 31%, p=0.019; claims: 20% vs 8%, p=0.006). Adherent MR initiators were more likely to have dual eligibility (18% v 2%, p=0.013), and low income subsidy (26% vs 2%, p=0.001) compared to MR non-adherent (Table 3).

Results

Table 1. Adherence to OAB Medication at 90-Days Post-Initiation

	Overall N = 332		Mirabegron initiators n = 146		Antimuscarinic initiators n = 186	
Adherence	**Mean**	**SD**	**Mean**	**SD**	**Mean**	**SD**
Self-Report Morisky Medication Adherence Scale -4 at 90-Day† [0-4]	3.6	± 0.60	3.7	± 0.60	3.6	± 0.70
Claims Proportion of Days C Overall at 90 Days	0.83	± 0.24	0.83	± 0.23	0.83	± 0.25
	r	***P* value**	***r***	***P* value**	***r***	***P* value**
Correlation between claims and self-report at 90-Day	0.05	0.363	0.08	0.321	0.03	0.692

† Higher score indicates preferred outcome. Morisky self-reported adherence data was collected at 30- and 90-day surveys. The Morisky items are summed, with a higher score indicating a greater level of medication adherence (0=low adherence; 4=high adherence).
P value based on Pearson correlation coefficient

Figure 1. Post-Index (90-Day) Claims-Based Adherence (Achieving ≥80% PDC) to Any OAB Medication by Study Group

Adherent was defined as PDC ≥ 0.80
Non-Adherent was defined as PDC < 0.80

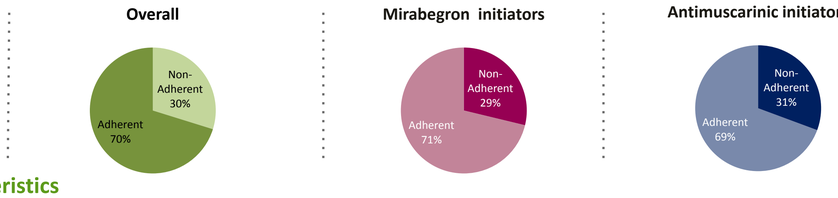

Table 2. Demographic Characteristics

	Overall			Mirabegron initiators			Antimuscarinic initiators		
	Non-Adherent	**Adherent**	**Adh vs. Non-Adh**	**Non-Adherent**	**Adherent**	**Adh vs. Non-Adh**	**Non-Adherent**	**Adherent**	**Adh vs. Non-Adh**
N	99	235	*P*	42	106	*P*	57	129	*P*
Age, mean ± SD	75.2 ± 7.2	75.2 ± 6.3	0.984 [a]	76.5 ± 7.2	75.6 ± 5.8	0.422 [a]	74.2 ± 7.2	74.8 ± 6.8	0.578 [a]
Gender , n (%)									
Female	69 (69.7%)	177 (75.3%)	0.287 [b]	28 (66.7%)	73 (68.9%)	0.795 [b]	41 (71.9%)	104 (80.6%)	0.188 [b]
Male	30 (30.3%)	58 (24.7%)		14 (33.3%)	33 (31.1%)		16 (28.1%)	25 (19.4%)	
Geographic Region, n (%)									
South	57 (57.6%)	121 (51.5%)	0.309 [b]	22 (52.4%)	65 (61.3%)	0.319 [b]	35 (61.4%)	56 (43.4%)	0.024 [b]
Other	42 (42.4%)	114 (48.5%)		20 (47.6%)	41 (38.7%)		22 (38.6%)	73 (56.6%)	
Race/ethnicity, n (%)									
White	85 (85.9%)	215 (91.5%)	0.120 [b]	38 (90.5%)	97 (91.5%)	0.841 [b]	47 (82.5%)	118 (91.5%)	0.073 [b]
Other	14 (14.1%)	20 (8.5%)		9.5 (9.0%)	9 (8.5%)		10 (17.5%)	11(8.5%)	
Plan Type, n (%)									
MAPD	54 (54.6%)	121 (51.5%)	0.610 [b]	19 (45.2%)	53 (50.0%)	0.601 [b]	35 (61.4%)	68 (52.7%)	0.272 [b]
PDP	45 (45.5%)	114 (48.5%)		23 (54.8%)	53 (50.0%)		22 (38.6%)	61 (47.3%)	
Other									
Dual eligibility status	13 (13.1%)	36 (15.3%)	0.606 [b]	1 (2.4%)	19 (17.9%)	0.013 [b]	12 (21.1%)	17 (13.2%)	0.172 [b]
Low-income subsidy status	15 (15.2%)	47 (20.0%)	0.298 [b]	1 (2.4%)	27 (25.5%)	0.001 [b]	14 (24.6%)	20 (15.5%)	0.141 [b]

Note: Dual-eligibility (DE) refers to Medicare members who are also eligible for Medicaid benefits. Dual-eligibility Medicare members often have more disease burdens and have different healthcare utilization patterns compared to other Medicare members. Low-income subsidy (LIS) status refers to Medicare beneficiaries with income below 150% of poverty and limited resources, who are eligible for additional premium and cost-share assistance for prescription drugs under the Medicare Part D program. These members are flagged as LIS members in Humana's claims database. This variable was measured for Medicare members only.

