Antipsychotic Medication use in Medicare Nursing Home Patients 2010-2015

A Medicare fee-for-service claims-based analysis

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Key Findings

- The portion of patients entering a nursing home receiving an antipsychotic medication (AP) decreased from 2011 to 2015
- The largest decrease was observed in patients with conditions other than those recognized by the FDA as an approved indication for treatment/management with APs
- Whether a patient had a condition measured by the CMS antipsychotic quality metric had an impact on their AP use. Patients with a measured condition had a greater decrease between 2011 to 2015

In the early 2000s, public health experts expressed concern that antipsychotic medications (APs) were being prescribed inappropriately in the residential nursing home (NH) setting.[1,2] The Beers Criteria, which provide guidance to prescribers and patients on safe drug selection and dosing, recommend avoiding APs in patients who are experiencing behavioral issues associated with delirium or dementia, except when patients have failed to respond to non-pharmacological interventions and are at significant risk of harming themselves or others.[3]

The primary concern was that APs, some of which have sedative effects, were being used as chemical restraints to manage residents, including those with disruptive or aggressive behaviors. In 2004, a study of patients ages 66 and older who were newly admitted to an NH with no history of major psychosis or neuroleptic drug use in the year prior to admission found that 17% of these patients received an AP within 100 days of entering the nursing home. Within the first year of NH residency, new AP use increased to 24%.[4]

In 2012, CMS introduced new quality metrics aimed at reducing AP misuse in nursing homes

These metrics, part of the Minimum Data Set (MDS) and a component of the CMS Nursing Home Quality Initiative (NHQI) Five-Star Quality Rating System, are publicly reported for each NH. The “star metrics” were intended by CMS to be used as indicators of NH quality of care and for comparisons among facilities. The MDS (data that nursing homes self-report) includes two different quality metrics related to AP use: one for short stay residents (≤100 cumulative days in a NH) and another for long-stay residents (>100 cumulative days in a NH). For short-stay NH residents, the metric reports the percentage of residents who newly received an AP without prior AP use indicated on their entry assessment. For long stay residents, the metric reports the percentage of residents who received APs, regardless of prior AP use. For both metrics, higher percentages suggest quality problems.

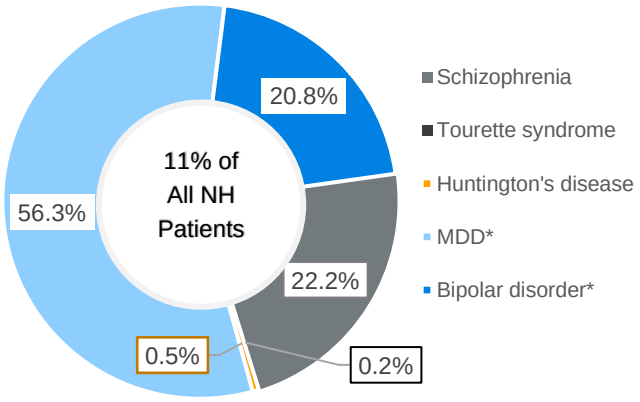
The current CMS long-stay AP use quality metric excludes patients identified with schizophrenia, Tourette syndrome, and or Huntington’s disease. Both schizophrenia and Tourette syndrome are FDA-approved indications for some APs. The exclusion of Huntington’s disease from the quality metric is consistent with the off-label use of some APs for suppressing chorea and for managing psychiatric symptoms associated with Huntington’s

disease, including agitation and psychosis.[5] However, bipolar disorder and major depressive disorder (MDD) — conditions designated as FDA-approved indications for many APs, particularly 2nd generation APs — are included. Long-stay patients who receive an AP and are not identified with schizophrenia, Tourette syndrome, or Huntington's disease would negatively impact the NH's quality score. Therefore, NHs with patients identified with MDD or bipolar disorder taking APs would have lower scores than if these patients did not take APs.

The fact that some FDA approved indications are included in the star metrics while others are excluded raises the concern that if the FDA approves new indications for APs, the star metrics may not be adjusted to align with approved uses.

