XEOMIN® incobotulinumtoxinA

MERZ CONNECT™

XEOMIN Patient Assistance Program (PAP)

Application for Uninsured Patients

1-844-4MYMERZ (1-844-469-6379) Fax: 1-866-471-3005

Hours: 8:00 AM – 8:00 PM (EST)

PLEASE READ: Patient/Legal Guardian's written consent has been obtained to release patient information to this Program to facilitate the insurance verification process: (if no, please obtain consent before submitting this form)

☐Yes ☐ No

To apply for assistance, please mail or fax the following items to:

PO Box 4280
Gaithersburg, MD 20885-4280
Fax: 1-866-471-3005

Please include the following information:

- **Patient Information Page**
- **Physician Certification (must be signed)**
- **Physician Information Page (must be completed)**
- **Patient Certification (must be signed)**
- **Patient HIPAA Authorization Page (must be signed)**
- **Copy of Patient's most recent federal tax return and/or W-2 statement**

Note: New York prescriptions must be mailed. We are unable to accept XEOMIN prescriptions from the state of New York via fax. Please mail application to the above address.

XEOMIN is available at no charge to eligible* patients who:

- **Are uninsured or underinsured**
- **Meet financial eligibility requirements (based on the Federal Poverty Guidelines)**
  - **Proof of income is required**
  - **Eligibility will be determined prior to the first injection for both uninsured and underinsured patients**
- **Are US residents**
- **Are not enrolled in Medicare, Medicaid, or any other government program**
- **Meet specific medical and clinical guidelines as determined by Merz**
- **Eligibility must be re-established annually**

***Criteria for the XEOMIN Patient Assistance Program are established by Merz Pharmaceuticals, LLC, and its affiliates, and their vendors. Acceptance into the XEOMIN Patient Assistance Program does not entitle patients to receive assistance indefinitely. Eligibility must be re-established annually, and assistance under the XEOMIN Patient Assistance Program may be terminated at any time. Please see this application for additional required eligibility information.**

PAP APPLICATION: PATIENT INFORMATION PAGE (TO BE COMPLETED BY THE PATIENT/LEGAL GUARDIAN)

Patient Name: Patient Name	Sex: ☐Male ☐Female
Address: Patient Address	Date of Birth: Patient's Date of Birth
City: State: ZIP: Patient City, State, ZIP	Patient/ Guardian Phone# Mobile/Other #
Social Security #: Patient Social Security #	Number of Persons Dependent upon Primary Income within Family:
Marital Status: ☐Married ☐Single ☐Widowed ☐Separated ☐ Divorced	If completing this on behalf of minor, authorized Legal Guardian Legal Guardian's Name Legal Guardian's Phone Number.

INCOME INFORMATION (TO BE COMPLETED BY THE PATIENT/LEGAL GUARDIAN)

Total Gross Monthly/Gross Annual Income: Gross Income	Household size: Enter Number

INSURANCE INFORMATION (TO BE COMPLETED BY THE PATIENT/LEGAL GUARDIAN)

Is Patient enrolled in Medicare? * ☐YES ☐NO

Is Patient enrolled in Medicaid? * ☐YES ☐NO

*Patients enrolled in Medicare and/or Medicaid are not eligible to participate in the Merz Patient Assistance Program.

Other State/Government	Is patient enrolled in any other state/government programs that provide prescription drug benefits (ADAP, SPAP – State Patient Assistant Program, Puerto Rico's Government Healthcare Plan)?	☐ Yes (If yes, patient does not qualify) ☐ No ☐ Applied ☐ Not Applied ☐ Unsure ☐ Application Pending Waitlist
Private/HMO Insurance Company:	Telephone:	
Policy ID:	Does this policy cover prescription drugs? ☐Yes ☐No	Group ID:
Group ID:		
Subscriber Name:		
Date of Birth:	Relation to Patient:	

PAP APPLICATION: Physician Certification (to be completed by treating physician)

By signing below, I certify the following:

- I will be supervising the above-named Patient's treatments.
- To the best of my knowledge, this Patient does not have prescription drug insurance coverage; including Medicare, Medicaid, state pharmaceutical assistance program, county funded, Veterans, or other public programs) for XEOMIN.
- I am not prohibited from participating in Federally-funded health care programs nor am I on the List of Excluded Individuals/Entities maintained by the HHS Office of Inspector General.
- Any product received from or on behalf of Merz Pharmaceuticals, LLC, or its affiliates ("Merz") in connection with the XEOMIN Patient Assistance Program (the "Program") will used only for the Patient. Any units not used to treat the patient are considered biomedical wastage and will be disposed.
- Neither I nor my practice shall
    - Charge the Patient any fee for enrollment or other activities associated solely with the Patient's participation in the Program,
    - Charge the Patient for those professional services associated with the Program not covered by the Patient's health insurer,
    - Bill, make any claim to, or collect from any third-party payer (e.g., Medicaid, Medicare, public or private insurance, etc.) concerning any product received from Merz in connection with the Program, or
    - Sell, trade, barter for or return for credit any XEOMIN provided under the Program.
- The Program may be modified or discontinued at any time, without further notice.

Print Physician Name:

Physician Signature:

Date:

PHYSICIAN INFORMATION PAGE

PHYSICIAN INFORMATION AND DIRECT SHIPPING ADDRESS (NO P.O. BOXES) (TO BE COMPLETED BY THE HEALTHCARE PROVIDER)

Prescriber Name	**Telephone:** **Fax:**
Facility Name	**Tax ID:**
Office Contact Name	**National Provider ID:**
Office Contact Email	**State License # (Required):**
Address, City, State, Zip	**Physician DEA (Required):**

TREATMENT/PRESCRIBING INFORMATION (TO BE COMPLETED BY THE HEALTHCARE PROVIDER)

Site of Service: **Physician Office:** ☐ **ASC: Hospital Outpatient:** ☐ **Hospital** **Inpatient:** ☐	**EMG Code:**
Other (Please Specify):	**CPT Code**
Drug Name:	**Date of Service (if known)**
Patient Dosage:	**Diagnosis Code 1:** **Diagnosis Code 2:**
Number of Vials: **50 Unit:** **100 Unit:** **200 Unit**:	

PAP APPLICATION: Patient Certification (to be completed by Patient/Legal Guardian)

By signing below, I (Patient/Legal Guardian) certify the following:

- The information on this form is correct and complete, including all copies of documents proving income. Merz Pharmaceuticals, LLC, its affiliates and/or its agents ("Merz"), including the XEOMIN Patient Assistance Program Administrator, Covance Market Access Services Inc. and its agents ("Administrator") may use this information to determine eligibility to participate in the XEOMIN Patient Assistance Program (the "Program").
- I understand that if the information is incomplete or the completed information does not allow participation in the Program, that I or my above-named healthcare provider may be notified of such by Merz or the Administrator.
- I am not/Patient is not currently receiving any benefits or coverage for XEOMIN from Medicaid, Medicare, or any other public or private insurance company or assistance program. I acknowledge and agree that I shall not report or count the value of any product provided to me/Patient through the Program toward any insurance deductible or, if I am/Patient is enrolled in Medicare Part D, as true out-of-pocket spending (TrOOP) under my/Patient's Medicare Part D prescription drug benefit.
- I/Patient will not seek reimbursement from any insurance provider or plan, including any Medicare Part B or Medicare Part D plan, for the cost of any free product provided through the Program, and for the remainder of my/Patient's eligibility period I/Patient will continue to receive all my/Patient's prescriptions for XEOMIN through the Program.
- I/Patient will notify the Program within thirty (30) days if there is any change in the status of my/Patient eligibility related to changes in income or health coverage to receive products through the Program. This includes a change in my/Patient's eligibility to participate in the Medicare program due to change in age or disability status or enrollment in Medicare Part D or in any other Governmental health care program.
- I understand that the Program does not cover any provider administration fee. If my/Patient's provider is not able or willing to waive this fee for administering XEOMIN, then this fee is my/legal guardian responsibility.
- I understand that this form expires in one year or when my/Patient's Program eligibility expires.
- The Program may be modified or discontinued at any time, without further notice.
- I authorize the above-named physician and any associated health care provider or staff to submit this Application on my/Patient's behalf.
- I understand that signing this authorization does not guarantee that I/Patient will be accepted into the Program.

Patient Name (Print) **Date:**

Patient/Legal Guardian Signature
(If the Patient cannot sign, the Patient's personal representative must sign below)

Patient Representative or Legal Guardian Name (Print)
Patient Representative or Legal Guardian Signature
Relationship to the Patient, and authority to make medical decisions for Patient:

PAP APPLICATION: PATIENT HIPAA AUTHORIZATION (to be completed by Patient/Legal Guardian)

MERZ PRIVACY PROMISE

Merz Pharmaceuticals, LLC respects patients and takes your privacy seriously. Merz promises that it:

- Does not and will not sell or rent your information to marketing companies or mailing list brokers:
- Only collects and/or uses our personal information for the purposes stated in this Authorization and as necessary to provide you the services and/or programs of your choice; and
- Enrollment is voluntary, and you can cancel at any time by emailing: dataprivacy@merz.com or by calling 1-844-4MYMERZ (1-844-469-6379).

