BlueCross BlueShield of Arizona
An Independent Licensee of the Blue Cross and Blue Shield Association

PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

ORIGINAL EFFECTIVE DATE: 5/21/2020
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ARCHIVE DATE:

CAPLYTA® (lumateperone)

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. **All requested data must be provided.** Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

CAPLYTA® (lumateperone)

Criteria:

- **Criteria for initial therapy:** Caplyta (lumateperone) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Prescriber is a physician specializing in the patient's diagnosis or is in consultation with a Psychiatrist
  2. Individual is 18 years of age or older
  3. A confirmed diagnosis of schizophrenia
  4. A Positive and Negative Syndrome Scale (PANSS) total score of 70 indicating moderate to extreme symptoms
  5. Individual does not have dementia-related psychosis
  6. Individual has failure, contraindication or intolerance to **ALL** the following preferred step therapy agents:
     - generic aripiprazole
     - generic ziprasidone
     - Latuda (lurasidone)
  7. **ALL** of the following **baseline tests** have been completed before initiation of treatment with continued monitoring as clinically appropriate:
     - Complete blood count with differential
     - Fasting plasma glucose
     - Fasting lipid profile
     - Weight
     - Blood pressure
  8. Individual does not have moderate to severe hepatic impairment (Child Pugh Class B and C)

  Initial approval duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Caplyta (lumateperone) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with a Psychiatrist
  2. Individual's condition responded while on therapy
     - Response is defined as:
       - No evidence of disease progression
       - Functionality retained in most activities of daily living

- Documented evidence of efficacy, disease stability and/or improvement demonstrated by an improvement in the Positive and Negative Syndrome Scale (PANSS) total score

3. Individual has been adherent with the medication

4. Individual has not developed any significant level 4 adverse drug effects that may exclude continued use
   - Contraindications as listed in the criteria for initial therapy section
   - Significant adverse effect such as:
     - Stroke or transient ischemic attack
     - Neuroleptic malignant syndrome
     - Tardive dyskinesia
     - Significant blood dyscrasia or absolute neutrophil count (ANC) < 1,000/mm^3

5. There are no significant interacting drugs

Renewal duration: 12 months

Description:

Caplyta (lumateperone) is indicated for the treatment of schizophrenia in adults. It is not approved for the treatment of patients with dementia-related psychosis.

Caplyta (lumateperone) is a second-generation antipsychotic with antagonist activity at central serotonin 5-HT_{2A} receptors and postsynaptic antagonist activity at central dopamine D_2 receptors. Lumateperone has high binding affinity for serotonin 5-HT_{2A} receptors and moderate binding affinity for dopamine D_2 receptors. Lumateperone also has moderate binding affinity for dopamine D_1 and D_4 and adrenergic $alpha_{1A}$ and $alpha_{1B}$ receptors but has low binding affinity for muscarinic and histaminergic receptors.

Metabolic syndrome is characterized by elevated lipid profile, hypertension, hyperglycemia, and obesity (especially abdominal weight gain). Antipsychotic agents with greatest risk for metabolic syndrome are clozapine, olanzapine, and quetiapine. Aripiprazole, asenapine, lurasidone, and ziprasidone have the least risk.

Definitions:

Atypical Antipsychotics:

Second Generation agents (so called atypical agents):

- Aripiprazole (Abilify, Abilify MyCite, Abilify Maintena)
- Aripiprazole lauroxil (Aristada, Aristada Initio)
- Asenapine (Saphris)
- Asenapine (Secuado)
- Brexpiprazole (Rexulti)
- Cariprazone (Vraylar)

CAPLYTA® (lumateperone)

- Clozapine (Clozaril, FazaClo, Versacloz)
- Iloperidone (Fanapt)
- Lumateperone (Caplyta)
- Lurasidone hydrochloride (Latuda)
- Olanzapine (Zyprexa, Zyprexa Zydis, Zyprexa Relprevv)
- Palperidone (Invega)
- Palperidone palmitate (Invega Sustenna, Invega Trinza)
- Primavanserin (Nuplazid)
- Quetiapine fumarate (Seroquel, Seroquel XR)
- Risperidone (Risperdal, Risperdal M-Tab, Risperidal Consta, Perseris)
- Ziprasidone hydrochloride (Geodon)
- Ziprasidone mesylate (Geodon)

Resources:

Caplyta (lumateperone) product information accessed 02-13-20 at DailyMed

UpToDate: Second-generation antipsychotic medications: Pharmacology, administration, and side effects. Current through Jan 2020, accessed 02-14-20

Correll CU, Davis RE, Weingart M, et. al.: Efficacy and Safety of Lumteperone for Treatment of Schizophrenia: A Randomized Clinical Trial. JAMA Psychiatry doi:10.1001/jamapsychiatry.2019.4379

Lieberman JA, Davis RE, Correll CU, et. al: ITI-007 for the treatment of schizophrenia: a 4-week randomized, double-blind, controlled trial. Biological Psychiatry June 15, 2016; 79:952–961