

Client/Brand: Otsuka	Client Code:	
Job Number: 0989	Job Name: Otsuka HCP Website 3.2 Update	
MS Version: 03	Reason for Update: Create 3.2 MS	Date: 11/23/2021

**Revision History:**

Version	Owner	Date	Changes Made
1.0	Kate Vaynshteyn	11/18/2021	Manuscript updated by copying 0821 POA M04 and updating to align with L16 of 0989
2.0	Kate Vaynshteyn	11/23/2021	MS updated after editorial w4s against L16, and updated to align with L19
3.0	Kate Vaynshteyn	11/23/2021	MS updated after editorial check change

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GLOBAL ELEMENTS

Global Header

Element / Section:	Global header
Content:	<p>[Global header / Navigation]</p> <p>[Body Copy] This site is intended for US healthcare professionals only.</p> <p>US FULL PRESCRIBING INFORMATION, including <b>BOXED WARNING</b> &lt;&lt;links to PI PDF (<a href="https://www.otsuka-us.com/media/static/ABILIFY-MYCITE-PI.pdf?_ga=2.267468686.1459049773.1601929805-570399579.1598025792">https://www.otsuka-us.com/media/static/ABILIFY-MYCITE-PI.pdf?_ga=2.267468686.1459049773.1601929805-570399579.1598025792</a>) &gt;&gt;</p> <p>Patient site &lt;&lt;links to <a href="https://www.abilifymycite.com/">https://www.abilifymycite.com/</a>, Interstitial 1 'Leaving the healthcare provider site'&gt;&gt;</p> <p>{{Icon/Body Copy: Contact us}} &lt;&lt;opens pop up&gt;&gt;</p> <p>&lt;Pop Up&gt;</p> <p>[Subhead] <b>Questions about the ABILIFY MYCITE® System?</b></p> <p>[Body Copy] The MYCITE® Team can help patients and your office staff with:</p> <ul style="list-style-type: none"><li>• {{Icon: Headset}}[Body Copy]<b>Questions and technical support</b></li><li>• {{Icon: Rx symbol}}[Body Copy]<b>Contacting the specialty pharmacy regarding a patient's prescription and refills</b></li><li>• {{Icon: Gear}}[Body Copy]<b>Setting up your MYCITE® Dashboard</b></li></ul>

	<p><b>Call us at 844-MYCITE-3 (844-692-4833).</b> We are available [8 AM to 8 PM eastern time, Monday through Friday].</p>
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## Global Navigation

Element / Section:	Global Nav/Sub Nav
Content:	<p>[Global Nav Content]</p> <p>{{ABILIFY MYCITE logo}} &lt;&lt;links to 0.0 Home&gt;&gt;</p> <p><b>HOME</b> &lt;&lt;links to 0.0 Home&gt;&gt;</p> <p><b>WHY</b> &lt;&lt;links to 1.0 Why&gt;&gt;</p> <p><b>ABOUT</b> &lt;&lt;links to 2.0 About&gt;&gt;</p> <p><b>WHO</b> &lt;&lt;links to 3.0 Who&gt;&gt;</p> <p><b>HOW</b> &lt;&lt;links 4.0 How&gt;&gt;</p> <p><b>GET STARTED</b> &lt;&lt;links to 5.0 Prescribe&gt;&gt;</p> <p><b>SUPPORT</b> &lt;&lt;links to 6.0 Support&gt;&gt;</p> <p><b>DASHBOARD</b> &lt;&lt;links to MYCITE Dashboard, Interstitial 8&gt;&gt;</p> <p>[Sub Navigation]</p> <p>{{Navigation/Body copy}} Scroll v</p> <p>{{Icon/Body Copy on side nav Top}} &lt;&lt;sends user back to top of the page&gt;&gt;</p> <p>{{+/- Symbol}}[Body Copy]&lt;&lt;expands/collapses ISI&gt;&gt;</p>

## Global Important Safety Information

Element / Section:	Global ISI
Content:	<p data-bbox="475 317 1416 394"><b>IMPORTANT SAFETY INFORMATION and INDICATIONS for ABILIFY MYCITE® (aripiprazole tablets with sensor)</b></p> <p data-bbox="475 457 613 489">[subhead]</p> <p data-bbox="475 506 982 537"><b>IMPORTANT SAFETY INFORMATION</b></p> <p data-bbox="475 548 1380 625"><b>WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS</b></p> <p data-bbox="475 636 1404 856">Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death (1.6 to 1.7 times) compared to placebo-treated patients. ABILIFY MYCITE is not approved for the treatment of patients with dementia-related psychosis.</p> <p data-bbox="475 915 1187 947"><b>WARNING: SUICIDAL THOUGHTS AND BEHAVIORS</b></p> <p data-bbox="475 957 1404 1314">Antidepressants increased the risk of suicidal thoughts and behavior in children, adolescents, and young adults. Those on antidepressant therapy should be monitored closely for worsening, and for emergence of suicidal thoughts and behaviors. Advise families and caregivers of the need for close observation and communication with the prescriber. The safety and effectiveness of ABILIFY MYCITE have not been established in pediatric patients.</p> <p data-bbox="475 1371 1386 1449"><b>Contraindication:</b> Known hypersensitivity reaction to aripiprazole. Reactions have ranged from pruritus/urticaria to anaphylaxis.</p> <p data-bbox="475 1505 1414 1770"><b>Cerebrovascular Adverse Events, Including Stroke, in Elderly Patients with Dementia-Related Psychosis:</b> Increased incidence of cerebrovascular adverse events (e.g., stroke, transient ischemic attack), including fatalities, have been reported in clinical trials of elderly patients with dementia-related psychosis treated with aripiprazole.</p>

**Neuroleptic Malignant Syndrome (NMS):** NMS is a potentially fatal symptom complex reported in association with administration of antipsychotic drugs, including ABILIFY MYCITE. Clinical signs of NMS are hyperpyrexia, muscle rigidity, altered mental status, and evidence of autonomic instability. Additional signs may include elevated creatine phosphokinase, myoglobinuria (rhabdomyolysis), and acute renal failure. Manage NMS with immediate discontinuation of ABILIFY MYCITE, intensive symptomatic treatment, and monitoring.

**Tardive Dyskinesia (TD):** Risk of TD, and the potential to become irreversible, are believed to increase with duration of treatment and in total cumulative dose of antipsychotic drugs. TD can develop after a relatively brief treatment period, even at low doses, or after discontinuation. If antipsychotic treatment is withdrawn, TD may remit, partially or completely. Prescribing should be consistent with the need to minimize TD.

**Metabolic Changes:** Atypical antipsychotic drugs have caused metabolic changes including:

- **Hyperglycemia/Diabetes Mellitus:** Hyperglycemia, in some cases extreme and associated with ketoacidosis, hyperosmolar coma, or death, has been reported in patients treated with atypical antipsychotics including aripiprazole. Patients with diabetes mellitus should be regularly monitored for worsening of glucose control; those with risk factors for diabetes (e.g., obesity, family history of diabetes), should undergo baseline and periodic fasting blood glucose testing. Any patient treated with atypical antipsychotics should be monitored for symptoms of hyperglycemia including polydipsia, polyuria, polyphagia, and weakness. Patients who develop symptoms of hyperglycemia should also undergo fasting blood glucose testing. In some cases, hyperglycemia has resolved when the atypical antipsychotic was discontinued; however, some patients required continuation

of anti-diabetic treatment despite discontinuation of the suspect drug.

- **Dyslipidemia:** Undesirable alterations in lipids have been observed in patients treated with atypical antipsychotics.
- **Weight Gain:** Weight gain has been observed with atypical antipsychotic use. Clinical monitoring of weight is recommended.

**Pathological Gambling and Other Compulsive Behaviors:** Intense urges, particularly for gambling, and the inability to control these urges have been reported while taking aripiprazole. Other compulsive urges have been reported less frequently. Prescribers should ask patients or their caregivers about the development of new or intense compulsive urges. Consider dose reduction or stopping ABILIFY MYCITE if such urges develop.

**Orthostatic Hypotension:** ABILIFY MYCITE may cause orthostatic hypotension and should be used with caution in patients with known cardiovascular disease, cerebrovascular disease, or conditions which would predispose them to hypotension.

**Falls:** Antipsychotics may cause somnolence, postural hypotension, motor and sensory instability, which may lead to falls causing fractures or other injuries. For patients with diseases, conditions, or medications that could exacerbate these effects, complete fall risk assessments when initiating treatment and recurrently during therapy.

**Leukopenia, Neutropenia, and Agranulocytosis:** Leukopenia, neutropenia and agranulocytosis have been reported with antipsychotics. Monitor complete blood count in patients with pre-existing low white blood cell count (WBC)/absolute neutrophil count or history of drug-induced leukopenia/neutropenia. Discontinue ABILIFY MYCITE at the first sign of a clinically significant decline in WBC and in severely neutropenic patients.

**Seizures:** ABILIFY MYCITE should be used with caution in patients with a history of seizures or with conditions that lower the seizure threshold.

**Potential for Cognitive and Motor Impairment:** ABILIFY MYCITE may impair judgment, thinking, or motor skills. Instruct patients to avoid operating hazardous machinery, including automobiles, until they are certain ABILIFY MYCITE does not affect them adversely.

**Body Temperature Regulation:** Use ABILIFY MYCITE with caution in patients who may experience conditions that increase body temperature (e.g., strenuous exercise, extreme heat, dehydration, or concomitant use with anticholinergics).

**Dysphagia:** Esophageal dysmotility and aspiration have been associated with ABILIFY MYCITE. Use caution in patients at risk for aspiration pneumonia.

**Dosage Adjustments and Cytochrome P450 Considerations:** For patients with schizophrenia and bipolar I disorder taking ABILIFY MYCITE who are:

- Known CYP2D6 poor metabolizers, administer half the recommended dose
- Known CYP2D6 poor metabolizers taking concomitant strong CYP3A4 inhibitors (e.g., itraconazole, clarithromycin), administer a quarter the recommended dose.
- Taking strong CYP2D6 (e.g., quinidine, fluoxetine, paroxetine) or CYP3A4 inhibitors, administer half the recommended dose.
- Taking strong CYP2D6 and CYP3A4 inhibitors, administer a quarter the recommended dose. When co-administered drug is withdrawn, adjust ABILIFY MYCITE dosage to its original level.
- Taking strong CYP3A4 inducers (e.g., carbamazepine, rifampin), double recommended dose over 1 to 2 weeks. When co-administered drug is withdrawn, reduce ABILIFY MYCITE dosage to original level over 1 to 2 weeks.

**Commonly Observed Adverse Reactions** (incidence  $\geq 5\%$  and at least twice that for placebo) in adult patients:

- Schizophrenia: akathisia
- Bipolar mania (monotherapy): akathisia, sedation, restlessness, tremor, and extrapyramidal disorder
- Bipolar mania (adjunctive therapy with lithium or valproate): akathisia, insomnia, and extrapyramidal disorder
- Major depressive disorder (adjunctive treatment to antidepressant therapy): akathisia, restlessness, insomnia, constipation, fatigue, and blurred vision

**Dystonia:** Symptoms of dystonia may occur in susceptible individuals during the first days of treatment and at low doses.

**Skin Irritation for MYCITE Patch:** Symptoms of skin irritation localized at the site of the MYCITE Patch may occur. In clinical studies, 12.4% of patients (n=61) experienced skin rashes at the site of patch placement.

**Pregnancy:** Neonates exposed to antipsychotic drugs, including ABILIFY MYCITE, during the third trimester of pregnancy are at risk for extrapyramidal and/or withdrawal symptoms. Consider the benefits and risks of ABILIFY MYCITE and possible risks to the fetus when prescribing ABILIFY MYCITE to a pregnant woman. Advise pregnant women of potential fetal risk. There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to ABILIFY MYCITE during pregnancy. For more information contact the National Pregnancy Registry for Atypical Antipsychotics at 1-866-961-2388 or visit <http://womensmentalhealth.org/clinical-and-research-programs/pregnancyregistry/> <<Link, interstitial 2 opens; redirect to:  
<https://womensmentalhealth.org/research/pregnancyregistry/atypicalantipsychotic/>>>.

**Lactation:** Aripiprazole is present in human breast milk; however, there are insufficient data to assess the amount in human milk, effects on the breastfed infant, or effects on milk production. The development and health benefits of breastfeeding should be considered along with the mother's clinical need for ABILIFY MYCITE and any potential adverse effects on the infant or from the underlying maternal condition.

