

Fulfillment Resource Guide

A guide to help your office navigate patient access for ZILBRYSQ (zilucoplan)

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

Life-threatening and fatal meningococcal infections have occurred in patients treated with complement inhibitors; ZILBRYSQ is a complement inhibitor. Meningococcal infection may become rapidly life-threatening or fatal if not recognized and treated early.

- 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. Comply with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for meningococcal vaccinations in patients receiving a complement inhibitor.
- Persons receiving ZILBRYSQ are at increased risk for invasive disease caused by N. meningitidis, even if they develop antibodies following vaccination. Monitor patients for signs of 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.

The information provided in this guide is of a general nature and for informational purposes only. It is intended to assist healthcare professionals in understanding the fulfillment process for ZILBRYSQ when appropriately prescribed or administered. Coverage policies change periodically and often without warning. The responsibility to determine coverage parameters, and appropriate coding for a particular patient and/or procedure, is always the responsibility of the provider or physician. The information provided in this guide in no way represents a statement, promise, or guarantee by UCB, Inc. concerning access for ZILBRYSQ and administration services, and UCB, Inc. does not recommend or endorse the use of any particular diagnosis or procedure code.

Please refer to pages 15 and 16 for additional Important Safety Information.

Please refer to the full Prescribing Information, including Boxed Warning for serious meningococcal infections, provided by the UCB representative and visit ZILBRYSOhcp.com.



Contents

711	DD	VCO	F1431	Iment
ZIL	.DK	טכז	rullli	IIIIeiit

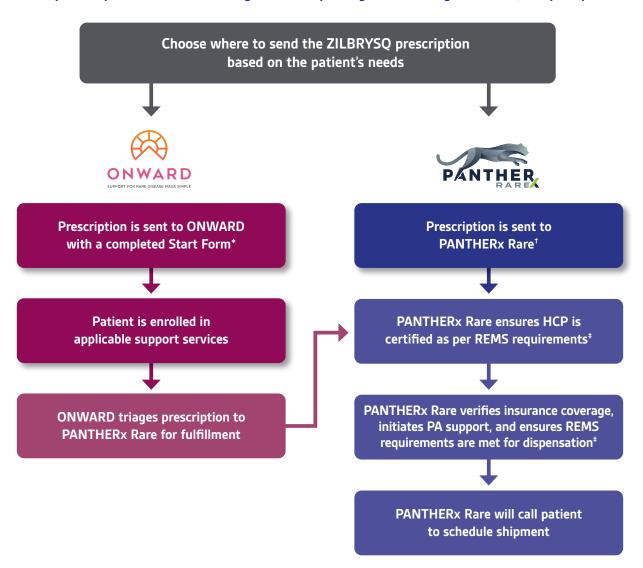
•	
ZILBRYSQ Fulfillment Pathways	3
Enrolling in ZILBRYSQ REMS	6
REMS Vaccination Requirements	9
Product Information, Dosing, and Administration	
Product Information and Dosing	11
Information Patients Need to Know Before Self-injecting ZILBRYSQ	12
How Patients Can Self-inject ZILBRYSQ	13
Support	
Personalized Support for ZILBRYSQ Patients	14
Important Safety Information	15

 $\label{eq:REMS} \textbf{REMS=Risk Evaluation and Mitigation Strategy}.$



ZILBRYSQ Fulfillment Pathways

ZILBRYSQ must be obtained through PANTHERx Rare, the authorized specialty pharmacy. Note that you may send the prescription for ZILBRYSQ to PANTHERx Rare or ONWARD™, UCB's personalized patient support program. ONWARD will ensure your patient's prescription is shared with PANTHERx Rare for fulfillment. Depending on where the prescription is sent, the process slightly differs. See the fulfillment pathways below and use this guide to help navigate accessing ZILBRYSQ for your patients.



Please note: If the Start Form is sent directly to PANTHERx Rare and patient consent is provided, PANTHERx Rare will contact the patient to enroll in applicable ONWARD support services. If patient consent is not provided OR if the prescription was sent without a Start Form, PANTHERx Rare will educate the patient on ONWARD services and transfer the patient to ONWARD if the patient agrees.

