

# **Medicaid Prescribed Drug Program**

**Report of Policy Review:  
Oversight of Off-Label Prescribing of Atypical Antipsychotic Medications  
for Children Under Six Years of Age  
Covered by the Florida Medicaid Program**

**March 27, 2009**



**Policy Review: Oversight of Off-Label Prescribing of Atypical Anti-Psychotic Medications for Children Under Six Years of Age Covered by the Florida Medicaid Program**

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# **Policy Review: Oversight of Off-Label Prescribing of Atypical Antipsychotic Medications for Children Under Six Years of Age Covered by the Florida Medicaid Program**

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## **Executive Summary**

In 2005 the Agency for Health Care Administration (Agency) implemented the Florida Medicaid Drug Therapy Management Program for Behavioral Health pursuant to section 409.912(39)(a)10, Florida Statutes. The program's mandate is to improve the quality of behavioral health drug prescribing and improve patient adherence while reducing clinical risks and controlling costs. In pursuing this purpose, the program convened an expert panel to develop evidence-based best practice guidelines for the safe and effective use of psychotherapeutic drugs for adults and for children and adolescents. For additional information about these guidelines and other activities of the program, please see the Florida Medicaid Drug Therapy Management Program for Behavioral Health at [www.flmedicaidbh.com](http://www.flmedicaidbh.com).

Although there are Food and Drug Administration (FDA) approved indications for certain psychotherapeutic medications in this population, approximately half of the prescriptions for children and adolescents are for "off-label" uses.<sup>1</sup> In order to assure that the use of atypical antipsychotic medications in very young children within the Medicaid population is confined to specific circumstances, a prior authorization process was developed with input from the statewide medical community and children's mental health experts. The prior authorization process was formally implemented in April 2008. Concurrently, then Agency Secretary Agwunobi convened an Ad Hoc Medical Advisory Committee of representative stakeholders to evaluate the process and to make specific recommendations to ensure ongoing safe, effective, and efficient use of atypical antipsychotic medications in children younger than six years of age who are covered by Florida Medicaid.

At the June 2008 public meeting of the Ad Hoc Medical Advisory Committee, consensus of the stakeholders recommended that the existing prior authorization process continue, directly overseen by the child psychiatry reviewers at the University of South Florida. Requests for initiation of therapy with an atypical antipsychotic medication for a child under the age of six years are individually reviewed, and a second medical review is performed, before authorization for Medicaid reimbursement is given. Upon the Agency's implementation of the Committee's recommendation that the individualized reviews continue, the Ad Hoc Committee's work was concluded.

This report details the focus on children's issues within the broader scope of the Florida Medicaid Drug Therapy Management Program for Behavioral Health, and the work of the Ad Hoc Committee to review the guidelines and prior authorization process for prescribing of atypical antipsychotic medications for children younger than six years. The report also articulates Agency policy and specific conditions under which off-label prescribing may be authorized within the Florida Medicaid program.

The Agency for Health Care Administration acknowledges and thanks all the participants who provided input to this analysis. In particular, the Agency wishes to recognize the concerned citizens who took the time to provide insightful written testimony. Through this process of review, the needs and concerns of all stakeholders were balanced to ensure that patients receive appropriate medical care.

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<sup>1</sup> Efficacy and Comparative Effectiveness of Off-Label Use of Atypical Antipsychotic (2007) Southern California/Rand Evidence-based Practice Center: a summary for clinicians and policymakers. AHRQ Pub No 07-EHC003-2

## **The Florida Medicaid Drug Therapy Management Program for Behavioral Health**

### *Legislative Mandate and Scope*

The Florida Medicaid Drug Therapy Management Program for Behavioral Health (MDTMP for BH) was created by the Florida Legislature in the context of the 2004 Medicaid Reform Legislation. In 2005, SB 838 was passed to amend Florida Statute 409.912(39)(a)(10) to accomplish the following:

- Improve the quality of behavioral health drug prescribing.
- Improve patient adherence to therapy.
- Reduce clinical risks.
- Lower cost while providing appropriate therapy.

It is important to note that the MDTMP for BH is meant to encompass all patients in need of mental health medications, not just children. Within the broader scope of the program's mandate, the Agency will continue to update and refine existing best practice guidelines, and to develop new guidelines as new medications and data become available. For additional information about the program, please see the website at [www.flmedicaidbh.com](http://www.flmedicaidbh.com).

