# CENTER FOR DRUG EVALUATION AND RESEARCH

***APPLICATION NUMBER:***

# 216834Orig1s000

# REMS

# Risk Evaluation and Mitigation Strategy (REMS) Document

# ZILBRYSQ (zilucoplan) REMS

## I. Administrative Information

Risk: Serious meningococcal infections
Application Number: NDA 216834
Application Holder: UCB, Inc.
Initial REMS Approval: 10/2023

## II. REMS Goal

The goal of the ZILBRYSQ REMS is to mitigate the risk of serious meningococcal infections.

1. Patients are vaccinated against meningococcal infections caused by Neisseria meningitidis serogroups A, C, W, Y (MenACWY) and serogroup B (MenB) prior to starting therapy according to the current Advisory Committee on Immunization Practices (ACIP) recommendations and receive antibacterial drug prophylaxis if needed.
2. Patients are aware of early signs and symptoms of meningococcal infection and the need for immediate medical evaluation.
3. Prescribers are aware of early signs and symptoms of meningococcal infection and the need for immediate medical evaluation.

## III. REMS Requirements

**UCB, Inc. must ensure that healthcare providers, patients, pharmacies, and wholesalers, distributors, and other entities that distribute ZILBRYSQ comply with the following requirements:**

**1. Healthcare providers who prescribe ZILBRYSQ must:**

| | |
|---|---|
| To become certified to prescribe | 1. Review the drug's Prescribing Information.<br>2. Review the following: Healthcare Provider Safety Brochure, Patient Guide, and Patient Safety Card.<br>3. Enroll by completing and submitting the Prescriber Enrollment Form to the REMS. |
| Before treatment initiation | 4. Assess the patient for unresolved meningococcal infection.<br>5. For patients with unresolved meningococcal infection: Not initiate ZILBRSYQ.<br>6. Assess the patient's vaccination status for meningococcal serogroups A, C, W, and Y (MenACWY) and serogroup B (MenB) and vaccinate as |

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| | needed according to the current Advisory Committee on Immunization Practices (ACIP) recommendations for meningococcal vaccinations in patients receiving a complement inhibitor.<br><br>7. For patients who are not up to date with MenACWY and MenB vaccines at least two weeks prior to initiation of treatment and who must start ZILBRYSQ urgently: Provide the patient with a prescription for antibacterial drug prophylaxis.<br><br>8. Counsel the patient 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. |
| During treatment | 9. Assess the patient for early signs and symptoms of meningococcal infection and evaluate immediately, if infection is suspected.<br><br>10. For patients who are being treated for meningococcal infection: Withhold administration of ZILBRYSQ.<br><br>11. Revaccinate patients according to the current Advisory Committee on Immunization Practices (ACIP) recommendations on meningococcal vaccinations for patients receiving a complement inhibitor. |
| At all times | 12. Report adverse events suggestive of meningococcal infection, including the patient's clinical outcomes, to UCB, Inc. |

**2. Patients who are prescribed ZILBRYSQ:**

| | |
|---|---|
| Before treatment initiation | 1. Get both meningococcal vaccines (MenACWY and MenB) as directed by your prescriber.<br><br>2. Take antibiotics as directed by your prescriber if you have to start ZILBRYSQ right away.<br><br>3. Receive counseling from the prescriber using the Patient Safety Card and Patient Guide.<br><br>4. Get the Patient Safety Card and Patient Guide from your prescriber. |
| During treatment | 5. Get additional meningococcal vaccines as directed by your prescriber. |
| At all times during treatment and for 2 months after the last dose | 6. Inform the prescriber or get emergency medical care right away if any of the following occur: headache with nausea or vomiting, stiff neck, stiff back, or fever; fever with or without rash; sensitivity of eyes to light; confusion; muscle aches with flu-like symptoms.<br><br>7. Have the Patient Safety Card with you. |

**3. Pharmacies that dispense ZILBRYSQ must:**

| | |
|---|---|
| To become certified to dispense | 1. Designate an Authorized Representative to carry out the certification process and oversee implementation and compliance with the REMS on behalf of the pharmacy.<br><br>2. Have the Authorized Representative review the Healthcare Provider Safety Brochure.<br><br>3. Have the Authorized Representative enroll in the REMS by completing and submitting the Pharmacy Enrollment Form to the REMS.<br><br>4. Train all relevant staff involved in dispensing ZILBRYSQ using the Healthcare Provider Safety Brochure.<br><br>5. Establish processes and procedures to verify the prescriber is certified and document the findings.<br><br>6. Establish processes and procedures to contact the prescriber to assess the patient's vaccination status for up to date meningococcal vaccines (MenACWY and MenB) according to the current Advisory Committee on Immunization Practices (ACIP) recommendations including antibacterial drug prophylaxis if needed before treatment initiation and document the findings.<br><br>7. For patients who are not up to date with meningococcal vaccines when starting treatment: Establish processes and procedures to assess the patient's vaccination status for up to date meningococcal vaccines including antibacterial drug prophylaxis if needed by contacting the prescriber before dispensing prescriptions up to 6 months after the first dose and document the findings. |
| Before dispensing, first dose | 8. Verify the prescriber is certified and document the findings through the processes and procedures established as a requirement of the REMS.<br><br>9. Assess the patient's vaccination status for up to date meningococcal vaccines (MenACWY and MenB) including antibacterial drug prophylaxis if needed by contacting the prescriber and document the findings through the processes and procedures established as a requirement of the REMS. |
| Before dispensing, up to 6 months after the first dose | 10. Verify the prescriber is certified and document the findings through the processes and procedures established as a requirement of the REMS.<br><br>11. For patients who are not initially up to date with meningococcal vaccines when starting treatment: Assess the patient's vaccination status for up to date meningococcal vaccines (MenACWY and MenB) including antibacterial drug prophylaxis if needed by contacting the prescriber and document the findings through the processes and procedures established as a requirement of the REMS. |