Please refer to pages 15 and 16 for Important Safety Information.

Please refer to the full Prescribing Information, including Boxed Warning for serious meningococcal infections, provided by the UCB representative and visit ZILBRYSQhcp.com.

^{*}The Start Form is required to submit a prescription directly to ONWARD and is used to enroll patients in the ONWARD Patient Support Program for access to important resources and support.

[†]PANTHERx Rare accepts prescriptions in multiple formats: eRx, Start Form, phone, and fax.

^{*}Please note: ZILBRYSQ is available only through a restricted program under a REMS called ZILBRYSQ REMS, because of the risk of serious meningococcal infections. HCPs prescribing ZILBRYSQ must enroll in the REMS and complete ZILBRYSQ REMS training to become registered as a certified provider. To learn more, see pages 6 and 7.

 $eRx = electronic\ prescription;\ HCP = health care\ professional;\ PA = prior\ authorization;\ REMS = Risk\ Evaluation\ and\ Mitigation\ Strategy.$



ZILBRYSQ Fulfillment Pathways (cont'd)

Steps to Accessing ZILBRYSQ for Your Patients

1 Set expectations with your patients

- Collect information that may be required by your patient's health plan before approving ZILBRYSQ (eg, copy of your patient's insurance cards, appropriate ICD-10-CM diagnosis code(s), documented prescription/medication order, use of prior medications)
 - Reference the "Prior Authorization Checklist" for more information if a PA is required. PANTHERX Rare will work with your office during the PA approval process
- ☐ Inform your patient on next steps:
 - ONWARD will contact your patient to enroll in applicable support services
 - PANTHERx Rare will call your patient to schedule a shipment of ZILBRYSQ (see Step 4 on the next page)
 - If applicable, communicate with your patient that they can obtain ZILBRYSQ from PANTHERx
 Rare even if their health insurance has a preferred specialty pharmacy

Ensure REMS requirements are met (see page 8 ▶)

- ☐ Enroll in the ZILBRYSQ REMS
- At least 2 weeks prior to the first dose of ZILBRYSQ, complete or update meningococcal vaccinations if needed, according to the most current ACIP guidelines, to mitigate the risk of serious meningococcal infections. For more information, see page 9 ▶

3 Send prescription

- ☐ Determine dosage based on patient weight. For information on recommended doses, see page 11 ▶
- Send the prescription for ZILBRYSQ to PANTHERx Rare, the authorized specialty pharmacy:

ePrescribe	Fax	Phone
NPI #1659762524*	412-567-6135	833-418-7760

 $^{^*}$ Use this NPI number when submitting a prescription electronically to PANTHERx Rare.

OR

Send the prescription and a completed Start Form to ONWARD. ONWARD will ensure the prescription is sent to PANTHERx Rare

ACIP=Advisory Committee on Immunization Practices; ICD-10-CM=International Classification of Diseases, 10th Revision, Clinical Modification; NPI=National Provider Identifier; PA=prior authorization; REMS=Risk Evaluation and Mitigation Strategy.

Please refer to pages 15 and 16 for Important Safety Information.

Please refer to the full Prescribing Information, including Boxed Warning for serious meningococcal infections, provided by the UCB representative and visit ZILBRYSQhcp.com.



ZILBRYSQ Fulfillment Pathways (cont'd)

Steps to Accessing ZILBRYSQ for Your Patients (cont'd)

4 Consider enrolling patients in ONWARD

- ☐ If not previously initiated, consider enrolling your patients in ONWARD by filling out the ONWARD Start Form when prescribing. ONWARD offers patients a wide range of support to help them throughout ZILBRYSQ therapy. For more information, see page 14 ▶
- Inform patients to expect a call from ONWARD (844-669-2731) and/or PANTHERx Rare (833-418-7760) to confirm their enrollment in support services and schedule their shipment

5 Provide self-injection training

- ☐ Train the patient and/or caregiver in subcutaneous injection technique prior to the patient's first ZILBRYSQ dose (see page 12 ▶)
 - The patient may self-inject ZILBRYSQ at home or elsewhere after training¹
 - Supplemental virtual injection training may be scheduled through ONWARD or PANTHERx Rare* if requested by the patient

^{*}To access virtual injection training through ONWARD, the patient must be enrolled in patient support services by providing consent on the ONWARD Start Form.



