CAPLYTA HAS BROAD FORMULARY COVERAGE

>99% of Medicare Part D/Medicaid patients

~90% of eligible adult Commercial patients

277 million Americans have access to CAPLYTA **across all payer channels**

CAPLYTA is covered on top commercial plans

- CVS Health/Caremark
- United Healthcare
- Prime Therapeutics
- BCBS Federal
- Cigna
- Express Scripts
- OptumRX
- Anthem BCBS
- Tricare
- Aetna

Source: Data on file, Intra-Cellular Therapies, Inc. Formulary data provided by Managed Markets Insight and Technology, LLC™, a trademark of MMIT, as of September 2024. Because formularies do change and many health plans offer more than one formulary, please check directly with the health plan to confirm coverage for individual patients.

CAPLYTA is indicated in adults for the treatment of schizophrenia and depressive episodes associated with bipolar I or II disorder (bipolar depression), as monotherapy and as adjunctive therapy with lithium or valproate.

Important Safety Information

Boxed Warnings:

- **Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. CAPLYTA is not approved for the treatment of patients with dementia-related psychosis.**
- **Antidepressants increased the risk of suicidal thoughts and behaviors in pediatric and young adults in short-term studies. Closely monitor all antidepressant-treated patients for clinical worsening, and for emergence of suicidal thoughts and behaviors. The safety and effectiveness of CAPLYTA have not been established in pediatric patients.**

Contraindications: CAPLYTA is contraindicated in patients with known hypersensitivity to lumateperone or any components of CAPLYTA. Reactions have included pruritus, rash (e.g., allergic dermatitis, papular rash, and generalized rash), and urticaria.

Please see additional Important Safety Information on pages 9-10 and full Prescribing Information.

CAPLYTA® (lumateperone) capsules

Approved for a broad range of adults with bipolar depression[1]

The first and only treatment for depressive episodes associated with bipolar I and bipolar II disorder as monotherapy and adjunctive therapy (with lithium or valproate)[1-5]

Clinical studies evaluating adults with a depressive episode associated with bipolar disorder (bipolar depression)[1-5]	Monotherapy		Adjunctive (with lithium or valproate)	
	Bipolar I	Bipolar II	Bipolar I	Bipolar II
CAPLYTA	✓	✓	✓	✓
Cariprazine	✓			
Quetiapine/Quetiapine XR	✓	✓		
Olanzapine/Fluoxetine	✓			
Lurasidone	✓		✓	

There are no head-to-head clinical studies comparing the safety and efficacy of these products. This chart is descriptive of the FDA-approved indications in adults with bipolar depression and does not represent all approved indications for each product.

Examples of ICD-10 Codes for CAPLYTA[6,7]*

Examples of ICD-10 Codes for Bipolar Depression (I & II)	
F31.30	Bipolar disorder, current episode depressed, mild or moderate severity, unspecified
F31.31	Bipolar disorder, current episode depressed, mild
F31.32	Bipolar disorder, current episode depressed, moderate
F31.4	Bipolar disorder, current episode depressed, severe, without psychotic features
F31.5	Bipolar disorder, current episode depressed, severe, with psychotic features
F31.81	Bipolar II disorder
F31.89	Other bipolar disorder
F31.9	Bipolar disorder, unspecified

Examples of ICD-10 Codes for Schizophrenia	
F20.0	Paranoid schizophrenia
F20.1	Disorganized schizophrenia
F20.2	Catatonic schizophrenia
F20.3	Undifferentiated schizophrenia
F20.5	Residual schizophrenia
F20.89	Other schizophrenia
F20.9	Schizophrenia, unspecified

*Disclaimer: These codes are presented for informational purposes only. They represent no statement, promise, or guarantee by Intra-Cellular Therapies, Inc., concerning coverage and/or levels of reimbursement, payment, or charge and are not intended to increase or maximize reimbursement by any payer. It is the responsibility of the healthcare provider to determine the appropriate code(s) for service provided to his or her patient. Laws, regulations, and policies concerning reimbursement are complex and updated frequently. Although we have made an effort to be current as of September 2024, the information may not be current or comprehensive when you view it. Please consult the applicable payer organization with regard to local or actual coverage, reimbursement policies, and determination processes.

ICD-10=International Classification of Diseases, Tenth Revision

Important Safety Information

Warnings & Precautions: Antipsychotic drugs have been reported to cause:

- **Cerebrovascular Adverse Reactions in Elderly Patients with Dementia-Related Psychosis,** including stroke and transient ischemic attack. See Boxed Warning on cover.

Please see additional Important Safety Information, including Boxed Warnings, on pages 9-10 and full Prescribing Information.