Between 2011 and 2015, over three quarters of all long-stay NH residents on an oral AP were identified with an FDA-approved condition included in the star metric (see Figure 1).

FIGURE 1: RELATIVE IMPACT OF CONDITION FOR FDA-APPROVED AP USE INDICATIONS



Footnote:
* Included in CMS AP use star metric for long-stay NH residents
** The following hierarchy was used to assign patients to a single condition if they were identified with more than one condition: 1. schizophrenia 2. Tourette syndrome 3. Huntington's disease 4 bipolar disorder 5. major depressive disorder.

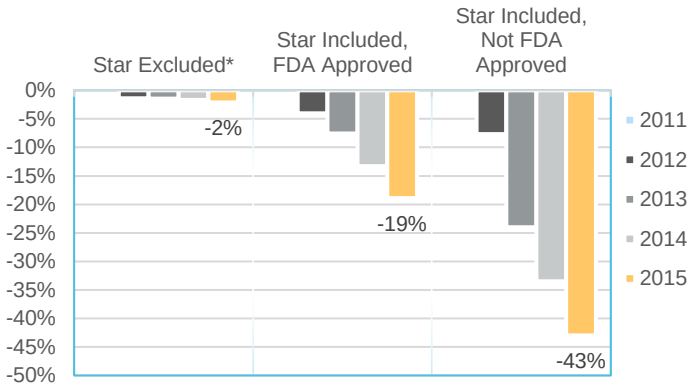
From 2011 to 2015, Medicare patients entering the NH increased by 12% while the percent of patients on APs decreased by 26%.

In the first six months of NH experience of each entrance cohort, the portion of patients with at least one fill for an AP decreased from 19.4% in 2011 to 14.4% in 2015. This reduction in patients with AP use in the NH varied based on the patients' condition. In our analysis, the largest decrease in AP use occurred in NH patients with off-label AP use – a 43% decrease from 2011 to 2015 (14.9% to 8.5%). NH patients with the smallest change in portion of patients with AP use was the star excluded (and FDA approved) group. This group experienced a 2% decrease in AP use in the first 6 months between 2011 to 2015 (75.6% to 74.0%).

AP use decreased by 19% over the observed period for patients with an FDA-approved condition not excluded from the CMS AP use quality metric.

For these patients, the portion on an AP in 2011 was 21.8% and decreased to 17.7% in 2015. It is also of note that the only condition cohorts to increase as a share of total nursing home patients regardless of AP use were bipolar disorder and MDD (from 34% in 2011 to 40% in 2015).

FIGURE 2: PERCENT DECREASE FROM 2011 IN PORTION OF NH PATIENTS ON AN AP BY CONDITION COHORT OVER TIME



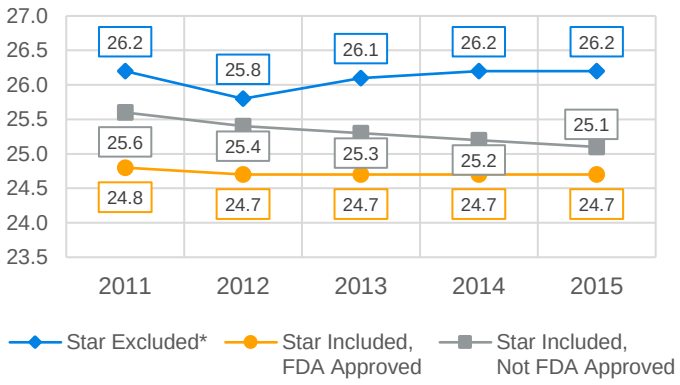
Footnote:
* Star excluded includes conditions which are also FDA-approved indications for APs.

NH patients on APs experienced either consistent use or full AP cessation.