To report SUSPECTED ADVERSE REACTIONS, contact Otsuka America Pharmaceutical, Inc. at 1-800-438-9927 <<link phone number>> or FDA at 1-800-FDA-1088 <<link phone number>> ([www.fda.gov/medwatch](http://www.fda.gov/medwatch)).<<Link, Interstitial 3>>

Please see FULL PRESCRIBING INFORMATION <<links to <https://www.otsuka-us.com/media/static/ABILIFY-MYCITE-PI.pdf>>>, including **BOXED WARNING**.

[subhead]

## **INDICATIONS**

ABILIFY MYCITE, a drug-device combination product comprised of aripiprazole tablets embedded with an Ingestible Event Marker (IEM) sensor intended to track drug ingestion, is indicated in adults for the:

- Treatment of schizophrenia
- Treatment of bipolar I disorder as monotherapy and as adjunct to lithium or valproate for:
  - Acute treatment of manic and mixed episodes
  - Maintenance treatment
- Adjunctive treatment of major depressive disorder

**Limitations of Use:** ABILIFY MYCITE has not been shown to improve patient compliance or for use in modifying aripiprazole dosage. It should not be used in "real-time" or during an emergency, because detection may be delayed or not occur.

## Global Footer

Element / Section:	Global Footer
Content:	<p>[Module 1] {{Image: Carlos}}</p> <p>[Subhead]</p> <p>[Body Copy] Hear from a real patient using the ABILIFY MYCITE System.</p> <p>[Button] Watch video &lt;&lt;links to WHO page, Module 1, Carlos's Story&gt;&gt;</p> <p>[Module 2] [Headline] Your patient can share their ABILIFY MYCITE System story</p> <p>[Subhead] Do you have a patient who wants to share about their experience using the ABILIFY MYCITE System?</p> <p>Your patients can contact us to learn more about this opportunity: [Button] Call 1-844-815-0984 [Button] Email [jade@mypatientstory.com] &lt;&lt;mailto:jade@mypatientstory.com&gt;&gt;</p> <p>[Directional] Back to top ^ &lt;&lt;scrolls to top of page&gt;&gt;</p>

[Module 2]

EXPLORE THE ABILIFY MYCITE SYSTEM

Home <<links to 0.0 Home>>

Why <<links to 1.0 Why>>

About <<links to 2.0 About>>

Who <<links to 3.0 Who>>

How <<links 4.0 How>>

Get started <<links to 5.0 Prescribe>>

Support <<links to 6.0 Support>>

Dashboard <<links to Interstitial 8, MYCITE Dashboard>>

US Full Prescribing Information

<<links to PI PDF ([https://www.otsuka-us.com/media/static/ABILIFY-MYCITE-PI.pdf?\\_ga=2.267468686.1459049773.1601929805-570399579.1598025792](https://www.otsuka-us.com/media/static/ABILIFY-MYCITE-PI.pdf?_ga=2.267468686.1459049773.1601929805-570399579.1598025792)) >>

Contact us <<opens Contact us pop up>>

ABILIFY MYCITE System Terms of Use, Privacy Notice, and Authorization & Consent <<links to <https://www.otsuka-us.com/products-solutions-and-patient-support/abilify-mycite-information>, Interstitial 4>>

Otsuka America Pharmaceutical, Inc. Corporate Site <<links to <https://www.otsuka-us.com/>, Interstitial 5>>

Federal Communications Commission (FCC) Statement <<links to [https://www.abilifmycite.com/sites/g/files/qhldwo1746/files/inline-files/12US19EBC0021%20Federal%20Communications%20Commission%20Statement\\_0.pdf](https://www.abilifmycite.com/sites/g/files/qhldwo1746/files/inline-files/12US19EBC0021%20Federal%20Communications%20Commission%20Statement_0.pdf) >>

Privacy Policy <<links to OAPI Privacy Policy, Interstitial 6>>

Terms of Use <<links to Terms of Use, Interstitial 7>>

Site map <<links to Site map>>

{{OAPI logo}} <<links to <https://www.otsuka-us.com/>, Interstitial 5>>

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[Date and job number at the bottom of the Global Footer]

November 2021      ((job number))

HOME ((12US21EBP0057))

WHY ((12US21EBP0019))

ABOUT ((12US21EBP0059))

WHO ((12US20EBP0061))

HOW ((12US21EBP0091))

PRESCRIBE ((12US21EBP0092))

SUPPORT ((12US21EBP0064))

## WEBPAGES

Webpage - Site Map

Element / Section:	E4 - Site Map
URL:	<a href="https://www.abilifymycite.com/site-map">https://www.abilifymycite.com/site-map</a>
Page Title:	Site Map - ABILIFY MYCITE® System
Key Words:	
H1 Tag:	
H2 Tag:	
Page Description	

[Subhead]

### Site map

[Body Copy]

Home <<[links to 0.0 Home](#)>>

Why <<[links to 1.0 Why](#)>>

About <<[links to 2.0 About](#)>>

Who <<[links to 3.0 Who](#)>>

How <<[links 4.0 How](#)>>

Get started <<[links to 5.0 Prescribe](#)>>

Support <<[links to 6.0 Support](#)>>

Dashboard <<[links to MYCITE Dashboard, Interstitial 8](#)>>

US Full Prescribing Information

<<[links to PI PDF \(https://www.otsuka-us.com/media/static/ABILIFY-MYCITE-PI.pdf?\\_ga=2.267468686.1459049773.1601929805-570399579.1598025792\)](https://www.otsuka-us.com/media/static/ABILIFY-MYCITE-PI.pdf?_ga=2.267468686.1459049773.1601929805-570399579.1598025792)>>

Contact us <<opens Contact us pop up>>

ABILIFY MYCITE® System Terms of Use, Privacy Notice, and Authorization & Consent <<links to <https://www.otsuka-us.com/products-solutions-and-patient-support/abilify-mycite-information>, Interstitial 4>>

Otsuka America Pharmaceutical, Inc. Corporate Site <<links to <https://www.otsuka-us.com/>, Interstitial 5>>

Federal Communications Commission (FCC) Statement <<links to [https://www.abilifymycite.com/sites/g/files/qhldwo1746/files/inline-files/12US19EBC0021%20Federal%20Communications%20Commission%20Statement\\_0.pdf](https://www.abilifymycite.com/sites/g/files/qhldwo1746/files/inline-files/12US19EBC0021%20Federal%20Communications%20Commission%20Statement_0.pdf)>>

Element / Section:	0.0 Home
URL:	https://www.abilifymycitehcp.com/
Page Title:	The ABILIFY MYCITE® System - Official HCP Site
Key Words:	
H1 Tag:	
H2 Tag:	
Page Description	

{{Calendar imagery}}

[Image Footnote]

Not a real patient.

[Headline]

**An appointment may only show part of the story.**

[Subhead]

Use data from the ABILIFY MYCITE® System to help spark a rich conversation.

[Button] <<jumps further down page when clicked>>

Learn more

[Directional]

Scroll v

[Subhead]

Could tech support your patient?

[Button]

Learn more <<links to WHY page>>

{{Image: patient}}

[Subhead]

Who is the system for?

[Button]

Find out <<links to WHO page>>

{{Image: Carlos}}

[Subhead]

How does the system work?

[Button]

Discover more <<links to HOW page>>

{{Image: system graphic}}

[Subhead]

Get your patient started

[Button]

Learn how <<links to GET STARTED page>>

{{Image: hand holding phone with MYCITE App}}

Element / Section:	1.0 Why
URL:	<a href="https://www.abilifymycitechcp.com/why-technology-supports-patients">https://www.abilifymycitechcp.com/why-technology-supports-patients</a>
Page Title:	Why Technology Supports Patients - ABILIFY MYCITE® System
Key Words:	
H1 Tag:	
H2 Tag:	
Page Description	

[Sub-menu navigation]

- Understanding adherence <<links to Module 1>>
- How tech supports patients <<links to Module 2>>

[Directional]

Top ↑

[Module 1]

{{Image: Patient}}

[Headline]

**Is there a need for an objective measure of adherence?**

[Body Copy]

**Knowing how often your patients are taking their medication may change how you treat them.** Without an objective measure of medication ingestion, healthcare providers are often left to rely on subjective reports to assess adherence, an important factor in determining whether or not a patient is responding to medication.<sup>1,2</sup>

[Directional]

Scroll v

[Module 1]

[Subhead]

## **Did you know?**

{{54% graphic}}

**In a study of patients taking oral antipsychotics, 54% of physicians (N=153) over- or underestimated adherence<sup>3</sup>**

{{50% graphic}}

**Nonadherence was estimated to be up to 50% in patients with bipolar disorder, major depressive disorder, and/or schizophrenia<sup>3-5</sup>**

[Body Copy]

### **Study design**

Based on survey responses from 153 physicians and retrospective claims data for 214 of their commercial patients with schizophrenia and/or bipolar disorder. Patients were regularly seen for at least 1 year and were treated with an oral antipsychotic between May 2008 and April 2009 (1 to 2 patients per physician). The survey assessed physician perceptions of the level of medication adherence (for a maximum of 2 specific patients in their practice) and the physician's beliefs, attitudes, and behaviors regarding medication adherence in general.<sup>3</sup>

[Module 2]

{{Icon: Smartphone}}

[Subhead]

## **How tech supports patients**

[Subhead]

**Technology may help patients take a more active role in their treatment<sup>6-8</sup>**

[Body Copy]

Some patients with mental health disorders may feel more comfortable sharing information about their mental health using a mobile app. In fact, they may already be using their smartphones to monitor their behavior and activity.

[Module 3]

[Subhead]

**In a survey of 82 patients with mental health disorders,<sup>8</sup>**

**{{89% graphic}}**

**owned smartphones and used them daily**

**{{84% graphic}}**

**said they might use an app to monitor their mental health**

[Body Copy]

**Study design**

The 2016-2017 survey was conducted with 82 patients at the START (Stress, Trauma, Anxiety, Rehabilitation, Treatment) Clinic for Mood and Anxiety Disorders. The survey measured mobile phone ownership, use, and willingness to install a mental health monitoring app and provide relevant data through the app.<sup>8</sup>

[Module 6]

[Subhead]

**81 participants in a survey found value in using smartphones to record various factors related to their mental health to help<sup>9</sup>:**

**{{Icon:Magnifying glass}}[Body copy] Get insights into patterns of behavior**

**{{Icon:Clipboard}}[Body copy] Keep track of progress**

**{{Icon:Person}}[Body copy] See if behavior is changing**

**{{Icon:Mood emojis}}[Body copy] Self-report and quantify moods**

[Body Copy]

**Study design**

Responses from 81 patients were analyzed in the 2017 online survey. Patients were recruited on social networks and the survey explored the user's usage patterns, frequently used features, and engagement with technology.<sup>9</sup>

[Module 7]

[Callout]

{{Image: In-Situ/Kit}}

[Subhead]

**Discover how the ABILIFY MYCITE<sup>®</sup> System can provide data-driven insights to help inform treatment decisions.**

[Button]

Learn more <<links to 2.0 About>>

[Footnote]

Not a real patient.