PATIENT HIPAA AUTHORIZATION

Use and Disclosure of Personal Information

I (Patient or Legal Guardian) authorize Merz Pharmaceuticals, LLC, and its affiliates, contractors and agents ("Merz"), including the XEOMIN Patient Assistance Program Administrator, Covance Market Access Services Inc. ("Administrator"), to use and disclose my/my and Patient's personal financial information and personal health information, only for the following purposes:

- To determine my/Patient's eligibility to participate in the Merz XEOMIN Patient Assistance Program (the "Program");
- To contact, with my permission, such third parties as may be necessary to confirm my/Patient's eligibility to participate in the Program;
- To operate, administer, enroll me/Patient in, and/or continue my/Patient's participation in the Program;
- To contact, with my permission, my/Patient's doctor and the rest of my/Patient's healthcare team and share with them my/Patient's health information that may be useful for my/Patient's care; and/or
- To determine eligibility for other programs and/or alternate sources of funding- such as Medicaid, healthcare exchanges, Medigap, state pharmaceutical assistant programs and charitable foundations, that may be able to provide assistance to me/Patient with the costs of my/patient's medications, to administer the Program, and to account for my/Patient's withdrawal should I decide to stop participating in the Program; and/or
- To improve, develop, and evaluate products, services, materials and programs related to my/Patient's condition or treatment

For Merz to provide me/Patient with the services related to the Program, I further understand and agree that Merz needs to collect and use my and/or Patient's personal information, including my/Patient's personal health information.

I understand that my and/or Patient's personal health information may include any information, in electronic or physical form, as well as spoken information, in the possession of or derived from a health care provider (and/or the health care provider's practice), healthcare plan, pharmacy, pharmaceutical company, laboratory and/or their contractor (each, a "Health Care Provider" or "HCP"). This may include select information from or about my/Patient's medical history and general health, my and/or Patient's healthcare plan benefits, payment limits or restrictions covered by my/Patient's healthcare plan policy, and/or my/Patient's adherence to my/Patient's treatment.

I understand that my and/or Patient's personal information may include any information, in electronic or physical form, as well as spoken information, in the possession of or derived from a Health Care Provider, government program or government or third-party payor. This may include my and/or Patient's name, birth date, address, telephone number, social security number, income, medical records, prescription coverage, and prescription for medication, financial documents, and insurance records.

I authorize my/Patient's Health Care Providers to disclose my/Patient's personal health information to Merz (including the Administrator), and between themselves, as necessary, but only for the purposes stated in this Authorization.

I authorize other third parties to disclose my and/or Patient's personal financial information and information regarding eligibility in and/or participation in any private and/or government health program(s), to Merz (including its Administrator), and between themselves, as necessary, but only for the purposes stated in this Authorization.

I authorize Merz (including its Administrator) to disclose information from this application to insurers, other potential funding sources, the government, social workers or patient advocates on my behalf in order to determine if I am/Patient is eligible for coverage or other funds for my/Patient's medicines.

I authorize Merz (including its Administrator) to communicate with my/Patient's Health Care Providers regarding my/Patient's eligibility for and enrollment in the Program.

Expiration, Right to Obtain a Copy and Right to Cancel

I understand that by signing this form, I authorize my/Patient's Health Care Providers or others who might hold my/Patient's health information to release it to Merz employees, as well as, to its contractors and agents, who are performing the services described in this Authorization, including the Administrator. I understand that by signing this form, I further authorize such other third parties as necessary that might hold my and/or Patient's personal information to release it to Merz employees, as well as to its contractors and agents, who are performing the services described in this Authorization, including the Administrator. I also understand I am authorizing my / my and/or Patient's personal information, including my/Patient's personal health information, to be used for the purposes described above.

This Authorization will be valid for one (1) year or until my/patient's participation in the Program ends through my/Patient's cancellation, unless a shorter time is required by applicable law.

I understand that I can withdraw this consent at any time, but it will not change any actions taken before I withdrew consent.

