Patient Enrollment and Consent

Fax Completed Form to (833) 392-8999

Note: If Patient Authorization and Consent is not completed, the patient will not have access to Verona Pathway Plus® Support Programs until it is received.

Patient Name: ______________________ **Date of Birth (MM/DD/YYYY):** ___ / ___ / ___

Cell Phone: ______________________ **E-mail:** ______________________

Authorized Representative: ______________________ **Authorized Representative Phone:** ______________________

Patient Authorization and Release of Health Information Consent Form

By signing this Authorization and Release of Health Information Consent Form ("Authorization"), I authorize my healthcare provider, my health insurance company, and my pharmacy providers ("Healthcare Entities") and each of their respective representatives, employees, and agents (collectively "Providers") to disclose information relating to my insurance benefits, medical condition, treatment, and prescription details (Protected Health Information, "PHI") to Verona Pharma, Inc. ("Verona Pharma"), Verona Pathway Plus, its service providers and affiliates (collectively "Verona Pathway Plus") to (i) provide me with support and related Information and materials on any of Verona Pharma's products, including, but not limited to, benefit verification, insurance coverage and education, financial assistance support, medication adherence support; (ii) conduct data analytics, market research and other internal business activities including, but not limited to, evaluating the support provided; and (iii) enroll me into the Verona Pathway Plus Co-pay Coupon Program; if eligible, I understand that Co-pay Coupon information will be sent to my specialty pharmacy, along with my prescription. I understand any assistance with my cost-sharing or co-payment for OHTUVAYRE® (ensifentrine) will be made in accordance with the Program Terms and Conditions. For purposes of clarification, "Verona Pharma" includes, but is not limited to, authorized third-party agents involved in administration of Verona Pathway Plus. I understand that I may be contacted by Verona Pathway Plus in the event that I report an adverse event. Once my health information has been disclosed to Verona Pharma, I understand that it may be re-disclosed and federal privacy laws no longer protect the information. However, Verona Pharma agrees to protect my health information by using and disclosing it only for purposes authorized in this Authorization or as required by law or regulations. I understand that my specialty pharmacy provider may receive remuneration from Verona Pharma in exchange for the health information and/or for any support provided to me. I understand that I am not required to sign this Authorization and that my Healthcare Entities will not condition my treatment, payment, enrollment, or eligibility for benefits on whether I sign this Authorization. This Authorization will expire in 5 years or a shorter period if required by state law, unless I revoke it sooner by writing to 6931 Arlington Road, Suite 400, Bethesda, MD 20814. I understand that revoking my Authorization will terminate my participation in Verona Pathway Plus but will not affect any use of my information that occurred before my request was processed. I am entitled to a copy of this signed Authorization. I also understand that, by listing an Authorized Representative above, they are authorized to be disclosed my health information and be contacted by Verona Pathway Plus, Healthcare Entities, and Providers in association with my Verona Pharma medication and prescription.

Patient Assistance Program

I authorize Verona Pathway Plus to verify my eligibility for the Patient Assistance Program (PAP), and I understand that such verification may include contacting me or my healthcare provider for additional information and/or reviewing additional financial, insurance, and/or medical information. I understand that, upon request, Verona Pathway Plus will tell me whether an individual consumer report was requested and the name and address of the agency that furnished it. I further understand and authorize Verona Pathway Plus to use any consumer reports about me and information collected from me, along with other information they obtain from public and other sources, to estimate my income in conjunction with the PAP eligibility determination process, if applicable. I further understand that no free product may be submitted for reimbursement to any payer, including Medicare and Medicaid, nor counted toward any true out-of-pocket (TrOOP) cost, if applicable; and no free product may be sold, traded, or distributed for sale. Additionally, I understand that I must inform the PAP if my financial circumstance, insurance, or any other eligibility criteria changes. I understand that Verona Pharma does not have any obligation to provide the PAP to me and is not liable in the provision of these services. Verona Pathway Plus reserves the right at any time and without notice to modify or change eligibility criteria or discontinue the PAP.

I authorize Verona Pathway Plus under the Fair Credit Reporting Act to use my demographic information to access reports on my individual credit history from consumer reporting agencies and verify my eligibility for the program.

