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NC Division of Medical Assistance Off Label Antipsychotic Safety Monitoring In Beneficiaries Through Age 17	Medicaid and Health Choice Clinical Coverage Policy No: 9D Amended Date: October 1, 2015

Related Clinical Coverage Policies

Refer to http://www.ncdhhs.gov/dma/mp/ for the related coverage policies listed below:

9, *Outpatient Pharmacy Program*

1.0 Description of the Procedure, Product, or Service

This policy applies to safety monitoring for NC Medicaid (Medicaid) beneficiaries up to and including 17 years of age and NC Health Choice (NCHC) beneficiaries 6 through 17 years of age 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 (FDA). Safety monitoring shall target metabolic and neurologic side effects.

1.1 Definitions

None Apply.

2.0 Eligibility Requirements

2.1 Provisions

2.1.1 General

(*The term "General" found throughout this policy applies to all Medicaid and NCHC policies*)

a. An eligible beneficiary shall be enrolled in either:
   1. the NC Medicaid Program *(Medicaid is NC Medicaid program, unless context clearly indicates otherwise*); or
   2. the NC Health Choice (*NCHC is NC Health Choice program, unless context clearly indicates otherwise)* Program on the date of service and shall meet the criteria in **Section 3.0 of this policy**.

b. Provider(s) shall verify each Medicaid or NCHC beneficiary's eligibility each time a service is rendered.

c. The Medicaid beneficiary may have service restrictions due to their eligibility category that would make them ineligible for this service.

d. Following is only one of the eligibility and other requirements for participation in the NCHC Program under GS 108A-70.21(a): Children must be between the ages of 6 through 18.

Note: Outpatient pharmacy services are available to all eligible Medicaid and Health Choice beneficiaries.

2.1.2 Specific

(***The term "Specific" found throughout this policy only applies to this policy***)

a. <u>Medicaid</u>

None Apply.

b. <u>NCHC</u>

None Apply.

2.2 Special Provisions

2.2.1 EPSDT Special Provision: Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age

a. **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 beneficiary 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 practitioner).

This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his or 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 beneficiary'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 beneficiary's right to a free choice of providers.

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

1. that is unsafe, ineffective, or experimental or investigational.
2. 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 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 meets all EPSDT criteria, including to correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

b. **EPSDT and Prior Approval Requirements**

1. If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does **NOT** eliminate the requirement for prior approval.
2. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *NCTracks Provider Claims and Billing Assistance Guide*, and on the EPSDT provider page. The Web addresses are specified below.

NCTracks Provider Claims and Billing Assistance Guide: https://www.nctracks.nc.gov/content/public/providers/provider-manuals.html

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

2.2.2 EPSDT does not apply to NCHC beneficiaries

2.2.3 Health Choice Special Provision for a Health Choice Beneficiary age 6 through 18 years of age

The Division of Medical Assistance (DMA) shall deny the claim for coverage for an NCHC beneficiary who does not meet the criteria within **Section 3.0** of this policy. Only services included under the NCHC State Plan and the DMA clinical coverage policies, service definitions, or billing codes are covered for an NCHC beneficiary.

3.0 When the Procedure, Product, or Service Is Covered

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for Medicaid Beneficiaries under 21 Years of Age.

3.1 General Criteria Covered

Medicaid and NCHC shall cover the procedure, product, or service related to this policy when medically necessary, and:

a. the procedure, product, or service is individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the beneficiary's needs;

b. the procedure, product, or service can be safely furnished, and no equally effective and more conservative or less costly treatment is available statewide; and

c. the procedure, product, or service is furnished in a manner not primarily intended for the convenience of the beneficiary, the beneficiary's caretaker, or the provider.

3.2 Specific Criteria Covered

3.2.1 Specific criteria covered by both Medicaid and NCHC

None Apply.

3.2.2 Medicaid Additional Criteria Covered

None Apply.

3.2.3 NCHC Additional Criteria Covered

None Apply.

