ZILBRYSQ® (zilucoplan) Injection | ONWARD

Start Form for

ZILBRYSQ® (zilucoplan)

Injection for Subcutaneous Use

Instructions for Prescribers

To get a patient who has been prescribed ZILBRYSQ started in ONWARD®, please follow these steps:

1. Enroll in ZILBRYSQ REMS at www.ZILBRYSQREMS.com. (Once enrolled, you do not need to re-enroll for subsequent patients.)
2. Review the REMS safety information with your patient.
3. Complete the ZILBRYSQ Start Form, providing all required information.
4. Have your patient read and sign the Patient Authorization sections of the Start Form.
5. Fax the completed Start Form to 1-833-FAX-UCB1 (**1-833-329-8221**) or email it to **ucbonward@rxallcare.com**.

Instructions for Patients

1. Read and sign the Patient Authorization sections of the Start Form to enroll in ONWARD.
2. If you would like us to communicate with you via email and/or text, make sure to check the appropriate consent boxes and provide your email address and/or mobile phone number.
3. You will receive a call from an ONWARD Care Coordinator to discuss the services being requested by you and/or your physician. Please note that when you receive this call, you may see "ONWARD" on your caller ID.

If you have any questions, please call us at 1-844-ONWARD1 (**1-844-669-2731**). A program associate is available to help you **Monday through Friday, 8 AM to 8 PM, Eastern Time**.

Please see Important Safety Information including Boxed Warning at the end of the document.

ZILBRYSQ® (zilucoplan) Injection for Subcutaneous Use Start Form

FAX: 1-833-FAX-UCB1 (1-833-329-8221) | ENROLL ONLINE: ONWARDhcp-enroll-ZILBRYSQ.com | QUESTIONS? CALL: 1-844-ONWARD1 (1-844-669-2731) | EMAIL: ucbonward@rxallcare.com

Services Requested: ☑ Financial Assistance ☑ Care Coordinator Support ☑ Patient Assistance Program (PAP) - Consent Required: see page 5

Step 1: Patient Information * Required field

☑ New to Therapy ☐ On Therapy

First Name* Jane | Middle Initial M | **Last Name*** Smith

Date of Birth* (MM/DD/YYYY) 08/13/1981 | **Phone Number*** 913-338-2234 ☐ Home ☑ Cell | Gender: M ☐ F ☑ Other ☐

Street Address* 1234 Carter Street | Apt#

City* Kansas City | **State*** KS | **ZIP*** 66101 | Preferred Language: ☑ English ☐ Spanish ☐ Other

Communication Preference: ☑ Email ☐ Phone ☐ Text | Email janemarysf381@gmail.com

☑ Please check here to authorize ONWARD Care Coordinators to leave detailed messages (which may include health information) on you/your caregiver's voicemail.

Authorized Patient Representative Information

By providing this information, you authorize ONWARD® to communicate with this person regarding your health condition and services provided by the program.

First Name | Last Name | Relationship to Patient

Phone ☐ Home ☐ Cell | Primary Point of Contact: ☐ Patient ☐ Authorized Patient Representative

Email

Step 2: Insurance Information * Required

NOTE: *You may attach copies of the front and back of the patient's insurance card(s) in lieu of completing this section.*

☐ Check here if patient does not have insurance	PRIMARY PHARMACY INSURANCE	PRIMARY MEDICAL INSURANCE (only required for vaccine coverage)	OTHER (e.g., Secondary)
INSURANCE PROVIDER	BCBS		
INSURANCE PHONE#	913-550-1234		
CARDHOLDER NAME	Jane M Smith		
RELATIONSHIP TO PATIENT	Self		
MEMBER ID	1234567-8904		
GROUP#	3456		
BIN#	1234		
PCN#	7891		