I understand that if I withdraw consent, I/Patient will no longer be able to receive assistance from the Program.

I understand that I can obtain a copy of this Authorization or cancel this Authorization at any time by calling Merz at **1-844-4MYMERZ (1-844-469-6379)** or by writing to the Administrator at the following address: The XEOMIN Patient Assistance Program, *PO Box 4280, Gaithersburg, MD 20885-4280.*

I understand I do not have to sign this Authorization and that my/Patient's enrollment in any of the services and/or programs described above is entirely voluntary. I understand that Merz, as well as Health Care Providers, cannot require me, as a condition of me/Patient having access to medications, prescription drugs, treatment or other care, to sign this Authorization and that I/Patient cannot participate in the Program without my signing this Authorization or an equivalent authorization with my/Patient's Health Care Providers.

Information Received from Health Care Providers

I understand that once my/Patient's personal health information has been disclosed to Merz and/or the Administrator, federal privacy laws may no longer apply and protect it from further disclosure. Merz and Administrator agree, however, to protect my/Patient's personal health information by only using and disclosing it as stated in the Authorization or as otherwise allowed or required by law.

Authorization to Contact

I understand and consent to Merz (including the Administrator) contacting me using the contact information provided during the enrollment process for the purpose of administering the Program. I further authorize and consent to Merz (including the Administrator) contacting my/patient's Health Care Provider during the enrollment process for administering the Program.

Please fax the signed form to: 1-866-471-3005 or mail to:
The XEOMIN® Patient Assistance Program, *PO Box 4280, Gaithersburg, MD 20885-4280*

Please see Important Safety Information below. For Full Prescribing Information, including BOXED WARNING, visit XEOMIN.com.

I KNOW THAT I MAY REFUSE TO SIGN THIS FORM. If I refuse to sign this form, I know this means that I/Patient will not be able to receive assistance from the XEOMIN Patient Assistance Program.

Patient/Legal Guardian Name (Print)	**Date:**
Patient Signature	
(If the patient cannot sign, the patient's personal representative must sign below)	
Patient Representative/Legal Guardian Name (Print)	
Patient Representative/Legal Guardian Signature	
Relationship to the Patient, and authority to make medical decisions for patient:	
Patient Representative/Legal Guardian Phone Number	

A copy of this form must be provided to the Patient/Legal Guardian.

XEOMIN® (incobotulinumtoxinA) IMPORTANT CONSUMER SAFETY INFORMATION
Read the Medication Guide before you start receiving XEOMIN® (Zeo-min) and each time XEOMIN is given to you as there may be new information. The risk information provided here is not comprehensive. To learn more:

- Talk to your health care provider or pharmacist
- Visit www.xeomin.com to obtain the FDA-approved product labeling
- Call 1-844-4MYMERZ (1-844-469-6379)

Uses
XEOMIN is a prescription medicine:

- that is injected into glands that make saliva and is used to treat long-lasting (chronic) drooling (sialorrhea) in adults and in children 2 to 17 years of age.
- that is injected into muscles and used to:
  - treat increased muscle stiffness in the arm because of upper limb spasticity in adults.
  - treat increased muscle stiffness in the arm in children 2 to 17 years of age with upper limb spasticity, excluding spasticity caused by cerebral palsy.
  - treat the abnormal head position and neck pain with cervical dystonia (CD) in adults.
  - treat abnormal spasm of the eyelids (blepharospasm) in adults.

It is not known if XEOMIN is safe and effective in children younger than:

- 2 years of age for the treatment of chronic sialorrhea
- 2 years of age for the treatment of upper limb spasticity
- 18 years of age for the treatment of cervical dystonia or blepharospasm

Warnings

XEOMIN may cause serious side effects that can be life threatening. Get medical help right away if you have any of these problems any time (hours to weeks) after injection of XEOMIN:

- **Problems swallowing, speaking, or breathing** can happen if the muscles that you use to breathe and swallow become weak. Death can happen as a complication if you have severe problems with swallowing or breathing after treatment with XEOMIN.
  - People with certain breathing problems may need to use muscles in their neck to help them breathe and may be at greater risk for serious breathing problems with XEOMIN.
  - Swallowing problems may last for several months, and during that time you may need a feeding tube to receive food and water. If swallowing problems are severe, food or liquids may go into your lungs. People who already have swallowing or breathing problems before receiving XEOMIN have the highest risk of getting these problems.
- **Spread of toxin effects**. In some cases, the effect of botulinum toxin may affect areas of the body away from the injection site and cause symptoms of a serious condition called botulism. The symptoms of botulism include: loss of strength and muscle weakness all over the body, double vision, blurred vision and drooping eyelids, hoarseness or change or loss of voice, trouble saying words clearly, loss of bladder control, trouble breathing, trouble swallowing.

