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1.0 Description of the Procedure, Product, or Service

This policy applies to safety monitoring for NC Medicaid (Medicaid) beneficiaries age 18 and older 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.

2.0 Eligible Beneficiaries

2.1 General Provisions

Medicaid beneficiaries shall be enrolled on the date of service and may have service restrictions due to their eligibility category that would make them ineligible for this service.

NCHC shall not **cover Off Label Antipsychotic Safety Monitoring In Beneficiaries 18 and Older.**

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

2.2 EPSDT Special Provision: Exception to Policy Limitations for Beneficiaries 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 beneficiaries 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 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

- 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 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.

****EPSDT and Prior Approval Requirements**

- a. 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.
- b. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *Basic Medicaid and NC Health Choice Billing Guide*, sections 2 and 6, and on the EPSDT provider page. The Web addresses are specified below.

Basic Medicaid and NC Health Choice Billing Guide:

<http://www.ncdhhs.gov/dma/basicmed/>

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

2.3 Health Choice Special Provision: Exceptions to Policy Limitations for Health Choice Beneficiaries ages 6 through 18 years of age

EPSDT does not apply to NCHC beneficiaries. If a NCHC beneficiary does not meet the clinical coverage criteria within **Section 3.0** of the clinical coverage policy, the NCHC beneficiary shall be denied services. Only services included under the Health Choice State Plan and the DMA clinical coverage policies, service definitions, or billing codes shall be covered for NCHC beneficiaries.

3.0 When the Procedure, Product, or Service Is Covered

Note: Refer to Subsection 2.2 regarding EPSDT Exception to Policy Limitations for Medicaid Beneficiaries under 21 Years of Age.

3.1 General Criteria

Procedures, products, and services related to this policy are covered when they are 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

No clinical coverage criteria.

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

Note: Refer to Subsection 2.2 regarding EPSDT Exception to Policy Limitations for Medicaid Beneficiaries under 21 Years of Age.

4.1 General Criteria

Procedures, products, and services related to this policy are not covered when

- a. the beneficiary does not meet the eligibility requirements listed in **Section 2.0**;
- b. the beneficiary does not meet the medical necessity criteria listed in **Section 3.0**;
- c. the procedure, product, or service unnecessarily 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 Non-Covered Criteria

No additional non-covered criteria.

5.0 Requirements for and Limitations on Coverage

Note: Refer to Subsection 2.2 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, may initiate a registration or prior authorization process for the off label prescribing of an antipsychotic for a beneficiary age 18 and older 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.

5.1.1 Exemptions

Beneficiaries with any of the following diagnoses are exempt from the registration or prior authorization requirements of the policy.

- a. Schizophrenia
- b. Schizophreniform disorder
- c. Schizoaffective disorder
- d. Delusional disorder
- e. Brief psychotic disorder
- f. Shared psychotic disorder

- g. Psychotic disorder Not Otherwise Specified (NOS)
- h. Bipolar disorder
- i. Major depressive disorder with psychotic features
- j. Treatment resistant depression (antipsychotic use for TRD is adjunctive only)
- k. Tourette syndrome
- l. Other psychoses

The pharmacist may override the prior authorization edit at point of sale if the prescriber writes on the face of the prescription in his or her own handwriting: **“Meets PA Criteria.”** This information may also be entered in the comment block on e-prescriptions.

5.1.2 Monitoring Portal for Prescriber Registry

Prescribers shall input information for each beneficiary age 18 and older for whom an antipsychotic is prescribed that meet any of the criteria listed in **Subsection 5.1**. The data elements collected are used to support a generally accepted clinical analysis of the safety and efficacy of the prescribed pharmacotherapy.

5.1.3 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 beneficiary 18 years of age and older
- 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.

5.1.4 Information Sources to Develop Monitoring Parameters

Safety monitoring parameters in the registry shall be based upon standards established by the American Psychiatric Association and currently accepted practice standards for the efficacious and safe use of antipsychotics.

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

5.1.6 Access Assured

If FDA approved guidelines for use are met for a specific beneficiary, further safety documentation will not be 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.