While the portion of patients on APs decreased over time in the NH, a similar decrease was not observed in AP use (as measured by average days supply per 30 days) for the patients taking APs. For patients entering the NH in 2011, the average days supply of APs provided via Medicare Part D in the first six

months of NH experience for the three condition cohorts were 26.2, 24.8, and 25.6 days ("Star Excluded, FDA Approved", and "Star Included, Not FDA Approved", respectively). For the same condition cohorts, we observed AP use for new entrance NH patients in 2015 of 26.2, 24.7, and 25.1 days (a change of 0%, -1%, and -2%, respectively) (see Figure 3).

FIGURE 3: AVERAGE DAYS SUPPLY PER 30 DAYS BY CONDITION COHORT OVER TIME



Footnote:
* Star excluded includes conditions which are also FDA-approved indications for APs.

Continued stability of AP days supply per patient was also found when observing entrance cohorts over longer stretches of NH experience. The 2011, 2012, and 2013 cohorts all had a minimum of 30 months of NH experience after the implementation of CMS AP specific star metrics in April 2012. In each of these three cohorts a slight increase in average days supply was observed for all NH patients with AP use over time. Average days supply increased by 1.5-1.6 days between the initial six months of NH experience to the final six months of NH experience (see Figure 3). This increase corresponds to a decrease in Part A covered SNF days (days in which AP use is typically included in a bundled reimbursement and not separately through Part D) as a portion of total nursing facility days. The rate of Part A covered SNF days decreased from 5% to 3% during the same period.

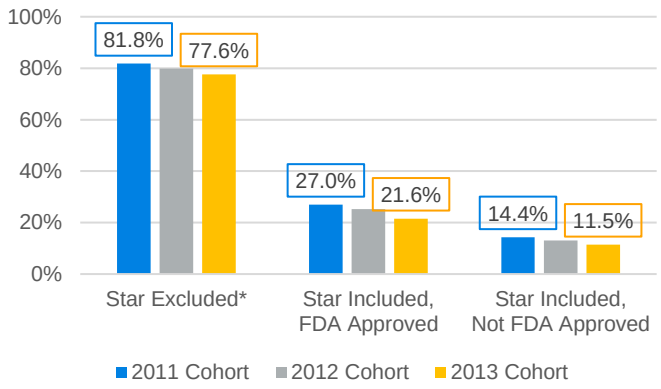
Acute nursing facility stays (Part A covered skilled nursing facility (SNF) admissions) accounted for less than 5% of total nursing facility experience for our sample population.

We analyzed AP medications provided through Medicare Part D coverage. Subsequently, APs provided as part of a bundled Part A service are not included in our analysis. However, for the long-stay population, the contribution of acute nursing facility days was low—from 4.7% to 2.5% of total days over a six-month period for the 2011 to 2013 cohorts. All patients in our analysis had at least 101 total days of nursing facility experience within the 365 days following first day of NH experience. This is to limit our analysis to a population more likely to meet the CMS long-stay designation. We feel that there is sufficient nursing home experience with Part D coverage for our subsequent findings to be representative of our study population's full experience.

Conclusions

In our analysis, we found a steady decrease in the portion of NH patients on an AP over time. The rate of decrease varied by condition category.

FIGURE 4: PORTION OF PATIENTS ON AN AP BY CONDITION COHORT – DECEMBER 2013



Footnote:
* Star excluded includes conditions which are also FDA-approved indications for APs.

Over time, more recent entrance cohorts showed lower use of APs (see Figure 4). Additionally, the change in the rate of AP use varied by condition cohort within each entrance cohort. Patients identified with conditions that were excluded from the long-stay AP metric experienced the smallest decrease over time while those without an FDA-approved condition experienced the largest decrease (43%). However, patients identified with an FDA-approved condition but not excluded from the CMS star metric (e.g., bipolar disorder and MDD) decreased by 19%. This indicates a need to safeguard patients with FDA-approved conditions and exclude them from the denominator of the star metric calculation to ensure they receive the treatment they require.

The introduction of the CMS long-stay star metric aimed at reducing AP use in NHs in 2012 coincided with declines in the portion of new entrant NH patients using APs.