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|---|---|
| Before dispensing, 6 months after the first dose and thereafter | 12. Verify the prescriber is certified and document the findings through the processes and procedures established as a requirement of the REMS. |
| To maintain certification to dispense | 13. If the Authorized Representative changes, have a new Authorized Representative enroll in the REMS by completing and submitting the Pharmacy Enrollment Form to the REMS. |
| At all times | 14. Report adverse events suggestive of meningococcal infection to UCB, Inc.<br>15. Not distribute, transfer, loan, or sell ZILBRYSQ, except to certified pharmacies.<br>16. Maintain records of staff's completion of REMS training.<br>17. Maintain records that all processes and procedures are in place and are being followed.<br>18. Comply with audits carried out by UCB, Inc. or a third party acting on behalf of UCB, Inc. to ensure that all processes and procedures are in place and are being followed. |

**4. Wholesalers, distributors, and other entities that distribute ZILBRYSQ must:**

| | |
|---|---|
| To be able to distribute | 1. Establish processes and procedures to ensure that the drug is distributed only to certified pharmacies.<br>2. Train all relevant staff involved in distributing ZILBRYSQ on the REMS requirements. |
| At all times | 3. Distribute only to certified pharmacies.<br>4. Maintain records of all drug distributions.<br>5. Comply with audits carried out by UCB, Inc. or a third party acting on behalf of UCB, Inc. to ensure all processes and procedures are in place and are being followed. |

**UCB, Inc. must provide training to healthcare providers who prescribe ZILBRYSQ.**

The training includes the following educational materials: Healthcare Provider Safety Brochure, Patient Guide, and Patient Safety Card. The training must be available on a website and in hardcopy format via mail.

**UCB, Inc. must provide training to pharmacies that dispense ZILBRYSQ.**

The training includes the following educational material: Healthcare Provider Safety Brochure. The training must be available on a website and in hardcopy format via mail.

**To inform healthcare providers about the REMS and the risks and safe use of ZILBRYSQ, UCB, Inc. must disseminate REMS communication materials according to the table below:**

| Target Audience | Communication Materials & Dissemination Plans |
|---|---|
| REMS certified prescribers of ZILBRYSQ | REMS Letter: Vaccination reminder to REMS certified prescribers<br><br>1. Fax or email annually |

**To support REMS operations, UCB, Inc. must:**

1. Establish and maintain a REMS website, www.ZILBRYSQREMS.com. The REMS website must include the capability for prescribers and pharmacies to enroll in the REMS online, by fax, or by email, and the option to print the Prescribing Information, Medication Guide, and REMS materials. All product websites for consumers and healthcare providers must include prominent REMS-specific links to the REMS website. The REMS website must not link back to the promotional product website(s).

2. Make the REMS website fully operational and all REMS materials available through the website or call center by the date ZILBRYSQ is first commercially distributed.

3. Establish and maintain a REMS call center for REMS participants at 1-877-414-8353.

4. Establish and maintain a validated, secure database of all REMS participants who are enrolled and/or certified in the ZILBRYSQ REMS.

5. Ensure prescribers and pharmacies are able to enroll in the REMS by fax, email, and online.

6. Ensure prescribers are able to report adverse events suggestive of meningococcal infection by phone.

7. Ensure pharmacies are able to report adverse events suggestive of meningococcal infection by email.

8. Ensure that once a report suggestive of meningococcal infection is received, UCB, Inc. will follow up with the healthcare providers to obtain all required data. This requirement does not affect UCB, Inc.'s other reporting and follow up requirements under FDA regulations.

9. Provide the Healthcare Provider Safety Brochure, Prescriber Enrollment Form, Patient Guide, Patient Safety Card, and the Prescribing Information to prescribers who (1) attempt to prescribe ZILBRYSQ and are not yet certified or (2) inquire about how to become certified.

10. Provide Healthcare Provider Safety Brochure and Pharmacy Enrollment Form to pharmacies that (1) attempt to order/dispense and are not yet certified or (2) inquire about how to become certified.

11. Notify prescribers and pharmacies within 2 business days after they become certified in the REMS.

12. Provide certified pharmacies access to a database of certified prescribers.

13. Provide certified prescribers access to a database of certified pharmacies.

14. Provide authorized wholesalers, distributors, and other entities that distribute ZILBRYSQ access to a database of certified pharmacies.