Enrolling in ZILBRYSQ REMS

ZILBRYSQ is available only through a restricted program under a REMS called ZILBRYSQ REMS, because of the risk of serious meningococcal infections. HCPs prescribing ZILBRYSQ must enroll in the REMS and complete ZILBRYSQ REMS training to become registered as a certified provider. Visit <u>ZILBRYSQREMS.com</u> and complete the following steps to become certified.

1 Become certified to prescribe

- Review the ZILBRYSQ Prescribing Information
- Review the following:
 - Healthcare Provider Safety Brochure
 - Patient Guide
 - Patient Safety Card
- Agree to:
 - Assess for unresolved meningococcal infection and meningococcal vaccination status
 - Complete or update meningococcal vaccinations if needed, according to the most current ACIP guidelines
 - Counsel and provide the patient with the Patient Safety Card and Patient Guide
- Enroll by completing and submitting the **Prescriber Enrollment Form** to ZILBRYSQ REMS by
 - Clicking "Start Online Prescriber Enrollment" at ZILBRYSQREMS.com; or
 - Scanning and emailing the form to ZILBRYSQREMS@ppd.com; or
 - Faxing the form to 1-877-411-3609

Before starting a patient on ZILBRYSQ

- Assess the patient for unresolved meningococcal infection
 - DO NOT initiate ZILBRYSQ in a patient with an unresolved meningococcal infection
- Assess the patient's vaccination status for meningococcal serogroups A, C, W, and Y (MenACWY)
 and serogroup B (MenB) and complete or update vaccinations as needed at least 2 weeks prior
 to the first dose of ZILBRYSQ according to the current ACIP recommendations for meningococcal
 vaccinations in patients receiving a complement inhibitor
 - If the patient is not up to date with MenACWY and MenB vaccines at least 2 weeks prior to initiation of treatment and must start ZILBRYSQ urgently, provide the patient with a prescription for antibacterial drug prophylaxis and administer meningococcal vaccines as soon as possible



ACIP=Advisory Committee on Immunization Practices; HCP=healthcare professional; REMS=Risk Evaluation and Mitigation Strategy.



Enrolling in ZILBRYSQ REMS (cont'd)

Before starting a patient on ZILBRYSQ (cont'd)

- Counsel the patient about the risk of serious meningococcal infections and using the Patient Safety Card and Patient Guide
 - Counsel the patient to carry the Patient Safety Card at all times during and for 2 months following treatment with ZILBRYSQ
 - Provide a copy of the materials to the patient

3 While the patient is on ZILBRYSQ

- Closely monitor the patient for early signs and symptoms of meningococcal infection and evaluate the patient immediately if infection is suspected
- Withhold administration of ZILBRYSQ for a patient who is undergoing treatment for meningococcal infection until the infection is resolved
- Revaccinate the patient according to the current ACIP recommendations on meningococcal vaccinations for patients receiving a complement inhibitor

4 At all times

 Report adverse events suggestive of meningococcal infection, including the patient's clinical outcomes, to UCB, Inc. by calling 1-844-599-2273

ACIP=Advisory Committee on Immunization Practices.



Enrolling in ZILBRYSQ REMS (cont'd)

Notable requirements of the ZILBRYSQ REMS include the following¹:



Prescribers MUST:

- Enroll in the REMS
- · Counsel patients about the risk of meningococcal infection
- Provide the patients with the REMS educational materials
- Assess patient vaccination status for both meningococcal vaccines (MenACWY and MenB)
 - Vaccinate if needed according to current ACIP recommendations for meningococcal vaccinations in patients receiving a complement inhibitor 2 weeks prior to the first dose of ZILBRYSQ
- Provide a prescription for antibacterial drug prophylaxis if treatment must be started urgently
 and a patient is not up to date with both MenACWY and MenB vaccines according to current ACIP
 recommendations at least 2 weeks prior to the first dose of ZILBRYSQ



Pharmacies that dispense ZILBRYSQ MUST:

Be certified in the REMS and verify that prescribers are certified



Patients MUST:

- Receive counseling from the prescriber. Counseling points may include:
 - The need to receive both meningococcal vaccines (MenACWY and MenB) per ACIP recommendations
 - The need to take antibiotics as directed by the prescriber
 - Signs and symptoms of meningococcal infection
- Be instructed to carry the Patient Safety Card with them at all times during and for 2 months following treatment discontinuation with ZILBRYSQ



Scan the QR code to visit <u>ZILBRYSQREMS.com</u> or call 1-877-414-8353 for questions or to learn more

ACIP=Advisory Committee on Immunization Practice; MenACWY=meningococcal serogroups ACWY; MenB=meningococcal serogroup B; REMS=Risk Evaluation and Mitigation Strategy.

Please refer to pages 15 and 16 for Important Safety Information.

Please refer to the full Prescribing Information, including Boxed Warning for serious meningococcal infections, provided by the UCB representative and visit <u>ZILBRYSQhcp.com</u>.

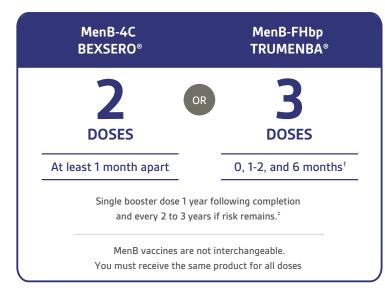


REMS Vaccination Requirements

ZILBRYSQ REMS Vaccination Requirements

REMS requires your office to vaccinate patients or ensure patients are vaccinated for meningococcal disease according to current ACIP guidelines to reduce the risk of serious meningococcal infection.¹ The 2022 ACIP guidelines recommend that patients with persistent complement component deficiency or patients receiving complement inhibitors, including ZILBRYSQ, follow the meningococcal vaccination schedule below.²





OR

MenABCWY PENBRAYA™

2 DOSES

6 months apart^{3,5}

Recommended interval between booster doses varies by vaccine type. MenABCWY vaccine can be used only when both MenACWY and MenB vaccines are indicated at the same visit. Otherwise, MenACWY and MenB vaccines should be given separately as appropriate.⁴

Patients should complete or update both MenACWY and MenB vaccinations at least 2 weeks prior to receiving the first dose of ZILBRYSQ¹

If both MenACWY and MenB vaccines are indicated at the same visit, a single MenABCWY vaccine may be used for all serogroups.

MenACWY=meningococcal serogroups ACWY; MenB=meningococcal serogroup B; MenB-4C=4-component meningococcal group B; MenB-FHbp=meningococcal serogroup B factor H binding protein; REMS=Risk Evaluation and Mitigation Strategy.

Please refer to pages 15 and 16 for Important Safety Information.

Please refer to the full Prescribing Information, including Boxed Warning for serious meningococcal infections, provided by the UCB representative and visit ZILBRYSQhcp.com.

^{*}The Centers for Disease Control and Prevention Advisory Committee on Immunization Practices (ACIP) guidelines recommend all patients taking a complement inhibitor receive the MenACWY booster 5 years after primary vaccination. If risk remains, booster doses should be given every 5 years thereafter.⁵ 1f dose 2 is administered at least 6 months after dose 1, dose 3 is not needed.²

[‡]For patients taking a complement inhibitor, ACIP recommends a MenB booster dose 1 year after the completion of a MenB primary series. If risk remains, booster doses should be given every 2 to 3 years thereafter.⁵

[§]PENBRAYA was FDA-approved on October 20, 2023 and is a vaccination option for meningococcal prophylaxis against meningococcal serogroups ABCWY. ACIP=Advisory Committee on Immunization Practice; FDA=Food and Drug Administration; MenABCWY=meningococcal serogroups ABCWY;



REMS Vaccination Requirements (cont'd)

REMS Support

Committed to patient safety, UCB is working with PANTHERx Rare to help patients access their REMS-required vaccines.

