Select Antipsychotic Drugs

Policy # 00707
Original Effective Date: 07/13/2020
Current Effective Date: 07/12/2021

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider select antipsychotic drugs, including, but not limited to Caplyta™‡ (lumateperone) and Secuado®‡ (asenapine), to be **eligible for coverage**** when the below patient selection criteria are met.

Patient Selection Criteria

Coverage eligibility will be considered for select antipsychotic drugs, including, but not limited to Caplyta (lumateperone) and Secuado (asenapine), when the following criteria are met:

- Patient has a diagnosis of schizophrenia; AND
- Patient is 18 years of age or older; AND
- Patient has tried and failed (e.g., intolerance or inadequate response) at least TWO generic alternatives unless there is clinical evidence or patient history that suggests the use of generic alternatives to treat schizophrenia will be ineffective or cause an adverse reaction to the patient. Examples of generic alternatives include aripiprazole (tablets, oral solution, or oral disintegrating tablets), paliperidone tablets, olanzapine (tablets or oral disintegrating tablets), quetiapine tablets, risperidone (tablets, oral solution, or oral disintegrating tablets), and ziprasidone capsules.
  *(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*

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When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of select antipsychotic drugs, including, but not limited to Caplyta (lumateperone) and Secuado (asenapine), when the patient has NOT tried and failed at least TWO generic alternatives to treat schizophrenia to be **not medically necessary.****

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of select antipsychotic drugs, including, but not limited to Caplyta (lumateperone) and Secuado (asenapine), when the patient is under 18 years of age OR for any indication other than schizophrenia to be **investigational.***

Background/Overview

Schizophrenia is a psychiatric disorder involving chronic or recurrent psychosis. Symptoms are classified as either "positive" or "negative". Positive symptoms include hallucinations or delusions, while negative symptoms include a flat affect. Of course, these symptoms are coupled with social and occupational impairments. The treatment of choice for schizophrenia is antipsychotic medications. Drug examples include aripiprazole, paliperidone, olanzapine, quetiapine, risperidone, and ziprasidone.

This policy currently addresses two new drugs for the treatment of schizophrenia: Caplyta and Secuado. Caplyta is an oral atypical antipsychotic that demonstrated moderate efficacy in two published, short term trials (placebo-controlled). Only the 42 mg dose proved to be efficacious while lower and higher doses were not shown to be efficacious. Additional unpublished studies did not demostrate efficacy of Caplyta. No studies exist that provide a direct comparison of Caplyta to other available antipsychotic products.

Secuado is a topical atypical antipsychotic which demonstrated modest efficacy in an unpublished trial in patients with schizophrenia. Its approval relied upon the efficacy data of a drug containing the same active ingredient, asenapine. There is a lack of head to head data versus other available

antipsychotic agents. While the patch gives another alternative for therapy, it is associated with safety issues (including warnings regarding the application of external heat and application site reactions).

Both medications targeted by this policy are considered alternatives for medications that already exist on the market today.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)
Both Caplyta and Secuado were approved in late 2019 for the treatment of schizophrenia in adult patients.

Rationale/Source

This policy addresses two new antipsychotic agents that do not bring any unique clinical advantages to the existing array of antipsychotic drugs that are available on the market. Given the lack of head to head data with these products compared to existing antipsychotic medications, Caplyta and Secuado are considered alternatives to already existing antipsychotic medications on the market today.

References

1. Caplyta [package insert]. Intra-cellular Therapies, Inc. New York, New York. Updated December 2019.
2. Secuado [package insert]. Hisamitsu Pharmaceutical Company. Japan. Updated October 2019.
3. Caplyta Drug Evaluation. Express Scripts. Updated January 2020.
4. Secuado Drug Evaluation. Express Scripts. Updated December 2019.

Policy History

Original Effective Date: 07/13/2020
Current Effective Date: 07/12/2021
06/04/2020 Medical Policy Committee review
06/10/2020 Medical Policy Implementation Committee approval. New policy.
06/03/2021 Medical Policy Committee review

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06/09/2021 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
Next Scheduled Review Date: 06/2022

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.