



## **PATIENT AUTHORIZATION & CONSENT FOR USE & DISCLOSURE OF INFORMATION**

Welcome to the Patient Authorization & Consent for Use & Disclosure of Information (the “Authorization”) for the ABILIFY MYCITE® System (the “System”). The System was developed and manufactured by Otsuka America Pharmaceutical, Inc. and its affiliates and alliance companies (including its employees and contractors, “Otsuka” or “we/us/our”). The System includes several components:

- ABILIFY MYCITE (oral aripiprazole tablets embedded with an Ingestible Event Marker (IEM) sensor)
- MYCITE® Patch (wearable sensor) (the “Patch”)
- MYCITE® APP (a smartphone application) (the “APP”)
- Web-based portals (one interface through which patient-selected health care providers can access ABILIFY MYCITE information, and a second interface through which patient-selected family members and friends can access ABILIFY MYCITE information) (each a “Portal” and together the “Portals”)

The System tracks medication ingestion. The System is also designed to collect data on your activity level, rest, and mood. The System can display ingestion data and information on activity level, rest, and mood to you and to your selected health care providers as well as to your selected family members and friends who serve as your caregivers. The System provides a personal health record that is managed, shared, and controlled primarily by and for you.

**You already accepted and agreed to the [Patient Privacy Notice](#) relating to the System. Information about you will be used and disclosed as described in the Patient Privacy Notice. By signing this Authorization, you are providing additional legal consent for all of the uses and disclosures of your information described in the Patient Privacy Notice. To make sure we have obtained meaningful consent from you, this Authorization provides a simpler statement of how information about you will be used and disclosed as a result of your use of the System.**

## **1. Patient Personal Information to Be Used or Disclosed**

Information about you that will be used and disclosed pursuant to this Authorization and consistent with the Patient Privacy Notice includes:

- Enrollment information you provided when you decided to use the System, and information that is created as your enrollment is processed.
- Information you provide to the MYCITE Support call center, including information you provide during the onboarding process.
- Information that the APP prompts you to provide when you set up your account, including your name, email address, password of your choosing, and your health care provider's name and email address.
- The names and email addresses of any additional health care providers, family members, or friends whom you choose to invite to access your information on the relevant Portal.
- Information the System is designed to collect automatically from the Patch, such as the date and time that you take your medication, your step count, information related to your heart rate, whether you are upright or lying down, information related to your body surface temperature, and whether your Patch is working or something is preventing its proper function. The System also automatically collects your smartphone's time zone setting and information regarding your use of the APP (including log-in frequency), as well as technical information (including your Internet Protocol (IP) address).
- Information that you manually provide through your use of the APP, such as information about your mood, quality of rest, or the time you take your medication.
- Information relating to your use of the System that is legally collected and shared with us and our vendors from other sources (such as your health care provider, the pharmacy that fills your ABILIFY MYCITE prescription, and any health plan that pays for your care).

We refer to this information altogether as your “Patient Personal Information.” For a more detailed description, please look at the [Patient Privacy Notice](#).

## 2. **Persons Authorized to Use, Disclose, and Receive Your Patient Personal Information**

Your Patient Personal Information will be collected, used, and shared among a group of authorized parties (“Authorized Parties”) as described in this Authorization and the [Patient Privacy Notice](#), and as permitted or required by applicable law. These Authorized Parties include:

- **Otsuka and Its Vendors.** Otsuka and its vendors (such as the MYCITE Support call center), which may use, disclose, and receive Patient Personal Information for purposes such as supporting the operation of the System.
- **Your Selected Health Care Providers.** The doctor who prescribed ABILIFY MYCITE for you and any other doctors or health care providers you invite to have access to your Patient Personal Information.
  - Their access to your Patient Personal Information collected through the System will be limited consistent with choices you make through your use of the APP, and will be subject to the [Terms of Use](#).
  - All doctors and other health care providers with whom you connect will have access to medication ingestion information collected through the System. You may choose whether to give them access to your mood, rest, and activity level information collected through the System.
  - Doctors and other health care providers with whom you connect may use and share your Patient Personal Information when they communicate with Otsuka and its vendors about the System (for example, to provide us with feedback on how to improve the System).