**To ensure REMS participants' compliance with the REMS, UCB, Inc. must:**

15. Maintain adequate records to demonstrate that REMS requirements have been met, including, but not limited to records of: ZILBRYSQ distribution and dispensing; certification of prescribers and pharmacies; and audits of REMS participants. These records must be readily available for FDA inspections.

16. Verify annually that the designated Authorized Representative's name and contact information correspond to those of the current designated authorized representative for the pharmacy. If different, the pharmacy must be required to re-certify with a new Authorized Representative.

17. Establish and maintain a plan for addressing noncompliance with REMS requirements.

18. Monitor prescribers and pharmacies on an ongoing basis to ensure the requirements of the REMS are being met. Take corrective action if noncompliance is identified, including de-certification.

19. Audit certified pharmacies no later than 180 calendar days from the date the first shipment was sent from the pharmacy, then annually thereafter, to ensure that all REMS processes and procedures are in place, functioning, and support the REMS requirements.

20. Audit wholesalers, distributors, and other entities that distribute ZILBRYSQ no later than 180 calendar days after their first commercial distribution of ZILBRYSQ and annually thereafter to ensure all REMS processes and procedures are in place, functioning, and comply with REMS requirements.

21. Take reasonable steps to improve operations of and compliance with the requirements in the ZILBRYSQ REMS based on monitoring and evaluation of the ZILBRYSQ REMS.

# IV. REMS Assessment Timetable

UCB, Inc. must submit REMS Assessments at 6 months, 12 months, and annually thereafter from the date of the initial approval of the REMS. To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 calendar days before the submission date for that assessment. UCB, Inc. must submit each assessment so that it will be received by the FDA on or before the due date.

# V. REMS Materials

The following materials are part of the ZILBRYSQ REMS.

**Enrollment Forms**

Prescriber:

1. Prescriber Enrollment Form

Pharmacy:

2. Pharmacy Enrollment Form

**Training and Educational Materials**

Prescriber:

3. Healthcare Provider Safety Brochure

Patient:

4. Patient Safety Card
5. Patient Guide

Pharmacy:

6. Healthcare Provider Safety Brochure

**Communication Materials**

7. REMS Letter: Vaccination reminder to REMS certified prescribers

**Other Materials**

8. REMS website

## VI. Statutory Elements

This REMS is required under section 505-1 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355-1) and consists of the following elements:

1. Elements to Assure Safe Use (ETASU):
    a. Health care providers who prescribe ZILBRYSQ are specially certified under 505-1(f)(3)(A)
    b. Pharmacies that dispense ZILBRYSQ are specially certified under 505-1(f)(3)(B)
    c. ZILBRYSQ is dispensed to patients with evidence or other documentation of safe-use conditions under 505-1(f)(3)(D)
2. Implementation System
3. Timetable for submission of Assessments

ZILBRYSQ®
(zilucoplan) Injection REMS

Fax: 1-877-411-3609
Website: www.ZILBRYSQREMS.com

# PRESCRIBER ENROLLMENT FORM

Instructions:

1. Review the ZILBRYSQ Prescribing Information, **Healthcare Provider Safety Brochure, Patient Guide**, and **Patient Safety Card.**
2. Submit this completed **Prescriber Enrollment Form** to the ZILBRYSQ REMS:

   - Online at www.ZILBRYSQREMS.com
   - By scanning and emailing to ZILBRYSQREMS@ppd.com
   - By fax at 1-877-411-3609

**Prescriber Information** (* fields required)

| | | |
|---|---|---|
| *First Name: | *Last Name: | |
| *National Provider Identifier (NPI): | *Email: | |
| *Credentials: ☐ MD ☐ DO ☐ APRN ☐ PA ☐ Other (please specify): | | |
| *Medical Specialty: ☐ Neurology ☐ Other (please specify): | | |
| Clinic / Practice Name: | | |
| *Address Line 1: | | |
| Address Line 2: | | |
| *City: | *State: | *Zip Code: |
| *Office Phone Number: | *Office Fax Number: | |
| Alternative Office Phone Number: | | |

## Prescriber Attestations

By completing, signing, and submitting this form, I acknowledge and agree that:

- I have read and understand the ZILBRYSQ Prescribing Information, **Healthcare Provider Safety Brochure, Patient Guide,** and **Patient Safety Card.**
- **Before treatment initiation, I must:**
  - Assess the patient for unresolved meningococcal infection.
  - For patients with unresolved meningococcal infection: Not initiate ZILBRYSQ.
  - Assess the patient's vaccination status for meningococcal serogroups A, C, W, and Y (MenACWY) and serogroup B (MenB) and vaccinate as needed according to the current Advisory Committee on Immunization Practices (ACIP) recommendations for meningococcal vaccinations in patients receiving a complement inhibitor.
  - For patients who are not up to date with MenACWY and MenB vaccines at least two weeks prior to initiation of treatment and must start ZILBRYSQ urgently: Provide the patient with a prescription for antibacterial drug prophylaxis.
  - Counsel the patient using the **Patient Safety Card** and **Patient Guide**. Provide the patient with copies of these materials. Instruct the patient to carry the **Patient Safety Card** at all times and for 2 months after their last ZILBRYSQ dose.
- **During treatment, I must:**
  - Assess the patient for early signs and symptoms of meningococcal infection and evaluate immediately, if infection is suspected.
  - For patients who are being treated for meningococcal infections: Withhold administration of ZILBRYSQ.
  - Revaccinate patients according to the current Advisory Committee on Immunization Practices (ACIP) recommendations on meningococcal vaccinations for patients receiving a complement inhibitor.
- **At all times, I must:**
  - Report adverse events suggestive of meningococcal infection, including the patient's clinical outcomes, to UCB, Inc. at 1-844-599-2273.
- I understand that if I do not maintain compliance with the requirements of the REMS, I will no longer be able to prescribe ZILBRYSQ.
- I understand that ZILBRYSQ REMS and its agents or contractors may contact me to support the administration of the REMS.