[References]

[Body Copy]

**References** <<flip arrow to expand>>

1. Shafrin J, May SG, Shrestha A, et al. Access to credible information on schizophrenia patients' medication adherence by prescribers can change their treatment strategies: evidence from an online survey of providers. *Patient Prefer Adherence*. 2017;11:1071-1081. doi:10.2147/PPA.S135957
2. Peters-Strickland T, Pestreich L, Hatch A, et al. Usability of a novel digital medicine system in adults with schizophrenia treated with sensor-embedded tablets of aripiprazole. *Neuropsychiatr Dis Treat*. 2016;12:2587-2594. doi:10.2147/NDT.S116029
3. Stephenson JJ, Tunceli O, Gu T, et al. Adherence to oral second-generation antipsychotic medications in patients with schizophrenia and bipolar disorder: physicians' perceptions of adherence vs. pharmacy claims. *Int J Clin Pract*. 2012;66(6):565-573. doi:10.1111/j.1742-1241.2012.02918.x
4. Haddad PM, Brain C, Scott J. Nonadherence with antipsychotic medication in schizophrenia: challenges and management strategies. *Patient Rel Outcome Meas*. 2014;5:43-62. doi:10.2147/PROM.S42735
5. Sansone RA, Sansone LA. Antidepressant adherence: are patients taking their medications? *Innov Clin Neurosci*. 2012;9(5-6):41-46.
6. Torous J, Chan SR, Yee-Marie TS, et al. Patient smartphone ownership and interest in mobile apps to monitor symptoms of

mental health conditions: a survey in four geographically distinct psychiatric clinics. *JMIR Ment Health*. 2014;1(1):e5. doi:10.2196/mental.4004 **7.** Gay K, Torous J, Joseph A, Pandya A, Duckworth K. Digital technology among individuals with schizophrenia: results of an online survey. *JMIR Ment Health*. 2016;3(2):e15. doi:10.2196/mental.5379 **8.** Di Matteo D, Fine A, Fotinos K, Rose J, Katzman M. Patient willingness to consent to mobile phone data collection for mental health apps: structured questionnaire. *JMIR Ment Health*. 2018;5(3):e56. doi:10.2196/mental.9539 **9.** Stawarz K, Preist C, Coyle D. Use of smartphone apps, social media, and web-based resources to support mental health and well-being: online survey. *JMIR Ment Health*. 2019;6(7):e12546. doi:10.2196/12546

Element / Section:	2.0 About
URL:	https://www.abilifymycitechcp.com/about
Page Title:	About the System - ABILIFY MYCITE® System
Key Words:	
H1 Tag:	
H2 Tag:	
Page Description	

[Sub-menu navigation]

- What the ABILIFY MYCITE System does <<links to Module 2>>
- Explore the MYCITE® Dashboard <<links to Module 3>>
- Explore the MYCITE® App <<links to Module 4>>
- Why the ABILIFY MYCITE System <<links to Module 5>>

[Directional]

Top ↑

[Module 1]

{{Image: ABILIFY MYCITE System Starter Kit}}

[Footnote]

ABILIFY MYCITE® Starter Kit

[Headline]

**About the ABILIFY MYCITE® System**

[Body Copy]

Meet the first FDA-approved digital medicine system. It captures robust objective and patient-reported data to help encourage communication among care-team members and creates opportunities for more personalized treatment decisions.<sup>1,2</sup>

[Directional]

Scroll v

[Safety]

ABILIFY MYCITE<sup>®</sup> (aripiprazole tablets with sensor) has not been shown to improve patient compliance or for use in modifying aripiprazole dosage. It should not be used in “real-time” or during an emergency, because detection may be delayed or not occur.

[Module 2]

[Subhead]

## What the ABILIFY MYCITE System does

[Body Copy]

The system combines wearable and ingestible sensors, smartphone technology, and patient-reported experiences to record a combination of<sup>1</sup>:

[Subhead]

### Objective data

[Grid]

{{Icon: Pill}} [Body Copy] **Medication ingestion**

[Flip] Date and time of ingestion of ABILIFY MYCITE

{{Icon: Person walking}} [Body Copy] **Activity level (number of steps)**

[Flip] Steps taken and miles walked every 24 hours

{{Icon: Clock}} [Body Copy] **Time spent resting**

[Flip] Extended periods of time when a patient’s body is resting in a flat position up to an angle of 30°

[Grid]

[Subhead]

### Patient-reported data

{{Icon: Mood emojis}} [Body Copy] **Mood**

[Flip] Self-reported data, based on a 7-point visual scale from 1 (angry) to 7 (excited)

{{Icon: Resting person}} [Body Copy] **Rest quality**

[Flip] Quality of rest, based on a 5-point visual scale

{{Icon: Smartphone + question}} [Body Copy] **Reason for a missed dose**

[Flip] Self-reported reasons for missing a dose:

- I didn't feel like it
- I forgot
- I couldn't
- I took it after midnight
- I took my tablet but it did not register on the app

[Body Copy]

**Only functions related to tracking drug ingestion have been evaluated or approved by FDA.**

[/Grid]

[Callout]

**Use data-driven insights captured by the ABILIFY MYCITE System to help inform treatment decisions.<sup>1</sup>**

[Module 3]

[Headline]

**Explore the MYCITE® Dashboard**

[Subhead]

Get a more complete view of what's happening between appointments, with the MYCITE Dashboard. View each tab below to learn about dashboard features.

[<<Icons and copy for each tab shows different dashboard screens when clicked>>]

{{Icon: Desktop}}[Copy] Overview

{{Icon: Pill}}[Copy] Medication ingestion

{{Icon: Emoji}}[Copy] Mood

{{Icon: Person walking}}[Copy] Activity

{{Icon: Person resting}}[Copy] Rest

{{Images: Dashboard screens}} <<different screens of the dashboard for HCP to flip through with arrows and breadcrumbs>>

[Image Footnote under each dashboard screen]

Illustrative data. Not from a real patient.

[Body Copy corresponding to dashboard screens and icons above]

Review patients' daily data at a glance

Keep track of when they take ABILIFY MYCITE

Review patient-reported mood

View activity level

See rest and patient-reported rest quality

[Safety - under each view of the dashboard screens]

**The impact of the ABILIFY MYCITE System on treatment adherence has not been demonstrated. Some factors, such as connectivity, transmitter malfunction, or device availability, may impact the consistency and reliability of data detection, collection and transmission. Only functions related to tracking drug ingestion have been evaluated or approved by FDA.**

[Subhead]

The MYCITE Dashboard is an online portal for healthcare providers<sup>1,2</sup>

[Grid]

[Subhead]

You can:

[Body Copy]

- {{Icon: Desktop}}[Body Copy] **Get insight into medication-taking patterns**
- {{Icon: Phone with question mark}}[Body Copy] **See snapshot views of patient medication ingestion and other daily data**

- **Review daily data with your patient to better support their treatment plan**

[Callout]

**By looking at the same set of patient data in the MYCITE Dashboard, healthcare providers and other care-team members are able to align on objective data and patient-reported information.<sup>1</sup>**

[Module 4]

[Subhead]

### **Explore the MYCITE® App**

[Body Copy] Get an inside look at the app and what it can offer your patients. View each tab below to learn about app features. [<<MYCITE App video and 4 different screens of the MYCITE® App to flip through with arrows on the side and breadcrumbs>>](#)

[<<Icons and copy for each tab shows app video and different app screens when clicked>>](#)

**Video**

**Pill status**

**Mood**

**Rest**

**Activity**

**Overview**

[Screen 1: MYCITE App video]

[Image Footnote for each screen]

Illustrative data. Not from a real patient.

**[Body copy for each screen, screens 2-5]**

**Patients can keep track of when they take ABILIFY MYCITE**

**Patients can see how they rated their mood**

**Patients can see rest and rate how well they rested**

Patients can check their activity level

Patients can see weekly and monthly views of their data

[Safety - under each view of the App screen]

**The impact of the ABILIFY MYCITE System on treatment adherence has not been demonstrated. Some factors, such as connectivity, transmitter malfunction, or device availability, may impact the consistency and reliability of data detection, collection and transmission. Only functions related to tracking drug ingestion have been evaluated or approved by FDA.**

[Module 6]

[Headline]

## **Why the ABILIFY MYCITE System**

[Subhead]

### **Benefits for you**

[Grid]

[Body Copy]

Visibility into your patients' medication-taking patterns and other data may help you<sup>2,4</sup>:

- **Identify factors contributing to nonadherence**
- **Assess treatment response, if adherent**
- **Personalize treatment strategies**
- **Strengthen the therapeutic alliance**
- **Foster a more open dialogue**
- **Engage and empower patients**

[Subhead]

### **Benefits for your patient**

[Grid]

[Body Copy]

By seeing their daily data, your patients have the opportunity to<sup>1,2,5</sup>:

- **Icon: Rising Star** **Be proactive** in managing their mental health condition and reaching their treatment goals
- **Icon: Pill** **Better understand** their treatment, see if they're taking their medication, and have greater insight into their medication ingestion patterns, mood, activity level, and rest
- **Icon: Laptop** **Share their information** with their care team and support network so patients:
  - Don't have to remember everything that has happened between appointments
  - Stay connected throughout their treatment

#### [Safety]

**The impact of the ABILIFY MYCITE System on treatment adherence has not been demonstrated. Some factors, such as connectivity, transmitter malfunction, or device availability, may impact the consistency and reliability of data detection, collection and transmission. Only functions related to tracking drug ingestion have been evaluated or approved by FDA.**

#### [Callout]

**The ABILIFY MYCITE System gives patients more ways to connect to their care team and support network. When everyone is working with the same information, it can help reduce uncertainty and foster trust.<sup>1,2</sup>**

#### [Callout]

**Image: Patient**

#### [Image Footnote]

Not a real patient.

#### [Subhead]

**Which of your patients are appropriate for the ABILIFY MYCITE System?**

#### [Button]

Find out <<[links to 3.0 Who](#)>>

#### [References]

#### [Body Copy]

## References <<flip to show references>>

1. Otsuka and Proteus® announce the first U.S. FDA approval of a digital medicine system: ABILIFY MYCITE® (aripiprazole tablets with sensor). News release. Otsuka America Pharmaceutical, Inc. November 14, 2017. Accessed November 1, 2021. <https://www.otsuka-us.com/discover/articles-1075>
2. Hatch A, Docherty JP, Carpenter D, Ross R, Weiden PJ. Expert consensus survey on medication adherence in psychiatric patients and use of a digital medicine system. *J Clin Psychiatry*. 2017;78(7):e803-e812. doi:10.4088/JCP.16m11252
3. Shafrin J, May SG, Shrestha A, et al. Access to credible information on schizophrenia patients' medication adherence by prescribers can change their treatment strategies: evidence from an online survey of providers. *Patient Prefer Adherence*. 2017;11:1071-1081. doi:10.2147/PPA.S135957
4. Elenko E, Underwood L, Zohar D. Defining digital medicine. *Nat Biotechnol*. 2015;33(5):456-461. doi:10.1038/nbt.3222
5. Sawesi S, Rashrash M, Phalakornkule K, Carpenter JS, Jones JF. The impact of information technology on patient engagement and health behavior change: a systematic review of the literature. *JMIR Med Inform*. 2016;4(1):e1. doi:10.2196/medinform.4514

Element / Section:	3.0 Who
URL:	<a href="https://www.abilifymycitechcp.com/who-system-is-right-for">https://www.abilifymycitechcp.com/who-system-is-right-for</a>
Page Title:	The Right Patient - ABILIFY MYCITE® System
Key Words:	
H1 Tag:	
H2 Tag:	
Page Description	

[Sub-menu navigation]

- Video: Carlos's Story—Finding the right support <<links to Module 1>>
- The right patient <<links to Module 2>>
- When to use the ABILIFY MYCITE System <<links to Module 3>>
- Potential patients <<links to Module 4>>

[Directional]

Top ↑

[Directional]

Scroll v

[Module 1]

[Headline]

**Video: Carlos's Story—Finding the right support**

[Body copy]

Learn more about Carlos, a real patient with major depressive disorder (MDD) who uses the ABILIFY MYCITE System.

[Video - Carlos's Story]

## [Module 2]

### [Subhead]

#### **The right patient**

##### [Body copy]

Consider patients who are<sup>1-3</sup>:

##### [Grid]

##### [Subhead/Body Copy]

{{Icon: Person with star}}

##### **Appropriate:**

Adult patients within the indicated population for ABILIFY MYCITE® (aripiprazole tablets with sensor)

{{Icon: Calendar}}

##### **Future focused:**

Patients who have goals and want to move forward or are going through a transitional time in their lives, like changing care settings, or starting something new, like a job or a relationship

{{Icon: Clipboard with checkmark}}

##### **Involved in their treatment:**

Patients who are engaged and want to be more involved in their treatment

{{Icon: Smartphone}}

##### **Tech equipped:**

Patients who are smartphone users, feel comfortable using apps, and have access to a reliable internet connection

##### [Callout]

**Consider the ABILIFY MYCITE System for your patients who could benefit from you having more quantitative data and qualitative information when managing their condition.**

##### [Safety]

The ABILIFY MYCITE System is appropriate for adult patients within the indicated population for ABILIFY MYCITE. Please see INDICATIONS and IMPORTANT SAFETY INFORMATION, including **BOXED WARNING**, [here](https://www.otsuka-us.com/media/static/ABILIFY-MYCITE-PI.pdf).<<links to https://www.otsuka-us.com/media/static/ABILIFY-MYCITE-PI.pdf>>

[Module 3]

[Headline]

## When to use the ABILIFY MYCITE System

[Body Copy]

There may be times in your patient's life when an option like the ABILIFY MYCITE System can be an important part of managing their condition.

