

HIPAA Authorization & Patient Services Consent for VA Patients

Complete these forms if you are electing Circle of Care™ services

PRINT HERE Patient Name: _____ Phone #: _____

Please read the following. If you agree, please sign and date the corresponding section below. This document is a legal document and as such, consent must be given by the patient or the patient's legal representative. A patient should sign their own name. If the patient is unable to sign and the document is signed by a legal representative of the patient, the legal representative should sign their own name and attach proof of patient representation such as a Power of Attorney or other legal document.

I. Authorization to Share Health Information

By signing this Authorization, I authorize my healthcare provider, Veterans Health Administration (VHA), and my pharmacy providers ("Healthcare Entities") to disclose to US WorldMeds, and companies working with US WorldMeds, which may be branded as Circle of Care™ (collectively, "US WorldMeds"), my contact information, health information relating to my medical condition to the extent necessary to support treatment that may also include identifying any potential drug interactions evaluation and allergies, and insurance coverage for US WorldMeds to (i) provide me with support services (which may be branded as Circle of Care™) and related information and materials on APOKYN, including educational support provided in-person, online or by telephone, financial assistance services, medication adherence services, (ii) conduct data analytics, market research and other internal business activities, including evaluating the services provided, and (iii) provide me with information about US WorldMeds' products, services, and programs and other topics of interest for educational or other purposes. Once my health information has been disclosed to US WorldMeds, I understand that Federal privacy laws no longer protect the information and that the information may be subject to further disclosure by US WorldMeds. However, US WorldMeds agrees to protect my health information by using and disclosing it only for purposes authorized in this Patient Authorization and Consent or as required by law or regulations.

I understand that my pharmacy provider may receive remuneration from US WorldMeds in exchange for sharing information concerning any services that the pharmacy may provide to me.

I understand that I may refuse to sign this Authorization, and I further understand that my treatment (including with a US WorldMeds' product), payment for treatment, or eligibility for VHA benefits are not conditioned upon my agreement to sign this Authorization. However, if I do not sign this Authorization, or later cancel it, I will not be able to receive any support services from US WorldMeds including those branded as Circle of Care™.

I may cancel this Authorization at any time by mailing a letter to: Circle of Care/US WorldMeds, c/o CareMetx, 6931 Arlington Road, Suite 308, Bethesda, MD 20814. Canceling this Authorization will end my consent to further disclose health information to US WorldMeds by my Healthcare Entities after they are notified of my cancellation, but will not affect previous disclosures by them pursuant to this Authorization. Canceling this authorization will not affect my ability to receive treatment, payment for treatment, or my eligibility for health insurance.

This Authorization expires December 31, 2028 or such shorter timeframe required by applicable law, from the day I sign it as indicated by the date next to my signature unless otherwise canceled earlier as set forth above.

II. Consent to Contact for Patient Services and Other Communications

Patient Services: I authorize US WorldMeds, and companies working with US WorldMeds any of which may be branded as Circle of Care™ (collectively "US WorldMeds"), to provide me with support services related to APOKYN, including: educational support provided in-person, online or by telephone, medication adherence services, as well as any information or materials related to such services. I authorize US WorldMeds, and companies working with US WorldMeds, to contact me to provide such services and information by mail, e-mail, fax, telephone call, text message (including calls and text messages made with an automatic telephone dialing system or a prerecorded voice), and other mutually agreed upon means. I also authorize US WorldMeds, and companies working with US WorldMeds, to use my health information in connection with the services, including sharing such information with my healthcare provider, insurance provider, or pharmacy. I also authorize the disclosure of my health information to specific individuals that I have designated.

Other Communications: I further authorize US WorldMeds, and companies working with US WorldMeds any of which may be branded as Circle of Care™ (collectively "US WorldMeds"), to contact me by mail, email, fax, telephone call, and text message to provide me with information about APOKYN services and programs. I understand and agree that any information that I provide may be used by US WorldMeds to help develop new products, services, and programs. Note that US WorldMeds will not sell or transfer my personal data to any unrelated third party for marketing purposes without my express permission. I understand that I may revoke this consent and choose not to receive services or information from US WorldMeds by mailing a letter to the address set forth above in Section I of this Patient Authorization and Consent.