| ***Prescriber's Signature:** | ***Date (MM/DD/YYYY):** |
|---|---|
| | |

ZILBRYSQ® (zilucoplan) Injection

ZILBRYSQ®
(zilucoplan) Injection REMS

Fax: 1-877-411-3609
Website: www.ZILBRYSQREMS.com

# PHARMACY ENROLLMENT FORM

Instructions:

1. Designate an Authorized Representative to complete training and to commit to training all staff who will be involved in dispensing ZILBRYSQ.
2. Review the **Healthcare Provider Safety Brochure**.
3. Submit this completed **Pharmacy Enrollment Form** to the ZILBRYSQ REMS:

   - Online at www.ZILBRYSQREMS.com
   - By scanning and emailing to ZILBRYSQREMS@ppd.com
   - By fax at 1-877-411-3609

**REMS Pharmacy Information** (* fields required)

☐ Initial pharmacy enrollment
☐ Change of information for enrolled pharmacy
☐ Change of authorized representative

| **Authorized Representative Information** | | |
|---|---|---|
| *First Name: | *Last Name: | |
| *Title/Position: ☐ Pharmacist ☐ Nurse ☐ Other (please specify): | | |
| *Authorized Representative National Provider Identifier (NPI): | | |
| *Email: | *Preferred Method of Communication: ☐ Email ☐ Phone | |
| **Pharmacy Information** | | |
| *Pharmacy Name: | | |
| * Address Line 1: | | |
| Address Line 2: | | |
| * City: | * State: | *Zip Code: |
| * Phone Number: | * Fax Number: | |
| ***Pharmacy National Provider Identifier (NPI):** | | |

## Authorized Representative Attestations

**As the Authorized Representative, I must:**

- Review the **Healthcare Provider Safety Brochure**.
- Train all relevant staff who will be involved in dispensing ZILBRYSQ using the **Healthcare Provider Safety Brochure**.
- Establish processes and procedures to verify the prescriber is certified and document the findings.
- Establish processes and procedures to contact the prescriber to assess the patient's vaccination status for up to date meningococcal vaccines (MenACWY and MenB) according to the current Advisory Committee on Immunization Practices (ACIP) recommendations including antibacterial drug prophylaxis if needed before treatment initiation and document the findings.
- For patients who are not up to date with meningococcal vaccines when starting treatment: Establish processes and procedures to assess the patient's vaccination status for up to date meningococcal vaccines including antibacterial drug prophylaxis if needed by contacting the prescriber before dispensing prescriptions up to 6 months after the first dose and document the findings.

**Before dispensing the first dose, all pharmacy staff must:**

- Verify the prescriber is certified and document the findings through the processes and procedures established as a requirement of the REMS.
- Assess the patient's vaccination status for up to date meningococcal vaccines (MenACWY and MenB) including antibacterial drug prophylaxis if needed by contacting the prescriber and document the findings through the processes and procedures established as a requirement of the REMS.

**For up to 6 months after dispensing the first dose, all pharmacy staff must:**

- Verify the prescriber is certified and document the findings through the processes and procedures established as a requirement of the REMS.
- For patients who are not initially up to date with meningococcal vaccines when starting treatment: Assess the patient's vaccination status for up to date meningococcal vaccines (MenACWY and MenB) including antibacterial drug prophylaxis if needed by contacting the prescriber and document the findings through the processes and procedures established as a requirement of the REMS.

**After the first 6 months of dispensing, all pharmacy staff must:**

- Verify the prescriber is certified and document the findings through the processes and procedures established as a requirement of the REMS.

**At all times, my pharmacy must:**

- Report adverse events suggestive of meningococcal infection to UCB, Inc. by email at ds.usa@ucb.com.
- Not distribute, transfer, loan, or sell ZILBRYSQ, except to certified pharmacies.
- Maintain records of staff's completion of REMS training.
- Maintain records that all processes and procedures are in place and are being followed.
- Comply with audits carried out by UCB, Inc. or a third party acting on behalf of UCB, Inc. to ensure that all processes and procedures are in place and are being followed.