Messaging from Verona Pathway Plus

If I am unavailable when contacted by Verona Pathway Plus, I authorize the following options for a detailed message.*

Any Phone Text (*Must have cell listed above*)

**I understand a non-detailed message will be left by voicemail, if nothing is selected*

Other Resources

By checking below, I authorize Verona Pharma and its affiliates to contact me by mail, email, fax, text messaging, and/or telephone regarding other helpful resources, services, potential market research, and other related topics of interest. I understand that I am not required to provide this consent as a condition of receiving any Verona Pharma medication or Patient Support. Note that Verona Pharma will not sell or trade my personal data to any unrelated third party.

Full Terms and Conditions can be found at www.veronapharma.com/terms-conditions/ and our Privacy Policy at www.veronapharma.com/privacy-notice/

I consent to receiving other resources, as listed above.

By signing below, I confirm that I have read and understand the Patient Authorization and Release of Health Information Consent Form and agree to all Program Terms and Conditions.

Patient Signature: ______________________ **Date:** ______________

Verona Pharma Inc., a subsidiary of Merck & Co., Inc., Rahway, NJ, USA

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Ohtuvayre (ensifentrine) Inhalation Suspension 3 mg/2.5 mL

Prescription Form

Fax Completed Form to (833) 392-8999

SECTION 1 Patient Information (Required)

Patient Name:______ Date of Birth (MM/DD/YYYY):______
Address:______ City/State/Zip:______ Phone:______
Gender Designation at Birth: Male Female Preferred Language:______ Translator needed?: No Yes
Alternate Contact:______ Alternate Phone:______

SECTION 2 Insurance Card (Required)

Payer type: Medicare Commercial Medicaid Uninsured **Copy of Insurance Card and Demographics are being provided instead of filling out:** No Yes

Medical	Primary Insurance	Secondary/Supplemental Insurance
Insurance Name		
Insurance Phone		
Subscriber ID		
Group #		

Pharmacy
Insurance Name:______ RX Bin:______
Insurance Phone:______ RX PCN:______
Subscriber ID:______
RX Group:______

SECTION 3 Prescriber Information (Required)

Prescriber:______
Prescriber NPI:______
Address:______
City/State/Zip:______
Tax ID:______

Medicaid ID:______
State License:______
Facility Name:______
Facility NPI:______

Office Contact:______
Contact Fax:______
Contact Phone:______
Contact Email:______

SECTION 4 Diagnosis (Required)

ICD-10 Diagnosis(es):______
COPD ICD-10 Codes generally range from J41-J44.9. Other codes may apply. The following ICD-10 codes do not suggest approval, coverage, or reimbursement for specific uses or indications.
Clinical documentation attached: Yes
All Medicare Plans require clinical documentation; electronic signature accepted.

Has the patient been on nebulized medications before?: No Yes
If YES, does the patient have a standard jet nebulizer?: No Yes
Approximate date the patient received standard jet nebulizer:______
Required for Medicare Patients, if they are not receiving a compressor with OHTUVAYRE.

SECTION 5 Prescription (Required)

OHTUVAYRE Prescription

Rx: OHTUVAYRE inhalation suspension: 3 mg ensifentrine per 2.5 mL aqueous suspension in unit-dose ampule. Oral inhalation use only.
Directions: 3 mg (one unit-dose ampule) twice daily, once in the morning and once in the evening, administered by oral inhalation using a Standard Jet Nebulizer with a mouthpiece.
Quantity: 30-day supply; 60 ampules (per box); 11 refills or ____ refills 90-day supply; 180 ampules (3 boxes); 3 refills

Standard Jet Nebulizer Prescription

Rx: Standard Jet Compressor: E0570; Qty: 1; Refill 0
Rx: Administration Set: A7005; Qty: 1; Refill 1