(OPTIONAL): I authorize the disclosure of my health information to the following designated individual(s) which are not a part of, endorsed by, or administered by the U.S. Department of Veterans Affairs:

NOTE HERE _____
Designated individual (print name) Relationship
E-mail _____

I have read, understand, and agree to the terms in section I above, Authorization to Share Health Information and section II above, Consent to Contact for Patient Services and Other Communications which are not a part of, endorsed by, or administered by the U.S. Department of Veterans Affairs, and I hereby authorize disclosures to the designated individual that I identified above (if applicable).

SIGN HERE _____
Signature of patient or legal representative Date
E-mail _____

Please fax pages 1 and 3 to 888-525-2431

HIPAA Authorization & Patient Services Consent for VA Patients – *Patient Copy*

Complete these forms if you are electing Circle of Care™ services

This document is a legal document and as such, consent must be given by the patient or the patient’s legal representative. A patient should sign their own name. If the patient is unable to sign and the document is signed by a legal representative of the patient, the legal representative should sign their own name and attach proof of patient representation such as a Power of Attorney or other legal document.

I. Authorization to Share Health Information

By signing this Authorization, I authorize my healthcare provider, Veterans Health Administration (VHA), and my pharmacy providers (“Healthcare Entities”) to disclose to US WorldMeds, and companies working with US WorldMeds, which may be branded as Circle of Care™ (collectively, “US WorldMeds”), my contact information, health information relating to my medical condition to the extent necessary to support treatment that may also include identifying any potential drug interactions evaluation and allergies, and insurance coverage for US WorldMeds to (i) provide me with support services (which may be branded as Circle of Care™) and related information and materials on APOKYN, including educational support provided in-person, online or by telephone, financial assistance services, medication adherence services, (ii) conduct data analytics, market research and other internal business activities, including evaluating the services provided, and (iii) provide me with information about US WorldMeds’ products, services, and programs and other topics of interest for educational or other purposes. Once my health information has been disclosed to US WorldMeds, I understand that Federal privacy laws no longer protect the information and that the information may be subject to further disclosure by US WorldMeds. However, US WorldMeds agrees to protect my health information by using and disclosing it only for purposes authorized in this Patient Authorization and Consent or as required by law or regulations.

I understand that my pharmacy provider may receive remuneration from US WorldMeds in exchange for sharing information concerning any services that the pharmacy may provide to me.

I understand that I may refuse to sign this Authorization, and I further understand that my treatment (including with a US WorldMeds’ product), payment for treatment, or eligibility for VHA benefits are not conditioned upon my agreement to sign this Authorization. However, if I do not sign this Authorization, or later cancel it, I will not be able to receive any support services from US WorldMeds including those branded as Circle of Care™.

I may cancel this Authorization at any time by mailing a letter to: Circle of Care/US WorldMeds, c/o CareMetx, 6931 Arlington Road, Suite 308, Bethesda, MD 20814. Canceling this Authorization will end my consent to further disclose health information to US WorldMeds by my Healthcare Entities after they are notified of my cancellation, but will not affect previous disclosures by them pursuant to this Authorization. Canceling this authorization will not affect my ability to receive treatment, payment for treatment, or my eligibility for health insurance.

This Authorization expires December 31, 2028 or such shorter timeframe required by applicable law, from the day I sign it as indicated by the date next to my signature unless otherwise canceled earlier as set forth above.

II. Consent to Contact for Patient Services and Other Communications

Patient Services: I authorize US WorldMeds, and companies working with US WorldMeds any of which may be branded as Circle of Care™ (collectively “US WorldMeds”), to provide me with support services related to APOKYN, including: educational support provided in-person, online or by telephone, medication adherence services, as well as any information or materials related to such services. I authorize US WorldMeds, and companies working with US WorldMeds, to contact me to provide such services and information by mail, e-mail, fax, telephone call, text message (including calls and text messages made with an automatic telephone dialing system or a prerecorded voice), and other mutually agreed upon means. I also authorize US WorldMeds, and companies working with US WorldMeds, to use my health information in connection with the services including sharing such information with my healthcare provider, insurance provider, or pharmacy. I also authorize the disclosure of my health information to specific individuals that I have designated.

