MEDICAL NECESSITY GUIDELINE

DEPARTMENT: Pharmacy	**DOCUMENT NAME:** Long Acting Injectable Atypical Antipsychotics
PAGE: 1 of 5	**REFERENCE NUMBER:** NH.PMN.41
EFFECTIVE DATE: 02/11	**REPLACES DOCUMENT:**
RETIRED:	**REVIEWED:** 06/16, 03/17
PRODUCT TYPE: Medicaid	**REVISED:** 02/12, 02/13, 08/14, 07/15

IMPORTANT REMINDER

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: Long Acting Injectable Atypical Antipsychotics are indicated for the treatment of psychiatric conditions where nonadherence to oral drug therapy is present. The atypical antipsychotics offer decreased presence of extrapyrmidal adverse effects over the typical antipsychotics, but generally demonstrate increased metabolic adverse effects in comparison to the typical antipsychotics.

Brand:

1. Risperdal® Consta® - 12.5 mg, 25 mg, 37.5 mg, 50 mg. powder for injection.
2. Invega® Sustenna® - 39 mg, 78 mg, 117 mg, 156 mg, 234 mg. extended release suspension for injection.
3. Zyprexa® RelprevvTM - 210 mg, 300 mg, 405 mg. extended release powder for injection.
4. Abilify® Maintena® – 300 mg, 400mg extended release powder for suspension for injection.

MEDICAL NECESSITY GUIDELINE

DEPARTMENT: Pharmacy	**DOCUMENT NAME:** Long Acting Injectable Atypical Antipsychotics
PAGE: 2 of 5	**REFERENCE NUMBER:** NH.PMN.41
EFFECTIVE DATE: 02/11	**REPLACES DOCUMENT:**
RETIRED:	**REVIEWED:** 06/16, 03/17
PRODUCT TYPE: Medicaid	**REVISED:** 02/12, 02/13, 08/14, 07/15

FDA Labeled Indications:

1. Risperdal® Consta® - schizophrenia; bipolar disorder, or other psychotic disorder
2. Invega® Sustenna® - schizophrenia, or other psychotic disorder
3. Zyprexa® RelprevvTM - schizophrenia, or other psychotic disorder.
4. Abilify® Maintena® - schizophrenia, or other psychotic disorder

Criteria for Approval:

A. Member must be ≥ 18 years of age.
B. Medication must be prescribed by a psychiatrist.
C. Oral therapy must be trialed and documented to have failed in the member. This will be confirmed by irregular claims records and/or prescriber attestation of erratic, non-adherent use of a Preferred Drug List (PDL) atypical antipsychotic agent.
D. The oral atypical antipsychotic must be discontinued within three months of the initiation of long acting injectable atypical antipsychotic. Concurrent administration of both the oral and the injectable atypical antipsychotic for longer than 3 months will require clinical documentation to support rationale for dual therapy. In the case of Invega Sustenna, discontinue oral therapy immediately.
E. Preferred agents will be considered as first line agents (See plan Preferred Drug List)
F. Member must not be taking carbamazepine concurrently.

Approval: Approval: 12 months.

CENTENE Corporation

MEDICAL NECESSITY GUIDELINE

DEPARTMENT: Pharmacy	**DOCUMENT NAME:** Long Acting Injectable Atypical Antipsychotics
PAGE: 3 of 5	**REFERENCE NUMBER:** NH.PMN.41
EFFECTIVE DATE: 02/11	**REPLACES DOCUMENT:**
RETIRED:	**REVIEWED:** 06/16, 03/17
PRODUCT TYPE: Medicaid	**REVISED:** 02/12, 02/13, 08/14, 07/15

Justification may include:

- Lack of insight or awareness of having a mental illness
- Perception of ineffectiveness of medication
- Intellectually Disabled
- Living environment inconsistent with retaining oral medication supply in the patient possession (e.g. shelter, transitional housing or homelessness
- One or more previous episodes of non-adherence to oral therapy leading to hospitalization

Special Instructions

> Risperdal® Consta®, Invega® Sustenna®, Zyprexa® RelprevvTM - Pregnancy Category C.
> Appropriate dosage adjustment for Risperdal® Consta® may be required in members with renal and/or hepatic impairment.
> Invega® Sustenna® is recommended in members with moderate or severe renal impairment.
> Antipsychotics, both typical and atypical, are not indicated for the treatment of dememtia-related psychosis. The FDA has concluded that both typicals and atypicals, are associated with increased mortality when used in the elderly when used for dementia related psychosis and has been added as a black box warning to all affected agents.