- **Your Selected Family and Friends.** Any family or friends you invite through your use of the APP to have access to your Patient Personal Information.
  - Their access to your Patient Personal Information collected through the System will be limited consistent with choices you make through your use of the APP, and will be subject to the [Terms of Use](#).
  - You may choose whether to give them access to your medication ingestion, mood, rest, and activity level information collected through the System.
  - Family members and friends with whom you connect may use and share your Patient Personal Information when they communicate with Otsuka and its vendors about the System (for example, to provide us with feedback on how to improve the System or to get help with the Portal from the MYCITE Support call center).
  
- **Your Pharmacy.** Any pharmacy that fills your ABILIFY MYCITE prescription.
  - Your pharmacy may collect, access, receive, maintain, and use certain Patient Personal Information, and may share it with other Authorized Parties. For example, your pharmacy may share with us information from the MYCITE patient enrollment form you completed when you decided to use the System, as well as information that is created as your enrollment is processed.
  - Importantly, your pharmacy will not have access to personally identifiable information about your medication ingestion, activity level, rest, or mood collected by the System.
  
- **Your Health Plan.** Any health plan that pays for your care.
  - Your health plan may collect, access, receive, maintain, and use certain Patient Personal Information, and may share it with other Authorized Parties. For example, we may provide your

health plan aggregated information about outcomes for plan participants who use the System.

### **3. Purposes for Which Your Patient Personal Information Will Be Used and Disclosed**

Your Patient Personal Information will be used and disclosed by Authorized Parties for purposes relating to the operation of the System, to improve the System, to provide services to System users, and for management and administration purposes. For example, your Patient Personal Information may be used and disclosed for the following reasons:

- To enable vendors (like the MYCITE Support call center) to provide services related to the System.
- To keep your health care providers, family members, and friends informed, consistent with choices you make through your use of the APP.

Your Patient Personal Information may also be used and disclosed for the following purposes:

- To obey the law (for example, we may disclose Patient Personal Information in response to a court order).
- To respond to subpoenas and other legal process (for example, we may disclose Patient Personal Information if we receive a valid subpoena requesting the information).
- To protect our legal rights (for example, we may use Patient Personal Information to defend against claims brought against us by third parties).
- To investigate suspected wrongdoing (for example, we may use Patient Personal Information as needed to conduct a fraud investigation).

- To create de-identified data that can be used and shared for purposes such as improving the System, conducting research, and developing products.

#### **4. Encryption**

We use encryption and other methods in an effort to protect your Patient Personal Information.

All of the information collected from the Patch is encrypted when it travels from the Patch to our cloud-based storage vendor, when it is transmitted to you through the APP, and when it is transmitted to your selected health care providers, family members, and friends through the Portals. Similarly, the information you provide to us through the APP is encrypted when it is transmitted to our cloud-based storage vendor where it may be viewed by your selected health care providers, family members, and friends through the Portals. All Patient Personal Information we collect remains encrypted at all times while it is stored by our cloud-based storage vendor. Our cloud-based storage vendor does not have the key to access your encrypted information.

The System may generate certain communications that will be sent to you or your selected health care providers, family members, and friends via text or email. Such communications will not be encrypted.

The System generates emails that will be sent to you for purposes such as welcoming you to the System once you have created an account, allowing you to reset your password, and notifying you when changes have been made to your account. The System will send emails to your selected health care providers, family members, and friends for purposes such as inviting them to access the Portals and notifying them if you choose to disconnect from them. Neither the subject line nor the body of these emails will contain your name or any other personally identifiable information about you. To the extent that you elect to share medication information with selected health care providers, family members, or friends, in the event that you have missed doses, the System may send a generic text or email advising them to check the Portal.