4.0 When the Procedure, Product, or Service Is Not Covered

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for Medicaid Beneficiaries under 21 Years of Age.

4.1 General Criteria Not Covered

Medicaid and NCHC shall not cover the procedure, product, or service related to this policy when:

a. the beneficiary does not meet the eligibility requirements listed in **Section 2.0;**

b. the beneficiary does not meet the criteria listed in **Section 3.0;**
c. the procedure, product, or service duplicates another provider's procedure, product, or service; or
d. the procedure, product, or service is experimental, investigational, or part of a clinical trial.

4.2 Specific Criteria Not Covered

4.2.1 Specific Criteria Not Covered by both Medicaid and NCHC

None Apply.

4.2.2 Medicaid Additional Criteria Not Covered

None Apply.

4.2.3 NCHC Additional Criteria Not Covered

a. NCGS § 108A-70.21(b) "Except as otherwise provided for eligibility, fees, deductibles, copayments, and other cost sharing charges, health benefits coverage provided to children eligible under the Program shall be equivalent to coverage provided for dependents under North Carolina Medicaid Program except for the following:
   1. No services for long-term care.
   2. No nonemergency medical transportation.
   3. No EPSDT.
   4. Dental services shall be provided on a restricted basis in accordance with criteria adopted by the Department to implement this subsection."

5.0 Requirements for and Limitations on Coverage

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for Medicaid Beneficiaries under 21 Years of Age.

5.1 Prior Approval

The Department of Health and Human Services, Division of Medical Assistance (DMA), may initiate a registration or prior authorization process for the off label prescribing of an antipsychotic for a Medicaid beneficiary up to and including 17 years of age or a NCHC beneficiary 6 through 17 years of age to ensure safety monitoring documentation by the prescriber if:

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

5.1.1 Monitoring Portal for Prescriber Registry

Prescribers shall input information for each Medicaid beneficiary age 17 and under or NCHC beneficiary 6 through 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.

5.1.2 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 Medicaid beneficiary up to and including age 17 or an NCHC beneficiary 6 through 17 years of age.
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 calendar day window allowing for cross titration when converting agents.

5.1.3 Information Sources to Develop Monitoring Parameters

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

5.1.4 Provider Education

Providers shall be offered training and regular follow-up with a review of recent prescribing data. The initial education will focus on clinical issues related to the use of antipsychotics in children, including:

a. levels of evidence for use;
b. safety and outcomes assessments;
c. use of psychosocial supports; and
d. interventions to consider if adverse effects present during antipsychotic therapy.

Subsequent education will focus on clinical issues identified either statewide or at the specific practice level. Child psychiatry specialists shall be available as needed for consultative support.

5.1.5 Access Assured

If FDA approved guidelines for use are met for a specific beneficiary, further safety documentation is not required by the provider for a period of up to 365 days. The ability to bypass the documentation shall be granted on a beneficiary-specific basis. Systems will be built to assure beneficiaries will be able to obtain the appropriate medications as prescribed by the physician.

5.1.6 Indications and Maximum Dose Parameters

Selected antipsychotic agents have age dependent FDA approved indications and recommended dosage. Drug specific parameters by diagnosis shall be in accordance with the FDA guidelines.

5.1.7 Adverse Effects and Clinical Assessment Monitoring

Specific monitoring parameters recommended by the APA and the AACAP at baseline and predetermined therapy intervals may include Body Mass Index (BMI) percentile, blood pressure, glucose, lipid, complete blood count (CBC) and electrocardiogram (ECG). Parameters shall be monitored at baseline and then at recommended frequencies.

6.0 Providers Eligible to Bill for the Procedure, Product, or Service

To be eligible to bill for the procedure, product, or service related to this policy, the provider(s) shall:

a. meet Medicaid or NCHC qualifications for participation;
b. have a current and signed Department of Health and Human Services (DHHS) Provider Administrative Participation Agreement; and
c. bill only for procedures, products, and services that are within the scope of their clinical practice, as defined by the appropriate licensing entity.

6.1 Provider Qualifications and Occupational Licensing Entity Regulations

None Apply.