**To maintain certification to dispense, any new Authorized Representative must:**

- Enroll in the REMS by completing and submitting this **Pharmacy Enrollment Form** to the REMS.

| *Authorized Representative Signature: | *Date (MM/DD/YYYY): |
|---|---|
| | |

# ZILBRYSQ REMS

## HEALTHCARE PROVIDER SAFETY BROCHURE

ZILBRYSQ®
(zilucoplan) Injection

For more information about the ZILBRYSQ REMS (Risk Evaluation and Mitigation Strategy):

Visit: www.ZILBRYSQREMS.com
Call: 1-877-414-8353
Monday through Friday, 9:00 am to 5:00 pm ET

This brochure is for healthcare providers who will prescribe or dispense ZILBRYSQ (zilucoplan). It describes:

- The increased risk of meningococcal infections with ZILBRYSQ
- Information about meningococcal vaccinations and antibacterial drug prophylaxis in patients receiving ZILBRYSQ
- How to counsel patients with the **Patient Guide** and **Patient Safety Card**
- How to become certified to prescribe or dispense ZILBRYSQ

Please see Prescribing Information, including BOXED WARNING for serious meningococcal infections, for more detailed safety information about ZILBRYSQ.

## What is ZILBRYSQ?

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

### Risk of 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. Meningococcal infections may rapidly become life-threatening or fatal if not recognized and treated early.

- At least 2 weeks prior to the first dose of ZILBRYSQ, complete or update meningococcal vaccination (for both serogroups A, C, W, and Y [MenACWY] and serogroup B [MenB]) according to the current Advisory Committee on Immunization Practices (ACIP) recommendations for meningococcal vaccinations in patients receiving a complement inhibitor.
- Revaccinate patients in accordance with ACIP recommendations considering the duration of ZILBRYSQ therapy.
- 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.
- Because of inhibition of complement activity by ZILBRYSQ and risk of infection caused by nongroupable strains of *N. meningitidis*, vaccination does not eliminate the risk of meningococcal infections, despite development of antibodies following vaccination.
- Closely monitor patients for early signs and symptoms of meningococcal infection and evaluate immediately if infection is suspected.
- Inform patients of these signs and symptoms of meningococcal infections and instruct patients to seek immediate medical care if these signs and symptoms occur.
- Withhold administration of ZILBRYSQ in patients who are undergoing treatment for meningococcal infection until the infection is resolved.

Please see Prescribing Information, including BOXED WARNING for serious meningococcal infections, for more detailed safety information about ZILBRYSQ.

## What Do Prescribers Need to Do to Prescribe ZILBRYSQ?

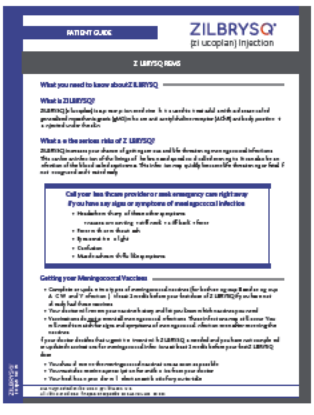
Prescribers must be certified in the ZILBRYSQ REMS before they are eligible to prescribe ZILBRYSQ.

### To become certified to prescribe ZILBRYSQ

- Review the ZILBRYSQ **Prescribing Information**
- Review the **Healthcare Provider Safety Brochure** (this document)
- Review the **Patient Guide**
- Review the **Patient Safety Card**
- Complete and submit the **Prescriber Enrollment Form** to the ZILBRYSQ REMS.

### Before initiating a patient's ZILBRYSQ treatment

- Assess the patient for unresolved meningococcal infection and do not initiate ZILBRYSQ therapy in any patient with this infection.
- Assess the patient's meningococcal vaccination status for serogroups A, C, W, and Y (MenACWY) and serogroup B (MenB) and vaccinate the patient as needed according to the current Advisory Committee on Immunization Practices (ACIP) recommendations for meningococcal vaccinations in patients receiving a complement inhibitor, which may be found at https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/mening.html. A link to these recommendations may be found at the ZILBRYSQ REMS website, www.ZILBRYSQREMS.com.
- For patients who are not up to date with MenACWY and MenB vaccines at least two weeks prior to initiation of treatment with ZILBRSYQ and must start ZILBRYSQ urgently:
  - Administer meningococcal vaccines as soon as possible.
  - Provide the patient with a prescription for antibacterial drug prophylaxis.
- Counsel patients who will receive ZILBRYSQ on the increased risk of meningococcal infections, the importance of vaccination (both MenACWY and MenB), and the need for antibiotics if they are not up to date on both meningococcal vaccines and have to start ZILBRYSQ right away. Provide patients with both the **Patient Guide** and **Patient Safety Card**.
  - The **Patient Guide** provides information your patients can carry with them to find out more about ZILBRYSQ, including:
    - The risk of meningococcal infections
    - The need for meningococcal vaccination
    - Signs and symptoms of meningococcal infections


PATIENT GUIDE

ZILBRYSQ
(zi ucoplan) injection

Z LBRYSQ REMS

What you need to know about Z LBRYSQ

What is ZILBRYSQ?

What is the serious risk of Z LBRYSQ?