5.1.7 Indications and Maximum Dose Parameters

Selected antipsychotic agents have age dependent FDA approved indications and recommended dosages. Drug specific parameters by diagnosis shall be in accordance with the FDA guidelines. (Refer to **Table 1**)

Table 1

Medication *SGA/second generation antipsychotic agent	Rec. Max Daily Dose	FDA Approved Psychiatric Indication			
		Schizophrenia	Bipolar Disorder	Adjunctive Tx of Depression	Tourette's Syndrome
Abilify/ Aripiprazole*	30mg	X	X	X	
Clozaril/Clozapine*	900mg	X			
Etrafon/Triavil/Duo-vil	16mg/200mg			X	
Fanapt/Iloperidone*	24mg	X (acute only)			
Geodon / Ziprasidone*	160mg	X	X		
Haldol / Haloperidol	100mg	X	X		X
Haldol/Haloperidol Decanoate (IM)	450mg/month	X			
Invega / Paliperidone*	12mg	X			
Invega/Paliperidone Sustenna (IM)*	234mg/q4wk	X			
Latuda/Lurasidone*	160mg	X (acute only)	X (Bipolar depression)		
Loxitane / Loxapine	250mg	X			
Mellaril / Thioridazine	800mg	X			
Navane / Thiothixene	60mg	X			
Orap / Pimozide	10mg				X
Prolixin / Fluphenazine	40mg	X			
Prolixin / Fluphenazine Decanoate (IM)	100mg	X			
Risperdal / Risperidone*	16mg	X	X		
Risperdal / Risperidone Consta (IM)*	50mg/2weeks	X	X		
Saphris / Asenapine*	20mg	X	X		
Seroquel IR / Quetiapine*	800mg	X (acute only)	X		
Seroquel XR / Quetiapine*	800mg	X	X	X	
Stelazine / Trifluoperazine	40mg	X			
Symbyax	18mg / 75mg		X	X	
Thorazine/Chlorpromazine	1600mg	X	X		
Trilafon / Perphenazine	64mg	X			
Zyprexa/ Olanzapine*	20mg	X	X		
Zyprexa Relprevv (IM)	300mg/q2wk or 405mg/q4wk	X			

5.1.8 Adverse Effects and Clinical Assessment Monitoring

Specific monitoring parameters recommended by the American Psychiatric Association and other evidence based sources 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 procedures, products, and services related to this policy, providers shall

- a. meet Medicaid or NCHC qualifications for participation;
- b. be currently Medicaid - enrolled; 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.

7.0 Additional Requirements

Note: Refer to Subsection 2.2 regarding EPSDT Exception to Policy Limitations for Medicaid Beneficiaries under 21 Years of Age.

7.1 Compliance

Providers shall comply with all of the following: applicable agreements, federal, state and local laws and regulations, including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements.

8.0 Policy Implementation/Revision Information

Original Effective Date: March 20, 2012

Revision Information:

Date	Section Revised	Change
03/20/2012	Throughout policy	Initial promulgation of new coverage for Medicaid
03/20/2012	Sub-Section 2.2.1	Additional diagnoses h. – l. were added to the list of exemptions; procedures for point of sale override were added
07/01/2012	Throughout	Policy number changed from A7 to 9E. Technical changes to merge Medicaid and NCHC current coverage into one policy
07/01/2012	Throughout	Change recipient and beneficiary and recipient to beneficiaries
11/01/2013	Section 5.0 Table 1	Latuda max dose changed to 160mg and bipolar depression indication added
11/01/2013	References	Added Up to Date Online

Attachment A: Claims-Related Information

Reimbursement requires compliance with all Medicaid or NCHC guidelines, including obtaining appropriate referrals for beneficiaries enrolled in the Medicaid and NCHC managed care programs.

A. Claim Type

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

B. Diagnosis Codes

Does not apply.

C. Billing 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 pharmacy provider

G. Co-payments

Co-payment(s) may apply to covered services, procedures, prescription drugs, and over-the-counter drugs.

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, indexed at: <http://www.ncdhhs.gov/dma/mp/>

Attachment B: References

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