6.2 Provider Certifications

None Apply.

7.0 Additional Requirements

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for Medicaid Beneficiaries under 21 Years of Age.

7.1 Compliance

Provider(s) shall comply with the following in effect at the time the service is rendered:

a. All applicable agreements, federal, state and local laws and regulations including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements; and
b. All DMA's clinical (medical) coverage policies, guidelines, policies, provider manuals, implementation updates, and bulletins published by the Centers for Medicare and Medicaid Services (CMS), DHHS, DHHS division(s) or fiscal contractor(s).

8.0 Policy Implementation/Revision Information

Original Effective Date: April 12, 2011

Revision Information:

Date	Section Revised	Change
04/12/2011	Throughout policy (Medicaid)	Initial promulgation of new coverage
12/01/2011	Subsection 2.2 Prior Authorization (Medicaid)	Added wording to clarify process
12/01/2011	Subsection 2.4 Safety Monitoring Documentation (Medicaid)	Removed exceeding dose limitation
12/01/2011	Subsection 2.8 Indications and Maximum Dose Parameters (Medicaid)	Removed exceeding dose limitations
12/01/2011	Throughout policy (Medicaid)	Children/child/patient(s) without clinical context changed to recipient(s)
12/01/2011	Subsection 2.4 Safety Monitoring Documentation (Medicaid)	Replaced be filled by the pharmacy with successfully complete point of sale processing
12/01/2011	Subsection 2.9 Adverse Effects and Clinical Assessment Monitoring (Medicaid)	Replaced (such as overweight 25 -29.9; obese greater than or equal to 30) with percentile.
12/01/2011	Table 1 and Table 2 (Medicaid)	Deleted * and revised note explanation to clarify "Not recommended" comment in table
02/08/2012	Throughout (NCHC)	Initial promulgation of a new NCHC service, to be equivalent where applicable to NC DMA's Clinical Coverage Policy #A-6 under Session Law 2011-145.
03/12/2012	Throughout (Medicaid)	Policy number changed from A6 to 9D to be equivalent where applicable to NC DMA's Clinical Coverage Policy # 9D under Session Law 2011-145, § 10.41.(b).
03/12/2012	Throughout	Technical changes to merge Medicaid and NCHC current coverage into one policy.
07/01/2012	Table 1 and 2 (NCHC)	Deleted * and revised note explanation to clarify "Not recommended" comment in table
07/01/2012	Throughout	Changed recipient to beneficiary and recipients to beneficiaries
06/21/2013	Headers	Replaced period in Revised Date with a comma so it reads "July 1, 2012"
11/01/2013	Table 1	Added disorder after Bipolar I
11/01/2013	Table 1	Added Paliperidone for Schizophrenia
11/01/2013	Table 1	Added olanzapine&fluoxetine for Bipolar Disorder
11/01/2013	Table 2	Added drug Olanzapine&fluoxetine
11/01/2013	Table 2	Added drug Paliperidone

Date	Section Revised	Change
11/01/2013	References	Added Up to Date online
11/01/2014	Table 1	Revised Risperidone dose from 6mg to 3mg
11/01/2014	References	Added Risperdal Product Information
11/01/2014	All Sections and Attachments	Reviewed policy grammar, readability, typographical accuracy, and format. Policy amended as needed to correct, without affecting coverage. Updated policy template language.
2/2/2015	Table 1	Added Aripiprazole for indication of Tourette's Disorder
2/2/2015	References	Added Abilify Product Information
04/01/2015	Table 1	Added Asenapine for indication of Bipolar Disorder
04/01/2015	Table 2`	Added maximum dose for Asenapine
04/01/2015	References	Added Saphris Product Information
10/01/2015	Subsection 5.1.6	Removed, "Refer to Table 1 and Table 2"
10/01/2015	Subsection 5.1.6	Removed Table 1
10/01/2015	Subsection 5.1.6	Removed Table 2
10/01/2015	All Sections and Attachments	Updated policy template language and added ICD-10 codes to comply with federally mandated 10/1/2015 implementation where applicable.