Step 3: Prescriber Information * Required field

Prescriber First Name* Jessica | **Prescriber Last Name*** Barry

Specialty Neurology | **NPI#*** 5678912345 | Tax ID# 1234567893

Supervising Physician | Supervising Physician NPI

Practice/Clinic Name Barry Medical

Address* 9087 Field Street

City Kansas City | State KS | ZIP 66401

Office Phone#* 913-902-2038 | Office Fax# 913-902-2037

Office Contact Name John D. | Office Contact Email john.doe@barrymedical.com

Office Contact Phone# | Office Contact Communication Preference: ☑ Phone ☐ Email

STEP 4: Clinical Information * Required field

ICD-10 Diagnosis* ☑ G70.00 ☐ G70.01 ☐ Other _____ MGFA Classification (I, II, III, IV, V) _____

MG-ADL Score 19 Date of Assessment 04/22/2025

AChR Antibody Test ☑ Positive ☐ Negative ☐ Not Known

Current Therapies

- ☐ Eculizumab
- ☐ Efgartigimod
- ☐ Ravulizumab
- ☑ Oral Corticosteroids
- ☐ Acetylcholinesterase Inhibitors
- ☐ Other
- ☑ Rituximab
- ☑ IVIG
- ☐ SCIG
- ☐ PLEX

Non-steroidal ISTs

- ☐ Azathioprine
- ☐ Cyclophosphamide
- ☐ Cyclosporine
- ☐ Methotrexate
- ☐ Tacrolimus
- ☐ Mycophenolate

Previous Therapies

- ☐ Eculizumab
- ☐ Efgartigimod
- ☐ Ravulizumab
- ☑ Oral Corticosteroids
- ☑ Acetylcholinesterase Inhibitors
- ☐ Other
- ☐ Rituximab
- ☑ IVIG
- ☐ SCIG
- ☐ PLEX

Non-steroidal ISTs

- ☐ Azathioprine
- ☐ Cyclophosphamide
- ☐ Cyclosporine
- ☐ Methotrexate
- ☐ Tacrolimus
- ☐ Mycophenolate

Medical Allergies ☑ No allergies

STEP 5: ZILBRYSQ® Prescription * Required field

ZILBRYSQ prescription will be triaged to PANTHERx RARE.
Your patient will be contacted by PANTHERx to arrange for delivery of ZILBRYSQ.

Patient First & Last Name* Jane M Smith Date of Birth* (MM/DD/YYYY) 08/13/1981

Patient Weight (kg)* 72 Date Weight Measured* 03/12/2025

MEDICATION	WEIGHT CLASS	STRENGTH/FORM	DIRECTIONS FOR ADMINISTRATION	QUANTITY	REFILLS
ZILBRYSQ (zilucoplan)	Less than 56 kg	☐ 16.6 mg/0.416 mL prefilled syringe NDC 50474-990-80	Administer 1 prefilled syringe subcutaneously once daily as directed	28 prefilled syringes	11
	56 kg to less than 77 kg	☑ 23 mg/0.574 mL prefilled syringe NDC 50474-991-80			
	77 kg and above	☐ 32.4 mg/0.81 mL prefilled syringe NDC 50474-992-80			

Appropriate ancillary supplies will be dispensed with the medication unless otherwise indicated.

Physician Attestation and Signature

By signing below, I certify: 1) The therapy is medically necessary and that this information is accurate to the best of my knowledge; 2) I am disclosing this information to UCB, their affiliates, agents, representatives, business partners, and service providers (together "UCB") to help enable treatment for this Patient; 3) The Patient is aware of, has consented to, and has directed my disclosure of their information to UCB so that UCB may contact the Patient to further enable services for those purposes and that such consent and direction applies to disclosures made through the duration of the Patient's therapy; 4) I will not seek reimbursement from any third party for the support UCB provides; and 5) I am licensed to prescribe the prescription medication identified in this form, the prescription complies with my state-specific prescribing requirements and I appoint UCB as my agent for the limited purposes of conveying this prescription by any means under applicable law only to the dispensing pharmacy. I understand that by signing this form, I am requesting support from UCB for Patients receiving ZILBRYSQ®. PRESCRIBER SIGNATURE: PRESCRIBER MUST MANUALLY SIGN AND DATE. RUBBER STAMPS AND SIGNATURE BY OTHER OFFICE PERSONNEL FOR THE PRESCRIBER WILL NOT BE ACCEPTED.