Other Communications: I further authorize US WorldMeds, and companies working with US WorldMeds any of which may be branded as Circle of Care™ (collectively “US WorldMeds”), to contact me by mail, email, fax, telephone call, and text message to provide me with information about APOKYN services and programs. I understand and agree that any information that I provide may be used by US WorldMeds to help develop new products, services, and programs. Note that US WorldMeds will not sell or transfer my personal data to any unrelated third party for marketing purposes without my express permission. I understand that I may revoke this consent and choose not to receive services or information from US WorldMeds by mailing a letter to the address set forth above in Section I of this Patient Authorization and Consent.

I have read, understand, and agree to the terms in section I above, Authorization to Share Health Information and section II above, Consent to Contact for Patient Services and Other Communications which are not a part of, endorsed by, or administered by the U.S. Department of Veterans Affairs, and I hereby authorize disclosures to the designated individual that I identified on page 1 (if applicable).

Please see the Important Safety Information on the back of this page.

Indication

APOKYN is used by injection, as needed, to treat loss of control of body movements in people with advanced Parkinson's disease (PD). This condition is also called hypomobility or *off* episodes. An *off* episode may include symptoms such as muscle stiffness, slow movements, and difficulty starting movements. APOKYN may improve your ability to control your movements when it is used during an *off* episode. This may help you walk, talk, or move around easier. APOKYN is not used to prevent *off* episodes. APOKYN does not take the place of your other medicines for PD.

Important Safety Information for Patients

Do not take APOKYN if you are being treated with certain drugs called 5HT₃ antagonists (including Anzemet[®], Kytril[®], Zofran[®], Lotronex[®], and Aloxi[®]) that are used for nausea and vomiting or irritable bowel syndrome. People taking these types of drugs with apomorphine experienced severely low blood pressure and lost consciousness or “blacked out.”

Do not take APOKYN if you are allergic to APOKYN or its ingredients, notably sodium metabisulfite. Sulfites can cause severe, life-threatening allergic reactions in some people, especially in people with asthma.

Before taking APOKYN, tell your healthcare provider about all your medical conditions, including if you have dizziness, fainting spells, low blood pressure, asthma, liver problems, kidney problems, heart problems, a mental disorder called major psychotic disorder, have had a stroke or other brain problems, or drink alcohol.

Tell your healthcare provider about all medicines that you take because APOKYN may interact with other medicines causing serious side effects.

APOKYN must be injected just under the skin and not into a vein. Injecting APOKYN into a vein could cause a blood clot.

Your healthcare provider may prescribe a medicine called Tigan[®] (trimethobenzamide hydrochloride) to help prevent the severe nausea and vomiting that may occur when taking APOKYN. If Tigan is prescribed, your healthcare provider will determine how long you should remain on this medicine.

Some patients taking APOKYN may get sleepy during the day or fall asleep without warning doing everyday activities. Do not take medicines that make you sleepy while you are taking APOKYN. Until it is known how APOKYN affects your ability to stay alert, you should not drive a car or operate heavy machinery.

APOKYN may lower blood pressure and cause dizziness and fainting, especially when starting treatment or if the dose is increased. Alcohol, antihypertensives, and nitrates may increase this risk. Patients should not get up too fast from sitting or after lying down to minimize these problems.

The changes that occur with PD and the effects of some PD medicines can increase the risk of falling. APOKYN can also increase this risk.

APOKYN can cause or worsen psychotic-like behavior including hallucinations (seeing or hearing things that are not real), confusion, excessive suspicion, aggressive behavior, agitation, delusional beliefs (believing things that are not real), and disorganized thinking. Call your healthcare provider right away if you experience any of these symptoms.

Some people with PD may get sudden, uncontrolled movements after treatment with some PD medicines. APOKYN can cause or worsen this effect.

Some people with PD have reported new or increased gambling urges, increased sexual urges, and other intense urges, while taking PD medicines, including APOKYN. If you experience new or increased urges, tell your healthcare provider.

If you experience shortness of breath, fast heartbeat, chest pain, or if you have a change in your heartbeat, or faint while taking APOKYN, you should call your healthcare provider right away.

Some people with PD may have an increased chance of getting a skin cancer called melanoma. People with PD should have a healthcare provider check their skin for skin cancer regularly.

The most common side effects seen in clinical studies with APOKYN were: yawning; sleepiness; sudden uncontrolled movements; dizziness; runny nose; nausea and/or vomiting; seeing and hearing things that are not real; swelling of hands, arms, legs, and feet.