Call your hea thcare provider or seek emergency care right away
if you have any signs or symptoms of meni gococcal infection

Getting your Meningococcal Vaccines

- The **Patient Safety Card** provides quick, portable guidance for the patient and for any of the patient's healthcare providers about:
    - The patient's ZILBRYSQ treatment
    - Signs and symptoms of meningococcal infection
    - Importance of immediate care for any suspected meningococcal infection


Show this PATIENT SAFETY CARD to any healthcare provider involved in your health care and if you go to the hospital.
• ZILBRYSQ® (zilucoplan) increases your chance of getting a meningococcal infection. This can be an infection of the linings of the brain and spinal cord called meningitis. It can also be an infection of the blood called septicemia. These infections may quickly become life-threatening or fatal if not recognized and treated early.
• Call your healthcare provider or seek emergency care immediately if you have any signs or symptoms of meningococcal infection.
ZILBRYSQ®
PATIENT SAFETY CARD

- Discuss the importance and the proper use of the safety card with any patient who is receiving ZILBRYSQ.
    - Counsel patients to carry the safety card at all times during therapy and for 2 months after the last dose of ZILBRYSQ.
    - Counsel patients to show the card to any healthcare provider involved in their care.
- Tell your patients about the risk of meningococcal infections and that this risk may continue for several weeks after the last dose of ZILBRYSQ.
- Advise patients of the need to complete or update both meningococcal vaccines for serogroups A, C, W, and Y (MenACWY) and serogroup B (MenB) according to current medical guidelines.
- Advise patients that meningococcal vaccines do not prevent all meningococcal infections.
- Advise patients of the need for antibiotics if they are not up to date on both meningococcal vaccines and have to start ZILBRYSQ right away.
- Educate patients to recognize the early signs and symptoms of meningococcal infections and instruct patients to seek immediate medical attention if any of these signs or symptoms occur. Signs and symptoms include:
    - Headache with any of the following:
        - Nausea or vomiting
        - Stiff neck or stiff back
        - Fever
    - Fever with or without rash
    - Eyes sensitive to light
    - Confusion
    - Muscle aches with flu-like symptoms

## During ZILBRYSQ treatment

- Assess the patient for early signs and symptoms of meningococcal infections and evaluate immediately, if infection is suspected.
- For patients who are being treated for meningococcal infection: Withhold administration of ZILBRYSQ.
- Revaccinate patients according to the current ACIP recommendations on meningococcal vaccination for patients receiving a complement inhibitor.

## At all times

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

## What Do Pharmacists Need to Do to Dispense ZILBRYSQ?

Pharmacies must be certified in the ZILBRYSQ REMS before they are eligible to dispense ZILBRYSQ.

### To become certified to dispense ZILBRYSQ

- Designate an Authorized Representative to carry out the certification process and oversee implementation and compliance with the REMS on behalf of the pharmacy.
- Review the **Healthcare Provider Safety Brochure** (this document).
- Submit a completed **Pharmacy Enrollment Form** to the ZILBRYSQ REMS.
- Establish processes to ensure that the pharmacy meets all REMS requirements, including:
  - Providing training for all staff involved in dispensing ZILBRYSQ using the **Healthcare Provider Safety Brochure**.
  - Verifying the prescriber is certified and document the findings.
  - Contacting the prescriber to assess the patient's vaccination status for up to date meningococcal vaccines (MenACWY and MenB) according to the current Advisory Committee on Immunization Practices (ACIP) recommendations including antibacterial drug prophylaxis if needed before treatment initiation and document the findings.
  - For patients who are not up to date with meningococcal vaccines when starting treatment: Contact the prescriber before dispensing prescriptions up to 6 months after the first dose to assess the patient's vaccination status for up to date meningococcal vaccines including antibacterial drug prophylaxis if needed and document the findings.

### Before dispensing the first dose of ZILBRYSQ

- Verify the prescriber is certified and document the findings through the processes and procedures established as a requirement of the REMS.
- Assess the patient's vaccination status for up to date meningococcal vaccines (MenACWY and MenB) including antibacterial drug prophylaxis if needed by contacting the prescriber and document the findings through the processes and procedures established as a requirement of the REMS.

## For up to 6 months after dispensing the first dose of ZILBRYSQ

- Verify the prescriber is certified and document the findings through the processes and procedures established as a requirement of the REMS.
- Assess the patient's vaccination status for up to date meningococcal vaccines (MenACWY and MenB) including antibacterial drug prophylaxis if needed by contacting the prescriber and document the findings through the processes and procedures established as a requirement of the REMS.

## After the first 6 months of dispensing the first dose of ZILBRYSQ

- Verify the prescriber is certified and document the findings through the processes and procedures established as a requirement of the REMS.

## To maintain certification to dispense

- If the Authorized Representative changes, have a new Authorized Representative enroll in the REMS by completing and submitting the **Pharmacy Enrollment Form** to the REMS.

## At all times

- Do not distribute, transfer, loan, or sell ZILBRYSQ, except to certified pharmacies.
- Report any adverse events suggestive of meningococcal infection in a patient taking ZILBRYSQ to UCB, Inc. by email at ds.usa@ucb.com.
- Maintain records of staff's completion of REMS training.
- Maintain records to show that processes and procedures that fulfill all REMS requirements are in place and being followed.
- Comply with audits carried out by UCB, Inc. or a third party acting on behalf of UCB, Inc. to ensure that all processes and procedures are in place and being followed.