Print Prescriber First and Last Name* Jessica Barry

Prescriber Signature* _____ **Date*** 04/22/2025

ATTN: If your local prescribing requirements call for submission of an electronic prescription, please submit to PANTHERx, NPI# 1659762524.

Patient Vaccination History (including Antibiotic Prophylaxis History) **& Prescription(s)**
(to be completed by healthcare provider)

The **ZILBRYSQ REMS program requires** the certified dispensing pharmacy (PANTHERx Rare) to contact the prescriber to assess the patient's vaccination status. ZILBRYSQ REMS program requirements are available at: www.ZILBRYSQREMS.com. Full ZILBRYSQ Prescribing Information is available at: www.ZILBRYSQ.com.

Please ensure your patient has had the following in accordance **with ZILBRYSQ REMS program requirements:**
- **Complete and up-to-date vaccinations against MenACWY & MenB, and/or provide prophylactic antibiotics when urgent start needed**
- **A copy of the ZILBRYSQ REMS Patient Guide & Safety Card**

Please provide all vaccination records and prophylactic antibiotic records associated with ZILBRYSQ to the dispensing pharmacy.

Patient Name Jane M Smith **DOB** 08/13/1981

- **IF URGENT ZILBRYSQ THERAPY** IS INDICATED in a patient **who is not up to date with both MenACWY and MenB vaccines, administer meningococcal vaccine(s) as soon as possible and provide the patient with antibacterial drug prophylaxis.** Refer to full ZILBRYSQ Prescribing Information.
- **DOES PATIENT NEED TO START ON ZILBRYSQ URGENTLY?** O YES ● NO
- **IF YES, ANTIBIOTIC PROPHYLAXIS WILL BE NEEDED. Start date of antibiotic prophylaxis** _____

VACCINE HISTORY: Check the appropriate brand and provide the dose date details. As part of the REMS program the date is used to confirm vaccination prior to the start of ZILBRYSQ therapy. **Note:** MenB-4C (Bexsero) and MenB-FHbp (Trumenba) **are not interchangeable.**

MenACWY		MenB		MenABCWY
☐ Menveo ☐ Menactra ☐ MenQuadfi 1st Dose Date: _____	☐ Menveo ☐ Menactra ☐ MenQuadfi 2nd Dose Date: _____	☑ Bexsero ☐ Trumenba	1st Dose Date: 9/10/24 2nd Dose Date: 11/6/24 3rd Dose Date: 3/13/25	Penbraya 1st Dose Date: _____
☐ Menveo ☑ Menactra ☐ MenQuadfi Most Recent Booster Date: 9/23/23	If MenACWY history is **not available,** please select below: ☐ History Unknown ☐ No Vaccine Doses Received	Most Recent Booster Date: _____	If MenB history is **not available,** please select below: ☐ History Unknown ☐ No Vaccine Doses Received	Penbraya 2nd Dose Date: _____

VACCINE PRESCRIPTION: If vaccination series is **not completed or not up to date**, submit prescription order below.

- **Vaccine Coordination:** With an order for ZILBRYSQ/vaccination(s) for your patient, PANTHERx Rare will work with your office, the patient, and the retail pharmacy (as applicable) to help coordinate the needed vaccination(s)
- According to the full ZILBRYSQ Prescribing Information, complete or update meningococcal vaccination (for serogroups A, C, W, and Y, and serogroup B) at least 2 weeks prior to administering the first dose of ZILBRYSQ, unless the risk of delaying therapy outweighs the risk of developing a meningococcal infection.