### *Development of Best Practice Guidelines*

Initially, the MDTMP for BH was focused on cost containment. During the first two years of the program, the focus was broadened to include quality and safety. To address those issues, the program assembled an expert panel of psychiatrists, convened in June 2006, to review the most current research in psychotherapeutic medication prescribing. This panel's first goal was to develop evidence-based best practice guidelines for the safe and effective use of psychotherapeutic drugs in children and adolescents. The initial guidelines for prescribing for children were published in October, 2006. The expert panel most recently convened in July 2008 to update the guidelines for children. The Florida Best Practice Guidelines include:

- Assessment tools to aid in the proper diagnosis of mental illness;
- Diagnosis-specific therapy for psychotherapeutic prescribing in children;
- Safe and effective dose ranges for each medication prescribed for mental illness for children aged 0-5 years; 6-12 years; and 13-17 years ( as determined by the panel of experts);
- Medication tables that provide the highest dose appropriate for children and adolescents;
- General Principles of Best Practice for children under 6 years of age; and
- General Principles of Best Practice for older Children and Adolescents.

### *Best Practice Guidelines for Prescribing for Children*

The program's comprehensive best practice statement regarding use of psychotherapeutic drugs in children younger than six years of age is as follows:

"The use of antipsychotic medications in preschoolers (children under six years of age) is generally 'off-label' and is not recommended and should only be considered under the most extraordinary circumstances. Disruptive aggression in autism is one such circumstance. Adequately powered studies have not been conducted in preschoolers."

The Florida Best Practice guidelines have been widely distributed to psychiatrists, pediatricians, and general practitioners. A convenient pocket reference was distributed; seminars have been presented to physicians

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### **The Florida Medicaid Drug Therapy Management Program for Behavioral Health (continued)**

throughout the state; and the guidelines are also available on the MDTMP for BH website at: <http://flmedicaidbh.fmhi.usf.edu/>.

In addition to the creation of Best Practice Guidelines, the MDTMP for BH is committed to partnership with the Florida medical associations to provide continuing medical education for physicians who prescribe psychotherapeutic drugs to children. Goals of this initiative include the following:

- Disseminate best practices information to pediatricians and other primary care physicians.
- Provide tools to promote safe prescribing practices.
- Initiate a dialogue among local practitioners and visiting experts with the intent that local physicians continue to communicate with each other.
- Build a reference of frequently asked questions on prescribing psychotherapeutic drugs.
- Identify and strengthen local and supportive referral networks.

As previously stated, the focus on children is one segment within the broader focus of the Florida Medicaid Drug Therapy Management Program for Behavioral Health. The scope of the program is broader, and the Agency, through this program, will continue to refine existing best practice guidelines, and to develop additional guidelines as new medications become available.

#### *Prior Authorization Review Process for Prescribing of Atypical Antipsychotic Medications for Children Younger than Age Six*

In an effort to help assure that the use of atypical antipsychotic medications in very young children is confined to specific circumstances, the Agency has collaborated with the Medicaid Drug Therapy Management Program for Behavioral Health (MDTMP for BH) at FMHI, the Department of Psychiatry at the University of South Florida and Florida's medical community in the design and implementation of a prior review process. The clinical criteria embodied in the process are drawn from the MDTMP for BH guidelines for the treatment of children with emotional disturbances.

In understanding the many challenges in every day practice of treating children with severe behavioral disorders, the prior authorization process was designed to balance clinical rigor, efficiency, and immediate responsiveness to the needs of children. Only essential information needed to support a decision is required from the prescriber, and the goal for response time is within 24 hours of receiving a completed request package. The clinical reviewers' thoughtful feedback provides important support for physicians with limited psychiatric training and experience who may be confronted with the need to treat children with emotional problems in the Medicaid Program.

#### *Measurable Benefits of the Prior Authorization Review Program*

Assessment in November, 2008, after eight months of experience with the prior authorization process, revealed the following impacts:

- Prescribers are increasingly receptive to the feedback provided by the reviewers and are willing to accept their suggestions and recommendations
- The proposed doses of antipsychotic medication have declined.
- The number of Medicaid claims for antipsychotic medications for young children has declined.

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- There has been an overall improvement in the quality of prescribing of antipsychotic medications, as measured by consistency with the published guidelines.

### **The Florida Medicaid Drug Therapy Management Program for Behavioral Health (continued)**

#### *Ongoing Activities*

The collaboration between the Agency, the Florida Mental Health Institute, the USF Department of Psychiatry and community practitioners that has been the hallmark of the prior review development process will continue as the process is periodically reviewed, updated and improved. For the most current information about the program, please see the website at <http://flmedicaidbh.fmhi.usf.edu/> .

