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1.0 Description of the Procedure, Product, or Service

This policy applies to safety monitoring for Health Choice recipients 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 Eligible Recipients

2.1 General Provisions

To be eligible, NC Health Choice (NCHC) recipients must be enrolled on the date of service. A NCHC recipient is age 6 through 18 years of age.

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

3.0 When the Procedure, Product, or Service Is Covered

3.1 General Criteria

NCHC covers procedures, products, and services related to this policy 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 recipient'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; **AND**
- c. the procedure, product, or service is furnished in a manner not primarily intended for the convenience of the recipient, the recipient's caretaker, or the provider.

3.2 Specific Criteria

Refer to **Section 5.0** of this policy.

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

4.1 General Criteria

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

- a. the recipient does not meet the eligibility requirements listed in **Section 2.0**;
- b. the recipient 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 or investigational

5.0 Requirements for and Limitations on Coverage

5.1 Prior Approval (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 Health Choice recipient 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.

5.2 Monitoring Portal for Prescriber Registry

Prescribers shall input information for each NCHC recipient 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.

5.3 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 NCHC recipient.
 - 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.

5.4 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.

5.5 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.

5.6 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.

5.7 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)
	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: *Not recommended by the FDA or the pharmaceutical manufacturer to be used in this population. 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: *Not recommended by the FDA or the pharmaceutical manufacturer to be used in this population.
 If antipsychotic does not appear in above table, it is not currently FDA approved for this population.

5.8 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.

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 NCHC qualifications for participation;
- b. be currently enrolled with NCHC; **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

7.1 Compliance

Providers shall comply with all applicable 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: February 8, 2012

Revision Information:

Date	Section Revised	Change
2/8/12	Throughout	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.

Attachment A: Claims-Related Information

Reimbursement requires compliance with all NCHC guidelines.

A. Claim Type

Online Real-Time Point of Sale using current version of NCPDP

B. Diagnosis Codes

n/a

C. Procedure Code(s)

Codes	Description
n/a	

D. Modifiers

n/a

E. Billing Units

The NDC determines the billing unit(s).

F. Place of Service

Active NCHC pharmacy provider

G. Co-payments

Co-payment(s) may apply to covered prescription drugs

H. Reimbursement

Refer to Outpatient Pharmacy Program Clinical Coverage Policy No.: 9; Attachment A: Claims-Related Information; B. Directions for Drug Reimbursement

Attachment B: References

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