MenACWY Rx: (Select one)	MenB Rx: (Select one from each column)	
☐ Menveo® (MenACWY-CRM) ☐ MenQuadfi® (MenACWY-TT)	☐ Bexsero® (MenB-4C) ☐ Trumenba® (MenB-FHbp)	☐ 2-Dose Series (Day 0, Month 6) ☐ 3-Dose Series (Day 0, Month 1 to 2, Month 6) ☐ Booster
Directions: Administer Intramuscularly as directed Quantity: _____ Refills#: _____ • 2-dose series at least 8 weeks apart • Revaccinate every 5 years if risk remains	Directions: Administer Intramuscularly as directed Quantity: _____ Refills#: _____ • **Note:** MenB-4C (Bexsero) and MenB-FHbp (Trumenba) **are not interchangeable** • 1 dose booster 1 year after primary series • Revaccinate every 2-3 years if risk remains	

Prescriber Signature (Stamps not accepted)*  Date* 04/22/2025

I certify that the completed information above is accurate based on my clinical and professional judgment. Please select one option:

☐ **HOLD SHIPMENT to allow for administration of all missing vaccinations:** I have reviewed the ZILBRYSQ REMS vaccination requirements and my patient's vaccination history, and **I request** that the **ZILBRYSQ shipment be held with additional follow-up to my office to confirm appropriate timing for dispense and allow for administration of missing vaccinations as prescribed.** Patient is to **start ZILBRYSQ (1) after at least 2 weeks post completion** of the vaccination series (or booster if applicable) for both MenACWY and MenB; or (2) if urgent therapy is indicated, after administration of meningococcal vaccine(s) as soon as possible and patient is provided with antibiotic prophylaxis.

☑ **DISPENSE:** I have reviewed the ZILBRYSQ REMS vaccination requirements and my patient's vaccination history **and certify** that my patient **has been or will be** vaccinated as per the full ZILBRYSQ prescribing information prior to beginning treatment with ZILBRYSQ. Patient is to **start ZILBRYSQ after at least 2 weeks post completion** of the vaccination series (or booster if applicable) for both MenACWY and MenB. PANTHERx Rare is authorized to **dispense as soon as possible if urgent therapy** is indicated above (**antibiotic prophylaxis start date must be provided** as requested in the **urgent ZILBRYSQ therapy request above**).

Prescriber Signature (Stamps not accepted)*  Date* 04/22/2025

Patient Authorization

Please see next page for required HIPAA Authorization

❑ **PAP Consent* (Required for the Patient Assistance Program):**

By checking here, applicants authorize ONWARD® PAP and its Administrators to obtain a consumer report. The consumer report, and the information derived from public and other sources, will be used to estimate income as part of the process to decide eligibility to receive free medication from the ONWARD PAP. Upon request, the ONWARD PAP will provide applicants with the name and address of the consumer reporting agency that provides the consumer report. For additional questions about eligibility, please call ONWARD at 1-844-669-2731 (1-844-ONWARD1).

☑ **Text Message Consent Language:**

By checking here, you agree to receive text messages from UCB ONWARD for patient support. Message and data rates may apply. Message frequency will vary based on need. Text "**HELP**" to **844669** for help. Text "**STOP**" to **844669** to cancel. If you have questions, call 1-844-669-2731 (1-844-ONWARD-1). For more information on how UCB will use your information, please view our privacy policy at www.ucb-usa.com/policy and our text messaging terms and conditions at www.ucbONWARD.com/Text-Terms-Conditions.

If giving consent, please provide your mobile number in Step 1: Patient Information to receive SMS communication.

☑ **Marketing Consent (Optional):**

By checking here & providing your information, you acknowledge you are a U.S. resident and give UCB and its business partners permission to send you information or contact you and/or your healthcare provider regarding your disease as well as information on other related treatments, products and services, and for marketing and informational purposes by phone, email, or mail. You understand that UCB or its business partners will not sell your name, address, email address, or any other information to another party for their own marketing use.

