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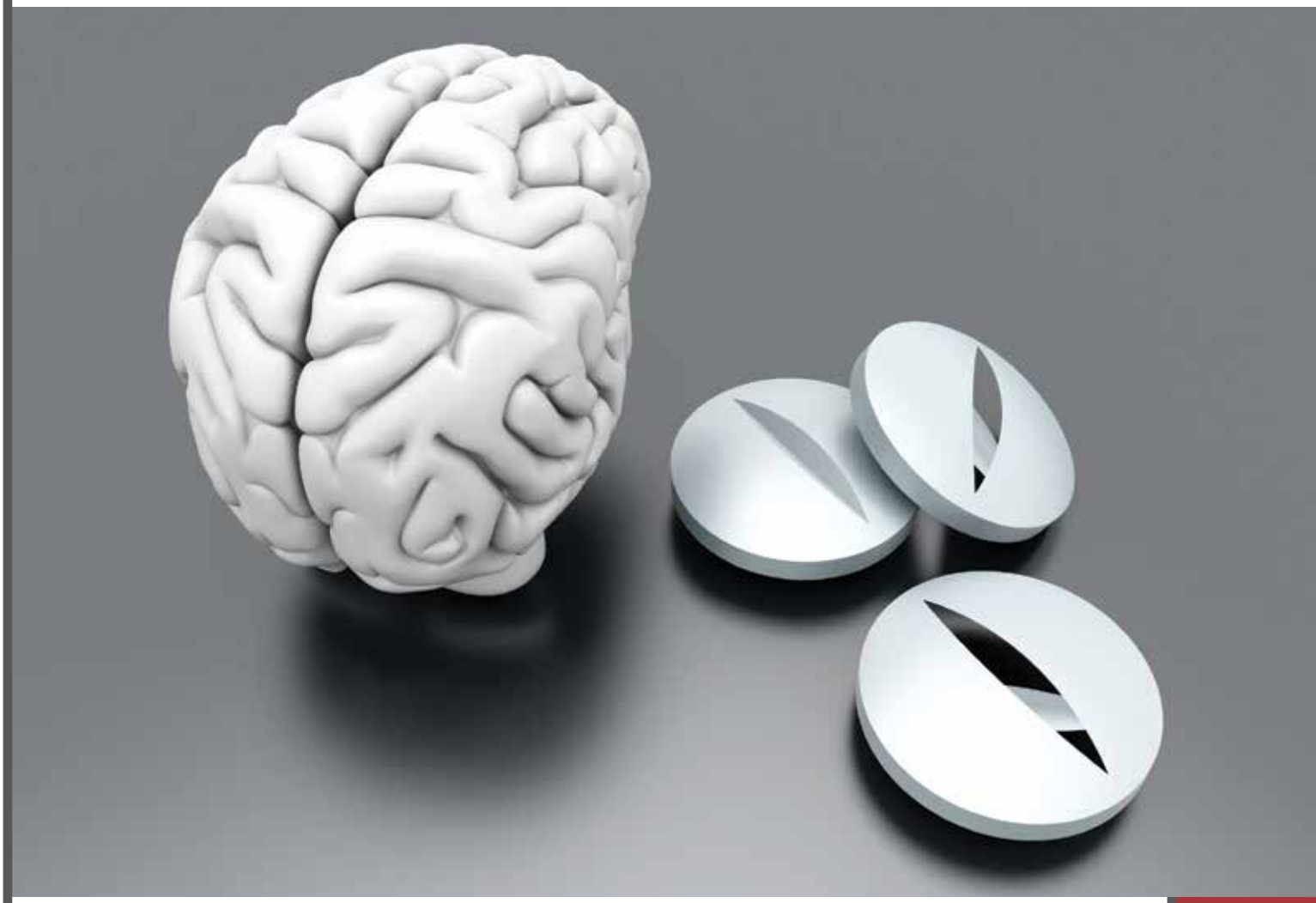
WHITE PAPER



Preparing For Government Audits: Atypical Antipsychotic Medications

INTRODUCTION

Most people would agree that the Centers for Medicare & Medicaid Services (CMS) are justified in seeking to ensure that the long-term and acute care services they pay for are appropriate and meet federal standards. After all, ours is a rapidly aging population that is increasingly reliant on the Medicare/Medicaid system. From a purely budgetary standpoint, it makes perfect sense to put checks and balances in place to make sure the dollars are spent where they should be.

In 2010, CMS launched its Medicare Recovery Audit Contractors (RAC) program to help do exactly that—primarily, to review care provider billings to identify and recover overpayments and, to a lesser extent, identify and reimburse for underpayments. CMS reports that in fiscal year 2016 alone, the program had recouped $4.7 billion.

