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1.0 Policy Statement

This policy applies to safety monitoring for recipients through age 17 who are prescribed antipsychotic agents. Safety monitoring with documentation shall result when an antipsychotic medication is used without indications and dosage levels approved by the federal Food and Drug Administration. Safety monitoring will target metabolic and neurologic side effects.

2.0 Policy Guidelines

2.1 Eligible Recipients

2.1.1 General Provisions

Medicaid recipients may have service restrictions due to their eligibility category, which would make them ineligible for this service.

Note: Outpatient pharmacy services are available to all eligible Medicaid recipients.

2.1.2 EPSDT Special Provision: Exception to Policy Limitations for Recipients under 21 Years of Age

42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid recipients under 21 years of age **if** the service is **medically necessary health care** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination** (includes any evaluation by a physician or other licensed clinician). This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his/her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems. Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the recipient's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the recipient's right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product, or procedure

- a. that is unsafe, ineffective, or experimental/investigational.
- b. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and/or other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure will correct or improve or maintain the recipient's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

****EPSDT and Prior Approval Requirements**

- a. If the service, product, or procedure requires prior approval, the fact that the recipient is under 21 years of age does **NOT** eliminate the requirement for prior approval.
- b. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *Basic Medicaid Billing Guide*, sections 2 and 6, and on the EPSDT provider page. The Web addresses are specified below.

Basic Medicaid Billing Guide: <http://www.ncdhhs.gov/dma/basicmed/>

EPSDT provider page: <http://www.ncdhhs.gov/dma/epsdt/>

2.2 Prior Authorization

The Department of Health and Human Services, Division of Medical Assistance, may initiate a registration and/or prior authorization process for the off label prescribing of an antipsychotic for a recipient age 17 and under to ensure safety monitoring documentation by the prescriber if:

- a. The antipsychotic is prescribed for an indication that is not approved by the federal Food and Drug Administration.
- b. The antipsychotic is prescribed at a different dosage than approved for an indication by the federal Food and Drug Administration.
- c. The prescribed antipsychotic will result in the concomitant use of two or more antipsychotics.

2.3 Monitoring Portal for Prescriber Registry

Prescribers shall input information for each recipient through age 17 for whom an antipsychotic agent is prescribed. The data elements collected are used to support a generally accepted clinical analysis of the safety and efficacy of the prescribed pharmacotherapy.

2.4 Safety Monitoring Documentation

A request for an antipsychotic medication meeting any of the descriptions as outlined below will require safety monitoring documentation by the prescriber in order for the claim to successfully complete point of sale processing.

- a. An antipsychotic prescribed without a clinical diagnosis corresponding to an FDA approved indication.

- b. An antipsychotic prescribed in an amount differing from the FDA approved dosage for that indication for a recipient 17 years of age or younger.
- c. An antipsychotic prescribed that meets the definition of intraclass polypharmacy*.
Note: *Intraclass polypharmacy is defined as combination therapy with two or more agents outside of a 60 day window allowing for cross titration when converting agents.

2.5 Information Sources to Develop Monitoring Parameters

Safety monitoring parameters in the registry shall be based upon standards established by the American Psychiatric Association, the American Academy of Child and Adolescent Psychiatry, and currently accepted practice standards for the efficacious and safe use of antipsychotics in children and adolescents.

2.6 Provider Education

Providers shall be offered training and regular follow-up with a review of recent prescribing data. The initial education shall focus on clinical issues related to the use of antipsychotics in children, including levels of evidence for use, safety and outcomes assessments, use of psychosocial supports, and interventions to consider if adverse effects present during antipsychotic therapy. Subsequent education shall focus on clinical issues identified either statewide or at the specific practice level. Consultative support by child psychiatry specialists shall be available as needed.

2.7 Access Assured

If FDA approved guidelines for use are met for a specific recipient, further safety documentation will not be required by the provider for a period of up to one year. The ability to bypass the documentation shall be granted on a recipient specific basis. Systems will be built to assure recipients will be able to obtain the appropriate medications as prescribed by the physician.