Please ensure an email address and phone number are provided in Step 1: Patient Information.

Patient Authorization to Use/Disclose Health Information (HIPAA Authorization) Required*

By signing this form, I hereby authorize each of my physicians, pharmacists (including any specialty pharmacy) that receives my prescription for a UCB medication, and other of my healthcare providers (together, "Providers") and each of my health insurers (together, "Insurers") to disclose information related to my medical condition and treatment (including prescription information), my health insurance coverage and policy number, my name, mailing and email addresses, telephone number, date of birth and Social Security Number (together, "Protected Health Information"), to UCB, Inc. and its agents, service providers, contractors and representatives (together, "UCB"), so that UCB may:

(i) enroll me in, and contact me about, UCB medication support programs.
(ii) provide me with educational materials, information, and services related to UCB medications.
(iii) verify, investigate, assist with, and coordinate my coverage for a UCB medication with my Insurers and Providers.
(iv) conduct market analyses/research or other commercial activity, including aggregating my Protected Health Information with other data for such analyses.
(v) assist with analysis related to quality, efficacy, and safety for UCB medication, and, in some cases, contact you to follow up on adverse events in order to obtain additional information.
(vi) de-identify my Protected Health Information for use for any purpose under applicable law.

I understand that once my Protected Health Information has been disclosed to UCB, federal privacy laws may no longer protect the information and it may be subject to re-disclosure. I understand that one or more Provider and/or Insurer may receive payment from UCB for disclosing my Protected Health Information for some or all of the purposes listed above.

I understand that I am not required to sign this Patient Authorization to Use/Disclose Health Information Authorization, and that if I decline to sign, that will not affect my treatment (including the receipt of UCB medication), payment for treatment, insurance enrollment, or eligibility for insurance benefits, but it may mean that I will not receive the other services described above.

I understand that I may cancel (revoke) this Authorization at any time by calling ONWARD at 1-844-669-2731 (1-844-ONWARD-1) or mailing a letter with my notice of withdrawal to ONWARD, 50 Bearfoot Road, Northborough, MA 01532.

UCB shall provide timely notification of my cancellation (revocation) to my Providers and Insurers. Once my Providers and Insurers receive and process the notice of cancellation (revocation) of this Authorization, my Providers and Insurers may no longer make disclosures of my Protected Health Information to UCB as permitted by this Authorization.

However, canceling this Authorization will not affect any action(s) taken by my Providers or Insurers based on this Authorization before receipt of my notice of cancellation. This authorization expires 10 years from the date it was signed, or such earlier date as required by applicable law unless I cancel it beforehand. I understand that I have the right to receive a copy of this Authorization when it is signed.

I agree to this Patient Authorization Form.

Print Patient First and Last Name:

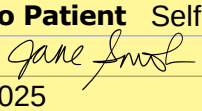
Date of Birth:

(If applicable) Print Patient-Authorized Representative First and Last Name:

Patient or Authorized Patient Representative Signature:

If authorized patient representative is signing, indicate the authorized patient representative's relationship to patient:

Relationship to Patient Self

Signature* 

Date:* 04/22/2025

INDICATION
ZILBRYSQ (zilucoplan) is indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive.

IMPORTANT SAFETY INFORMATION INCLUDING BOXED WARNING

WARNING: SERIOUS MENINGOCOCCAL INFECTIONS

ZILBRYSQ, a complement inhibitor, increases the risk of serious infections caused by *Neisseria meningitidis*. Life-threatening and fatal meningococcal infections have occurred in patients treated with complement inhibitors. These infections may become rapidly life-threatening or fatal if not recognized and treated early.