Note to pharmacist: *Compressor may include administration set.*

SECTION 6 Patient Support Programs

OHTUVAYRE Bridge Program Prescription
Enroll my patient, if eligible
Rx: OHTUVAYRE inhalation suspension: 3 mg ensifentrine per 2.5 mL aqueous suspension in unit-dose ampule. Oral inhalation use only.
Directions: 3 mg (one unit-dose ampule) twice daily, once in the morning and once in the evening, administered by oral inhalation using a Standard Jet Nebulizer with a mouthpiece.
Quantity: 60 ampules (per box); 30-day supply with up to 1 refill
Rx: E0570 - Standard Jet Nebulizer; Refill 0
Rx: A7005 - Administration Set; Refill 0

OHTUVAYRE Patient Assistance Program Prescription
Enroll my patient, if eligible
Rx: OHTUVAYRE inhalation suspension: 3 mg ensifentrine per 2.5 mL aqueous suspension in unit-dose ampule. Oral inhalation use only.
Directions: 3 mg (one unit-dose ampule) twice daily, once in the morning and once in the evening, administered by oral inhalation using a Standard Jet Nebulizer with a mouthpiece.
Quantity: 90-day supply; 180 ampules (3 boxes); 3 refills
Rx: E0570 - Standard Jet Nebulizer; Refill 0
Rx: A7005 - Administration Set; Refill 0

SECTION 7 Prescriber Certification (Required)

Prescriber Certification and Signature
I certify that the information provided in the form is complete and accurate to the best of my knowledge. I have prescribed OHTUVAYRE based on my judgment of medical necessity. I understand that my patient's information provided to Verona Pharma, Verona Pathway Plus® and its affiliates is solely for the use of verifying my patient's insurance coverage; facilitating the filling of my patient's prescription; and assessing, if applicable, my patient's eligibility for patient assistance and other support programs. I certify that I have obtained my patient's written authorization in accordance with applicable state and federal law, including the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations, to provide the individually identifiable health information on this form to affiliates and service providers of Verona Pharma and Verona Pathway Plus for eligibility, coverage authorization, coordination, and dispensing of OHTUVAYRE and necessary durable medical equipment prescribed in the above form. I authorize Verona Pathway Plus to conduct a benefits investigation for my patient and to act on my behalf for the limited purpose of transmitting this prescription to the appropriate pharmacy designated by the patient per their benefit plan if provided or to transmit this prescription to a network pharmacy. I understand that any free product distributed through the Bridge Program or Patient Assistance Program (PAP) is not contingent on any purchase obligations. I also understand that no free product may be submitted for reimbursement to any payer, including Medicare and Medicaid, and no free product may be sold, traded, or distributed for sale. I authorize Verona Pathway Plus to forward this prescription to the pharmacy dispensing the BridgeRx and PAP product to the patient named herein, if eligible. I agree that Verona Pathway Plus may contact me for additional information relating to OHTUVAYRE and necessary durable medical equipment, including, but not limited to, email, fax, and telephone. I understand that Verona Pathway Plus may revise, change, or terminate any program support at any time without notice to me.

Prescriber Signature______ **Date:** ___ /___ /___

Dispense as Written: Exact terminology may be based on state regulations.______
Please provide state-specific prescription language here.

Collaborating MD Name:______ (NP and PA Prescribers)

CA, MA, NC: Interchanging is mandated unless the Prescriber writes the words "No Substitution."
NY Prescribers: Must ePrescribe directly to the **dispensing pharmacy** identified on the enrollment or attach a separate prescription on a **NY state prescription pad** in accordance with NY pharmacy law.
ATTN: Where law requires the prescriber to comply with state-specific prescription requirements, such as electronic prescription. Non-compliance with the specific state requirements may result in outreach to the prescriber.
Electronic Prescriptions to be sent to Phyz Pharmacy, NCPDP: 5828809, Phone: (844) 590-5792

Ohtuvayre®
(ensifentrine) Inhalation Suspension
3 mg/2.5 mL

Prescription Form

Fax Completed Form to (833) 392-8999

Patient Name:______________________ Date of Birth (MM/DD/YYYY):______________ Address:______________________

SECTION 8
Clinical History

Clinical History

Known drug allergies:______________________

Does the patient have an ineffective inspiratory flow to utilize inhalers?: No Yes

Current or tried and failed maintenance COPD medications:

LABA	Current	OR	Tried and Failed Product(s):______
LAMA	Current	OR	Tried and Failed Product(s):______
LAMA+LABA	Current	OR	Tried and Failed Product(s):______
LABA+ICS	Current	OR	Tried and Failed Product(s):______
LAMA+ICS	Current	OR	Tried and Failed Product(s):______
LAMA+LABA+ICS	Current	OR	Tried and Failed Product(s):______
Other	Current	OR	Tried and Failed Product(s):______

How many exacerbations has the patient experienced within the past year?______________________

How many hospitalizations due to the patient's COPD have they had within the past year?______________________

Does the patient have manual dexterity issues with utilizing inhalers? No Yes

Other important clinical details:______________________

SECTION 9
Specialty Pharmacy

Preferred Specialty Pharmacy(ies): (If you selected a pharmacy in which the patient's insurance is out-of-network, the prescription will be triaged to an in-network pharmacy.)

No Preference PromptCare DirectRx Specialty Pharmacy CVS Specialty Pharmacy CenterWell Specialty Pharmacy

SECTION 10
Long-Term Care

Is the patient currently in a long-term care facility?:

No Yes Facility:______________________

SECTION 11
Additional Information

Available Information

Healthcare providers:

- *Fax completed prescription form, copy of all insurance cards (front and back), and copy of patient's clinical chart notes to* ***(833) 392-8999***.
  - *Have the patient read page 1 and sign to access support*
  - *If your office has not received a confirmation fax that the OHTUVAYRE Prescription Form has been received within one (1) business day after submission, please resubmit or call Verona Pathway Plus at* ***(833) 372-8492****, Monday to Friday, 8 AM to 8 PM ET*

State Requirements:

- *Some states will require an additional prescription to be sent directly to the dispensing pharmacy. If this is the case, the patient's OHTUVAYRE Specialty Pharmacy will contact your office.*

Medicare Requirements:

- *Medicare requires Clinical Documentation to support the diagnosis of COPD and the need for OHTUVAYRE. Clinical Documentation must include at least an electronic signature*
- *Standard Jet Nebulizer (compressor) information is required for patients when a Standard Jet Nebulizer is not being dispensed with OHTUVAYRE. At a minimum, the approximate date is required, but the pharmacy may need further information for claim submission to CMS*

For additional forms or information, visit ohtuvayrehcp.com.

Available Support Programs*

Co-pay Coupon Program

- *Eligible commercially insured patients enrolled in the Verona Pathway Plus Co-pay Coupon Program may pay as little as $0 per month. Maximum program savings is $10,000 per patient. Maximum single fill benefit is $2,925. Coupon may be redeemed once every 21 days. Not all patients are eligible. Please see Co-pay Coupon Program Terms and Conditions below.*

Bridge Rx Program

- *Available for eligible patients during a coverage delay*

Patient Assistance Program

- *Patient is required to submit an application and meet program criteria*
- *Prescription will expire one (1) year from the written date unless otherwise noted*

*Patients must be enrolled in Verona Pathway Plus to access these benefits.

CO-PAY COUPON PROGRAM TERMS AND CONDITIONS

Eligible, privately insured patients may pay as little as $0 per prescription. The coupon is valid on qualifying prescriptions for OHTUVAYRE. Maximum annual program savings is $10,000 per patient. Maximum single-fill benefit is $2,925.

The coupon is valid for up to a 90-day supply per prescription fill. The coupon may be redeemed only once every 21 days.

Patient must have private insurance. Not valid for uninsured patients or patients covered under Medicaid (including Medicaid patients enrolled in a qualified health plan purchased through a health insurance exchange [marketplace] established by a state government or the federal government), Medicare, a Medicare Part D or Medicare Advantage plan (regardless of whether a specific prescription is covered), TRICARE, CHAMPUS, Puerto Rico Government Health Insurance Plan ("Healthcare Reform"), or any other state or federal medical or pharmaceutical benefit program or pharmaceutical assistance program (collectively, "Government Programs").

By participating in the Co-pay Coupon Program, the patient is confirming they are privately insured. The patient is responsible for notifying Verona Pharma Inc., a subsidiary of Merck & Co., Inc., Rahway, NJ, USA or any of its affiliates (collectively "Verona Pharma") if their insurance status changes.