We have determined that it is reasonable and appropriate not to encrypt these communications because they contain such limited information. It is

possible that these unencrypted communications may be intercepted by others. By clicking “I accept” below, you are requesting that we send these unencrypted communications to you and your selected health care providers, family members, and friends.

## **5. Your Right to Refuse to Sign This Authorization**

You do not have to sign this Authorization. If you choose not to sign this Authorization, you cannot use the System.

Your refusal to sign this Authorization will not affect your right to receive treatment from your health care provider. It also will not affect your eligibility for health care benefits for which you may otherwise be entitled.

## **6. Your Right to Revoke This Authorization**

You may revoke this Authorization at any time. To revoke this Authorization, you can delete the APP from your smartphone and remove the Patch. No more Patient Personal Information about you will be collected by the System after you uninstall the APP and remove the Patch. If you would prefer to write us a letter to revoke this Authorization, you may certainly do so, and we can disable the APP. Please send your letter to the Privacy Officer at the contact information provided below.

Any such revocation, however, will not apply to Patient Personal Information that has already been collected and disclosed under this Authorization. Uninstalling the APP does not delete your Patient Personal Information. Health care providers with whom you had connected will still have Portal access to this information. Family members and friends with whom you had connected will continue to have Portal access to this information, unless you disconnect them before deleting the APP.

Keep in mind that you may use the APP to make a number of choices relating to the use and disclosure of your Patient Personal Information:

- **Edit Your Sharing Preferences.** You may use the APP to make choices about how much of your Patient Personal Information is shared with your selected health care providers, family members, and friends. If you change your mind at any time, you can use the APP to update your sharing preferences.

- **Add or Remove Connections.** You may use the APP to disconnect from any health care providers, family members, and friends whom you had previously invited to have access to your Patient Personal Information. Disconnected family members and friends will lose all access to your Patient Personal Information. They will not be able to see any information you had previously shared with them. Disconnected health care providers will still have Portal access to information you had previously shared with them, but no new information will be shared with them in the future.

Also, if you would like us to delete any of your Patient Personal Information, please contact us at [privacyofficer@otsuka-us.com](mailto:privacyofficer@otsuka-us.com) and we will evaluate your request and respond. We may be required by law to retain Patient Personal Information.

## **7. Redisclosure of Your Patient Personal Information**

Once your Patient Personal Information has been disclosed as described in this Authorization, it may be used or re-disclosed by the recipient(s), to the extent permitted by applicable law. This may happen even if you revoke this Authorization.

## **8. Questions and Support**

It is very important to us that you understand how information about you will be used and shared as a result of your use of the System. Please contact the Privacy Officer or MYCITE Support, using the contact information provided below, if you have any questions about how your Patient Personal Information will be used and disclosed.

You may reach the Privacy Officer by email at [privacyofficer@otsuka-us.com](mailto:privacyofficer@otsuka-us.com) or by regular mail at:

Privacy Officer  
Otsuka America Pharmaceutical, Inc.  
508 Carnegie Center Drive  
Princeton, NJ 08540



You can call MYCITE Support at 844-MYCITE-H (844-692-4834) for assistance.

You have a right to receive of a copy of this Authorization after you click “I accept” below to sign it. Please call MYCITE Support at the phone number noted above if you want to exercise this right and get a copy of this Authorization.

**Effective Date: January 1, 2018**

**Expiration Date:** This Authorization expires one year after the Effective Date.

**By clicking “I accept” below:**

- You acknowledge and agree that you have read and understand this Authorization, which relates to the ABILIFY MYCITE® System.
- You authorize the use and disclosure of your Patient Personal Information as described in this Authorization.
- You acknowledge that you intend to be bound by and to sign this Authorization.

If you do not authorize the use and disclosure of your Patient Personal Information as described in this Authorization, please delete the APP from your smartphone, remove any Patch you may have applied, and contact the health care provider who prescribed ABILIFY MYCITE® for you to discuss alternative treatment options.

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