2.8 Indications and Maximum Dose Parameters

Selected antipsychotic agents have age dependant FDA approved indications and recommended dosage. Drug specific parameters by diagnosis shall be in accordance with the FDA guidelines. (Refer to table 1 and table 2)

Table 1 **Approved Indications**

Schizophrenia:	Haloperidol 3 years and older (FDA approved indication for psychosis)
	Aripiprazole -13 years and older
	Olanzapine -13 years and older
	Risperidone -13 years and older
	Quetiapine IR-13 years and older
	Chlorpromazine – 12 years and older (FDA approved indication for psychosis)
	Perphenazine – 12 years and older (FDA approval for psychotic disorders)
	Thioridazine – FDA approved in children unresponsive to other agents
	<i>No atypicals indicated for younger than 13 years of age for schizophrenia.</i>
Bipolar Disorder	Aripiprazole -10 years and older; 30mg maximum dosage (acute treatment of manic or mixed episodes associated with bipolar I as monotherapy and adjunctive to lithium or valproic acid)
	Risperidone -10 years and older- 6mg/day (acute treatment of manic or mixed episodes associated with bipolar I as monotherapy)
	Quetiapine IR -10 years and older- 600 mg/day (acute treatment of manic episodes associated with bipolar I as monotherapy and adjunctive to lithium or valproic acid)
	Olanzapine - 13 years and older (acute treatment of manic and mixed episodes; and maintenance treatment of bipolar I)
Autism with Irritability	Risperidone: 5 years and older - 6mg/day
	Aripiprazole: 6 years and older - 15mg/day
Tourette's Disorder	Pimozide: 2 years and older
	Haloperidol: 3 years and older
Behavior Disorder/ Hyperactivity	Haloperidol: 3 years and older
	Chlorpromazine: 6 months and older

Note: If antipsychotic does not appear in above table, it is not currently FDA approved for this population.

Table 2 Maximum Dose

DRUG	Maximum Dose (Children under 6 years of age)	Maximum Dose (Children 6 years to 12 years of age)	Maximum Dose (Children 13 years to 17 years of age)
Aripiprazole (Abilify®)	Not recommended	15 mg per day (6 to 9 years of age) 30 mg per day (10 to 17 years of age)	30 mg per day
Chlorpromazine (Thorazine®)	100 mg per day	200 mg per day	800 mg per day
Haloperidol (Haldol®)	6 mg per day	6 mg per day	15 mg per day
Olanzapine (Zyprexa®)	Not recommended	Not recommended	20 mg per day
Quetiapine IR (Seroquel®)	Not recommended	Not recommended in children under 10 years of age 600 mg per day (10 to 12 years of age)	800 mg per day
Risperidone (Risperdal®)	Children 5 years of age or above is 2.5 mg per day Not recommended in children less than 5 years of age	Children 5 to 9 years of age is 2.5 mg per day Children 10 to 17 years of age is 6 mg per day	6 mg per day
Perphenazine	Not recommended	Not recommended	24 mg per day
Thioridazine	60 mg per day	140 mg per day	140 mg per day or 800 mg per day
Trifluoperazine	Not recommended	15 mg per day	20 mg per day
Pimozide (Orap®)	10mg/day or 0.2mg/kg/day (2 years or older)	10 mg per day	10 mg per day

Note: If antipsychotic does not appear in above table, it is not currently FDA approved for this population.

2.9 Adverse Effects and Clinical Assessment Monitoring

Specific monitoring parameters recommended by the American Psychiatric Association and the American Academy of Child and Adolescent Psychiatry at baseline and predetermined therapy intervals may include BMI percentile, blood pressure, glucose, lipid, CBC and EKG.

Parameters should be monitored at baseline and then at recommended frequencies.

3.0 Policy Implementation/Revision Information

Original Effective Date: April 12, 2011

Revision Information:

Date	Section Revised	Change
4/12/2011	Throughout policy	Initial promulgation of new coverage
12/1/2011	Subsection 2.2 Prior Authorization	Added wording to clarify process
12/1/2011	Subsection 2.4 Safety Monitoring Documentation	Removed exceeding dose limitation
12/1/2011	Subsection 2.8 Indications and Maximum Dose Parameters	Removed exceeding dose limitation
12/1/2011	Throughout policy	Children/child/patient(s) without clinical context changed to recipient(s)
12/1/2011	Subsection 2.4 Safety Monitoring Documentation	Replaced be filled by the pharmacy with successfully complete point of sale processing
12/1/2011	Subsection 2.9 Adverse Effects and Clinical Assessment Monitoring	Replaced (such as overweight 25 – 29.9; obese greater than or equal to 30) with percentile
12/1/2011	Table 1 and Table 2	Deleted * and revised note explanation to clarify “Not recommended” comment in table

Attachment A: References

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4. Kumra S, Oberstar JV, Sikich L, et. al. Efficacy and tolerability of second generation antipsychotics in children and adolescents with schizophrenia. *Schizophrenia Bulletin* 2008. 34(1): 60-71.
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