Patient cohorts identified with conditions explicitly excluded from the star metric (i.e., schizophrenia, Tourette syndrome, and/or Huntington's disease) experienced only a slight decrease in the portion of patients on an AP. Patient cohorts with conditions not recognized by the FDA as approved indications for treatment with APs experienced a much larger decrease in the portion of patients on an AP.

Currently, patients with bipolar disorder and MDD are included in the AP quality metric, even though APs are approved by the FDA for the treatment and management of patients with these conditions.

Over the time period of this study, the decrease in AP use was greater in patients whose conditions were not FDA approved for APs. Furthermore, patients whose conditions were included in the AP star metrics saw a greater decline in AP use than patients whose conditions were not included. Because the conditions included in the star metrics have an impact on physician prescribing patterns of APs, policymakers should consider the unintended consequences of the conditions included.

Methodology and Data Sources

This analysis analyzed administrative claims from the 100% Medicare fee-for-service (FFS) research identifiable files (RIF) from 2010-2015. Cohorts of patients newly entering NHs were identified in the second quarter of each calendar year (2011-2015) and observed over multiple years to evaluate changes in AP use relative to the implementation of the AP quality metric in 2012.

Nursing Home Identification

An algorithm identified patient days in NHs based on patient's receipt of NH-specific evaluation and management (E&M) services, including initial nursing facility care, subsequent nursing facility care, nursing facility discharge care and annual nursing facility assessment.

In our algorithm, each NH E&M claim would begin a nursing facility period which would last until the earliest of:

- Subsequent NH E&M claim
- 75 consecutive days
- Subsequent home health claim
- Patient cessation (death)
- Study period end (12/31/2015)

Days within a nursing facility period were separately identified for three instances during which measurement of our primary variable of interest (AP medications supplied through Part D Medicare) would be limited, including Part A covered SNF admission, Part A covered acute inpatient admission, and Part A overed hospice stay. The nursing facility days which did not overlap with these Part A services are what we limited our analysis to (i.e., residential nursing home days). All calculations are limited to residential nursing home days. This study explicitly excludes from both the numerator and denominator any experience while in a Part A covered acute nursing stay (SNF admission).

Study Population Requirements

All patients in our analysis, which includes aged, disabled and dual eligible patients, were required to have continuous coverage of Medicare Part A, Part B and Part D for the entire study period. Patients were assigned to an entrance cohort based on the date of their earliest NH E&M claim. A lookback period of 6 months was applied to limit our analysis to patients with relatively new NH experience. Entrance cohorts included in our analysis were restricted to patients whose first NH E&M claim occurred during the second quarter (April 1 – June 30) of each calendar year (2011-2015). To restrict the analysis to long-stay NH residents only, patients were required to have at least 101 cumulative days of Part A covered SNF days and residential NH days within the first 365 days of their observation period.

Patient Condition Identification

Patients were assigned to one of seven diagnosis-based condition categories of interest based on International Classification of Diseases (ICD)-9-CM and ICD-10-CM diagnosis codes on qualified claims:

- Schizophrenia
- Tourette syndrome
- Huntington's disease
- Bipolar disorder
- Major depressive disorder
- Dementia
- No condition of interest

Patients could be identified with multiple conditions of interest or none of the conditions of interest. Identification was based on the patient's 6-month clean period (prior to the first NH E&M claim), and conditions were reassessed every 6 months. Patients identified with any of the conditions listed at any point in each subsequent six-month reassessment period were classified with that condition for the entirety of the six months.

We classified NH patients with AP use into three broader condition cohorts based on their identified condition categories. Condition categories are mutually exclusive, and no patient could be included in more than one in each month. Condition cohorts were:

- Star excluded:
    - Conditions excluded from the star metric (schizophrenia, Tourette syndrome, and Huntington's disease). Schizophrenia and Tourette's are FDA-approved indications for treatment with APs, Huntington's disease is not.
- Star included, FDA approved:
    - Conditions included in the star metric but FDA approved for treatment with APs (bipolar disorder and MDD)
- Star included, not FDA approved:
    - Conditions included in the star metric and not FDA approved for treatment with APs (colloquially referred to as "off-label" indications; includes dementia).