These symptoms can happen hours to weeks after you receive an injection of XEOMIN. These problems could make it unsafe for you to drive a car or do other dangerous activities.

Do not take XEOMIN if you: are allergic to XEOMIN or any of the ingredients in XEOMIN (see below for a list of ingredients in XEOMIN), had an allergic reaction to any other botulinum toxin product such as rimabotulinumtoxinB (Myobloc®), onabotulinumtoxinA (Botox®, Botox® Cosmetic), or abobotulinumtoxinA (Dysport®) or have a skin infection at the planned injection site.

Before receiving XEOMIN, tell your doctor about all of your medical conditions, including if you:

- have a disease that affects your muscles and nerves (such as amyotrophic lateral sclerosis [ALS or Lou Gehrig's disease], myasthenia gravis or Lambert-Eaton syndrome)
- have had any side effect from any other botulinum toxin in the past
- have a breathing problem, such as asthma or emphysema
- have a history of swallowing problems or inhaling food or fluid into your lungs (aspiration)
- have drooping eyelids
- have had eye surgery
- have had surgery on your face
- are pregnant or plan to become pregnant. It is not known if XEOMIN can harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if XEOMIN passes into breast milk.

Tell your doctor about all of the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements. **Talk to your doctor before you take any new medicines after you receive XEOMIN.**

Using XEOMIN with certain other medicines may cause serious side effects. **Do not start any new medicines until you have told your doctor that you have received XEOMIN in the past. Especially tell your doctor if you:**

- have received any other botulinum toxin product in the last four months
- have received injections of botulinum toxin such as rimabotulinumtoxinB (MYOBLOC®), onabotulinumtoxinA (BOTOX®, BOTOX® COSMETIC) and abobotulinumtoxinA

(DYSPORT®) in the past. Be sure your doctor knows exactly which product you received. The dose of XEOMIN may be different from other botulinum toxin products that you have received.
- have recently received an antibiotic by injection or inhalation
- take muscle relaxants
- take an allergy or cold medicine
- take a sleep medicine

Ask your doctor if you are not sure if your medicine is one that is listed above.

Know the medicines you take. Keep a list of your medicines with you to show your doctor and pharmacist each time you get a new medicine.

Possible Side Effects

XEOMIN can cause serious side effects including:

- **Injury to the cornea (the clear front surface of the eye) in people treated for blepharospasm.** People who receive XEOMIN to treat spasm of the eyelid may have reduced blinking that can cause a sore on their cornea or other problems of the cornea. Call your healthcare provider or get medical care right away if you have eye pain or irritation after treatment with XEOMIN.
- **XEOMIN may cause other serious side effects including** allergic reactions. Symptoms of an allergic reaction to XEOMIN may include: itching, rash, redness, swelling, wheezing, trouble breathing, or dizziness or feeling faint. Tell your doctor or get medical help right away if you get wheezing or trouble breathing, or if you get dizzy or faint.

The most common side effects of XEOMIN in adults with chronic sialorrhea include:

- needing to have a tooth pulled (extracted)
- dry mouth
- diarrhea
- high blood pressure

The most common side effects of XEOMIN in children 2 to 17 years of age with chronic sialorrhea include:

- bronchitis
- nausea
- headache
- vomiting

The most common side effects of XEOMIN in adults with upper limb spasticity include:

- seizure
- nasal congestion, sore throat and runny nose
- dry mouth
- upper respiratory infection

The most common side effects of XEOMIN in children 2 to 17 years of age with upper limb spasticity include:

- nasal congestion, sore throat and runny nose
- bronchitis

The most common side effects of XEOMIN in adults with cervical dystonia include:

- difficulty swallowing
- neck pain
- muscle weakness
- pain at the injection site
- muscle and bone pain

The most common side effects of XEOMIN in adults with blepharospasm include:

- drooping of the eyelid
- dry eye
- vision problems
- dry mouth

These are not all the possible side effects of XEOMIN.
Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of XEOMIN

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. You can ask your pharmacist or doctor for information about XEOMIN that is written for health professionals.
Active Ingredient: botulinum toxin type A **Inactive Ingredients:** human albumin and sucrose