## **The Ad Hoc Medical Advisory Committee on the Use of Psychotherapeutic Medications in Children and Adolescents**

### *Background*

A key objective of the Agency is to ensure that Florida Medicaid recipients have access to medical treatments that are clinically efficacious and cost effective. The U.S. Food and Drug Administration performs an extensive process to review the efficacy and safety of different treatments, and on the basis of its review, may approve individual treatments for use in specific conditions and populations. Medical practitioners may also prescribe these treatments for use in other conditions and for other populations based upon their clinical experience and judgment. Such prescribing is called “off-label” prescribing, because the practices are supported by a more limited body of clinical information. The Agency recognizes that off-label prescribing is often appropriate and may best suit the needs of individual patients, although such practices have not yet undergone the rigorous scrutiny of the formal F.D.A. review process. In keeping with the Agency’s mandate to ensure the provision of the most safe and efficacious treatments for each individual covered by Florida Medicaid, ongoing efforts are being made to study the practice of off-label prescribing.

As previously noted, although there are F.D.A.-approved indications for several psychotherapeutic medications in the pediatric population, approximately half of the utilization for children and adolescents is for “off-label” conditions.<sup>2</sup> The Florida Medicaid program has undertaken a thorough review of the practice of off-label prescribing of specific psychotherapeutic medications for children and adolescents. Particular attention was focused on the use of atypical antipsychotics with very young children (0-5 years old). Virtually all the antipsychotic prescribing in this population is “off label” and there are limited clinical trial data about the safety and effectiveness of this practice. Since very young children are highly vulnerable, the decision to use antipsychotic medications should be made only after carefully weighing potential risks and benefits. Further, medication therapy should represent one component of a comprehensive treatment plan.

Since 2005, the Agency has contracted with the Florida Mental Health Institute (FMHI) at the University of South Florida to implement the Medicaid Drug Therapy Program for Behavioral Health. As part of this program, a study was conducted of the use of antipsychotics among children aged 0-5 years; 6-12 years; and 13-18 years.<sup>3</sup> The study recommended focused monitoring and follow-up of very young children who are treated with anti-psychotic medications. To this end, a prior authorization process was developed in concert with Florida’s medical community and children’s mental health experts. This process of review prior to authorization of atypical antipsychotic drug therapy was formally implemented in April 2008.

### *Charge of the Committee*

Concurrent with implementation of the prior authorization review process, then Agency Secretary Agwunobi convened the Ad Hoc Medical Advisory Committee on the Use of Psychotherapeutic Medications in Children and Adolescents. Comprised of a range of stakeholders, the Committee’s charge was to evaluate the newly implemented prior authorization process and to make specific recommendations to the Agency regarding policies to ensure safe, effective, and efficient use of atypical antipsychotic medications among Florida Medicaid recipients from birth through five years of age.

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<sup>2</sup> Efficacy and Comparative Effectiveness of Off-Label Use of Atypical Antipsychotic (2007) Southern California/Rand Evidence-based Practice Center: a summary for clinicians and policymakers. AHRQ Pub No 07-EHC003-2

<sup>3</sup> Constantine, R., Larsen, B. (2007). The Use of Antipsychotic Medications with Children: A Comprehensive and Current View

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**Ad Hoc Medicaid Advisory Committee on the Use of Psychotherapeutic Medications in Children and Adolescents (continued)**

*Agency Ad Hoc Medical Advisory Committee Members*

The members of the Ad Hoc Medical Advisory Committee and their specialties or constituencies were:

Daniel Castellanos, M.D.	Child and Adolescent Psychiatry
Elicia Coley, Pharm.D.	Senior Pharmacist, Medicaid Pharmacy Services
Lisa Cosgrove, M.D.	Practicing Pediatrician
Talisa Hardy, Pharm.D.	Clinical Program Manager, Medicaid Pharmacy Services
Jerome Isaac, M.D.	Florida Pediatric Society
Mary Elizabeth Jones, R.Ph.	Senior Pharmacist, Medicaid Pharmacy Services
John Lelekis, R.Ph., M.B.A.	Practicing Pharmacist
Joshua Lenchus, D.O., R.Ph.	Practicing Physician
Rajiv Tandon, M.D.	Chief Psychiatrist, Department of Children and Families
Richard Thacker, D.O.	Florida Osteopathic Medical Association
Anne Wells, Pharm.D.	Bureau Chief, Medicaid Pharmacy Services
Kathleen Wilson, D.S.N., A.R.N.P.	Nursing Director, Children's Medical Services, Florida Department of Health

*Ad Hoc Committee Activities:*

The Agency's Ad Hoc Medical Advisory Committee convened on June 25th, 2008 from 12:30 to 1:30PM. Official public notice of the meeting was given. The purpose was to provide a forum for group members and concerned citizens to give public testimony and provide input concerning Florida Medicaid coverage of atypical antipsychotic medications for children. Written public testimony was invited, and the response period was held open for one week following the meeting.<sup>4</sup>

