Clinical Policy: Lumateperone (Caplyta)

Reference Number: ERX.NPA.141
Effective Date: 03.01.20
Last Review Date: 02.22
Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Lumateperone (Caplyta®) is an atypical antipsychotic.

FDA Approved Indication(s)
Caplyta is indicated for the treatment of:
- Schizophrenia in adults
- Depressive episodes associated with bipolar I or II disorder (bipolar depression) in adults, as monotherapy and as adjunctive therapy with lithium or valproate.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Caplyta is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Schizophrenia (must meet all)**:**
1. Diagnosis of schizophrenia;
2. Age ≥ 18 years;
3. Member meets one of the following (a or b):
   a. Failure of two of the following generic atypical antipsychotics at up to maximally indicated doses, each used for ≥ 4 weeks, unless all are contraindicated or clinically significant adverse effects are experienced: risperidone, quetiapine, olanzapine, ziprasidone;
   b. Member has diabetes mellitus or body mass index (BMI) > 30;
4. Failure of a ≥ 4-week trial of aripiprazole at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
5. Dose does not exceed 42 mg (1 capsule) per day.

Approval duration:
Commercial – Length of Benefit
Medicaid – 12 months

B. Bipolar Disorder (must meet all)**:**
1. Diagnosis of bipolar disorder;
2. Age ≥ 18 years;
3. Failure of two preferred atypical antipsychotics (e.g., aripiprazole, ziprasidone, quetiapine, risperidone, or olanzapine) at up to maximally indicated doses, each used for ≥ 4 weeks, unless clinically significant adverse effects are experienced or all are contraindicated;
4. Dose does not exceed 42 mg (1 capsule) per day.

Approval duration:
Commercial – Length of Benefit
Medicaid – 12 months

C. Other diagnoses/indications
1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions, or documentation supports that member is currently receiving Caplyta for schizophrenia or bipolar disorder and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 42 mg (1 capsule) per day.

Approval duration:
Commercial – Length of Benefit
Medicaid – 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage document.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
BMI: body mass index
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
aripiprazole (Abilify®)	**Schizophrenia** 10 to 15 mg PO QD	30 mg/day
olanzapine (Zyprexa®)	**Schizophrenia** Initial: 5 to 10 mg PO QD; target: 10 mg PO QD **Bipolar Disorder** Monotherapy: 10 to 15 mg PO QD; adjunct to lithium or valproate: 10 mg PO QD	20 mg/day
quetiapine immediate-release (Seroquel®)	**Schizophrenia** Initial: 25 mg PO BID; target: 400 to 800 mg/day **Bipolar Disorder** Initial: 50 mg PO BID; target 400 to 800 mg/day	800 mg/day
risperidone (Risperdal®)	**Schizophrenia** Initial: 1 mg PO BID or 2 mg PO QD; target: 4 to 8 mg PO QD	Adolescents: 6 mg/day Adults: 16 mg/day
ziprasidone (Geodon®)	**Schizophrenia**	160 mg/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	Initial: 20 mg PO BID; increase as needed at intervals of 2 days or more up to 80 mg PO BID	

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): known hypersensitivity to lumateperone or any components of Caplyta
- Boxed warning(s): increased mortality in elderly patients with dementia-related psychosis; suicidal thoughts and behaviors

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Schizophrenia, bipolar disorder	42 mg PO QD Moderate or severe hepatic impairment: 21 mg PO QD	42 mg/day

VI. Product Availability

Capsule: 42 mg, 21 mg, 10.5 mg

VII. References

1. Caplyta Prescribing Information. New York, NY: Intrac-Cellular Therapies, Inc.; April 2022. Available at: www.caplyta.com. Accessed May 6, 2022.
2. Keepers GA, Fochtmann LJ, Anzia JM, et al. The American Psychiatric Association Practice Guideline for the Treatment of Patients with Schizophrenia. The American Psychiatric Association, December 2019. Available at: https://www.psychiatry.org/psychiatrists/practice/clinical-practice-guidelines. Accessed January 8, 2020.
3. Keepers G, Fochtmann L, Anzia J, et al. APA Practice guideline for the treatment of patients with schizophrenia, third edition. Am J Psychiatry.2020 Sept;177(9):868-872.
4. Kadakia A, Dembek C, Heller V, et al. Efficacy and tolerability of atypical antipsychotics for acute bipolar depression: a network meta-analysis. BMC Psychiatry. May 2021;21, 249. Available at: https://bmcpsychiatry.biomedcentral.com/articles/10.1186/s12888-021-03220-3#article-info. Accessed January 4, 2022.
5. Yatham LN, Kennedy SH, Parikh SV, et al. Canadian Network for Mood and Anxiety Treatments (CANMAT) and International Society for Bipolar Disorders (ISBD) 2018 guidelines for the management of patients with bipolar disorder. Bipolar Disord. 2018;20:97–170. https://doi.org/10.1111/bdi.12609.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	01.14.20	02.20
1Q 2021 annual review: no significant changes; references reviewed and updated.	12.02.20	02.21
1Q 2022 annual review: RT4: added criteria for the recently FDA-approved indication of bipolar depression; references reviewed and updated.	11.13.21	02.22
RT4: new strengths [10.5 mg, 21 mg] added.	05.06.22	

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of

physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or 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.

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