In the healthcare industry, new focus areas are being identified by the Office of Inspector General (OIG) and CMS on a regular basis, and these same focus areas can easily become the subject of investigation by the Department of Justice. Among the areas of focus most on the radar of our long-term care clients are atypical antipsychotic medications, hospice services, and physical therapy services. In this three-part series of white papers, we'll take a look at each of these issues—examining how they came to be focus areas, what your organization needs to do to be in compliance with CMS standards, and what you can do now to prepare for, or respond to, audits.

ATYPICAL ANTIPSYCHOTIC DRUGS: WHY NOW?

Prescription drugs are a fact of life in the long-term and acute care settings. Of all the drug categories to focus upon, why were atypical antipsychotics singled out? For starters, this category of drug is used in the long-term care setting with great frequency. For instance, in 2006, three of the top 10 drugs paid for by Medicare Part D were atypical antipsychotics.

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OIG launched an investigation into the use of these drugs at the request of Sen. Charles Grassley (R-IA), who sought to evaluate just how frequently they were being used in nursing homes and what the associated cost is to Medicare. The study also sought to evaluate how often these drugs were prescribed for residents suffering from dementia—a population susceptible to increased risk of death when using the drugs, according to the Food and Drug Administration's (FDA's) boxed warning on atypical antipsychotics.

MEDICARE REIMBURSEMENT CRITERIA 1: PROOF OF MEDICAL NECESSITY

Atypical antipsychotics account for three of the top 10 prescriptions paid by Medicare, and the drugs have both FDA-approved and off-label uses. But, does their prevalence and off-label use mean atypical antipsychotics should never be prescribed in the long-term care setting or will never qualify for reimbursement? Not necessarily. Atypical antipsychotics, like any other drug, are eligible for Medicare reimbursement if they meet CMS' criteria for use. CMS requires that long-term care residents' drug therapy regimens are free of unnecessary drugs, which include:

- Those given in excessive doses;
- Those given for excessive durations;
- Those given without adequate monitoring;
- Those not used for medically accepted indications;
- Those given in the presence of adverse consequences that indicate the dosage should be reduced or discontinued.

The use of off-label drugs are not outside CMS' criteria, provided that it is supported by one of the three official reference compendia used by CMS. These compendia include the American Society of Health System Pharmacists' American Hospital Formulary Services Drug Information; United States Pharmacopeia—Drug Information; and Thomson Reuters' DrugDEX Information System.

MEDICARE REIMBURSEMENT CRITERIA 2: REQUIRED DOCUMENTATION

Provided that the use of the atypical antipsychotic drugs is supported by CMS' compendia, providers may proceed. However, keep in mind that reimbursement isn't dependent on a simple physician order in a medical record, a diagnosis code or acceptance in a reference compendium. It's far more rigorous than that—it's really all about documentation.

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This documentation must include:

- Specific condition diagnosed and documented in the clinical record;
- Gradual dose reduction;
- Behavioral interventions; and
- Medication regimen review.

OIG FINDINGS (5/2011): DEEPER ISSUES EMERGE

The OIG investigation indeed revealed that the use of atypical antipsychotics is fairly widespread and accounts for significant payments by CMS. The major findings show that:

- 14% of nursing home residents had claims for atypical antipsychotic drugs (totaling $309 million);
- 83% of atypical antipsychotic drug claims were associated with off-label uses, and 88% of these were associated with dementia, the condition specified in the boxed warning;
- 51% of claims were erroneous, meaning they were either not administered for medically accepted indications or were not documented as having been administered (totaling $116 million); and
- 22% of the claimed drugs were not administered according to CMS standards regarding unnecessary drugs.

But the investigation shines a glaring spotlight on an issue that is perhaps more significant for long-term care providers than the administration of the drugs themselves: widespread failure to properly document their selection and use. The study found that:

- One-third of the records reviewed contained no evidence that the residents were ever assessed to identify a medical need for the drug;
- 18% of the records contained no intervention plan for the use of the drugs;
- 4% showed no use of the RAP (now changed to Care Area Assessment [CAA]) for the use of the drugs;
- 99% contained no documentation showing that a care plan was developed and/or instituted; and
- 48% failed to meet two or more federal requirements for the use of the drugs.

These findings carry two serious implications for providers. First, and particular to atypical antipsychotic drugs, this means a majority of the billings for the drugs may be considered erroneous, making CMS payments eligible for recoupment. The more systemic—and worrisome—problem is that, if documentation failures occurred at this rate for one issue, they've more than likely occurred in regard to most other regulatory issues as well. Widespread failure to properly document care is a vulnerability just waiting to become a catastrophic financial crisis for long-term care organizations.

