Patterns of use of atypical antipsychotics in children and young adults

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One problem with research in this area has been the difficulty of assessing appropriate use. This study utilized the level of evidence available in medical claims to support atypical antipsychotic use in Mississippi Medicaid children and young adults.

OBJECTIVES

• Atypical antipsychotics are used for treating a variety of mental health disorders such as schizophrenia, depression, and bipolar disorder among many others. There is increasing concern about use of atypical antipsychotics in children side effects and lack of evidence to substantiate their efficacy in children.
• Recently, the FDA has approved the use of a few atypical antipsychotics or second generation antipsychotics (SGAs) for diseases such as schizophrenia and bipolar disorder in children and adolescents. However much of the use of SGAs in children and adolescents is still not supported by labeled indications or clinical evidence.
• There is limited evidence studying the effects of these drugs in children, but most existing studies point towards a range of potentially serious adverse events such as weight gain, diabetes mellitus, metabolic and endocrine abnormalities, hyperprolactinemia, dyslipidemia in the short term and several other unknown long term effects.
• In 2011, a Government Accountability Office (GAO) study examined the rates of psychotropic medication use among foster children in several states and recommended to the Department of Health and Human Services (DHHS) the need for evidence to substantiate on best practices for overseeing psychiatric prescriptions.
• In response to this, the DHHS sent a letter to state directors of Medicaid. Mental health and substance abuse agencies and inquiring them aware of the results of the GAO study and other studies that provide evidence towards the growing problem of safe, appropriate and effective use of psychiatric medications among this population. They proposed an expansion of the activities and collaboration between the Administration for Children and Families (ACF), The Center for Medicare and Medicaid Services (CMS) and the Substance Abuse and Mental Health Services Administration (SAMHSA). This includes expansion of online resources and webinars, development of quality measures to evaluate states, working with states to enhance Drug Utilization Management Health Home, encouraging use of Health Information Technology and development of guidelines for the use of psychiatric medications in children and adolescents along with topics for discussion at state level meetings.
• These changes hold the potential to significantly alter the SGA market.

METHODS

• Data source: A retrospective analysis was conducted using Mississippi Medicaid claims data from the time period January 2008 to December 2011. An integrated pharmacy and medical claims database was used to determine the level of evidence needed in medical claims and the patient eligibility file. The patient eligibility file was used to collect demographic data and check for periods of eligibility.

Inclusion criteria:
• Medicaid beneficiaries were used at the prescription level. Prescription claims were included in the study if they met the following criteria:  
  • Claim was for an atypical antipsychotic.
  • Beneficiary was under 21 years of age on date of prescription was filled.
• Identified claims were checked for an appropriate diagnosis in the medical claims within 6 months before or 6 months after the date of dispensing. Prescription claims were classified as ‘evidence of medical acceptability’ based on the presence of a mental health diagnosis in the medical claims and a ‘medically accepted use’ being identified for the product, diagnosis, and patient of that age. In accordance with the CMS Manual System Medicare Benefit policy, a treatment was classified as medically accepted use if its evidence of efficacy was a Class I, Class IIa, or Class IIb in Micromedex Drugs. If any prescription taken by a beneficiary was classified as having evidence, all prescriptions for that product that beneficiary were classified as having evidence.

Outcome variables:
• percentage of prescriptions with evidence of medical acceptability total annual drug payment.
• Most analyses were the sum of all claims identified in a particular year and were adjusted to the 2011 dollar value using Consumer Price Index for medical care services available from the Bureau of Labor Statistics.

RESULTS

• The study population included children and young adults under 21 years of age receiving atypical antipsychotic prescriptions. A total of 7,847 beneficiaries were identified, accounting for 107,544 SGA prescriptions. 67.6% of the study population was male. 31.9% were Caucasian, 44.7% African American. The average age of population was 11.8 years. On average, each beneficiary in the study filled 3.59 SGA prescriptions per year.
• Of the 7,847 beneficiaries in the study, 5,568 (74%) of them had at least one SGA prescription associated with a mental health diagnosis. Only claims associated with mental health diagnoses were included in the analysis of medically acceptable use.

• Of the total SGA prescriptions associated with diagnoses, 13,841 (52.9%) were found to be medically acceptable according to the evidence ratings listed in Micromedex and the diagnoses observed in the medical claims.
• Risperidone and aripiprazole are the most used atypical antipsychotics. When appropriate prescriptions were considered to not be medically acceptable based on claims data, it was most often due to the age of the patient or for use when associated with a non-diagnosed such as depression.
• Similar patterns were seen in the case of risperidone, quetiapine, and olanzapine.

• Results from this study offer an insight into the problems of conducting research on treatment of mental disorders in children. Some SGA prescriptions are not associated with mental health diagnoses in the medical claims and are considered to be medically acceptable use. Some prescriptions were considered to ‘label’ a child with a mental health diagnosis in claims. There is also the problem of how frequently a diagnosis is actually coded on a subsequent medical claims data after a diagnosis has been coded once. The lack of diagnoses appearing in medical claims near the time prescriptions are filled is a significant limitation when trying to examine the ‘appropriateness’ of SGA use.

• When SGAs can be associated with mental health diagnoses, they are often associated with diagnoses that are not listed in FDA approved labeling, but are diagnoses considered to be medically acceptable use. This is further complicated by the fact that few, if any, SGAs have any labeled indications for children under 16 or 18 years of age. Most, if not all, treatment of children with antipsychotics is for indications not covered by FDA approved labeling. During the time period examined by this study, all SGAs were subject to age edits and prior authorization was required with providers exercising medical necessity and waiving the age limit for use of the medication prescribed. Therefore, evidence of medically acceptable use was gathered manually through the prior authorization process, but this information is not included as part of the administrative claims data. In conclusion, it appears that some antipsychotic use in this population may not be supported by evidence in medical claims. The lack of supporting diagnoses in medical claims is a significant limitation when examining the appropriateness of use of antipsychotics among children.

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REFERENCES