[Grid]

[Subhead]

The ABILIFY MYCITE System may be particularly useful for managing patients who are<sup>1,4</sup>:

[Body Copy]

**{{Icon: Rx with clock}}** Recently diagnosed

**{{Icon: Hospital}}** Recently discharged from the hospital

**{{Icon: House}}** Changing their living situation

**{{Icon: Alarm clock}}** Lacking a daily routine

**{{Icon: Arrow}}** Experiencing an increase in symptoms and/or side effects after being previously stable

[Module 3]

[Callout]

**{{Image: Patient}}**

[Image Footnote]

Not a real patient.

[Subhead]

**Talk to an Otsuka representative to get your patient started on the ABILIFY MYCITE System.**

[Button]

Get in touch <<links to 6.0 Support>>

[Module 4]

[Headline]

## Potential patients for the ABILIFY MYCITE System

[Subhead]

### Examples of adult patients who may be appropriate for the system

[Patient profile carousel with directional arrows and breadcrumbs]

[Patient 1]

[Headline]

#### Bipolar I disorder

{{Image: Michelle}}

[Image Footnote]

Not a real patient.

[Subhead]

#### Michelle, 33

Has previously tried different treatments and is now stable on aripiprazole after a recent episode.

[Subhead]

#### Relevant clinical history

[Body Copy]

- Initially misdiagnosed with major depressive disorder but was rediagnosed with bipolar I disorder after a manic episode in her early 20s

[Subhead]

## Treatment history

### [Body Copy]

- Has been prescribed different treatments through the years
- After her most recent episode, she was prescribed an oral atypical antipsychotic as monotherapy, which has helped improve her symptoms<sup>5</sup>

### [Subhead]

## Current situation

### [Body Copy]

- Lives with a close female friend, early 30s
- Recently began a new job at a fast-food restaurant but doesn't have a regular schedule of shifts yet
- Is beginning her first romantic relationship with someone she met through a dating app
- Understands the importance of taking her medication routinely
- Without a regular schedule, has expressed concern about taking her daily oral medication as prescribed
- Has insurance through Medicaid

## [Patient 2]

### [Headline]

## Major depressive disorder

{{Image: Erin}}

### [Image Footnote]

Not a real patient.

### [Subhead]

## Erin, 38

### [Body Copy]

Recently began treatment with aripiprazole as adjunctive therapy to an antidepressant. Lately, she has started to receive her care through telemedicine.

[Subhead]

## Relevant clinical history

[Body Copy]

- Diagnosed with major depressive disorder 10 years ago

[Subhead]

## Treatment history

[Body Copy]

- After initial diagnosis, her doctor prescribed an antidepressant<sup>6</sup>
- Following her most recent hospitalization for her depressive symptoms, her nurse practitioner recently added oral aripiprazole to her treatment regimen
- Her first few appointments after her hospitalization were in-office, but she has since switched to seeing her doctor primarily through telemedicine

[Subhead]

## Current situation

[Body Copy]

- Works from home as a marketing associate and uses her smartphone to keep in touch with her team remotely
- Has commercial insurance through her employer
- Married with 2 kids
- Lost interest in gardening, one of her favorite hobbies<sup>6</sup>
- Has recently experienced decreased interest in intimacy with her husband and has difficulty fulfilling daily family responsibilities<sup>6,7</sup>
- Admits she may not always take her medication as her doctor prescribed

[Patient 3]

[Headline]

## Schizophrenia

{{Image: Josh}}

[Image Footnote]

Not a real patient.

[Subhead]

**Josh, 24**

[Body Copy]

Has recently experienced symptoms despite a period of stabilization with his current antipsychotic treatment.

[Subhead]

### **Relevant clinical history**

[Body Copy]

- Diagnosed with schizophrenia 6 months ago
- Presented with symptoms that included apathy, social withdrawal, conceptual disorganization, auditory hallucinations, and disorganized thoughts<sup>8,9</sup>

[Subhead]

### **Treatment history**

[Body Copy]

- Has been on an oral antipsychotic and was stabilized for a few months<sup>8</sup>
- Has experienced symptoms recently

[Subhead]

### **Current situation**

[Body Copy]

- Uses his smartphone daily to listen to music and stream videos
- Wants to accumulate credits toward graduation from junior college
- Lives with his parents, both in their late 40s, but is moving into a new apartment
- Is on his parents' commercial insurance plan
- Knows that taking his medication as directed is important, but admitted to his doctor that he may not always take his oral medication because of his irregular schedule

[Module 5]

[Callout]

{{Image: Patient}}

[Image Footnote]

Not a real patient.

[Subhead]

**See how the ABILIFY MYCITE System works together.**

[Button]

Find out Learn more <<links to 4.0 How>>

[References]

[Body Copy]

**References** <<flips to show references>>

1. Hatch A, Docherty JP, Carpenter D, Ross R, Weiden PJ. Expert consensus survey on medication adherence in psychiatric patients and use of a digital medicine system. *J Clin Psychiatry*. 2017;78(7):e803-e812. doi:10.4088/JCP.16m11252
2. Otsuka and Proteus<sup>®</sup> announce the first U.S. FDA approval of a digital medicine system: ABILIFY MYCITE<sup>®</sup> (aripiprazole tablets with sensor). News release. Otsuka America Pharmaceutical, Inc. November 14, 2017. Accessed November 1, 2021. <https://www.otsuka-us.com/discover/articles-1075>
3. Sawesi S, Rashrash M, Phalakornkule K, Carpenter JS, Jones JF. The impact of information technology on patient engagement and health behavior change: a systematic review of the literature. *JMIR Med Inform*. 2016;4(1):e1. doi:10.2196/medinform.4514
4. Rossom RC, Shortreed S, Coleman KJ, et al. Antidepressant adherence across diverse populations and healthcare settings. *Depress Anxiety*. 2016;33(8):765-774. doi:10.1002/da.22532
5. Bipolar disorder. National Institute of Mental Health. Updated January 2020. Accessed November 1, 2021. <https://www.nimh.nih.gov/health/topics/bipolar-disorder>
6. Depression. National Institute of Mental Health. Updated February 2018. Accessed November 1, 2021. <https://www.nimh.nih.gov/health/topics/depression/index.shtml>
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8. Schizophrenia. National Institute of Mental Health. Updated May 2020. Accessed November 1, 2021. <https://www.nimh.nih.gov/health/topics/schizophrenia/index.shtml>
9. Porcelli S, Van Der

Wee N, van der Werff S, et al. Social brain, social dysfunction and social withdrawal.  
*Neurosci Biobehav Rev.* 2019;97:10-33. doi:10.1016/j.neubiorev.2018.09.012

## Webpage - How

Element / Section:	4.0 How
URL:	<a href="https://www.abilifymycitehcp.com/how-system-works">https://www.abilifymycitehcp.com/how-system-works</a>
Page Title:	How the System Works - ABILIFY MYCITE® System
Key Words:	
H1 Tag:	
H2 Tag:	
Page Description	

### [Sub-menu navigation]

- Meet the components of the system <<links to Module 1>>
  - **{{Icon: pill}}**[Body Copy] A pill
  - **{{Icon: patch}}**[Body Copy] A patch
  - **{{Icon: smartphone}}**[Body Copy] An app
  - **{{Icon: desktop}}**[Body Copy] A dashboard
  - **{{Icon: conversation bubbles}}**[Body Copy] A conversation
- When introducing the system to patients <<links to Module 2>>
- A connected-care system <<links to Module 4>>
- System privacy <<links to Module 5>>

### [Directional]

Top ↑

### [Module 1]

**{{Image: patient}}**

### [Footnote]

Not a real patient.

### [Headline]

**How the ABILIFY MYCITE® System works**

[Body copy]

Digital technology meets medicine in a smart pill.<sup>1</sup>

[Directional]

Scroll v

[Subhead]

## Meet the components of the system

[Body Copy]

A smart pill combined with a wearable Bluetooth<sup>®</sup>\* patch captures medication ingestion and objective physiological data, presented in the MYCITE<sup>®</sup> Dashboard alongside patient-reported data.<sup>1</sup>

[Footnote]

\*Bluetooth is a registered trademark of Bluetooth SIG, Inc.

{{Icon: all components of the system connected}}

[System graphic, with body copy next to each component in icon]

A pill

A patch

An app

A dashboard

A conversation

[Body Copy on Desktop Only]

Click each component to explore the system

[Subhead]

FOR YOUR PATIENT

{{Image: Pill}} [Image caption/title] A PILL

{{Image: Pill}} [Image footnote] Not actual size.

**[Body Copy]** ABILIFY MYCITE® (aripiprazole tablets with sensor) is a smart pill manufactured with integrated technology the size of a grain of sand. It sends a signal to the MYCITE® Patch after ingestion.<sup>1</sup>

ABILIFY MYCITE is available in 2 mg, 5 mg, 10 mg, 15 mg, 20 mg, and 30 mg strength tablets.

### **More questions about the pill?**

**[Button]**

Check FAQs <<[links to Support page, FAQs](#)>>

**[Directional]**

Scroll v

**{{Image: Patch}}** **[Image caption/title]** A PATCH

**[Image footnote]** Not actual size.

**[Body Copy]**

The MYCITE Patch is a nonmedicated, wearable sensor made up of 2 components: a reusable data pod and a weekly disposable adhesive strip that holds the pod in place. The pod contains a slim sensor that automatically logs when your patient takes their medication, as well as specific physiological data, such as activity and rest. Data are sent via Bluetooth® to the MYCITE® App.

### **More questions about the patch?**

**[Button]**

Check FAQs <<[links to Support page, FAQs](#)>>

**{{Image: Smartphone with MYCITE App}}** **[Image caption/title]** AN APP

**[Body Copy]**

The MYCITE App is an easy-to-use smartphone app for the patient to review their ingestion data and daily activity level and to report their rest quality, mood, and reason for missing a dose.

### **More questions about the app?**

**[Button]** Watch video <<[links to Meet the MYCITE App video](#)>>

[Subhead]

FOR YOU

{{Image: Dashboard on monitor}} [Image caption/title] A DASHBOARD

[Image footnote] Illustrative data. Not from real patients.

[Body Copy]

The MYCITE Dashboard is an online portal for healthcare providers and the patient's support network that displays 7-day, 30-day, and 90-day views of medication ingestion, objective physiological data, and patient-reported data over time.

[Icon: Conversation] [Icon caption/title] A CONVERSATION

[Body Copy]

Equipped with the data delivered to you by the ABILIFY MYCITE System, you, your patients, and their care team and support network can have more-informed conversations about your patients' mental health and treatment plans.<sup>1</sup>

[Safety]

The impact of the ABILIFY MYCITE System on treatment adherence has not been demonstrated. Some factors, such as connectivity, transmitter malfunction, or device availability, may impact the consistency and reliability of data detection, collection and transmission.

**Only functions related to tracking drug ingestion have been evaluated or approved by FDA.**

[Module 2]

[Headline]

**When introducing the system to patients**

{{Video: Patient Intro}}

[Body Copy]

Share these videos with your patients to introduce them to the ABILIFY MYCITE System and how it works.

[Videos with "Share video" links in each:

Meet the ABILIFY MYCITE System X:XX  
Meet the MYCITE App X:XX  
Opening the ABILIFY MYCITE Kit X:XX]

[Module 3]

[Callout]

{{Image: Patient}}

[Image Footnote]

Not a real patient.

[Subhead]

**Have more questions about the components of the ABILIFY MYCITE System?**

[Button]

Get answers <<links to 6.0 Support>>

[Module 4]

[Headline]

**A connected-care system for you, your patients, and those who care for them**

[Body Copy]

The ABILIFY MYCITE System gives patients more ways to connect with their care team and support network. With the system, you and your patients will have medication ingestion data at your fingertips. Patients can choose who they want to share their data with, and can change what data they are sharing at any time.<sup>1</sup>

[Grid]

{{Icon: 3 people}}

[Subhead] <<Drop down functionality to display body copy>>

**Care team**

[Body copy]

- Case manager
- Nurse practitioner

- Pharmacist
- Primary care provider
- Psychiatrist
- Psychologist
- Social worker
- Therapist

{{Icon: hands reaching}}

[Subhead] <<Drop down functionality to display body copy>>

## Support network

[Body copy]

- Family members
- Friends

{{Image: Dashboard}}

[Callout]

**When everyone is working with the same information, it can help reduce uncertainty and foster trust.<sup>1,2</sup>**

[Module 5]

[Headline]

## System privacy

[Subhead]

Your data are encrypted and stored securely in the cloud to protect your privacy

{{Icon: cloud with lock}}

[Body Copy]

The patient automatically starts sharing their data with you when they enter your code in the MYCITE App. Other members of the care team will not be able to access daily data unless the patient enters their code in the app. Patients will be able to invite members of their support network through email.