Vaccination Status and Tracking

- Upon receipt of prescription, PANTHERx Rare may contact your office to document the patient's vaccination history (if not provided already)
- If vaccination is required, PANTHERx Rare will track timing for subsequent vaccinations and boosters to communicate scheduled doses with the patient and your office as appropriate

Vaccination Support

- To support patient safety, PANTHERx Rare will:
 - Monitor all aspects of the patient journey as it relates to accessing vaccines as needed for the REMS requirements
 - Help facilitate vaccination access in alignment with a patient's benefit design by identifying local resources (retail/community pharmacies or local health departments) within a patient's geographic location that can administer the REMS-required vaccines to the patient
 - Follow up with you to document vaccinations received in patient records as appropriate

REMS=Risk Evaluation and Mitigation Strategy.



Product Information and Dosing¹

Product Information



The ZILBRYSQ injection prefilled syringe contains a sterile, preservative-free, clear to slightly opalescent, colorless solution.

Each single-dose prefilled syringe consists of a 1 mL glass syringe with a 29-gauge ½-inch needle, a needle safety guard, and a needle cover. The ZILBRYSQ prefilled syringe components are not made with natural rubber latex.

National Drug Code (NDC)

ZILBRYSQ is available as follows:

NDC	Pack size*	Dose
50474-990-80	28 prefilled, single-use safety syringes	16.6 mg/0.416 mL
50474-991-80	28 prefilled, single-use safety syringes	23 mg/0.574 mL
50474-992-80	28 prefilled, single-use safety syringes	32.4 mg/0.81 mL

^{*}Pack consists of 4 cartons, each containing 7 syringes for a total of 28 syringes.

Dosing

The recommended dosage of ZILBRYSQ is based on body weight

ZILBRYSQ is supplied in cartons with prefilled, single-use syringes.

Body weight of patient	Once-daily dosage	Plunger color
<56 kg	16.6 mg/0.416 mL	Rubine red
≥56 kg to <77 kg	23 mg/0.574 mL	Orange
≥77 kg	32.4 mg/0.81 mL	Dark blue

IMPORTANT SAFETY INFORMATION (cont'd) CONTRAINDICATIONS

ZILBRYSQ is contraindicated in patients with unresolved *Neisseria meningitidis* infection.

Please refer to pages 15 and 16 for additional Important Safety Information.

Please refer to the full Prescribing Information, including Boxed Warning for serious meningococcal infections, provided by the UCB representative and visit ZILBRYSQhcp.com.



Information Patients Need to Know Before Self-injecting ZILBRYSQ¹

ZILBRYSQ is intended for use under the guidance and supervision of a healthcare professional. Patients may self-inject ZILBRYSQ after training in subcutaneous injection technique. Prior to your patient's first dose, train the patient and/or caregiver in subcutaneous injection technique of ZILBRYSQ according to the "Instructions for Use" outlined in the <u>Prescribing Information</u>. See preparation and administration instructions below and on the next page.

Preparation prior to administration



Patients may store ZILBRYSQ prefilled syringes in a refrigerator in the original carton or at room temperature in the original carton for up to 3 months or until the expiration date, whichever occurs first



If stored in the refrigerator:

- Before injecting, take 1 ZILBRYSQ prefilled syringe out of the refrigerator and place on a clean, flat surface. Allow ZILBRYSQ to reach room temperature out of direct sunlight by waiting 30 to 45 minutes before injecting. Do not heat or place in microwave
- Immediately return the carton with the other prefilled syringes to the refrigerator



If stored at room temperature:

- Remove 1 ZILBRYSQ prefilled syringe from the carton
- Do not return ZILBRYSQ to the refrigerator after it has been stored at room temperature



Visually inspect ZILBRYSQ for particulate matter and discoloration prior to administration

- ZILBRYSQ is a clear to slightly opalescent, colorless solution. Do not use if the solution contains visible particles, is cloudy, or if foreign particulate matter is present
- ZILBRYSQ does not contain preservatives; unused portions of drug remaining in the syringe should be discarded
- Each prefilled syringe is for single use only



Injection Training

- Training kits are available for patients. Reach out to your UCB Account Executive for additional information if interested
- ONWARD offers Virtual Refresher Injection Training for enrolled patients. PANTHERx Rare also provides virtual injection training and administration technique counseling for patients. Inform patients that they can schedule refresher trainings as needed

IMPORTANT SAFETY INFORMATION (cont'd) WARNINGS AND PRECAUTIONS

Serious Meningococcal Infections

Life-threatening and fatal meningococcal infections have occurred in both vaccinated and unvaccinated patients treated with complement inhibitors; ZILBRYSQ is a complement inhibitor. The use of ZILBRYSQ increases a patient's susceptibility to serious and life-threatening meningococcal infections (septicemia and/or meningitis) caused by any serogroup, including non-groupable strains.