The Co-pay Coupon Program is void where prohibited by law, taxed, or restricted.

Subject to changes in state law, the coupon may become invalid for residents of Massachusetts prior to its expiration date.

This offer is non-transferable, no substitutions are permissible, and this offer cannot be combined with any other rebate/coupon, free trial, or similar offer for the specified prescription. No other purchase necessary.

Verona Pharma Inc. reserves the right to rescind, revoke, or amend this offer at any time without notice.

The Co-pay Coupon Program for OHTUVAYRE is not insurance and is not intended to substitute for insurance.

Patient must be 18 years of age or older to redeem the coupon. Patients, pharmacists, and healthcare providers must not seek reimbursement from health insurance or any third party for any part of the benefit received by the patient through this Co-pay Coupon Program. Patients must not seek reimbursement from any health savings, flexible spending, or other healthcare reimbursement accounts for the amount of assistance received from the Co-pay Coupon Program.

The coupon can be used only by eligible residents of the United States at participating eligible retail or mail-order pharmacies in the United States. Product must originate in the United States.

Certain information pertaining to the use of the Co-pay Coupon Program will be shared with Verona Pharma. The information disclosed will include the date the prescription is filled, the quantity of product dispensed by the pharmacist, and the amount of co-pay that will be covered by this Co-pay Coupon Program. Additional information may be found in the Verona Pharma Privacy Policy at https://www.veronapharma.com/privacy-notice/.

Acceptance in this Program is not dependent on any past, present, or future purchase, including additional doses of OHTUVAYRE.

Enrollment in the Co-pay Coupon Program is valid throughout the patient's treatment with OHTUVAYRE if they continue to meet the eligibility requirements, including having commercial insurance. Verona Pharma reserves the right to change Program terms at any time.

Indication and Important Safety Information

INDICATION

OHTUVAYRE is a prescription medicine used to treat chronic obstructive pulmonary disease (COPD) in adults. COPD is a chronic (long-term) lung disease that includes chronic bronchitis, emphysema, or both.

IMPORTANT SAFETY INFORMATION

What is the most important information I should know about OHTUVAYRE?

OHTUVAYRE can cause serious side effects, including:

- Sudden breathing problems immediately after inhaling your medicine. If you have sudden breathing problems immediately after inhaling your medicine, stop using OHTUVAYRE and call your healthcare provider right away or go to the nearest hospital emergency room right away.
- Mental health problems including suicidal thoughts and behavior. You may experience mood or behavior changes when taking OHTUVAYRE. Call your healthcare provider right away if you have any of these symptoms, especially if they are new, worse, or worry you: thoughts of suicide or dying, attempt to commit suicide, trouble sleeping (insomnia), new or worse anxiety, new or worse depression, acting on dangerous impulses, and/or other unusual changes in your behavior or mood.

Do not use OHTUVAYRE to treat sudden breathing problems. Always have a rescue inhaler with you.

Who should not use OHTUVAYRE?

Do not use OHTUVAYRE if you have had an allergic reaction to ensifentrine or any of the ingredients in OHTUVAYRE.

What should I tell my healthcare provider before using OHTUVAYRE?

Before you use OHTUVAYRE, tell your healthcare professional if you have or have had a history of mental health problems including depression and suicidal behavior; have liver problems; are pregnant or plan to become pregnant; or are breastfeeding. It is not known if OHTUVAYRE may harm your unborn baby. It is not known if the medicine in OHTUVAYRE passes into your breast milk and if it can harm your baby.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

What are the most common side effects of OHTUVAYRE?

The most common side effects of OHTUVAYRE include back pain, high blood pressure, bladder infection, and diarrhea.

These are not all the possible side effects of OHTUVAYRE. Call your doctor for medical advice about side effects.

This summary does not include all the information about OHTUVAYRE and is not meant to take the place of a discussion with your healthcare provider about your treatment. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please read the accompanying Patient Information for OHTUVAYRE, and discuss it with your doctor. The physician Prescribing Information also is available.

Verona Pathway Plus®

Call Verona Pathway Plus at (833) 372-8492, Monday to Friday, 8 AM to 8 PM ET, to learn more about how we can help your patients throughout treatment with OHTUVAYRE.

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