[Footnote]

The ABILIFY MYCITE System was designed with the privacy of patients' personal information in mind. Only those chosen by the patient may view patient information, and, at any time, the patients may change what information they want to share.

For more information about the system's privacy requirements, please review the [ABILIFY MYCITE System Terms of Use, Privacy Notice, and Authorization & Consent](https://www.otsuka-us.com/products-solutions-and-patient-support/abilify-mycite-information). <<link to <https://www.otsuka-us.com/products-solutions-and-patient-support/abilify-mycite-information>, Interstitial 4>

[Module 6]

[Callout]

{{Image: Patient}}

[Image Footnote]

Not a real patient.

[Subhead]

**Start your patient on the ABILIFY MYCITE System.**

[Button]

Check coverage <<links to 5.0 Prescribe>>

[References]

[Body Copy]

**References** <<flips to show references>>

1. Otsuka and Proteus<sup>®</sup> announce the first U.S. FDA approval of a digital medicine system: ABILIFY MYCITE<sup>®</sup> (aripiprazole tablets with sensor). News release. Otsuka America Pharmaceutical, Inc. November 14, 2017. Accessed **November 1, 2021**. <https://www.otsuka-us.com/discover/articles-1075>
2. Hatch A, Docherty JP, Carpenter D, Ross R, Weiden PJ. Expert consensus survey on medication adherence in psychiatric patients and use of a digital medicine system. *J Clin Psychiatry*. 2017;78(7):e803-e812. **doi:10.4088/JCP.16m11252**

Element / Section:	5.0 Get started
URL:	https://www.abilifymycitechcp.com/get-started
Page Title:	Prescribing for Your Patients - ABILIFY MYCITE® System
Key Words:	
H1 Tag:	
H2 Tag:	
Page Description	

[Sub-menu navigation]

- Is my patient covered? <<links to Module 1>>
- Get familiar with the prescription process <<links to Module 2>>
- Setting up the MYCITE® Dashboard <<links to Module 3>>
- Specialty pharmacy <<links to Module 4>>
- Instructions for Use <<links to Module 5>>
- Applying the MYCITE® Patch <<links to Module 6>>

[Directional]

Top ↑

{{Image: Hand holding phone with app}}

[Headline]

**Get your patients started on the ABILIFY MYCITE® System**

[Body Copy]

If you and your patient decide that the ABILIFY MYCITE System is right for them, here's how to start the prescription process.

[Directional]

Scroll v

[Module 1]

[Subhead]

## Is my patient covered?

[Body Copy]

The cost of an ABILIFY MYCITE® Kit depends on what kind(s) of health insurance your patient has.

[Callout]

[Subhead]

### Commercial plans

[Body Copy]

Eligible patients may pay as little as

**[\$5]** / month

for an ABILIFY MYCITE Kit through an instant copay program.\*

[Callout]

[Subhead]

### Medicaid

[Body Copy]

Most Medicaid plans also cover the ABILIFY MYCITE Kit with prior authorization from your state's Medicaid plan.

[Callout]

[Subhead]

### Medicare

[Body Copy]

For patients who are covered under Medicare and qualify for Low Income Subsidy (LIS), copays for brand-name products are

**[\$9.20]** / month

or less.<sup>1†</sup>

[Callout]

**The MYCITE® Team is here to provide you and your patients with cost and coverage information about the ABILIFY MYCITE Kit. Call 844-MYCITE-3 (844-692-4833) for more information.**

[Footnotes]

\*Offer not valid under Medicare, Medicaid, or other federal or state programs. Further conditions apply. Contact the specialty pharmacy for more information.

†Verified [October 30, 2020].

This resource is provided for informational purposes only and is not intended as reimbursement or legal advice. It does not guarantee that coverage and reimbursement will result. Providers should seek independent, qualified professional advice to ensure that their organization is in compliance with the complex legal and regulatory requirements governing healthcare services, and that treatment decisions are made consistent with the applicable standards of care.

[Subhead]

Formulary lookup

[Body Copy - for the whole formulary view section]

Use our formulary lookup to see which plans in your area include the ABILIFY MYCITE Kit.

[Formulary lookup - initial view and error state]

Please insert zip code to populate formulary coverage in your area, or enter your NPI number for more detailed information. **Must enter zip code or NPI number.**

[Form field with label]

**Zip code**

[Body Copy]

or

[Form field with label]

**NPI number**

[Body copy - error state only]

Please enter a valid zip code

Please enter a valid NPI Number

[Button]

Search

[/End of formulary lookup - initial view and error state]

[Formulary lookup - Results view]

[Body copy]

Showing zip code results for [XXXXX] [Change](#) <<resets form fields>>

(Optional) Enter your NPI number for more detailed information ^/v (Flips to expand and close)

[Form field]

**NPI number**

[Button]

Search

[Subhead]

[Message Text Options]

[Table]

[Overall Access]	Commercial	[Medicare Part D]	[Medicaid]	[Plan List]
[Plan - Channel]			Coverage	
[Plan - Channel Type]				[Coverage]
[Plan - Channel Type]				[Coverage]
[Plan - Channel Type]				[Coverage]
[Plan - Channel Type]				[Coverage]
[Plan - Channel Type]				[Coverage]

[Footnote]

#### Additional information ^/v

- 1.** The total of prescriptions referenced is [AMC%]. Of the total prescriptions, covered without restrictions represents [AMC%] of prescriptions, prior authorization represents an additional [AMC%] of prescriptions, and step edit represents an additional [AMC%] of prescriptions as defined in footnotes 4, 5, 6. Managed Markets Insights & Technology, LLC database as of [MONTH YYYY] and IMS Xponent PlanTrak data as of [MONTH YYYY].
- 2.** Your local area is determined as the geography associated with all ZIP codes around you that have the same first three digits.
- 3.** The tier represents the level of coverage the health plan will provide. The most cost-effective agents, as determined by the health plan (often generics), are usually assigned to the most preferred tier and have the lowest patient out-of-pocket costs. The least cost-effective agents, as determined by the health plan are usually assigned to the least preferred tier and have the highest patient out-of-pocket costs or offer no coverage.
- 4.** Covered without restrictions includes health plans with prior authorization requirements that are consistent with ABILIFY MYCITE® (aripiprazole tablets with sensor) Prescribing Information and also establish the appropriate patient. Patients associated with plans that implement only these types of requirements are not considered restricted.
- 5.** Prior Authorization is defined as an approach to prescription drug management where specific criteria are required, as determined by the health plan, to be met before receiving access to a drug originally prescribed.
- 6.** Step Edit is defined as an approach to prescription drug management where patients are required to try one or more drug therapies before receiving access to a drug originally prescribed.
- 7.** Coverage within the plan table is calculated by majority status. Specific formulary coverage under the plan may vary. Coverage is based on total prescriptions in a geography and may include travelling scripts.
- 8.** Medicare Part D is available to certain patients under 65 years of age. Information regarding Medicare Part D is intended to address those beneficiaries who are under 65 years of age.
- 9.** Medicare-Medicaid Dual Eligible patients receive income related subsidies to ensure continuous coverage. Those making less than 135% of the Federal Poverty Level are eligible for the full subsidy, while those making less than 150% of the Federal Poverty Level receive a partial subsidy.
- 10.** For those qualifying for the Low Income Subsidy, drug costs are limited to a maximum of [\$9.20] for each brand name covered drug.

[/End of formulary lookup - Results view]

[Body Copy under all views of formulary lookup section]

Data provided here do not guarantee coverage or payment (partial or full). Actual benefits are determined by respective plan administrators. Consult with payer for all relevant coverage requirements.

[Module 2]

[Headline]

## Get familiar with the prescription process

[Grid]

{{Icon: 1 in a circle}}

[Subhead/Body Copy]

### Dashboard

Before you prescribe an ABILIFY MYCITE Kit for your patient, you need to create an account for the MYCITE<sup>®</sup> Dashboard. During setup, the dashboard will assign you a unique connection code that is sent to the patient on the App Setup Card included in the ABILIFY MYCITE<sup>®</sup> Starter Kit. The patient then enters your connection code in the app to start sharing data with you.

You can also invite others in your practice who are part of the patient's care team to set up their own dashboard accounts. Make sure each member shares their connection code with the patient, so the patient can enter it in the app and start sharing data with the other team members.

{{Icon: 2 in a circle}}

[Subhead/Body Copy]

### Prescribe

You can prescribe an ABILIFY MYCITE Kit by faxing in the prescription form or by using your electronic health record (EHR) form. To fax the prescription, download and complete the prescription form. **Downloaded forms should be faxed to 844-9-MYCITE (844-969-2483).** The specialty pharmacy <<jumps to Module 3>> will verify the patient's insurance coverage (may require a prior authorization).

[Download button]

Download Rx Form <<links to <https://www.abilifymycitehcp.com/resources-support/patient-prescription-form>>>

[Button] Recommended dosing in adults <<opens pop-up>>

<<Pop-up>>

[Table // pick-up from Core Slide Deck + reskin]

[Table title] **Recommended dosing in adults**

[Body Copy]

ABILIFY MYCITE® Kits are available in 2 mg, 5 mg, 10 mg, 15 mg, 20 mg, and 30 mg strengths.

[Body Copy mobile only]

**Rotate phone to view table.**

	Initial	Titration	Recommended	Maximum
Major depressive disorder (adjunct to antidepressants)	2-5 mg/day	Dose adjustments of up to 5 mg/day should occur gradually, at intervals of no less than 1 week	5-10 mg/day	15 mg/day
Bipolar mania (monotherapy)	15 mg/day	Adjust dose gradually	15 mg/day	30 mg/day
Bipolar mania (adjunct to lithium or valproate)	10-15 mg/day			
Schizophrenia (monotherapy)	10-15 mg/day	Adjust dose gradually; increases should generally not be made before 2 weeks	10-15 mg/day	30 mg/day

<</Pop-up>>

[Body Copy]

If you're prescribing through your EHR platform, make sure to choose Orsini Pharmaceutical Services, Elk Grove Village, IL 60007 (NPI# 1073608998) as the pharmacy.

You can call the MYCITE Team [8 AM to 6 PM central time, Monday through Friday], if you have any questions: 844-MYCITE-3 (844-692-4833); press 4 for pharmacy.

{{Icon: 3 in a circle}}

[Subhead/Body Copy]

### **Shipment**

Once coverage is approved and the patient has provided payment information, the prescription will be filled. The pharmacy will send the kit to your office or the patient's home with setup instructions. You will get an email when the kit has shipped.

{{Icon: 4 in a circle}}

[Subhead/Body Copy]

### **Setup appointment**

When you are notified, schedule a setup appointment with the patient to get them started. Alternatively, the patient can set up at home with support from a Patient Experience Liaison. <<links to SUPPORT page Questions about the ABILIFY MYCITE System anchor>>

[Body Copy]

The ABILIFY MYCITE Starter Kit contains a 30-day supply of ABILIFY MYCITE® (aripiprazole tablets with sensor) and MYCITE® Patches (1 reusable pod and 7 disposable adhesive strips). The ABILIFY MYCITE Maintenance Kit contains a 30-day supply of ABILIFY MYCITE and 7 disposable adhesive strips.

[Module 3]

[Subhead]

### **Setting up the MYCITE Dashboard**

[Subhead]

**Before you prescribe an ABILIFY MYCITE Kit** for your patient, follow these next steps to create an account with the dashboard.

{{3 icons, one for each step in the Dashboard setup process}}

{{Icon: 1 in a circle}}

[Subhead/Body Copy]

### **Create an account**

You must create a dashboard account before prescribing the kit.

You can also invite others in your practice who are part of the patient's care team to set up their own dashboard accounts. When everyone on the care team sees the same data, it can make it easier to align on patient status.<sup>2</sup>

{{Icon: 2 in a circle}}

[Subhead/Body Copy]

### **Get your unique connection code**

This code will be generated for you when you finish creating your account. The patient receives the code on the App Setup Card in their ABILIFY MYCITE Starter Kit. Once they enter the code in the app, they start automatically sharing their data with you.