Please refer to pages 15 and 16 for additional Important Safety Information.

Please refer to the full Prescribing Information, including Boxed Warning for serious meningococcal infections, provided by the UCB representative and visit <u>ZILBRYSQhcp.com</u>.

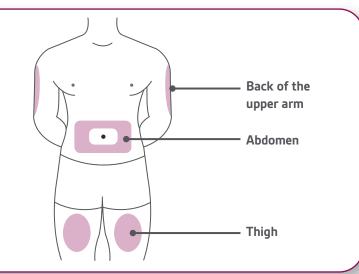


How Patients Can Self-inject ZILBRYSQ¹

Administration considerations

Administer ZILBRYSQ subcutaneously into areas of the abdomen, thighs, or back of the upper arms that are not tender, bruised, red, or hard

- Avoid injecting into areas with scars or stretch marks
- Rotate injection sites for each administration
- Please note: Administration of ZILBRYSQ in the upper, outer arm should be performed by a caregiver



- When using ZILBRYSQ prefilled syringes, inject the full contents of the single-dose prefilled syringe
- Discard ZILBRYSQ prefilled syringe after use. Do not reuse
- Instruct the patient that the daily dose should be administered at approximately the same time each day
 - If a dose is missed, administer the dose as soon as possible. Thereafter, resume dosing at the regularly scheduled time. Do not administer more than 1 dose per day

For more information on preparation and administration, please visit ucb-usa.com/ZILBRYSQ-prescribing-information.pdf and refer to the Instructions for Use

ACIP=Advisory Committee on Immunization Practices.

IMPORTANT SAFETY INFORMATION (cont'd)

Serious Meningococcal Infections (cont'd)

Complete or update meningococcal vaccination (for both serogroups A, C, W, and Y [MenACWY] and serogroup B [MenB]) at least 2 weeks prior to administering the first dose of ZILBRYSQ, according to current ACIP recommendations for meningococcal vaccinations in patients receiving a complement inhibitor.

Please refer to pages 15 and 16 for additional Important Safety Information.

Please refer to the full Prescribing Information, including Boxed Warning for serious meningococcal infections, provided by the UCB representative and visit ZILBRYSQhcp.com.



Personalized Support for ZILBRYSQ Patients



ONWARD* is an individualized support experience built to help patients through every step of their ZILBRYSQ treatment. With ONWARD, prescribed patients living with generalized myasthenia gravis (gMG) will have access to important resources, including:



Communication with a dedicated Care Coordinator to provide personalized support[†]



Help in reviewing insurance coverage and potential financial assistance options



Tools and resources to start and stay on treatment, as prescribed



Help tracking symptoms and ongoing treatment support

Consider enrolling your patients in ONWARD when prescribing ZILBRYSQ

Fill out the Start Form or use the online portal to enroll patients at your office

- Patients are automatically enrolled if the completed Start Form is sent to ONWARD
- If the Start Form and prescription are sent directly to PANTHERx Rare and patient consent is provided, PANTHERx Rare will transfer applicable information to ONWARD for enrollment

Inform patients to expect a call from an ONWARD Care Coordinator* (844-669-2731) to discuss the support services being requested.

Patient Support

If you have questions about getting your ZILBRYSQ patients started in the ONWARD™ Patient Support Program, please visit <u>ucbONWARD.com</u> to access resources for healthcare professionals or contact your Rare Reimbursement Executive for assistance.

Please refer to pages 15 and 16 for Important Safety Information.

Please refer to the full Prescribing Information, including Boxed Warning for serious meningococcal infections, provided by the UCB representative and visit <u>ZILBRYSQhcp.com</u>.