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Attachment A: Claims related Information

Provider(s) shall comply with the, *NCTracks Provider Claims and Billing Assistance Guide*, Medicaid bulletins, fee schedules, DMA's clinical coverage policies and any other relevant documents for specific coverage and reimbursement for Medicaid and NCHC:

A. Claim Type

Online Real-Time Point of Sale using the current version of the National Council for Prescription Drug Program (NCPDP)

B. International Classification of Diseases, Tenth Revisions, Clinical Modification (ICD-10-CM) and Procedural Coding System (PCS)

Does not apply

C. Code(s)

Does not apply

D. Modifiers

Does not apply

E. Billing Units

The National Drug Code (NDC) determines the billing unit(s).

F. Place of Service

Active Medicaid or NCHC pharmacy provider

G. Co-payments

For Medicaid refer to Medicaid State Plan, Attachment 4.18-A, page 1, located at http://www.ncdhhs.gov/dma/plan/sp.pdf.
For NCHC refer to G.S. 108A-70.21(d), located at http://www.ncleg.net/EnactedLegislation/Statutes/HTML/BySection/Chapter_108A/GS_108A-70.21.html.

H. Reimbursement

Providers shall bill their usual and customary charges.
For a schedule of rates, see: http://www.ncdhhs.gov/dma/fee/

Refer to clinical coverage policy 9, *Outpatient Pharmacy Program*; **Attachment A: Claims-Related Information; B**: Directions for Drug Reimbursement, on DMA's website at: http://www.ncdhhs.gov/dma/mp/

Attachment B: References

1. Walkup J, ed. Practice Parameter on the use of Psychotropic Medication in Children and Adolescents. J Acad Child Adolesc Psychiatry 2009. 48 (9). 961-973.

2. Fedorowicz VJ, Fombonne E. Metabolic side effects of atypical antipsychotics in children: a literature review. J Psychopharmacol 2005. 19(5). 533-50.

3. Consensus Development Conference on Antipsychotic Drugs and Obesity and Diabetes. American Diabetes Association-American Psychiatric Association. Diabetes Care 2004. 27(2). 596-601.

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.

5. Correll CU, Carlson HE. Endocrine and metabolic adverse effects of psychotropic medications in children and adolescents. J. Am.Acad.Child.Adolesc.Psychiatry 2007. 45:7. 771-791.

6. Correll CU, Kane JM. One year incidence rates of tardive dyskinesia in children and adolescents treated with second generation antipsychotics: a systematic review. J Child Adolesc Psychopharmacol 2007. 17(5): 647-56.

7. Zito JM, Derivan AT, Kratochvil CJ, et al. Off-label psychopharmacologic prescribing for children: History supports close clinical monitoring. Child and Adolescent Psychiatry and Mental Health 2008. 2:24; 1-11.

8. Publication Committee Medicaid Medical Directors Learning Network/Rutgers Center for Education and Research on Therapeutics. Antipsychotic Medication Use in Medicaid Children and Adolescents: Report and Resource Guide from a 16-State Study. Institute of Health, Healthcare Policy and Aging Research, Rutgers University. Publication Number 1, June 2010. http://rci.rutgers.edu/~cseap/MMDLNAPKIDS.html. Accessed 9/20/2010.

9. Facts & Comparisons® E Answers. http://www.factsandcomparisons.com/. Accessed 7/22/11;

10. Lexicomp Online. http://online.lexi.com.libproxy.lib.unc.edu/crlsql/servlet/crlonline. Accessed 7/25/2011

11. UpToDate Online. http://www.uptodate.com/home. Accessed 10/11/2013.

12. Risperdal Product Information. http://www.janssenpharmaceuticalsinc.com/assets/risperdal.pdf

13. Abilify Product Information. http://www.otsuka-us.com/Documents/Abilify.PI.pdf

14. Saphris Product Information http://pi.actavis.com/data_stream.asp?product_group=1908&p=pi&language=E