Note: Care-team members will also need to create an account on the dashboard to generate their own unique connection codes. The patient must add these connection codes in the MYCITE<sup>®</sup> App.

{{Icon: 3 in a circle}}

[Subhead/Body Copy]

### **See patient's daily data**

Once your patient is set up with the system, their data will automatically be shared with you in the MYCITE Dashboard. They can change their permissions, at any time, in their app settings. You will get an email letting you know you're connected.

[Module 4]

[Subhead]

### **The ABILIFY MYCITE Kit is dispensed exclusively by a specialty pharmacy**

[Grid]

- **The pharmacy will contact you** to verify patient coverage and prescription information, as needed, and to arrange shipping. The starter kit can be shipped directly to your office or to the patient's home.

The pharmacy will use CoverMyMeds<sup>®</sup> for any prior authorizations.

- **Maintenance kits can be shipped** to your office or to the patient's home.
- **Pod replacement shipments** are available upon request by calling 844-MYCITE-3 (844-692-4833).

[Callout]

The specialty pharmacy's hours of operation are **[8 AM to 6 PM central time, Monday through Friday]**. The pharmacy can be reached by calling **844-MYCITE-3 (844-692-4833)** and pressing 4.

[Footnote]

‡CoverMyMeds is a registered trademark of CoverMyMeds LLC, an independent third-party vendor that is solely responsible for its products and services.

[Module 5]

[Headline]

## Instructions for Use

[Body Copy]

Below are quick step-by-step videos designed to walk your patient through the setup for the ABILIFY MYCITE System. You can also watch them here to familiarize yourself with the process. They're available to patients on the MYCITE App and on [ABILIFYMYCITE.com](https://www.ABILIFYMYCITE.com).

<<links to <https://www.ABILIFYMYCITE.com>>>

[IFUs]

### 01 Getting started

Video length: 01:06

### 02 Preparing your skin

Video length: 00:45

### 03 Opening your pod & strip

Video length: 00:36

### 04 Pairing your patch

Video length: 00:30

### 05 Applying your patch

Video length: 00:56

## **06 Taking your tablet**

Video length: 00:50

## **07 Using your app**

Video length: 01:35

## **08 Using your timeline**

Video length: 00:42

## **09 Menu Overview**

Video length: 01:54

## **10 Entering your mood**

Video length: 00:28

## **11 Rating your rest**

Video length: 00:28

[Module 6]

[Subhead]

### **Applying the MYCITE Patch**

[Body Copy]

Once you have prescribed an ABILIFY MYCITE Kit, your patient should follow your instructions for using the system and for taking ABILIFY MYCITE.

The MYCITE Patch is made up of 2 components:

{{Icon of both parts with corresponding labels}}[Body Copy]

a disposable **adhesive strip**

a **reusable pod**

Your patient should follow the Instructions for Use videos and place the adhesive strip on a flat surface, then attach the pod. The pod will need to be paired only once, at the beginning of treatment.

The MYCITE App will prompt your patient when it's time to change the adhesive strip. Strips should be changed at least weekly, but let your patient know if they need to change strips more frequently.

{{image: torso with patch}}

The paired MYCITE Patch can be applied to the right or left side of the patient's stomach (area below chest and above their navel).

When prescribing an ABILIFY MYCITE Kit, make sure your patient follows these Instructions for Use:

**DO NOT** place the patch in areas where your skin is scraped, cracked, inflamed, or irritated.

**DO NOT** place the patch in a location that overlaps with the area of the most recently removed patch.

**DO NOT** dispose of the pod when changing your adhesive strip.

[Safety]

**The impact of the ABILIFY MYCITE System on treatment adherence has not been demonstrated. Some factors, such as connectivity, transmitter malfunction, or device availability, may impact the consistency and reliability of data detection, collection and transmission. Only functions related to tracking drug ingestion have been evaluated or approved by FDA.**

[Module 7]

[Callout]

{{Image: Hand holding phone with app}}

[Subhead]

**The MYCITE Team is here to support you and your patients.**

[Button]

Learn more <<links to 6.0 Support>>

[References]

[Body Copy]

**References** <<flip to show reference>>

1. US Dept of Health & Human Services. Centers for Medicare & Medicaid Services. 2021 resource and cost-sharing limits for low-income subsidy (LIS). Accessed September 17, 2021. <https://www.cms.gov/files/document/lis-memo.pdf> 2. Otsuka and Proteus<sup>®</sup> announce the first U.S. FDA approval of a digital medicine system: ABILIFY MYCITE<sup>®</sup> (aripiprazole tablets with sensor). News release. Otsuka America Pharmaceutical, Inc. November 14, 2017. Accessed September 17, 2021. <https://www.otsuka-us.com/discover/articles-1075>

## Webpage - Support

Element / Section:	6.0 Support
URL:	<a href="https://www.abilifymycitehcp.com/resources-support">https://www.abilifymycitehcp.com/resources-support</a>
Page Title:	HCP Resources & Support - ABILIFY MYCITE® System
Key Words:	
H1 Tag:	
H2 Tag:	
Page Description	

### [Sub-menu navigation]

- Frequently asked questions <<[links to Module 1](#)>>
- Get support for the ABILIFY MYCITE System <<[links to Module 2](#)>>
  -  Otsuka representative
  -  MYCITE® Team
  -  Patient Experience Liaison (PEL)
- Additional resources <<[links to Module 3](#)>>

### [Directional]

Top ↑



### [Headline]

## Support for the ABILIFY MYCITE® System

### [Body Copy]

These resources are designed to support you and your patients throughout your experience with the ABILIFY MYCITE System.

### [Directional]

Scroll v

[\[Module 1\]](#)

[Headline]

Popular links

{{Image: system icon with 5 circles}}[Body Copy]

How the system works <<Jump links to How does the system work?>>

{{Image: patch icon}}[Body Copy]

About the MYCITE® Patch <<Jump links to About the MYCITE Patch>>

{{Image: person icon}}[Body Copy]

Request a rep <<Jump links to subsection: Otsuka representative>>

[FAQ section 1]

[Subhead]

## Starting your patients on the ABILIFY MYCITE System

**Who is the ABILIFY MYCITE System for?** ^/v <<flips to expand and close answer, GLOBAL for FAQs>>

ABILIFY MYCITE® (aripiprazole tablets with sensor) is a drug-device combination product consisting of aripiprazole tablets embedded with an Ingestible Event Marker (IEM) sensor intended to track drug ingestion.

It is indicated in adults for the:

- Treatment of schizophrenia
- Treatment of bipolar I disorder as monotherapy and as adjunct to lithium or valproate for:
  - Acute treatment of manic and mixed episodes
  - Maintenance treatment
- Adjunctive treatment of major depressive disorder

**Limitations of Use:** ABILIFY MYCITE has not been shown to improve patient compliance or for use in modifying aripiprazole dosage. It should not be used in “real-time” or during an emergency, because detection may be delayed or not occur.

### **Who can prescribe an ABILIFY MYCITE® Kit? ^/v**

In most cases, an ABILIFY MYCITE Kit can be prescribed by a psychiatrist, psychiatric nurse practitioner, or primary care physician.

### **Is the ABILIFY MYCITE System available for my patients? ^/v**

The system is covered under many insurance plans. Find more information [here](#). <<links to 5.0 Get started >>

### **My office is planning to start a patient on the ABILIFY MYCITE System. What can we expect to receive in the first ABILIFY MYCITE Kit? ^/v**

The ABILIFY MYCITE® Starter Kit includes a 30-day supply of ABILIFY MYCITE and MYCITE Patches (1 reusable pod and 7 disposable adhesive strips). The kit will also include instructions on how to set up the system with the MYCITE® App. If the patient has any questions, they can call their [Patient Experience Liaison \(PEL\)](#) at 1-855-242-7787. <<links to Get support for the system, PEL section of this page>>

### **What is the difference between the MYCITE® Team and a Patient Experience Liaison (PEL?) ^/v**

The MYCITE Team can answer technical questions about the ABILIFY MYCITE System. You can call the team if you need help troubleshooting the MYCITE® Dashboard or need to contact the specialty pharmacy regarding a patient's prescription and refills.

Once you've prescribed an ABILIFY MYCITE Kit, your patient can enroll in our PEL program, and connect with a dedicated nurse. This PEL will provide resources and personalized support throughout the patient's treatment journey. They can help your patient get started on the ABILIFY MYCITE System and can answer questions they may have about their medication, the prescription process, and the MYCITE® App.

### **Can my patients share about their experience using the ABILIFY MYCITE System? ^/v**

**Yes.** If you have a patient who is currently being treated or was previously treated using the ABILIFY MYCITE System and is interested in sharing their experience, they can call 1-844-815-0984 or email [\[jade@mypatientstory.com\]](mailto:jade@mypatientstory.com) to learn more. <<mailto: [jade@mypatientstory.com](mailto:jade@mypatientstory.com)>>

You can also [hear a real patient](#) share their experience using the system. <<links to [WHO page, Module 1 \(Carlos's Story Video\)](#)>>

[FAQ Section 2]

[Subhead]

### About ABILIFY MYCITE® (aripiprazole tablets with sensor)

[Button] Learn more about the ABILIFY MYCITE System <<links to About page>>

**What are the available dose strengths and what is the recommended dosage for adults? ^/v**

ABILIFY MYCITE Kits are available in 2 mg, 5 mg, 10 mg, 15 mg, 20 mg, and 30 mg strengths.

[Body copy on mobile only]

**Tap to view table.**

	Initial	Titration	Recommended	Maximum
Major depressive disorder (adjunct to antidepressants)	2-5 mg/day	Dose adjustments of up to 5 mg/day should occur gradually, at intervals of no less than 1 week	5-10 mg/day	15 mg/day
Bipolar mania (monotherapy)	15 mg/day	Adjust dose gradually	15 mg/day	30 mg/day
Bipolar mania (adjunct to lithium or valproate)	10-15 mg/day			
Schizophrenia (monotherapy)	10-15 mg/day	Adjust dose gradually; increases should generally not be made before 2 weeks	10-15 mg/day	30 mg/day

**What is the most important information about the medication in ABILIFY MYCITE tablets? ^/v**

#### **WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS**

Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death (1.6 to 1.7 times) compared to placebo-treated patients. ABILIFY MYCITE is not approved for the treatment of patients with dementia-related psychosis.

#### **WARNING: SUICIDAL THOUGHTS AND BEHAVIORS**

**Antidepressants increased the risk of suicidal thoughts and behavior in children, adolescents, and young adults. Those on antidepressant therapy should be monitored closely for worsening, and for emergence of suicidal thoughts and behaviors. Advise families and caregivers of the need for close observation and communication with the prescriber. The safety and effectiveness of ABILIFY MYCITE have not been established in pediatric patients.**

**What are the most commonly observed adverse reactions associated with ABILIFY MYCITE tablets?** [^/v](#)

**Commonly Observed Adverse Reactions** (incidence  $\geq 5\%$  and at least twice that for placebo) in adult patients:

- Schizophrenia: akathisia
- Bipolar mania (monotherapy): akathisia, sedation, restlessness, tremor, and extrapyramidal disorder
- Bipolar mania (adjunctive therapy with lithium or valproate): akathisia, insomnia, and extrapyramidal disorder
- Major depressive disorder (adjunctive treatment to antidepressant therapy): akathisia, restlessness, insomnia, constipation, fatigue, and blurred vision

See additional IMPORTANT SAFETY INFORMATION for ABILIFY MYCITE. [<<jump links to ISI>>](#)

**What is ABILIFY MYCITE made of?** [^/v](#)

ABILIFY MYCITE is a smart pill with an embedded ingestible event marker (IEM) sensor the size of a grain of sand (1 mm). The sensor technology is made up of natural ingredients found in most diets and leaves the body as waste. The patient should not be able to feel the sensor or the signal it sends.<sup>1,2</sup>

[FAQ Section 3]

[Subhead]

**About the MYCITE Patch**

[Button] Learn more about the ABILIFY MYCITE System [<<links to About page>>](#)

### **What adverse reactions are associated with the MYCITE Patch? ^/v**

Symptoms of skin irritation localized at the site of the MYCITE Patch may occur in some patients. In clinical studies of 492 patients, 61 (12.4%) experienced skin rashes localized at the site of patch placement. No serious adverse reactions related to the ingestible sensor were reported in clinical studies.<sup>3</sup>

These are not all the adverse reactions associated with the ABILIFY MYCITE System. The safety of ABILIFY MYCITE for the treatment of adults with schizophrenia, treatment of adults with manic and mixed episodes associated with bipolar I disorder, and adjunctive treatment of adults with major depressive disorder (MDD) has been established and is based on trials of aripiprazole.