Some patients may notice soreness, redness, bruising, or itching at the injection site. Change the site with each injection.

Some people may develop depression while taking APOKYN. Call your healthcare provider right away if you become depressed with APOKYN.

Tell your healthcare provider if you are pregnant or plan to become pregnant or if you are breast-feeding or planning to breast-feed. It is not known if APOKYN can harm your unborn baby or if APOKYN passes into breast milk.

To report SUSPECTED ADVERSE REACTIONS or product complaints, contact US WorldMeds at 1-877-727-6596 (1-877-7APOKYN). You may also report SUSPECTED ADVERSE REACTIONS to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Patients and care partners must receive complete instructions on the proper use of APOKYN. Please see full Prescribing Information and Pen Instructions for Use/Patient Information.

All trademarks are the property of their respective owners.

HIPAA Authorization & Patient Services Consent Form

Complete these forms if you are electing Circle of Care™ services

PATIENT INFORMATION

Patient Name: _____ DOB: _____ Male Female

Address: _____ City: _____ State: _____ ZIP: _____

Daytime Phone: _____ Evening Phone: _____

E-mail: _____ Language Preference: English Spanish Other: _____

Care Partner/Alternate Contact:

Name: _____ Phone: _____

Relationship to Patient: _____ Best time to contact: Morning Afternoon

Prescribing Doctor Information

First Name: _____ Last Name: _____

VA Facility: _____

City: _____ State: _____ ZIP: _____ Phone: _____

PATIENT SERVICES CONSENT

By signing below, I request enrollment in the Circle of Care Patient Program, whereby I elect to receive nurse education support as selected, which are not a part of, endorsed by, or administered by the U.S. Department of Veterans Affairs:


The Circle of Care Program is optional and not required for APOKYN. You are not required to enroll. If you choose to enroll, select A or B below.

- A. **Pre- and Post-Initiation Patient Support and Education:** If you select A, your APOKYN initiation will occur in your doctor's office. Prior to the first administration of APOKYN by your doctor, the Circle of Care nurse educator will provide information about APOKYN and how to safely administer APOKYN via the injection device. Details include instructions on how to insert the cartridge and needle in the device and how to correctly operate the dial to ensure the proper dose. The Circle of Care nurse educator will make sure that you and your care partner are comfortable with the injection device and will also provide instructions about what to expect at the day of your initiation appointment when you receive your first APOKYN injection. If your doctor prescribes medication to be taken prior to your first APOKYN injection, the nurse educator will remind you of those instructions prior to your appointment. Pre-Initiation Education may be conducted in person or by telephone or video conference.

Circle of Care nurse education services are available throughout your APOKYN therapy. The Circle of Care nurse educator will provide post initiation education and support to you and your care partner at a time that is convenient for you. Education may be provided in person, by telephone, or by video conference. In addition, as prescribed by your doctor, the Circle of Care nurse educator will teach and provide instructions on how to titrate your dose, if applicable and as needed, to ensure an effective and tolerated dose up to a maximum recommend dose of 0.6 mL.

- B. **Initiation Support and Education:** By selecting option B, you will receive the pre- and post-initiation support and education as outlined above in option A, and your APOKYN initiation will occur in your home. The Circle of Care nurse educator will schedule and coordinate your APOKYN initiation appointment to occur in your home. As prescribed by your doctor, the Circle of Care nurse educator will monitor your response to the starting test dose of APOKYN. In addition, as prescribed by your doctor, the Circle of Care nurse educator will teach and provide instructions on how to titrate your dose, if applicable and as needed, to ensure an effective and tolerated dose up to a maximum recommend dose of 0.6 mL.

If in-home initiation support and education by the US WorldMeds Circle of Care Nurse Educator is requested by the patient, a copy of the Statement of Medical Necessity must be faxed to 888-525-2431.

SIGN HERE  Signature: _____ Date: _____

Or

By signing below, I attest that I am the Patient's Caregiver and/or Power of Attorney signing on behalf of the Patient, and that I am currently 18 years of age or older.

Authorized representative signature: _____

Date: _____ Relationship to patient: _____

Please fax pages 1 and 3 to 888-525-2431

Please see the Important Safety Information and the accompanying full Prescribing Information and Pen Instructions for Use/Patient Information.