CAPLYTA® (lumateperone) capsules

Help your eligible* patients pay less for CAPLYTA

Scan QR code to see how you can help your patients save on CAPLYTA

LYTAlink™ Savings Offer

ELIGIBLE* PATIENTS MAY PAY AS LITTLE AS $0 FOR THE FIRST TWO FILLS
Up to a 30-day supply

$15 FOR SUBSEQUENT FILLS OF CAPLYTA
Up to a 90-day supply

Eligible* patients can text "CAPLYTA" to 26789 to receive the CAPLYTA savings card on their phone

Message and data rates may apply. Message frequency varies. Text HELP for help. Text STOP to end. See Terms and Conditions and Privacy Policy.

When patients opt-in via text, they will also receive:

- **Text message updates** about their prescription
- **Alerts on savings** and the status of their insurance coverage
- **Refill reminders** and the option to order the refills via text

Patients can opt out at any time

*This offer is valid for eligible new or existing patients who are filling a prescription for CAPLYTA. Eligible patients must be 18 years of age or older, residents of the U.S., excluding Puerto Rico and have a valid prescription for CAPLYTA for a Food & Drug Administration approved indication. This Savings program is valid ONLY for patients with private commercial insurance and NOT valid for prescriptions reimbursed under Medicaid, a Medicare drug benefit plan, TRICARE, or other federal or state health programs. Offer is only good at participating retail pharmacies. Offer is not transferable, is not insurance, has no cash value, and may not be used in combination with other offers. Void if prohibited by law, taxed, or restricted.

All participants are responsible for reporting the receipt of all Program benefits as required by their insurance provider. No party may seek reimbursement for all or any of the benefit received through this Program. Intra-Cellular Therapies reserves the right to rescind, revoke or amend the Program without notice at any time. Additional eligibility criteria apply. Please see pages 5-6 for full Eligibility Criteria and Terms & Conditions.

Please see Important Safety Information, including Boxed Warnings, on pages 9-10 and full Prescribing Information.

CAPLYTA® (lumateperone) capsules

See how Medicare Part D/low-income subsidy patients can receive help with prescription costs through Medicare[8,9]*

Medicare Part D patients are automatically enrolled in Extra Help if they are:

- Dual eligible: receive both Medicare and Medicaid, or are older than 65 years and on Medicaid
- Receiving Supplemental Security Income
- Members of a Medicare Savings Program

Patients who are enrolled in Extra Help pay a maximum of $11.20 for brand name prescriptions[10]

Medicare beneficiaries receiving LIS get assistance in paying for their Part D monthly premium, annual deductible, coinsurance, and copayments. Also, individuals enrolled in the Extra Help program do not have a gap in prescription drug coverage, also known as the coverage gap, or the Medicare "donut hole"[8]

*This government program is also known as **Extra Help**.

***By using the CAPLYTA Savings Card, you acknowledge that you currently meet all Eligibility Criteria and Terms & Conditions and will comply with the terms & conditions below.**

PROGRAM ELIGIBILITY CRITERIA AND TERMS & CONDITIONS:

This offer is valid for eligible new or existing patients who are filling a prescription for CAPLYTA.

Patients must be 18 years of age or older, residents of the United States, excluding Puerto Rico, and have a valid prescription for CAPLYTA.

Patients must have private commercial insurance. Offer is **not** valid for prescriptions reimbursed under Medicaid, a Medicare drug benefit plan, TRICARE, or other federal or state health programs (such as medical assistance programs). This offer is not insurance, has no cash value and may not be used in combination with any other discount, coupon, rebate, free trial, savings, or similar offer.

This savings card is not valid when the entire cost of your prescription drug is eligible to be reimbursed by your private insurance plan or other private health or pharmacy benefit programs. You must deduct the value of this savings card from any reimbursement request submitted to your private insurance plan, either directly by you or on your behalf. You are responsible for reporting use of the savings card to any private commercial insurer, health plan, or other third party who pays for or reimburses any part of the prescription filled using the savings card, as may be required. You should not use the savings card if your insurer or health plan prohibits use of manufacturer savings cards.

This offer is good only at participating retail pharmacies. This card may not be redeemed for cash. Void if prohibited by law, taxed, or restricted. Eligible patients may pay as little as $0 on the first two fills, up to the maximum lifetime benefit based on current list price of 30-day supply. On subsequent uses, eligible patients may pay as little as $15, up to the maximum benefit of $600. Program benefit calculated on FDA-approved dosing.

A valid Prescriber ID# is required on the prescription. Intra-Cellular Therapies reserves the right to rescind, revoke, or amend this offer without notice at any time.

Data related to the redemption of this savings card may be collected, analyzed, and shared with Intra-Cellular Therapies for market research and/or other purposes related to assessing the CAPLYTA Savings Program.

By using this offer, you authorize the CAPLYTA Savings Program to share your prescription information with CoverMyMeds so that CoverMyMeds may contact your healthcare provider to request submission of information to support coverage of your CAPLYTA prescription by your health insurance plan.