CLAMPING DOWN: OIG RECOMMENDATIONS & IMPLICATIONS

To get long-term care facilities to comply with the standards for the use of atypical antipsychotics, OIG offered four recommendations to CMS:

- Facilitate access to information necessary to ensure accurate coverage and reimbursement determinations.
- Assess whether survey and certification processes offer adequate safeguards against unnecessary atypical antipsychotic drug use in nursing homes.
- Explore alternative methods beyond survey and certification processes to promote compliance with federal standards regarding unnecessary drug use in nursing homes.
- Take appropriate action regarding the claims associated with erroneous payments identified.

What should long-term care organizations take away from these recommendations? Essentially, expect more audits. Furthermore, it's likely that audits for this issue will tend to be "complex reviews" rather than simple, computer-automated checks. OIG notes that, "without access to diagnosis information, CMS cannot determine the indications for which drugs were used. For this reason, CMS is unable, absent a medical review, to determine whether claims meet payment requirements." Thus, it seems inevitable that complex medical reviews will be the norm for assessing compliance with CMS requirements in regard to atypical antipsychotics.

BECOME PROACTIVE WITH YOUR DOCUMENTATION

To be in compliance, your clinical documentation must meet strict criteria, every time. It's true that auditors are looking at cases from at least three years past, and there is no realistic way to go back in time to ensure that proper documentation happened. So, the best option is to take a proactive approach: Get a handle on what you're doing (or not doing) now, and make sure it's right going forward. The earlier you can get your own practices into alignment with compliance criteria, the better off you'll be in the long run.

Start with an objective assessment of a sample of your records that provides a look at how well you're doing overall with CMS requirements. Is all documentation regarding the use of atypical antipsychotic medications present and fully completed? Are care plans and evaluations consistently recorded?

Like any compliance issue, auditors are looking for specific information in the medical record to support the use of atypical antipsychotics. Your clinical documentation is the critical foundation upon which the auditor's decision will be made. A good independent partner will review a sample of your records and provide a summary report outlining whether the records contain all the specific documentation types and information required by CMS. Reviews can be customized to examine almost any criteria you specify, but a good starting point includes some or all of the following:

Types of CMS-required documentation, including:

- MDS (Minimum Data Set), CAA upon admission, and frequency thereafter;
- Appropriate written care plan(s); and
- Appropriate regimen reviews.

Factors impacting the use of atypical antipsychotics, including:

- Age;
- Comorbid conditions;
- Psychiatric diagnoses and symptoms;
- Medications and dosages administered;
- Length of time on medications;
- Behavior monitoring documentation;
- Physician documentation of need;
- Documentation that lower dosages or other drugs were unsuccessful;
- Documentation of unique factors of individual patients; and
- Documentation of regular assessments that support continuation of the drug.

You want a partner that will provide insight into where your documentation is sufficient and where it is not meeting CMS requirements. In the event that you are audited and faced with preparing dozens of records for release, your first instinct may be to gather and send them as quickly as possible. While it's true that deadlines are tight, releasing disorganized, incomplete or inaccurate medical records can shed a negative light on the facility and disrupt the efficient evaluation of records by auditors.

CONCLUSION

A few things seem certain. First, compliance audits are here to stay. They will come, and so will the incumbent stress of answering them. Second, appropriate medical decision-making and the proper documentation thereof is what will decide the outcome of your audit.

Assess your procedures now, whether or not you've been audited on this issue. Engage appropriate,dedicated and knowledgeable consultants and partners who can help you identify what you're doing right and where you need improvement. If you're appealing adverse decisions or answering allegations, the same holds true: Work with an independent partner who can help you draw out the information that will successfully support your claims.

Take the information your consultants provide and use it to your overall advantage, facility-wide. Educate nurses, physicians, case managers, medical record personnel, and billers on what they're doing well and where they need to improve. Then, inspire your teams to follow through on it—every resident, every time.

When you need objective assistance to conduct an internal audit, prepare records for release, or respond to adverse decisions, Excelas is just a phone call away. We've helped a growing list of clients manage their regulatory challenges. A quick, no-obligation conversation will show you the valuable difference we can make for your organization.

What are atypical antipsychotic drugs?

Currently, the Food and Drug Administration (FDA) has approved the following atypical antipsychotic drugs for treatment of schizophrenia, bipolar disorder, schizoaffective disorder, and major depressive disorder.

The drugs include Aripiprazole, Asenapine, Clozapine, Iloperidone, Lurasidone, Olanzapine, Paliperidone, Quetiapine, Paliperidone, Risperidone, Ziprasidone. These drugs are also commonly used off-label for the treatment of agitation in dementia, depression, obsessive-compulsive disorder, post-traumatic stress disorder, personality disorders, Tourette's syndrome, and autism.

Although these off-label uses are medically accepted, the FDA has nevertheless attached a boxed warning to the drugs that cautions of an increased risk of death when the drugs are used to treat behavioral disorders in elderly patients with dementia.

RESOURCES

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