If you have further questions, reach out to your [Otsuka representative](#). <<[jump links to Otsuka representative section of Get support for the system section on the page](#)>>

### **Is there any medication in the MYCITE Patch? ^/v**

**No.** The patch is not medicated.

### **How big is the patch? ^/v**

The adhesive strip of the MYCITE Patch is about the size of a large adhesive bandage (about 2" x 4.25"), while the pod, attached in the center, is about the size of a small watch face.

### **Where should the patient wear the patch? ^/v**

The paired MYCITE Patch can be applied to the right or left side of the patient's stomach (area below chest and above their navel). It should not be applied on areas where skin is scraped, cracked, inflamed, or irritated, or in a location that overlaps the area of the most recently removed patch. If there is skin irritation, the disposable adhesive strip should be removed.

### **Can patients with a latex allergy use the MYCITE Patch? ^/v**

All MYCITE Patch materials that contact the skin have been tested and meet appropriate biocompatibility standards. The patch adhesive area consists of hydrogels, hydrocolloids, and acrylic—it is not made with natural rubber latex.

### **How long do patients wear the patch? ^/v**

Each reusable pod can be paired once, at setup, and used for up to 1 year. The MYCITE® App will let the patient know when it's time to change the adhesive strip. Strips should be

changed at least weekly, but you can let your patient know if they need to change them more frequently. The patch can stay on through water and sweat and does not need to be taken off in the shower or during exercise.

[FAQ Section 4]

[Subhead]

## Technical questions

### **My patient is having trouble setting up the ABILIFY MYCITE System. Who can help?**

^/v

If a patient has any questions about setting up the ABILIFY MYCITE System, the MYCITE Team will be ready to help them at 844-MYCITE-4 (844-692-4834). The MYCITE Team is available [8 AM to 8 PM eastern time, Monday through Friday]. Their dedicated PEL can also walk them through the setup process, step-by-step. PELs are available at 1-855-242-7787, [9 AM to 5 PM eastern time, Monday through Friday, excluding holidays].

### **I am having trouble with the MYCITE® Dashboard and need technical assistance. Who can help?**

^/v  
The MYCITE Team is here to provide you and your office staff with any support you may need with the ABILIFY MYCITE System. Call the MYCITE Team for more information at 844-MYCITE-3 (844-692-4833).

### **How does the ABILIFY MYCITE System work?**

^/v  
The ABILIFY MYCITE System is a smart pill combined with a wearable Bluetooth®\* patch that captures medication ingestion and objective physiological data, presented in the MYCITE Dashboard with patient-reported data.

[Footnote]

\*Bluetooth is a registered trademark of Bluetooth SIG, Inc.

### **How long does it take for the signal to transmit from the sensor to the MYCITE® App?**

^/v

The ABILIFY MYCITE System is intended to track whether ABILIFY MYCITE has been taken. Approximately 94% of all ingestions are registered by the MYCITE Patch within 3 minutes after ingestion; however, it may take up to 2 hours for the MYCITE App and MYCITE Dashboard to detect ingestion. The patient will usually see the information on their

smartphone within 5 minutes. In some cases, tablet ingestion may not be detected. If this occurs, patients should be told not to repeat the dose.<sup>4</sup>

**Some factors, such as connectivity, transmitter malfunction, or device availability may impact the consistency and reliability of data detection, collection, and transmission.**

**How close does the patient need to be to their smartphone? ^/v**

The MYCITE Patch records ingestion of the tablet and other physiological data. It will connect with the MYCITE App once it is within Bluetooth<sup>®</sup>\* range, which is approximately 9 feet. Your patient will need to have access to a regular and reliable internet connection to be able to use the ABILIFY MYCITE System.

**[Footnote]**

\*Bluetooth is a registered trademark of Bluetooth SIG, Inc.

**Is the MYCITE App available for all smartphones and operating systems? ^/v**

The MYCITE App is compatible with most of the following devices and operating systems:

- Apple iPhone<sup>®</sup>: iPhone 6S (or higher) with iOS<sup>®</sup> 10.x (or higher)
- Android<sup>™</sup>: Samsung Galaxy<sup>™</sup> S7/S8, Google Pixel<sup>™</sup> 2 (or higher) with Android Nougat-7 (or higher)

It is advised that patients check their smartphones' app store or call the MYCITE Team at 844-MYCITE-4 (844-692-4834) to ensure compatibility with their specific smartphones and operating systems. If patients don't see their device, but it still meets the operating system requirements listed above, they will still likely be able to use the MYCITE App. The MYCITE App is designed to be identical across Android and iOS except where differences are required by the respective operating systems.

**[Footnote]**

iPhone and iOS are registered trademarks of Apple, Inc. "Samsung" and "Galaxy" are trademarks of Samsung in the United States or other countries. "Google," "Android," and "Pixel" are trademarks of Google, LLC.

**Does the ABILIFY MYCITE System work if a patient is traveling outside of the country?**

^/v

The ABILIFY MYCITE System will still work outside the country. Data plan and roaming charges may apply based on the patient's phone plan and WiFi connection.

When traveling by airplane within or outside of the country, the patient should consider requesting a medical waiver to indicate why they are wearing a patch. Additionally, when going through airport security, the patient may request a pat-down instead of going through the body scanner.

[FAQ Section 4]

[Subhead]

### **Privacy of the system**

#### **Who can view patient information? ^/v**

Patients can share the daily data in their app with you and other members of their care team. They can also share all or some of their data with anyone else they choose—like family members or close friends.<sup>1</sup>

Patients can stop sharing all or some of their data at any time, and data are encrypted and stored securely in the cloud, ensuring patient privacy.<sup>1</sup>

For more information on how your patients' and your information will be used, please read the [ABILIFY MYCITE® System Terms of Use, Privacy Notice, and Authorization & Consent](#).

<<links to <https://www.otsuka-us.com/products-solutions-and-patient-support/abilify-mycite-information>, Interstitial 4 >>

#### **Could the ABILIFY MYCITE System be used to track the location of the patient? ^/v**

**No.** There is no geolocation functionality associated with any element of the ABILIFY MYCITE System.

[Callout]

{{Image of hand holding smartphone with MYCITE App screenshot}}

[Subhead]

### **Questions about the ABILIFY MYCITE System?**

[Body Copy]

Get support at every step

## [Module 2]

### [Headline]

Get support for the ABILIFY MYCITE System

### [Subhead]

{{Icon: magnifying glass}} Otsuka representative ^/v

### [Body Copy]

Our Otsuka representatives can help you:  
Learn more about the ABILIFY MYCITE System

[Button] Request <<opens pop-up>>

<<Pop-up>>

### [Form field headline]

Please enter the following information. All fields are mandatory.

### [Form field 1]

<First name>

[Error message] This field is required

### [Form field 2]

<Last name>

[Error message] This field is required

### [Form field 3]

<Phone number>

[Ghosted copy inside field]

(000) 000-0000

[Error message] This field is required

### [Form field 4]

<Email address>

[Error message] This field is required

[Form field 5]

<Zip code>

[Error message] This field is required

[Checkbox field]

[Field headline]

I would like to request information from (select all that apply):

[Checkbox]

- An Otsuka sales representative
- An Otsuka medical science liaison

[Field footer]

By clicking "Submit" below, you agree to be contacted by phone or email regarding your request.

[Button]

Submit

[Form Output]

Thank you. Your request has been processed.

[Button] Back

<</Pop-up>>

{{Icon: headset}} [Subhead]

MYCITE Team ^/v

[Body Copy]

Our support team can help patients and your office staff with:

- Questions and technical support
- Contacting the specialty pharmacy regarding a patient's prescription and refills
- Setting up your MYCITE Dashboard

[Callout] **Call us at 844-MYCITE-3 (844-692-4833).** We are available [8 AM to 8 PM eastern time, Monday through Friday].

{{Icon: person with plus sign}} [Subhead]

Patient Experience Liaison (PEL) ^/v

[Body Copy]

Once you've prescribed an ABILIFY MYCITE Kit, your patients can connect with a liaison dedicated to them for resources and personalized support throughout their treatment journey. This PEL will be their point of contact for:

- Questions about insurance and the specialty pharmacy process
- Getting started with the ABILIFY MYCITE System
- Understanding and using the MYCITE App

[Callout]

Help your patient get enrolled in the PEL program. PELs are available at 1-855-242-7787, [9 AM to 5 PM eastern time, Monday through Friday, excluding holidays].

[Module 3]

[Headline]

### Additional resources

[Body Copy]

Find helpful resources for your patients and your practice by using the filter options below.

[Filter buttons]

For patients

For you

Video

PDF

[Subhead]

Learn about the system

[Body Copy] <b>Name</b>	[Body Copy] <b>Description</b>	[Body Copy on desktop only] <b>Image</b>
<b><i>Meet the ABILIFY MYCITE System Video</i></b>	This video introduces patients to the ABILIFY MYCITE System and explains	[Video thumbnail]

<p>Watch video &lt;&lt;Anchor link to Meet the ABILIFY MYCITE System Video on HOW page&gt;&gt;  [Orange body copy]  For patients</p>	<p>how it works.</p>	
<p><b>Meet the MYCITE App Video</b>  Watch video &lt;&lt;Anchor link to Meet the App Video on HOW page&gt;&gt;  [Orange body copy]  For patients</p>	<p>Your patients can watch this video to learn about the MYCITE App and its features</p>	<p>[Video thumbnail]</p>
<p><b>Carlos’s Story—Finding the Right Support Video</b>  Watch video &lt;&lt;Anchor link to Carlos’s Story Video on WHOpage&gt;&gt;  [Orange body copy]  For patients</p>	<p>Meet Carlos, a real patient living with major depressive disorder (MDD) who uses the ABILIFY MYCITE System.</p>	<p>[Video thumbnail]</p>
<p><b>ABILIFY MYCITE System Overview Brochure</b>  Download &lt;&lt;links to pdf: <a href="https://www.abilifmycitehcp.com/resources-support/abilify-mycite-system-overview-brochure">https://www.abilifmycitehcp.com/resources-support/abilify-mycite-system-overview-brochure</a>&gt;&gt;  [Blue body copy]  For you</p>	<p>Learn how the system can help you get more of your patient’s story.</p>	<p>[Brochure thumbnail]</p>
<p><b>Explore the MYCITE Dashboard Brochure</b>  Download &lt;&lt;links to pdf: <a href="#">Link TK</a>&gt;&gt;  [Blue body copy]  For you</p>	<p>Learn more about how data from the MYCITE Dashboard can help support you and your patients</p>	<p>[Brochure thumbnail]</p>

<p><b>Meet the ABILIFY MYCITE System Brochure</b></p> <p>Download &lt;&lt;links to pdf: <a href="https://www.abilifymycitehc.com/resources-support/meet-the-abilify-mycite-system-brochure">&lt;&lt;links to pdf: https://www.abilifymycitehc.com/resources-support/meet-the-abilify-mycite-system-brochure &gt;&gt;</a></p> <p>[Orange body copy]</p> <p>For patients</p>	<p>Share this brochure with your patients so they can decide if the ABILIFY MYCITE System might be a good fit for their lifestyle.</p>	<p>[Brochure thumbnail]</p>
<p><b>Self-Check Tool</b></p> <p>See tool &lt;&lt;Links to self-check tool on Consumer Who page: <a href="https://abilifymycite.com/right-for-you#system-fit-self-checker">&lt;&lt;Links to self-check tool on Consumer Who page: https://abilifymycite.com/right-for-you#system-fit-self-checker &gt;&gt;</a></p> <p>[Orange body copy]</p> <p>For patients</p>	<p>This tool helps patients determine if the ABILIFY MYCITE System might be a good fit for them, and they can share their results with you at their next appointment.</p>	<p>[Self-check tool thumbnail]</p>
<p><b>Medication Guide</b></p> <p>Download &lt;&lt;links to Med Guide: <a href="https://www.otsuka-us.com/media/static/ABILIFY-MYCITE-MEDGUIDE.pdf">&lt;&lt;links to Med Guide: https://www.otsuka-us.com/media/static/ABILIFY-MYCITE-MEDGUIDE.pdf &gt;&gt;</a></p> <p>[Orange body copy]</p> <p>For patients</p>	<p>This guide details the most important information your patient should know about ABILIFY MYCITE.</p>	<p>[Medication Guide thumbnail]</p>

