Prescription Drugs for Serious Mental Illnesses-REG

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

This coverage policy is developed in accordance with Texas Insurance Code Section 1369.0547 regarding step therapy protocols for prescription drugs to treat serious mental illnesses. This policy applies only to requests for drugs prescribed to members 18 years of age or older for the treatment of diagnoses listed as serious mental illnesses in Section 1355.001. These include:

1. Bipolar disorders (hypomanic, manic, depressive, and mixed);
2. Depression in childhood and adolescence;
3. Major depressive disorders (single episode or recurrent);
4. Obsessive-compulsive disorders;
5. Paranoid and other psychotic disorders;
6. Schizo-affective disorders (bipolar or depressive); *and*
7. Schizophrenia.

For covered outpatient prescription drugs to treat these diagnoses, the plan will provide coverage without implementing step therapy protocols that require a member to:

- Fail more than ONE (1) drug for each drug prescribed, excluding generic equivalents.
- Prove a history of failure of more than ONE (1) drug for each drug prescribed, excluding generic equivalents.

Definitions

"Brand Name Drug" means the first version of a particular medication to be developed or a medication that is sold under a pharmaceutical manufacturer's own registered trade name or trademark. The original manufacturer is granted a patent, which allows it to be the only company to make and sell the new drug for a certain number of years.

"Compendia" are summaries of drug information and medical evidence to support decision-making about the appropriate use of drugs and medical procedures. Examples include, but are not limited to:

1. American Hospital Formulary Service Drug Information
2. Elsevier Clinical Pharmacology
3. National Comprehensive Cancer Network Drugs and Biologics Compendium
4. Thomson Micromedex DrugDex
5. United States Pharmacopeia-National Formulary (USP-NF)

"Documentation" refers to written information, including but not limited to:

1. Up-to-date chart notes, relevant test results, and/or relevant imaging reports to support diagnoses;
2. Prescription claims records, and/or prescription receipts to support prior trials of formulary alternatives.

"FDA," or the Food and Drug Administration, is an agency of the United States federal government responsible for protecting and promoting public health through the regulation and supervision of food safety, tobacco products, dietary supplements, prescription and over-the-counter medications, vaccines, biopharmaceuticals, blood transfusions, medical devices, electromagnetic radiation emitting devices, cosmetics, and veterinary products. The FDA's main goal is to ensure that these products are safe and effective for their intended use, and that their labeling and marketing are truthful and not misleading.

"Formulary" means a list of medications available to members with or without Prior Authorization.

"Generic Drugs" means prescription Drugs that have been determined by the Food and Drug Administration (FDA) to be equivalent to Brand Name Drugs, but are not made or sold under a registered trade name or trademark. Generic Drugs have the same active ingredients, meet the same FDA requirements for safety, purity, and potency and must be dispensed in the same dosage form (e.g., tablet, capsule, cream) as the Brand Name Drug.

"Serious mental illness" is defined in accordance with the Texas Insurance Code Section 1355.001. This term refers to specific psychiatric illnesses as detailed by the American Psychiatric Association in the Diagnostic and Statistical Manual (DSM). These illnesses include:

A. Bipolar disorders (including hypomanic, manic, depressive, and mixed episodes);
B. Childhood and adolescent depression;
C. Major depressive disorders (whether single episode or recurrent);
D. Obsessive-compulsive disorders;
E. Paranoid and other related psychotic disorders;
F. Schizo-affective disorders (either bipolar or depressive types);
G. Schizophrenia.

Coverage Criteria

The Plan will provide coverage for the requested drug when ALL the following criteria are met:

1. The member is 18 years of age or older*; AND*
2. The drug is being prescribed to treat ONE (1) of the following diagnosis:
    a. bipolar disorders (hypomanic, manic, depressive, and mixed)*; or*
    b. depression in childhood and adolescence*; or*
    c. major depressive disorders (single episode or recurrent)*; or*
    d. obsessive-compulsive disorders*; or*
    e. paranoid and other psychotic disorders*; or*
    f. schizo-affective disorders (bipolar or depressive)*; or*
    g. schizophrenia*; AND*
3. The member meets the Medical Necessity Criteria listed below:

Clinical Indications

Medical Necessity Criteria for Initial Clinical Review

Initial Indication-Specific Criteria

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The Plan considers the requested drug medically necessary when ALL of the following criteria are met:

1. The safety and effectiveness of the drug has been established for the member's age and disease or condition*; AND*
2. The drug is being used for an FDA-approved or compendia supported indication*; AND*
3. The member has adequately tried and failed at least ONE (1) different FDA-approved drug for the given diagnosis, unless all alternatives are contraindicated*; AND*
4. IF the request is for a brand drug with a generic available - the member is unable to use, or has tried and failed the corresponding generic*; AND*
5. The member does NOT have ANY contraindications to the requested drug as defined in the FDA prescribing information*; AND*
6. The drug being requested meets BOTH of the following:
    a. is being used at the age, dosage, frequency, duration of therapy, and site of administration that is supported by ONE of the following:
        i. FDA-approved labeling (product information)*; or*
        ii. Compendia of current literature*; and*
    b. if the requested dosage exceeds the Plan's quantity limit AND the prescribed dosage cannot be achieved using a different dose or formulation that is within the Plan's limit.

If the above prior authorization criteria are met, the requested drug will be approved for up to 12-months.

Medical Necessity Criteria for Subsequent Clinical Review

Subsequent Indication-Specific Criteria

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Reauthorization for up to 12 months will be granted if the member has recent (within the last 6 months) clinical chart documentation indicating that the member has experienced a clinically meaningful improvement in symptoms related to their diagnosed serious mental illness. This improvement must be validated by clinical documentation showing, for example, a reduction in the frequency or severity of acute episodes, reduced need for higher levels of care, improved social/occupational functioning, improved quality of life, or other evidence that the medication is providing significant benefit

Experimental or Investigational / Not Medically Necessary

The use of any drug, including prescription drugs to treat a serious mental illness, for any indication that is not supported by the FDA or compendia is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven.

References

1. Texas HB1337 | 2023-2024 | 88th Legislature." LegiScan, legiscan.com/TX/text/HB1337/2023. Accessed 15 July 2025.
2. Insurance Code Chapter 1355. Benefits for Certain Mental Disorders. Statutes.capitol.texas.gov, statutes.capitol.texas.gov/Docs/IN/htm/IN.1355.htm. Accessed 15 July 2025.

Clinical Guideline Revision / History Information

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