## About the ZILBRYSQ REMS

A REMS is a program required by the Food and Drug Administration (FDA) to help ensure that the benefits associated with a medication outweigh its risks.

- ZILBRYSQ is available only through a restricted distribution program that is part of the ZILBRYSQ REMS.
- The goal of the ZILBRYSQ REMS is to mitigate the risk of serious meningococcal infections.

    1. Patients are vaccinated against meningococcal infections caused by *Neisseria meningitidis* serogroups A, C, W, Y (MenACWY) and serogroup B (MenB) prior to starting therapy according to the current Advisory Committee on Immunization Practices (ACIP) recommendations and receive antibacterial drug prophylaxis if needed.

    2. Patients are aware of early signs and symptoms of meningococcal infection and the need for immediate medical evaluation.

    3. Prescribers are aware of early signs and symptoms of meningococcal infection and the need for immediate medical evaluation.

### Adverse Events

Potential cases of meningococcal infections should be reported immediately to UCB, Inc. at 1-844-599-2273.

You are encouraged to report other adverse reactions of ZILBRYSQ to UCB Inc. or the FDA at www.fda.gov/medwatch or call 1-800-FDA-1088.

This guide does not provide a complete description of the risks associated with ZILBRYSQ.

Please see the Prescribing Information, including the BOXED WARNING regarding serious meningococcal infection, for more detailed safety information on ZILBRYSQ.

ZILBRYSQ®
(zilucoplan) Injection

For more information about the ZILBRYSQ REMS (Risk Evaluation and Mitigation Strategy):

Visit: www.ZILBRYSQREMS.com
Call: 1-877-414-8353
Monday through Friday, 9:00 am to 5:00 pm ET

**Show this PATIENT SAFETY CARD to any healthcare provider involved in your health care and if you go to the hospital.**

- ZILBRYSQ® (zilucoplan) increases your chance of getting a meningococcal infection. This can be an infection of the linings of the brain and spinal cord called meningitis. It can also be an infection of the blood called septicemia. These infections may quickly become life-threatening or fatal if not recognized and treated early.
- Call your healthcare provider or seek emergency care immediately if you have any signs or symptoms of meningococcal infection.

ZILBRYSQ® (zilucoplan) Injection

PATIENT SAFETY CARD

**Carry this Patient Safety Card at all times.**

Call your healthcare provider or seek emergency care immediately if you have any of these signs and symptoms of meningococcal infection:

- Headache with any of these other symptoms:
  - nausea or vomiting – stiff neck – stiff back – fever
- Fever with or without a rash
- Eyes sensitive to light
- Confusion
- Muscle aches with flu-like symptoms

**If you have any signs or symptoms of meningococcal infection, call your healthcare provider right away. If you can't reach your healthcare provider, seek emergency care immediately.**

**Show this card to the care provider.**

Keep this card with you at all times during treatment and for 2 months after your last ZILBRYSQ dose. Your risk of meningococcal infection may continue for several weeks after your last dose of ZILBRYSQ.

# ZILBRYSQ®
(zilucoplan) Injection



**Important Safety Information for Healthcare Providers**

This patient has been prescribed ZILBRYSQ (zilucoplan), a complement component 5 (C5) inhibitor that increases the patient's susceptibility to meningococcal infections caused by *Neisseria meningitidis*.
For more information about ZILBRYSQ, please refer to the Prescribing Information.

## PATIENT SAFETY CARD

- **Meningococcal infections may rapidly become life-threatening and can be fatal if not diagnosed and treated promptly.**
- **Evaluate the patient immediately. Withhold administration of ZILBRYSQ in patients who are undergoing treatment for meningococcal infection.**
- **Contact the healthcare provider who prescribed ZILBRYSQ as soon as possible if you suspect a meningococcal infection in this patient. The prescriber is listed on this card.**

**Contact the listed ZILBRYSQ prescriber as soon as possible if the patient has signs or symptoms of meningococcal infection.**

For more information about ZILBRYSQ, please refer to the Prescribing Information.

Potential cases of meningococcal infections should be reported immediately to UCB, Inc. at 1-844-599-2273
You are encouraged to report other adverse reactions of ZILBRYSQ to UCB Inc. or the FDA at www.fda.gov/medwatch or call 1-800-FDA-1088.

**Patient Name** _____

**Prescriber Name** _____

**Prescriber Phone Number** _____

**Emergency Contact Number** _____

PATIENT GUIDE

# ZILBRYSQ®
(zilucoplan) Injection

## ZILBRYSQ REMS

## What you need to know about ZILBRYSQ

### What is ZILBRYSQ?

ZILBRYSQ (zilucoplan) is a prescription medicine that is used to treat adults with a disease called generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody positive. It is injected under the skin.

### What are the serious risks of ZILBRYSQ?

ZILBRYSQ increases your chance of getting serious and life-threatening meningococcal infections. This can be an infection of the linings of the brain and spinal cord called meningitis. It can also be an infection of the blood called septicemia. This infection may quickly become life-threatening or fatal if not recognized and treated early.