^{*}ONWARD is provided as a service of UCB and is intended to support the appropriate use of UCB medicines. ONWARD may be amended or canceled at any time without notice. Some program and eligibility restrictions may apply.

[†]ONWARD does not provide medical advice and does not replace the care of the healthcare professional. Care Coordinators will refer patients to their healthcare provider for any treatment-related questions.

^{*}Please note that when patients receive this call, they may see "ONWARD" on their caller ID.



IMPORTANT SAFETY INFORMATION INCLUDING BOXED WARNING

WARNING: SERIOUS MENINGOCOCCAL INFECTIONS

Life-threatening and fatal meningococcal infections have occurred in patients treated with complement inhibitors; ZILBRYSQ is a complement inhibitor. Meningococcal infection may become rapidly life-threatening or fatal if not recognized and treated early.

- 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. Comply with the most current Advisory Committee on Immunization Practices (ACIP) recommendations for meningococcal vaccinations in patients receiving a complement inhibitor.
- Persons receiving ZILBRYSQ are at increased risk for invasive disease caused by N. meningitidis, even if they develop antibodies following vaccination. Monitor patients for signs of 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 in patients with unresolved *Neisseria meningitidis* infection.

WARNINGS AND PRECAUTIONS

Serious Meningococcal Infections

Life-threatening and fatal meningococcal infections have occurred in both vaccinated and unvaccinated patients treated with complement inhibitors; ZILBRYSQ is a complement inhibitor. The use of ZILBRYSQ increases a patient's susceptibility to serious and life-threatening meningococcal infections (septicemia and/or meningitis) caused by any serogroup, including non-groupable strains.

Complete or update meningococcal vaccination (for both serogroups A, C, W, and Y [MenACWY] and serogroup B [MenB]) at least 2 weeks prior to administering the first dose of ZILBRYSQ, according to current ACIP recommendations for meningococcal vaccinations in patients receiving a complement inhibitor.

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

Closely monitor patients for early signs and symptoms of meningococcal infection and evaluate patients immediately if infection is suspected. Withhold administration of ZILBRYSQ in patients who are undergoing treatment for meningococcal infection until the infection is resolved.

ZILBRYSO REMS

Due to the risk of 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 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.

Please refer to the next page for additional Important Safety Information.

Please refer to the full Prescribing Information, including Boxed Warning for serious meningococcal infections, provided by the UCB representative and visit <u>ZILBRYSQhcp.com</u>.



IMPORTANT SAFETY INFORMATION INCLUDING BOXED WARNING (cont'd) WARNINGS AND PRECAUTIONS (cont'd)

Other Infections

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* and *Haemophilus influenzae type b* (Hib) infections according to ACIP guidelines. Persons receiving ZILBRYSQ are at increased risk for infections due to these bacteria, even after 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, including Boxed Warning for serious meningococcal infections, provided by the UCB representative and visit <u>ZILBRYSQhcp.com</u>.

For more information about ZILBRYSQ, visit ZILBRYSQhcp.com.

For additional information, contact UCBCares® at 1-844-599-CARE (2273).

 $A CIP = Advisory\ Committee\ on\ Immunization\ Practices;\ gMG = generalized\ my as then ia\ gravis.$

References: 1. ZILBRYSQ [prescribing information]. Smyrna, GA: UCB, Inc. 2. Centers for Disease Control and Prevention. Adult immunization schedule by age. Updated November 16, 2023. Accessed November 27, 2023. https://www.cdc.gov/vaccines/schedules/hcp/imz/adult.html. 3. PENBRAYA [prescribing information]. New York, NY: Pfizer Inc. 4. Centers for Disease Control and Prevention. Meningococcal vaccine recommendations. Updated November 20, 2023. Accessed November 27, 2023. https://www.cdc.gov/vaccines/vpd/mening/hcp/recommendations.html. 5. Mbaeyi SA, Bozio CH, Duffy J, et al. Meningococcal vaccination: recommendations of the Advisory Committee on Immunization Practices, United States, 2020. MMWR Morb Mortal Wkly Rep. Published September 25, 2020. Accessed November 27, 2023. https://www.cdc.gov/mmwr/volumes/69/rr/pdfs/rr6909a1-H.pdf.