References: 1. Risperdal® Consta® prescribing information. Available at: http://www.risperdalconsta.com/sites/default/files/Risperdal ConstaPI.pdf#zoom=100
2. Invega® Sustenna® prescribing information. Available at: http://www.invegasustenna.com/pdf/invegasustenna-prescribing-info.pdf
3. Zyprexa® RelprevvTM prescribing information. Available at: http://pi.lilly.com/us/zyprexa relprevv.pdf

MEDICAL NECESSITY GUIDELINE

DEPARTMENT: Pharmacy	**DOCUMENT NAME:** Long Acting Injectable Atypical Antipsychotics
PAGE: 4 of 5	**REFERENCE NUMBER:** NH.PMN.41
EFFECTIVE DATE: 02/11	**REPLACES DOCUMENT:**
RETIRED:	**REVIEWED:** 06/16, 03/17
PRODUCT TYPE: Medicaid	**REVISED:** 02/12, 02/13, 08/14, 07/15

4. Abilify® Maintena® prescribing information. Available at: http://www.otsuka-us.com/Products/Documents/Abilify.M.PI.pdf
5. Rittmannsberger H, Pachinger T, Keppelmuller P, et al: Medication adherence among psychotic patients before admission to inpatient treatment. Psychiatric Services 55:174—179, 2004
6. Olfson M, Mechanic D, Hansell S, et al: Predicting medication noncompliance after hospital discharge among patients with schizophrenia. Psychiatric Services 51:216—222, 2000
7. Loffler W, Kilian R, Touni M, et al: Schizophrenic patients' subjective reasons for compliance and noncompliance with neuroleptic treatment. Pharmacopsychiatry 36:105—112, 2003
8. Smith TE, Hull JW, Goodman M, et al: The relative influences of symptoms, insight, and neurocognition on social adjustment in schizophrenia and schizoaffective disorder. Journal of Nervous and Mental Disease 187:102—108, 1999
9. Cuffel BJ, Alford J, Fischer EP, et al: Awareness of illness in schizophrenia and outpatient treatment adherence. Journal of Nervous and Mental Disease 184:653—659, 1996
10. Mark Olfson, M.D., M.P.H.; Steven C. Marcus, Ph.D.; Joshua Wilk, Ph.D.; Joyce C. West, Ph.D., M.P.P. Awareness of Illness and Nonadherence to Antipsychotic Medications Among Persons With Schizophrenia Psychiatric Services 2006; doi: 10.1176/appi.ps.57.2.205

Revision Log	
Revision	**Date**
References updated.	02/12
References updated	02/13
References updated.	02/14
References updated.	08/14

MEDICAL NECESSITY GUIDELINE

DEPARTMENT: Pharmacy	**DOCUMENT NAME:** Long Acting Injectable Atypical Antipsychotics
PAGE: 5 of 5	**REFERENCE NUMBER:** NH.PMN.41
EFFECTIVE DATE: 02/11	**REPLACES DOCUMENT:**
RETIRED:	**REVIEWED:** 06/16, 03/17
PRODUCT TYPE: Medicaid	**REVISED:** 02/12, 02/13, 08/14, 07/15

Approval criteria outlined.	08/14
Added "justifications" listing to the Approval section.	08/14
Added "Abilify Maintena" to the Brand section.	08/14
Removed member must meet the appropriate DSM criteria for the disease state and the medication must be FDA indicated for the disease state for which it is being prescribed	07/15
Added or other psychotic disorders to FDA labeled indications	07/15
Changed approval from 3 months to 1 year	07/15
Removed the requirement for documentation of non compliance and added prescriber attestation	07/15
Criteria reviewed with no changes	06/16
Annual Review, No Changes	03/17

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

Centene Medical Policy Statements represent technical documents developed by the Medical Management Staff. Questions regarding interpretation of these policies for the purposes of benefit coverage should be directed to a Medical Management Staff person.