[Subhead]

Getting set up

<p>[Body Copy] <b>Name</b></p>	<p>[Body Copy] <b>Description</b></p>	<p>[Body Copy on desktop only] <b>Image</b></p>
<p><b>Opening the ABILIFY MYCITE Kit Video</b></p>	<p>Patients can watch this unboxing video to get a</p>	<p>[Video thumbnail]</p>

<p><u>Watch video</u> &lt;&lt;<a href="#">Anchor link to Opening the ABILIFY MYCITE Kit Video on HOW page</a>&gt;&gt;  [Orange body copy]  For patients</p>	<p>sneak peek of what’s inside the kit and how to get started.</p>	
<p><b>Patient Setup for the ABILIFY MYCITE System</b></p> <p><u>Download</u> &lt;&lt;<a href="https://www.abilifymycitehcp.com/resources-support/patient-setup-for-the-abilify-mycite-system">links to pdf: https://www.abilifymycitehcp.com/resources-support/patient-setup-for-the-abilify-mycite-system</a>&gt;&gt;  [Blue body copy]  For you</p>	<p>Use this checklist before and during a patient’s setup appointment to help get them started with the ABILIFY MYCITE System.</p>	<p>[Setup card thumbnail]</p>
<p><b>Setup Appointment Email Template</b></p> <p><u>Download</u> &lt;&lt;<a href="https://www.abilifymycitehcp.com/resources-support/setup-appointment-email-template">links to pdf: https://www.abilifymycitehcp.com/resources-support/setup-appointment-email-template</a>&gt;&gt;  [Blue body copy]  For you</p>	<p>Here is a sample email you can send to your patients so they can be ready for their setup appointment.</p>	<p>[Email template thumbnail]</p>
<p><b>Talking to You Patients About the ABILIFY MYCITE System Brochure</b></p> <p><u>Download</u> &lt;&lt;<a href="https://www.abilifymycitehcp.com/resources-support/talking-to-your-patients-about-the-abilify-mycite-system-brochure">links to pdf: https://www.abilifymycitehcp.com/resources-support/talking-to-your-patients-about-the-abilify-mycite-system-brochure</a>&gt;&gt;  [Blue body copy]  For you</p>	<p>Use this conversation guide to help answer any questions your patients may have about the ABILIFY MYCITE System.</p>	<p>[Brochure thumbnail]</p>

<p><b>ABILIFY MYCITE Kit Prescription Form</b></p> <p>Download &lt;&lt;Links to: <a href="https://www.abilifymycitehc.com/resources-support/patient-prescription-form">https://www.abilifymycitehc.com/resources-support/patient-prescription-form</a> &gt;&gt;</p> <p>[Blue body copy]</p> <p>For you</p>	<p>Complete this form to prescribe an ABILIFY MYCITE Kit for an appropriate patient.</p>	<p>[Rx form thumbnail]</p>
<p><b>Getting Started with the ABILIFY MYCITE System Brochure</b></p> <p>Download &lt;&lt;links to pdf: <a href="https://www.abilifymycitehc.com/resources-support/getting-started-flashcard">https://www.abilifymycitehc.com/resources-support/getting-started-flashcard</a> &gt;&gt;</p> <p>[Orange body copy]</p> <p>For patients</p>	<p>After you prescribe an ABILIFY MYCITE Kit to your patients, share this brochure with them so they know what to expect before their setup appointment.</p>	<p>[Brochure thumbnail]</p>
<p><b>PEL Introduction Card</b></p> <p>Download &lt;&lt;links to: <a href="https://www.abilifymycitehc.com/resources-support/pel-introduction-card">https://www.abilifymycitehc.com/resources-support/pel-introduction-card</a>&gt;&gt;</p> <p>[Orange body copy]</p> <p>For patients</p>	<p>Your patients can learn about the benefits of the PEL program after they have been prescribed an ABILIFY MYCITE Kit.</p>	<p>[PEL Card thumbnail]</p>
<p><b>Patient Ambassador Card</b></p> <p>Download &lt;&lt;links to pdf: <a href="https://www.abilifymycitehc.com/resources-support/patient-ambassador-card">https://www.abilifymycitehc.com/resources-support/patient-ambassador-card</a> &gt;&gt;</p> <p>[Orange body copy]</p> <p>For patients</p>	<p>This card explains how patients can join our Patient Ambassador Program if they want to inspire others by sharing about their experience using the ABILIFY MYCITE System.</p>	<p>[Card thumbnail]</p>

[Module 5]

[Callout]

{{Image: Patient}}

[Footnote]

Not a real patient.

[Subhead]

**Discover how the ABILIFY MYCITE System can provide data-driven insights to help inform treatment decisions.**

[Button]

Learn more <<links to 2.0 About>>

[References]

[Body Copy]

**References** <<flips to show references>>

**1.** Otsuka and Proteus® announce the first U.S. FDA approval of a digital medicine system: ABILIFY MYCITE® (aripiprazole tablets with sensor). News release. Otsuka America Pharmaceutical, Inc. November 14, 2017. Accessed November 1, 2021. <https://www.otsuka-us.com/discover/articles-1075> **2.** Hafezi H, Robertson TL, Moon GD, Au-Yeung KY, Zdeblick MJ, Savage GM. An ingestible sensor for measuring medication adherence. *IEEE Trans Biomed Eng.* 2015;62(1):99-109. doi:10.1109/TBME.2014.2341272 **3.** Proteus Digital Health Feedback Device. Instructions for use. Proteus Digital Health, Inc; 2018. **4.** Profit D, Rohatagi S, Zhao C, Hatch A, Docherty JP, Peters-Strickland TS. Developing a digital medicine system in psychiatry: ingestion detection rate and latency period. *J Clin Psychiatry.* 2016;77(9):e1095-e1100. doi:10.4088/JCP.16m10643

Element / Section:	E1 - 404 Error
URL:	<a href="https://www.abilifymycite.com/XX">https://www.abilifymycite.com/XX</a>
Page Title:	Error - ABILIFY MYCITE® System
Key Words:	
H1 Tag:	
H2 Tag:	
Page Description	

[Headline]

**Page not found**

[Subhead]

Sorry, but we cannot find the page you are looking for.

[Small Body Copy]

Here are some topics you might find interesting:

[Body Copy]

Discover how the ABILIFY MYCITE® System can provide data-driven insights to help inform treatment decisions

[Button] Learn more <<[links to 2.0 About](#)>>

Which of your patients are appropriate for the ABILIFY MYCITE System?

[Button] Find out <<[links to 3.0 Who](#)>>

**Get started with the ABILIFY MYCITE System**

[Button] Learn how <<[links to 5.0 Prescribe](#)>>

INTERSTITIALS

Element / Section:	Interstitial 1 - Leaving ABILIFYMYCITEhcp.com - patient site
Content:	<p><b>[Headline]</b> <b>You are now leaving ABILIFYMYCITEhcp.com</b></p> <p><b>[Body Copy]</b> You are about to leave this Otsuka America Pharmaceutical, Inc. (OAPI) site. You are being redirected to another OAPI site.</p> <p>Thank you for visiting.</p> <p><b>[Buttons]</b> Continue &lt;&lt;links to patient site <a href="https://www.abilifymycite.com/">https://www.abilifymycite.com/</a>&gt;&gt; Back &lt;&lt;cancels interstitial and remains on page&gt;&gt;</p>

Element / Section:	Interstitial 2 - Leaving ABILIFYMYCITEhcp.com - Women's Mental Health
Content:	<p><b>[Headline]</b> <b>You are now leaving ABILIFYMYCITEhcp.com</b></p> <p><b>[Body Copy]</b> This link will take you to a site maintained by a third party who is solely responsible for its contents. We encourage you to read the Privacy Policy of every website you visit.</p> <p>Thank you for visiting.</p> <p><b>[Buttons]</b> Continue &lt;&lt;links to <a href="https://womensmentalhealth.org/research/pregnancyregistry/">https://womensmentalhealth.org/research/pregnancyregistry/</a>&gt;&gt; Back &lt;&lt;cancels interstitial and remains on page&gt;&gt;</p>

Element / Section:	Interstitial 3 - Leaving ABILIFYMYCITEhcp.com - FDA
Content:	<p><b>[Headline]</b>  <b>You are now leaving ABILIFYMYCITEhcp.com</b></p> <p><b>[Body Copy]</b>  This link will take you to a site maintained by a third party who is solely responsible for its contents. We encourage you to read the Privacy Policy of every website you visit.</p> <p>Thank you for visiting.</p> <p><b>[Buttons]</b>  Continue &lt;&lt;links to <a href="https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program">https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program</a>&gt;&gt;  Back &lt;&lt;cancels interstitial and remains on page&gt;&gt;</p>

Element / Section:	Interstitial 4 - Leaving ABILIFYMYCITEhcp.com - OAPI
Content:	<p><b>[Headline]</b>  <b>You are now leaving ABILIFYMYCITEhcp.com</b></p> <p><b>[Body Copy]</b>  You are about to leave this Otsuka America Pharmaceutical, Inc. (OAPI) site. You are being redirected to another OAPI site.</p> <p>Thank you for visiting.</p> <p><b>[Buttons]</b>  Continue &lt;&lt;links to <a href="https://www.otsuka-us.com/products-solutions-and-patient-support/abilify-mycite-information">https://www.otsuka-us.com/products-solutions-and-patient-support/abilify-mycite-information</a>&gt;&gt;  Back &lt;&lt;cancels interstitial and remains on page&gt;&gt;</p>

Element / Section:	Interstitial 5 - Leaving ABILIFYMYCITEhcp.com - OAPI
Content:	<p><b>[Headline]</b>  <b>You are now leaving ABILIFYMYCITEhcp.com</b></p> <p><b>[Body Copy]</b>  You are about to leave this Otsuka America Pharmaceutical, Inc. (OAPI) site. You are being redirected to another OAPI site.</p> <p>Thank you for visiting.</p> <p><b>[Buttons]</b>  Continue &lt;&lt;links to <a href="https://www.otsuka-us.com/">https://www.otsuka-us.com/</a>&gt;&gt;  Back &lt;&lt;cancels interstitial and remains on page&gt;&gt;</p>

Element / Section:	Interstitial 6 - Leaving ABILIFYMYCITEhcp.com - Privacy Policy
Content:	<p><b>[Headline]</b>  <b>You are now leaving ABILIFYMYCITEhcp.com</b></p> <p><b>[Body Copy]</b>  You are about to leave this Otsuka America Pharmaceutical, Inc. (OAPI) site. You are being redirected to another OAPI site.</p> <p>Thank you for visiting.</p> <p><b>[Buttons]</b>  Continue &lt;&lt;links to <a href="https://www.otsuka-us.com/oapi-and-opdc-privacy-policy">https://www.otsuka-us.com/oapi-and-opdc-privacy-policy</a>&gt;&gt;  Back &lt;&lt;cancels interstitial and remains on page&gt;&gt;</p>

Element / Section:	Interstitial 7 - Leaving ABILIFYMYCITEhcp.com - Terms of Use
Content:	<b>[Headline]</b>

	<p><b>You are now leaving ABILIFYMYCITEhcp.com</b></p> <p>[Body Copy]          You are about to leave this Otsuka America Pharmaceutical, Inc. (OAPI) site. You are being redirected to another OAPI site.</p> <p>Thank you for visiting.</p> <p>[Buttons]          Continue &lt;&lt;links to <a href="https://www.otsuka-us.com/terms-and-conditions">https://www.otsuka-us.com/terms-and-conditions</a>&gt;&gt;          Back &lt;&lt;cancels interstitial and remains on page&gt;&gt;</p>
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Element / Section:	Interstitial 8 - MYCITE Dashboard
Content:	<p>[Headline]  <b>You are now leaving ABILIFYMYCITEhcp.com</b></p> <p>[Body Copy]          This link will take you to the login page for the MYCITE® Dashboard.</p> <p>Thank you for visiting.</p> <p>[Footnote]          Only prescribers with accounts will be able to log in.</p> <p>[Buttons]          Continue &lt;&lt;links to <a href="https://www.myciteus.com/hcp-login">https://www.myciteus.com/hcp-login</a>, which redirects to <a href="https://www.myciteus.com/idp/Authn/UserPassword">https://www.myciteus.com/idp/Authn/UserPassword</a>&gt;&gt;          Back &lt;&lt;cancels interstitial and remains on page&gt;&gt;</p>

