

To all beneficiaries enrolled in a Prepaid Health Plan (PHP): for questions about benefits and services available on or after implementation, please contact your PHP.

Table of Contents

1.0 Description of the Procedure, Product, or Service..... 1
1.1 Definitions 1

2.0 Eligibility Requirements 1
2.1 Provisions..... 1
2.1.1 General..... 1
2.1.2 Specific 1
2.2 Special Provisions..... 2
2.2.1 EPSDT Special Provision: Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age 2

3.0 When the Procedure, Product, or Service Is Covered..... 3
3.1 General Criteria Covered 3
3.2 Specific Criteria Covered..... 3
3.2.1 Specific criteria covered by Medicaid 3
3.2.2 Medicaid Additional Criteria Covered..... 3

4.0 When the Procedure, Product, or Service Is Not Covered..... 3
4.1 General Criteria Not Covered 3
4.2 Specific Criteria Not Covered..... 3
4.2.1 Specific Criteria Not Covered by Medicaid..... 3
4.2.2 Medicaid Additional Criteria Not Covered..... 4

5.0 Requirements for and Limitations on Coverage 4
5.1 Prior Approval 4
5.1.1 Exemptions 4
5.1.2 Monitoring Portal for Prescriber Registry 4
5.1.3 Safety Monitoring Documentation 5
5.1.4 Information Sources to Develop Monitoring Parameters 5
5.1.5 Provider Education 5
5.1.6 Access Assured 5
5.1.7 Indications and Maximum Dose Parameters 5
5.1.8 Adverse Effects and Clinical Assessment Monitoring 5

6.0 Providers Eligible to Bill for the Procedure, Product, or Service 6

7.0 Additional Requirements 6
7.1 Compliance 6

8.0 Policy Implementation/Revision Information..... 7

Attachment A: Claims-Related Information..... 9
A. Claim Type 9

B. International Classification of Diseases and Related Health Problems, Tenth Revisions,
Clinical Modification (ICD-10-CM) and Procedural Coding System (PCS) 9

C. Code(s)..... 9

D. Modifiers..... 9

E. Billing Units..... 9

F. Place of Service 9

G. Co-payments 9

H. Reimbursement 9

Attachment B: References 10

Related Clinical Coverage Policies

Refer to <https://medicaid.ncdhhs.gov/> 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 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.

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 policies)

- a. An eligible beneficiary shall be enrolled in the NC Medicaid Program *(Medicaid is NC Medicaid program, unless context clearly indicates otherwise)*;
- b. Provider(s) shall verify each Medicaid 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.

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

2.1.2 Specific

(The term “Specific” found throughout this policy only applies to this policy)

- a. **Medicaid**
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: <https://medicaid.ncdhhs.gov/>

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 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 Medicaid

None Apply.

3.2.2 Medicaid Additional Criteria Covered

None Apply.

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

Note: Refer to Subsection 2.21 regarding EPSDT Exception to Policy Limitations for Medicaid Beneficiaries under 21 Years of Age.

4.1 General Criteria Not Covered

Medicaid 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 Medicaid

None Apply.

4.2.2 Medicaid Additional Criteria Not Covered

None Apply.

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, NC Medicaid, may initiate a registration or prior authorization (PA) 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 FDA.
- b. The antipsychotic is prescribed at a different dosage than approved for an indication by the FDA.
- c. The prescribed antipsychotic results 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 PA 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 PA 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 meets any of the criteria listed in **Subsection 5.1.1**. 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 (APA) 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:

- a. levels of evidence for use;
- b. safety and outcomes assessments;
- c. use of psychosocial supports; and
- d. interventions to consider if adverse effects are 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.