Nursing Home Drug Use Methodology

All AP use calculations in this analysis rely on the proportion of days covered: days supply per 30 residential nursing home days.

Only APs covered under Part D were included in our analysis, and we required that the fill date coincide with a residential nursing home day. Medication coverage began at the fill date and extended through the fill date plus the days supply indicated on the claim and required overlap with a residential nursing home day. APs provided via other mechanisms such as long-acting injections covered under Medicare Part B are not included in our analysis. Covered days overlapping with a Part A covered SNF stay, acute inpatient admission, or hospice stay were excluded from the calculation as medications taken during these stay types are the responsibility of the provider and the Part D plan.

Caveats and Limitations

Changes in AP use over time were determined using the difference in average days supply per 30 days. Increases or decreases in dose are not considered under this methodology. Medication therapy changes resulting in different dosing patterns would affect this calculation. For example, moving therapy from a medication dosed once-daily to twice-daily with half a dose would be identified as an increase in AP use. Our review of AP use found relatively consistent drug treatment use for patients in the study population although potential biases from our definition of changes in AP use should be considered. Our analysis evaluated only oral AP use, and it is possible that considering other AP treatment modalities (e.g., long acting injectables (LAI)) may produce different outcomes or results. Our analysis was limited to a Medicare FFS population in years 2011-2015 with Part A, B, and D coverage, and our findings may not be generalizable beyond this population and time period. Additionally, longitudinal patterns we report are affected by survivor bias and changes in patient conditions over time.

This report was commissioned by Otsuka America Pharmaceutical, Inc. The findings reflect the research of the authors; Milliman does not intend to endorse any product or organization. Otsuka America Pharmaceutical, Inc. did not author this paper or influence the findings.

If this report is reproduced, it should be reproduced in its entirety, as pieces taken out of context can be misleading. Our analysis is based on historical practice patterns and treatments which may change over time. Actual experience may vary from the estimates presented in this report for many reasons. As with any economic or actuarial analysis, it is not possible to capture all factors that may be significant. Further, no algorithm for identifying acute health outcomes and medication utilization based on administrative claims data alone will be perfect. We made no attempt to verify the validity or consistency of diagnosis codes or patient residence values that appeared in the Medicare data. Because we present average data from a five-year sample, the findings should be interpreted carefully before they are applied to any particular situation.

Guidelines issued by the American Academy of Actuaries require actuaries to include their professional qualifications in all actuarial communications. Bruce Pyenson is a member of the American Academy of Actuaries and meets the qualification standards for performing the analyses in this report and rendering the actuarial opinions contained herein. The authors, thank their Milliman co-worker Jared Hirsch for his assistance with the supporting analytics.

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ENDNOTES

[1]Briesacher BA, Limcangco MR, Simoni-Wastila L, et al. The quality of antipsychotic drug prescribing in nursing homes. *Arch Intern Med*. 2005;165(11):1280-1285. doi:10.1001/archinte.165.11.1280

[2] Mott S, Poole J, Kenrick M. Physical and chemical restraints in acute care: their potential impact on the rehabilitation of older people. *Int J Nurs Pract*. 2005;11(3):95-101. doi:10.1111/j.1440-172X.2005.00510.x

[3] American Geriatrics Society Beers Criteria® Update Expert Panel. American Geriatrics Society 2019 Updated AGS Beers Criteria® for Potentially Inappropriate Medication Use in Older Adults. *J Am Geriatr Soc.* 2019;67(4):674-694. doi:10.1111/jgs.15767

[4] Bronskill SE, Anderson GM, Sykora K, et al. Neuroleptic drug therapy in older adults newly admitted to nursing homes: incidence, dose, and specialist contact. *J Am Geriatr Soc*. 2004;52(5):749-755. doi:10.1111/j.1532-5415.2004.52212.x

[5] Zaunbrecher, Nicole. “Approved Treatments for Huntington's Disease” Huntington's Disease News, 10 May 2021, https://huntingtonsdiseasenews.com/approved-treatments-for-huntingtons-disease-2/.