- **Complete or update vaccination for meningococcal bacteria (for serogroups A, C, W, Y, and B) at least 2 weeks prior to the first dose of ZILBRYSQ, unless the risks of delaying therapy outweigh the risk of developing a serious infection. Comply with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for vaccination against meningococcal bacteria in patients receiving a complement inhibitor.**
- **Patients receiving ZILBRYSQ are at increased risk for invasive disease caused by *Neisseria meningitidis*, even if they develop antibodies following vaccination. Monitor patients for early signs and symptoms of serious meningococcal infections and evaluate immediately if infection is suspected.**

Because of the risk of serious meningococcal infections, ZILBRYSQ is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called ZILBRYSQ REMS.

CONTRAINDICATIONS
ZILBRYSQ is contraindicated for initiation in patients with unresolved serious *Neisseria meningitidis* infection.

WARNINGS AND PRECAUTIONS
Serious Meningococcal Infections
ZILBRYSQ, a complement inhibitor, increases a patient's susceptibility to serious, life-threatening, or fatal infections caused by meningococcal bacteria (septicemia and/or meningitis) in any serogroup, including non-groupable strains. Life-threatening and fatal meningococcal infections have occurred in both vaccinated and unvaccinated patients treated with complement inhibitors. The initiation of ZILBRYSQ treatment is contraindicated in patients with unresolved serious *Neisseria meningitidis* infection.

Complete or update meningococcal vaccination (for serogroups A, C, W, Y and B) at least 2 weeks prior to administration of the first dose of ZILBRYSQ, according to current ACIP recommendations for patients receiving a complement inhibitor.

If urgent ZILBRYSQ therapy is indicated in a patient who is not up to date with meningococcal vaccines according to ACIP recommendations, provide the patient with antibacterial drug prophylaxis and administer meningococcal vaccines as soon as possible.

Closely monitor patients for early signs and symptoms of meningococcal infection and evaluate patients immediately if infection is suspected. Consider interruption of ZILBRYSQ in patients who are undergoing treatment for serious meningococcal infection, depending on the risks of interrupting treatment in the disease being treated.

ZILBRYSQ REMS
Due to the risk of serious meningococcal infections, ZILBRYSQ is available only through a restricted program under a REMS called ZILBRYSQ REMS.

Under the ZILBRYSQ REMS, prescribers must enroll in the program. Prescribers must counsel patients about the risk of serious meningococcal infection, provide the patients with the REMS educational materials, and ensure patients are vaccinated with meningococcal vaccines. Additional information on the REMS requirements is available at www.ZILBRYSQREMS.com or 1-877-414-8353.

Other Infections
Serious infections with *Neisseria* species (other than *Neisseria meningitidis*), including disseminated gonococcal infections, have been reported in patients treated with complement inhibitors. ZILBRYSQ blocks terminal complement activation; therefore, patients may have increased susceptibility to infections, especially with encapsulated bacteria, such as infections caused by *Neisseria meningitidis* but also *Streptococcus pneumoniae*, *Haemophilus influenzae*, and to a lesser extent, *Neisseria gonorrhoeae*. Administer vaccinations for the prevention of *Streptococcus pneumoniae* infection according to ACIP recommendations. Patients receiving ZILBRYSQ are at increased risk for infections due to these organisms, even if they develop antibodies following vaccination.

Pancreatitis And Other Pancreatic Conditions
Pancreatitis and pancreatic cysts have been reported in patients treated with ZILBRYSQ. Patients should be informed of this risk before starting ZILBRYSQ. Obtain lipase and amylase levels at baseline before starting treatment with ZILBRYSQ. Discontinue ZILBRYSQ in patients with suspected pancreatitis and initiate appropriate management until pancreatitis is ruled out or has resolved.

ADVERSE REACTIONS
In a placebo-controlled study, the most common adverse reactions (reported in at least 10% of gMG patients treated with ZILBRYSQ) were injection site reactions, upper respiratory tract infections, and diarrhea.

Please refer to the full Prescribing Information provided by the UCB representative and visit www.ZILBRYSQHCP.com.