5.1.8 Adverse Effects and Clinical Assessment Monitoring

Specific monitoring parameters recommended by the APA 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 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 2.2.1 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 NC Medicaid'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: 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
11/01/2014	Table 1	Added Abilify Maintena
11/01/2014	References	Added Abilify 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.
02/02/2015	Table 1	Added Aripiprazole for indication of Tourette's Disorder
10/01/2015	Section 5.1.7	Removed "Refer to Table 1"
10/01/2015	Section 5.1.7	Removed Table 1
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.
03/15/2019	Table of Contents	Added, "To all beneficiaries enrolled in a Prepaid Health Plan (PHP): for questions about benefits and services available on or after November 1, 2019, please contact your PHP."
03/15/2019	All Sections and Attachments	Updated policy template language.
01/12/2020	Table of Contents	Updated policy template language, "To all beneficiaries enrolled in a Prepaid Health Plan (PHP): for questions about benefits and services available on or after implementation, please contact your PHP."
01/12/2020	Attachment A	Added, "Unless directed otherwise, Institutional Claims must be billed according to the National Uniform Billing Guidelines. All claims must comply with National Coding Guidelines".
4/15/2023	All Sections and Attachment(s)	Updated policy template language due to North Carolina Health Choice Program's move to Medicaid.

Date	Section Revised	Change
		Policy posted 4/15/2023 with an effective date of 4/1/2023.

Attachment A: Claims-Related Information

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

A. Claim Type

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

Unless directed otherwise, Institutional Claims must be billed according to the National Uniform Billing Guidelines. All claims must comply with National Coding Guidelines.

B. International Classification of Diseases and Related Health Problems, 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 pharmacy provider

G. Co-payments

For Medicaid refer to Medicaid State Plan:

<https://medicaid.ncdhhs.gov/meetings-notices/medicaid-state-plan-public-notices>

H. Reimbursement

Provider(s) shall bill their usual and customary charges.

For a schedule of rates, refer to: <https://medicaid.ncdhhs.gov/>

Refer to clinical coverage policy 9 *Outpatient Pharmacy Program*; Attachment A: Claims Related Information; B: Directions for Drug Reimbursement, indexed at: <https://medicaid.ncdhhs.gov/>

Attachment B: References

1. Buchanan RW, Kreyenbuhl J, Kelly DL, et al. The 2009 PORT psychopharmacological treatment recommendations and summary statements. *Schizophrenia Bulletin* 2009; (36) 1, 71-93.
2. Consensus Development Conference on Antipsychotic Drugs and Obesity and Diabetes. American Diabetes Association-American Psychiatric Association. *Diabetes Care* 2004. 27(2). 596-601.
3. Dixon L, Perkins D, Calmes C. Guideline Watch (September 2009): Practice guideline for the treatment of patients with schizophrenia. American Psychiatric Association. Available at http://www.psychiatryonline.com/pracGuide/PracticePDFs/Schizophrenia_Guideline%20Watch.pdf Accessed 8/25/2010.
4. Kreyenbuhl J, Buchanan RW, Dickerson FB, et al. The schizophrenia patient outcomes research team (PORT): updated treatment recommendations. *Schizophrenia Bulletin* 2009; (36) 1, 94-103.
5. Marder SR, Essock SM, Miller AL. The Mount Sinai conference on the pharmacotherapy of schizophrenia. *Schizophrenia Bulletin* 2002. 28(1): 5-16.
6. Parks J, Svendsen D, Singer P, et al. eds. *Morbidity and Mortality in People with Serious Mental Illness*. National Association of State Mental Health Program Directors. October 2006. www.nasmhpd.org. Accessed 8/24/2010.
7. Rosenheck RA, Leslie DL, Busch SB, et al. Rethinking antipsychotic formulary policy. *Schizophrenia Bulletin* 2008; (34) 2, 375-380.
8. Rosenheck RA. Outcomes, costs, and policy caution. A commentary on the Cost Utility of the Latest Antipsychotic Drugs in Schizophrenia Study (CUtLASS 1). *Arch Gen Psychiatry* 2006. 63: 1074-1076.
9. Sicouri S, Antzelevitch C. Sudden cardiac death secondary to antidepressant and antipsychotic drugs. *Expert Opinion on Drug Safety* 2008. 7(2):181-194.
10. UpToDate Online. <http://www.uptodate.com/home>. Accessed 10/11/2013.
11. Abilify Product Information. <http://www.otsuka-us.com/Products/Documents/Abilify.M.PI.pdf>
12. Abilify Product Information. <http://www.otsuka-us.com/Documents/Abilify.PI.pdf>