This program is valid through 04/30/2025.

No other purchase is necessary.

Intra-Cellular Therapies reserves the right to rescind, revoke, or amend this offer without notice.

Patients with questions about the CAPLYTA Savings Card should call 1-800-639-4047.

Pharmacist: When you apply this offer, you are certifying that you have not submitted a claim for reimbursement under any federal, state, or other governmental programs for this prescription. This offer is valid only for patients with commercial insurance. Participation in this program must comply with all applicable laws and regulations as a pharmacy provider. **By participating in this program, you are certifying that you will comply with the terms & conditions described in the Restrictions section below.**

Pharmacist instructions for a patient with an Eligible Third Party: Submit the claim to the primary Third-Party Payer first, then submit the balance due to **Change Healthcare** as a Secondary Payer as a copay-only billing using a valid Other Coverage Code. Eligible patients may pay as little as $0 on the first two uses, up to the maximum lifetime benefit based on current list price of 30-day supply. On subsequent uses, eligible patients may pay as little as $15, up to the maximum benefit of $600. Reimbursement will be received from **Change Healthcare**.

For any questions regarding **Change Healthcare** online processing, please call the Help Desk at 1-800-433-4893.

Restrictions: This offer is valid in the United States, excluding Puerto Rico. Offer not valid for prescriptions reimbursed under Medicaid, a Medicare drug benefit plan, TRICARE, or other federal or state health programs (such as medical assistance programs). This offer is valid only for patients with commercial insurance. Cash Discount Cards and other non-insurance plans are not valid as primary under this offer. If the patient is eligible for drug benefits under any such program, the patient cannot use this offer. **By using this offer, the patient certifies that he or she will comply with any terms of his or her health insurance contract requiring notification to his or her payer of the existence and/or value of this offer.** It is illegal to (or offer to) sell, purchase, or trade this offer. Program expires 04/30/2025. This offer is not transferable and is limited to one offer per person. Not valid if reproduced.

Void where prohibited by law. Program managed by ConnectiveRx on behalf of Intra-Cellular Therapies.

Intra-Cellular Therapies reserves the right to rescind, revoke, or amend this offer without notice at any time.

Please see Important Safety Information, including Boxed Warnings, on pages 9-10 and full Prescribing Information.

CAPLYTA® (lumateperone) capsules

PA submission information

The guidance outlined below may be helpful as you fill out and submit PAs for your patients

The following information may be needed for the PA:

CLINICAL DIAGNOSIS	PREVIOUS THERAPY WITHIN THE LAST 12 MONTHS
Please see ICD-10 codes *(available on page 2)* CAPLYTA is indicated in adults for the treatment of schizophrenia and depressive episodes associated with bipolar I or II disorder (bipolar depression), as monotherapy and as adjunctive therapy with lithium or valproate **Adult patients (aged ≥ 18 years):** List all of the patient's diagnoses for the product being requested	List all previous bipolar depression or schizophrenia products prescribed for the patient over the last 12 months

PA=prior authorization.

How to resolve common PA requirements for CAPLYTA

TOP REASONS	HOW TO RESOLVE
The patient must try/fail all preferred alternatives	Some plans require patients to try one or more generic options before covering CAPLYTA. Please list all previous therapy agents as appropriate.
The patient's diagnosis is not consistent with the drug's indication	See page 2 for ICD-10 codes that can be used with CAPLYTA*

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Important Safety Information

Warnings & Precautions: Antipsychotic drugs have been reported to cause:

- **Neuroleptic Malignant Syndrome,** which is a potentially fatal reaction. Signs and symptoms include hyperpyrexia, muscle rigidity, delirium, autonomic instability, elevated creatinine phosphokinase, myoglobinuria (and/or rhabdomyolysis), and acute renal failure. Manage with immediate discontinuation of CAPLYTA and provide intensive symptomatic treatment and monitoring.

Please see additional Important Safety Information, including Boxed Warnings, on pages 9-10 and full Prescribing Information.

Use CoverMyMeds for help navigating the PA process

CoverMyMeds services include:

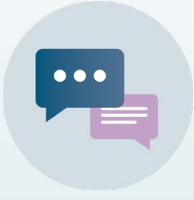
- **Support for submitting requests** to any health plan
- **Faster determinations** (often in real-time and with live monitoring)
- **Appeal forms** generated for denied requests

Visit CoverMyMeds.com and click **"Create an Account"** to register. Once registered, you can **log into CoverMyMeds and begin the ePA**

Need help getting started?

Visit **CoverMyMeds.com** to initiate the Prior Authorization process for both commercially- and government-insured patients.

