nh healthy families

MEDICAL NECESSITY GUIDELINE

DEPARTMENT: Pharmacy	**DOCUMENT NAME:** Atypical Antipsychotics
PAGE: 1 of 4	**REFERENCE NUMBER:** NH.PMN.56
EFFECTIVE DATE:	**REPLACES DOCUMENT:**
RETIRED:	**REVIEWED:** 10/16, 10/17
PRODUCT TYPE: Medicaid	**REVISED:** 02/12, 02/13, 08/13, 08/14, 11/16, 1/18

IMPORTANT REMINDER

This Clinical Policy has been developed by appropriately experienced and licensed health care professionals based on a thorough review and consideration of generally accepted standards of medical practice, peer-reviewed medical literature, government agency/program approval status, and other indicia of medical necessity.

The purpose of this Clinical Policy is to provide a guide to medical necessity. Benefit determinations should be based in all cases on the applicable contract provisions governing plan benefits ("Benefit Plan Contract") and applicable state and federal requirements, as well as applicable plan-level administrative policies and procedures. To the extent there are any conflicts between this Clinical Policy and the Benefit Plan Contract provisions, the Benefit Plan Contract provisions will control.

Clinical policies are intended to be reflective of current scientific research and clinical thinking. This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.

Description: Atypical Antipsychotics (AAP) are the second generation of antipsychotic medications. The first generation of antipsychotics block dopamine type 2 receptors while AAPs have a different and variable profile of receptor activity, characterized by a balanced antagonism of dopamine and serotonin receptors. The pharmacology of the AAPs distinguishes them as a class as well as individual agents. AAPs are generally first line treatment for schizophrenia and other psychiatric disorders, including schizoaffective disorder and bipolar mania.

Brand: Brexpiprazole (Rexulti®): 0.25mg, 0.5mg, 1mg, 2mg, 3mg, 4mg

Cariprazine (Vraylar®) 1.5mg, 3mg, 4.5mg, 6mg
clozapine (Clozaril®): 25mg, 100mg tablet
Fanapt® (iloperidone): 1mg, 2mg, 4mg, 6mg, 8mg, 10mg, 12mg tablets
Fazaclo® (clozapine): 12.5mg, 25mg, 100mg, 150mg, 200mg disintegrating tablet/injection

Invega® (paliperidone ER): 1.5mg, 3mg, 6mg, 9mg tablets Latuda® (lurasidone): 20mg, 40mg, 80mg, 120mg tablets

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olanzapine (Zyprexa®): 2.5mg, 5mg, 7.5mg, 10mg, 15mg, 20mg tablets
quetiapine (Seroquel®): 25mg, 50mg, 100mg, 200mg, 300mg, 400mg tablets
risperidone (Risperdal®): 0.25mg, 0.5mg, 1mg, 2mg, 3mg, 4mg tablet, 1mg/ml solution
risperidone ODT (Risperdal M®): 0.25mg, 0.5mg, 1mg, 2mg, 3mg, 4mg oral disintegrating tablet
Saphris® (asenapine): 5mg, 10mg sublingual tablets
Seroquel XR® (quetiapine ER): 50mg, 150mg, 200mg, 300mg, 400mg tabletsZyprexa® (olanzapine): 10mg injection
ziprasidone (Geodon®): 20mg, 40mg, 60mg, 80mg capsules
Zyprexa Zydis® (olanzapine): 5mg, 10mg, 15mg, 20mg disintegrating tablet

FDA Labeled Indications (see special instructions):

1. Schizophrenia, or other psychotic disorders
2. Schizoaffectve Disorder
3. Bipolar Disorder
4. Autism
5. Adjunct to depression therapy

Criteria for Approval:

A. Non-preferred AAPs will require a prior authorization request from the prescriber with rationale for use of the intended drug therapy. Acceptable rationale may include: prior trial and failure of at least two preferred AAPs or contraindications to PDL drugs, and/or diagnoses specific to the drug requested.
B. Requested non-preferred AAP must be appropriate to age and diagnoses as approved by the Food and Drug Administration. Continuity of care may be applied individually depending on the Health Plan, State mandates, transition between health care settings, and member eligibility.

Approval: Initial Approval: One year.
Continued Approval: One year

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References: 1. Clinical Pharmacology, on-line. Drug monographs. Accessed 9/2012.
2. Prescribing information (drug specific).

Special Instructions

> AAPs are FDA approved for different age populations. Off-label use of a drug based on age will only be approved if previous AAPs approved for that age population have been tried and failed.

> Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Antipsychotics are not approved for treatment of dementia-related psychosis.

Revision Log	
Revision	**Date**
Updated indications and references.	02/12
Description revised.	02/13
Listed out PDL agents and non-PDL agents separately.	02/13
Changed criteria language to better describe step therapy.	02/13
References updated to reflect current literature search.	02/13
Removed ST for olanzapine, quetiapine, and ziprasidone.	08/13
Removed ST for non-PDL drugs and replaced with required PA. Changed status of Seroquel XR to non-PDL.	08/13
Changed status of Abilify to PA.	08/13
Added Abilify Maintena as a non-PDL drug.	08/13
Added COC language noting that it may be applied variably depending on Health Plan, State mandates, transition between health care settings, and member eligibility.	08/13

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References updated to reflect current literature search.	08/13
Change Brand section to list all products (not specific to preferred/non-preferred status).	08/14
Removed injectables from the Brand section (as they have a separate guideline).	08/14
Removed the following from the Special Instructions section: All AAPs are indicated for treatment of schizophrenia. However the other FDA approved indications vary by drug (i.e. not all AAPs are approved for autism, etc.)."	08/14
Added other psychotic disorders to FDA labeled indications	07/15
Removed maximum tolerated dose from criterion A	07/15
Annual Review, No Changes	10/16
Added Brexpiprazole (Rexulti) to drug list	11/16
Annual Review, No Changes	10/17
Added Cariprazine (Vraylar) to list of medications. Removed note about Aripiprazole requiring prior authorization.	1/18

POLICY AND PROCEDURE APPROVAL

Pharmacy & Therapeutics Committee: Approval on file

V.P., Pharmacy Operations: Approval on file

Sr. V.P., Chief Medical Officer: Approval on file