The Ad Hoc Committee reviewed the practice of antipsychotic utilization among children aged 0-5 years at the public meeting on June 25th, 2008. The consensus of the Committee was that, in view of the vulnerability of the population, the limited supporting clinical trial data, and the off-label nature of the prescribing, close monitoring of the practice was recommended. The Ad Hoc Committee endorsed the several initiatives of the Agency in ensuring the informed, individualized, monitored, and efficient use of antipsychotic medications in this population based on the best scientific evidence. In particular, the Ad Hoc Committee was enthusiastic about the process of developing and updating best-practice guidelines and the fact that the clinical criteria embodied in the prior authorization process were drawn from these guidelines. Updated in July 2008, the Florida Medicaid Best Practice Guidelines for Behavioral Health reflect the consensus of a group of national and state child psychiatry experts, and are supported by the most current evidence. The process provides safeguards by assuring clinical criteria are satisfied, and that first line standards of care have been attempted and the risks and benefits carefully weighed before prescribing atypical antipsychotic treatment to very young children.

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<sup>4</sup> Prior to the drafting of the Agency's final report, public notice was given of second opportunity to submit written testimony between December 17, 2008 and December 24, 2008.

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**Ad Hoc Medicaid Advisory Committee on the Use of  
Psychotherapeutic Medications in Children and Adolescents (continued)**

*Final Recommendation of the Ad Hoc Medical Advisory Committee*

The consensus of the Ad Hoc Medical Advisory Committee at the June 2008 public meeting was that the prior authorization process should continue to be directly overseen by the child psychiatry reviewers at the University of South Florida (USF). This individualized review of initiation of therapy with an atypical antipsychotic medication for children under the age of six years is performed before authorization for Medicaid reimbursement is given. Since the program has produced measurable benefits, the Agency has directed the USF clinical team to continue to provide prompt, individualized consultations. Upon the Agency's continued operation of the prior authorization program, the work of the Ad Hoc Committee was completed.

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### **Conclusion: Florida Medicaid Policy Regarding Coverage of a Drug in Accordance with Section 1927 of the Social Security Act**

Rule 59G-4.250, F.A.C., regarding Florida Medicaid coverage of prescribed drugs, states:

“To be reimbursed by Medicaid, a drug must be medically necessary and either (a) prescribed for medically accepted indications and dosages found in the drug labeling or drug compendia in accordance with Section 1927(k)(6) of the Social Security Act, or (b) prior authorized by a qualified clinical specialist approved by the Agency. Notwithstanding this rule, the Agency may exclude or otherwise restrict coverage of a drug in accordance with Section 1927 of the Social Security Act.”

Medications may be prescribed under the following circumstances:

1. For an FDA approved indication;
2. For an indication not approved by the FDA, but in which the prescribing practice is recognized in the official drug compendia such as American Hospital Formulary Service (AHFS™) or DrugDex®<sup>5</sup>; or
3. For an indication not approved by the FDA, and where the prescribing practice is not recognized in the official drug compendia.

Prescribing certain atypical antipsychotic medications for a young child would be consistent with item 3 above. However, there are small clinical trials and multiple case reports that document positive outcomes with use of these medications in young children. Limited clinical documentation exists, but data is not sufficient to be noted in the compendia.

Section 1927 of the Social Security Act allows state Medicaid programs to exclude or restrict coverage of prescriptions in circumstance #3. Florida Medicaid opted to restrict coverage via an individualized prior authorization process, and included in its rule the requirement for review by a qualified clinical specialist. In the case of atypical antipsychotic medications for children younger than six years, child psychiatry specialists provide individualized review (in effect, a second medical opinion) before authorization for Medicaid reimbursement is given.

Providing prompt, individual review of each case in consideration of the published best practice guidelines is an expensive process due to the staff credentials required, the exacting nature of the clinical information, and the need for immediate response. However, expending the time and attention required to meet the needs of those children who may receive benefit from such therapies is a better option than absolute denial of access to atypical antipsychotic medication for all children. In addition to prescribing for mental illness, Florida Medicaid recognizes that there are other areas of prescribing, such as oncology, which may fail to meet the requirement of compendia listing. Excluding coverage for other areas of prescribing creates the potential to deny life-extending or life-saving therapies to children with other medical needs. After careful consideration of all available data and input from stakeholders of diverse interests, and in keeping with its mission to provide access to health care for all Floridians, the Agency opted to perform oversight through a documented process of individualized qualified clinical review.

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<sup>5</sup> The Drugdex® System has been written into the U.S. Code as a reference standard for drug use review under Subchapter XIX, "Grants to States for Medical Assistance Programs.