Call CoverMyMeds at
1-866-452-5017



Live chat at
CoverMyMeds.com

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CAPLYTA® (lumateperone) capsules

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- **Neuroleptic Malignant Syndrome,** which is a potentially fatal reaction. Signs and symptoms include hyperpyrexia, muscle rigidity, delirium, autonomic instability, elevated creatinine phosphokinase, myoglobinuria (and/or rhabdomyolysis), and acute renal failure. Manage with immediate discontinuation of CAPLYTA and provide intensive symptomatic treatment and monitoring.
- **Tardive Dyskinesia (TD),** a syndrome of potentially irreversible, dyskinetic, and involuntary movements which may increase as the duration of treatment and total cumulative dose increases. The syndrome can develop after a relatively brief treatment period, even at low doses, or after treatment discontinuation. Given these considerations, CAPLYTA should be prescribed in a manner most likely to reduce the risk of TD. Discontinue CAPLYTA if clinically appropriate.
- **Metabolic Changes,** including hyperglycemia, diabetes mellitus, dyslipidemia, and weight gain. Hyperglycemia, in some cases extreme and associated with ketoacidosis, hyperosmolar coma or death, has been reported in patients treated with antipsychotics. Measure weight and assess fasting plasma glucose and lipids when initiating CAPLYTA and monitor periodically during long-term treatment.
- **Leukopenia, Neutropenia, and Agranulocytosis (including fatal cases).** Perform complete blood counts in patients with pre-existing low white blood cell count (WBC) or history of leukopenia or neutropenia. Discontinue CAPLYTA if clinically significant decline in WBC occurs in absence of other causative factors.
- **Orthostatic Hypotension and Syncope.** Monitor heart rate and blood pressure and warn patients with known cardiovascular or cerebrovascular disease. Orthostatic vital signs should be monitored in patients who are vulnerable to hypotension.
- **Falls.** CAPLYTA may cause somnolence, postural hypotension, and motor and/or sensory instability, which may lead to falls and, consequently, fractures and other injuries. Assess patients for risk when using CAPLYTA.
- **Seizures.** Use CAPLYTA cautiously in patients with a history of seizures or with conditions that lower seizure threshold.
- **Potential for Cognitive and Motor Impairment.** Advise patients to use caution when operating machinery or motor vehicles until they know how CAPLYTA affects them.
- **Body Temperature Dysregulation.** Use CAPLYTA with caution in patients who may experience conditions that may increase core body temperature such as strenuous exercise, extreme heat, dehydration, or concomitant anticholinergics.

- **Dysphagia.** Use CAPLYTA with caution in patients at risk for aspiration.

Drug Interactions: Avoid concomitant use with CYP3A4 inducers. Reduce dose for concomitant use with strong CYP3A4 inhibitors (10.5 mg) or moderate CYP3A4 inhibitors (21 mg).

Special Populations: Neonates exposed to antipsychotic drugs during the third trimester of pregnancy are at risk for extrapyramidal and/or withdrawal symptoms following delivery. Reduce dose for patients with moderate or severe hepatic impairment (21 mg).

Adverse Reactions: The most common adverse reactions in clinical trials with CAPLYTA vs placebo were:

- Schizophrenia: somnolence/sedation (24% vs 10%) and dry mouth (6% vs 2%).
- Bipolar Depression (Monotherapy, Adjunctive therapy): somnolence/sedation (13% vs 3%, 13% vs 3%), dizziness (8% vs 4%, 11% vs 2%), nausea (8% vs 3%, 9% vs 4%), and dry mouth (5% vs 1%, 5% vs 1%).

CAPLYTA is available in 10.5 mg, 21 mg, and 42 mg capsules.

Please see full Prescribing Information, including Boxed Warnings.

References: 1. CAPLYTA prescribing information. **2.** Vraylar prescribing information. **3.** Seroquel prescribing information. **4.** Zyprexa prescribing information. **5.** Latuda prescribing information. **6.** 2024 ICD-10-CM Codes F31: Bipolar disorder. ICD10Data.com website. https://www.icd10data.com/ICD10CM/Codes/F01-F99/F30-F39/F31- Accessed July 19, 2024. **7.** 2024 ICD-10-CM Codes F20: Schizophrenia. ICD10Data.com website. https://www.icd10data.com/ICD10CM/Codes/F01-F99/F20-F29/F20- Accessed July 19, 2024. **8.** Data on File. **9.** eHealth Insurance. Low-income subsidy-Medicare Extra Help Program. Accessed July 19, 2024. https://www.ehealthinsurance.com/medicare/cost/low-income-subsidy-medicare-extra-help-program **10.** Centers for Medicare and Medicaid Services. Help with drug costs. Updated May 1, 2022. Accessed July 19, 2024. https://www.medicare.gov/basics/costs/help/drug-costs.

CAPLYTA® (lumateperone) capsules

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(lumateperone) capsules

Intra-Cellular THERAPIES

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