Table 3. Clinical Characteristics

	Overall			Mirabegron initiators			Antimuscarinic initiators		
	Non-Adherent	**Adherent**	**Adh vs. Non-Adh**	**Non-Adherent**	**Adherent**	**Adh vs. Non-Adh**	**Non-Adherent**	**Adherent**	**Adh vs. Non-Adh**
N	99	235	*P*	42	106	*P*	57	129	*P*
Clinical Characteristics									
OAB severity (Baseline Self-Reported PPBC), n (%)									
Minor problems	74 (74.8%)	177 (75.3%)	0.912 [b]	33 (78.6%)	78 (73.6%)	0.528 [b]	41 (71.9%)	99 (76.7%)	0.483 [b]
Major problems	25 (25.3%)	58 (24.7%)		9 (21.4%)	28 (26.4%)		16 (28.1%)	30 (23.3%)	
Self-Report Therapy Experienced, [c] n (%)	31 (31.3%)	106 (45.1%)	0.019 [b]	17 (40.5%)	58 (54.7%)	0.118 [b]	14 (24.6%)	48 (37.2%)	0.092 [b]
Claims Data Therapy Experienced, [d] n (%)	8 (8.1%)	48 (20.4%)	0.006 [b]	5 (11.9%)	27 (25.5%)	0.071 [b]	3 (5.3%)	21 (16.3%)	0.039 [b]
RxRisk-V, mean ± SD	9.4 ± 5.7	9.4 ± 4.9	0.992 [a]	9.9 ± 5.4	10.3 ± 4.9	0.664 [a]	8.9 ± 6.0	8.6 ± 4.8	0.636 [a]
Number of unique medications, mean ± SD	5.7 ± 3.1	5.8 ± 2.9	0.700 [a]	5.6 ± 3.2	6.2 ± 2.9	0.279 [a]	5.7 ± 3.0	5.4 ± 2.8	0.609 [a]

[a] P values between Groups based on 2-sided t-tests
[b] P values between Groups based on chi square
[c] Based on patient self-report. Treatment history (patient self-reported) was defined as a dichotomous variable, treatment experienced vs. treatment naïve. At the introduction of the baseline survey, patients were asked if they had been on a previous therapy to treat OAB, prior to starting the new medication. Treatment experienced was defined as a 'yes' answer to the question and treatment naïve was defined as 'no' answer to the question.
[d] Based on any Rx claims. Treatment history (claims data) was defined as a dichotomous variable, treatment experienced vs. treatment naïve using claims data available in the 6 month pre-index period. Treatment experienced was defined as a pharmacy claim for MR or AM in the 6 month pre-index period. Treatment naïve was defined as no pharmacy claim for MR or AM in the 6 month pre-index period.

Conclusions

- Results (unadjusted) from claims and self-report differed but both showed similar adherence for MR or AM during the first 90 days of treatment (for those that completed 3 surveys at 90 days).
- Clinical characteristics differ for MR and AM initiators, so may make comparisons between groups difficult.
- Adherence to OAB medication was high compared to the literature.
  - The telephone surveys may have served as a refill reminder and may have had a positive impact on adherence for both groups.
  - This may be a more engaged Medicare patient population for this symptomatic disease; research indicates older age beneficiaries tend to be more adherent.[2]
- Adherent initiators had more therapy experience. Adherence initiatives could focus on patients who are therapy naïve to help impact and improve adherence rates at treatment initiation.

Sources of Support/Disclosures

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Limitations

- OAB diagnosis was not a claims-based diagnosis.
- Eligible patients may be overestimated based on the use of real-time data for identification; instances where the daily Rx claims was processed and later reversed would not have been captured as an eligible patient at the time of identification.
- Baseline survey data was collected proximal to newly initiated treatment .
- Limitations common to studies involving survey methodology will also apply to this study, including response bias and problems with missing data.
- Limitations common to studies using administrative claims data apply to this study. These include lack of certain information in the database and errors in claims coding.
- Data were from Humana members only, the results may not be generalized to the overall population.
- Current analysis is for 3 months only and follow-up beyond this may result in changes to adherence rates in this population.

References

1. Couto JR, Panchai JM, Lal, LS, et al. Geographic variation in medication adherence in commercial and Medicare Part D Populations. J Manag Care Pharm. 2014; 20 (8): 834-842b.
2. Haab F, Castro-Diaz D. Persistence with antimuscarinic therapy in patients with overactive bladder. Int J Clin Pract. 2005; 59: 931–937.
3. Morisky DE, Green LW, Levine DM. Concurrent and predictive validity of a self-reported measure of medication adherence. Medical Care. 1986; 24(1):67-74.
4. Coyne KS, Matza LS, Kopp Z, et al. The Validation of the Patient Perception of Bladder Condition (PPBC): A Single Item Global Measure for Patients with Overactive Bladder. European Urology. 2006; 49: 1079-1086.