Clinical Policy Title:	lumateperone
Policy Number:	RxA.621
Drug(s) Applied:	Caplyta™
Original Policy Date:	05/21/2020
Last Review Date:	03/09/2021
Line of Business Policy Applies to:	All lines of business

Background

Caplyta™ is an atypical antipsychotic indicated for the treatment of schizophrenia in adults. The mechanism of action of lumateperone in the treatment of schizophrenia is unknown. However, the efficacy of lumateperone could be mediated through a combination of antagonist activity at central serotonin 5-HT2A receptors and postsynaptic antagonist activity at central dopamine D2 receptors.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
lumateperone (Caplyta™)	Schizophrenia	42 mg PO once daily with food	42 mg/day

Dosage Forms

- Oral capsule: 42mg

Clinical Policy

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

I. Initial Approval Criteria

A. Schizophrenia (must meet all):

1. Diagnosis of schizophrenia;
2. Member is 18 years of age or older;
3. Prescriber is a psychiatrist or prescribing in consultation with a psychiatrist;
4. Documented failure of at least 2 generic atypical antipsychotic drugs (risperidone, aripiprazole, quetiapine, olanzapine, or ziprasidone) at up to maximally indicated doses, each used for ≥ 4 weeks, unless contraindicated or clinically significant adverse effects are experienced;
5. Dose does not exceed 1 capsule per day.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

II. Continued Therapy Approval

A. Schizophrenia (must meet all):

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
2. Member has experienced and maintained positive response to therapy;
3. Dose does not exceed 1 capsule per day.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

APPENDIX B: Therapeutic Alternatives

Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
aripiprazole (Abilify®)	10 to 15 mg PO once daily	30 mg/day
olanzapine (Zyprexa®)	Initial: 5 to 10 mg PO once daily; target: 10 mg PO once daily	20 mg/day
Quetiapine immediate release (Seroquel®)	Initial: 25 mg PO BID; target: 400 to 800 mg/day	800 mg/day
risperidone (Risperdal®)	Initial: 1 mg PO BID or 2 mg PO once daily; target: 4 to 8 mg PO once daily	Adolescents: 6 mg/day Adults: 16 mg/day
ziprasidone (Geodon®)	Initial: 20 mg PO BID; increase as needed at intervals of 2 days or more up to 80 mg PO BID	160 mg/day

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.

APPENDIX D: General Information

- Positive and Negative Syndrome Scale - A 30-item scale used to measure symptoms of schizophrenia. The scoring range for each item is between 1 and 7, with a score of 1 indicating absence of symptoms and a score of 7 indicating extremely severe symptoms. The PANSS total score ranges between 30 and 210 with higher scores indicating greater overall symptom severity.
- Use of Caplyta™ should be avoided in patients with moderate or severe hepatic impairment (Child-Pugh B

or C).

References

1. Caplyta (lumateperone) [prescribing information]. New York, NY: Intra-Cellular Therapies Inc; December 2019. Available at: https://www.intracellulartherapies.com/docs/caplyta_pi.pdf. Accessed February 05, 2021.
2. American Psychiatric Association: Guideline Watch: Practice Guideline for the Treatment of Patients With Schizophrenia. Arlington, VA, American Psychiatric Association Publishing, 2009a. Accessed February 05, 2021.
3. American Psychiatric Association . Diagnostic and Statistical Manual of Mental Disorders. 5th ed. Washington, DC: American Psychiatric Association; 2013. Accessed February 05, 2021.
4. Lehman AF, Lieberman JA, Dixon LB, et al. American Psychiatric Association Practice Guidelines; Work Group on Schizophrenia. Practice guideline for the treatment of patients with schizophrenia. Am J Psychiatry. (2nd ed) 2004. Accessed February 05, 2021.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	05/18/2020	05/21/2020
Policy was reviewed: 1. Clinical policy title was updated. 2. Line of business applies to was updated to all lines of business. 3. Continued therapy criteria II.A.1 was updated to “Member is currently receiving medication..”. 4. Initial approval criteria I.A.4 was updated: added “risperidone, quetiapine, olanzapine, or ziprasidone”. 5. Updated Appendix A and B. 6. Updated Appendix D: added avoid use in moderate or severe hepatic impairment. 7. References were reviewed and updated.	02/05/2021	03/09/2021