**Call your healthcare provider or seek emergency care right away if you have any signs or symptoms of meningococcal infection:**

- Headache with any of these other symptoms:
  - nausea or vomiting • stiff neck • stiff back • fever
- Fever with or without rash
- Eyes sensitive to light
- Confusion
- Muscle aches with flu-like symptoms

## Getting your Meningococcal Vaccines

- Complete or update two types of meningococcal vaccines (for both serogroup B and serogroup A, C, W, and Y infections) at least 2 weeks before your first dose of ZILBRYSQ if you have not already had these vaccines.
- Your doctor will review your vaccine history and let you know which vaccines you need.
- Vaccinations do not prevent all meningococcal infections. These infections may still occur. You will need to watch for signs and symptoms of meningococcal infection even after receiving the vaccines.

If your doctor decides that urgent treatment with ZILBRYSQ is needed and you have not completed or updated vaccinations for meningococcal infections at least 2 weeks before your first ZILBRYSQ dose:

- You should receive the meningococcal vaccinations as soon as possible.
- You must also receive a prescription for antibiotics from your doctor.
- Your healthcare provider will select an antibiotic for you to take.

# ZILBRYSQ®
(zilucoplan) Injection

If you have already had both meningococcal vaccines in the past, discuss this with your doctor. You might need to get additional vaccines before you start ZILBRYSQ.

During treatment with ZILBRYSQ, you may also need additional doses of meningococcal vaccines. It is important to discuss this with your doctor to ensure that your vaccination status is always up to date throughout treatment with ZILBRYSQ.

## Patient Safety Card

Your doctor will give you a **Patient Safety Card.**


Show this PATIENT SAFETY CARD to any healthcare provider involved in your health care and if you go to the hospital
• ZILBRYSQ® (zilucoplan) increases your chance of getting a meningococcal infection. This can be an infection of the linings of the brain and spinal cord called meningitis. It can also be an infection of the blood called septicemia. These infections may quickly become life threatening or fatal if not recognized and treated early.
• Call your healthcare provider or seek emergency care immediately if you have any signs or symptoms of meningococcal infection.
ZILBRYSQ® (zilucoplan) injection
PATIENT SAFETY CARD

- The card includes important information about your medical treatment.
- Keep this card with you at all times during treatment and for 2 months after your last ZILBRYSQ dose. Your risk of meningococcal infection may continue for several weeks after your last dose of ZILBRYSQ.

Show the **Patient Safety Card** to any healthcare provider you go to for treatment.

- The card lets them know about your ZILBRYSQ treatment.
- It will help them diagnose and treat possible meningococcal infection promptly.

Call your doctor or seek emergency care right away for any symptoms of meningococcal infection.

## What is the ZILBRYSQ REMS?

A Risk Evaluation and Mitigation Strategy (REMS) is a drug safety program that the US Food and Drug Administration (FDA) can require for certain medicines to ensure they are used safely. When there is a REMS, drug companies and healthcare providers must take extra steps to make sure the benefits of using the drug are greater than the risks.

ZILBRYSQ has a REMS because it increases your chance of getting a meningococcal infection. This infection can quickly become life-threatening or fatal if not recognized and treated early.

## How will I get ZILBRYSQ?

Only certain pharmacies can fill your ZILBRYSQ prescription. The pharmacies that are part of the ZILBRYSQ REMS will fill your prescription and ship it to you.

**If you have questions about the ZILBRYSQ REMS, you can call the REMS or visit the REMS website.**

**Call: 1-877-414-8353 Monday through Friday, 9:00 AM – 5:00 PM Eastern Time**

**Visit: www.ZILBRYSQREMS.com**

Potential cases of meningococcal infections should be reported immediately to UCB, Inc. at 1-844-599-2273

You are encouraged to report other adverse reactions of ZILBRYSQ to UCB Inc. or the FDA at www.fda.gov/medwatch or call 1-800-FDA-1088.

[Date]
[HCP_Title][HCP_First Name] [HCP_Last_Name]
[HCP_Address_Line1]
[HCP_Address_Line2]
[HCP_City», «HCP_State» «HCP_ZIP]

Dear [HCP_Title][HCP_First Name] [HCP_Last_Name]:

You are receiving this letter because you are enrolled as a prescriber in the ZILBRYSQ® Risk Evaluation and Mitigation Strategy (REMS).

We would like to remind you to check the vaccination status of any patient who is receiving ZILBRYSQ (zilucoplan) therapy to ensure the patient is up to date on both MenACWY and MenB meningococcal vaccines and to ensure that booster doses of the meningococcal vaccines are administered in a timely and appropriate manner.

Because of the risk of meningococcal infections with ZILBRYSQ therapy, the ZILBRYSQ REMS requires that prescribers and patients comply with the current Advisory Committee on Immunization Practices (ACIP) recommendations for meningococcal vaccinations for people who are receiving a complement inhibitor. These recommendations may be found at https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/mening.html.

These recommendations are periodically updated. Therefore, please check the latest recommendations to ensure the vaccination status of your patients is up to date.

If you have any questions about the vaccination schedules required for participation in the ZILBRYSQ REMS, please call the REMS at 1-877-414-8353, Monday through Friday, 9:00 am to 5:00 pm ET.

Sincerely,

ZILBRYSQ REMS

# UCB ZILBRYSQ Webscreens

**V 4.0**

**9/12/2023**

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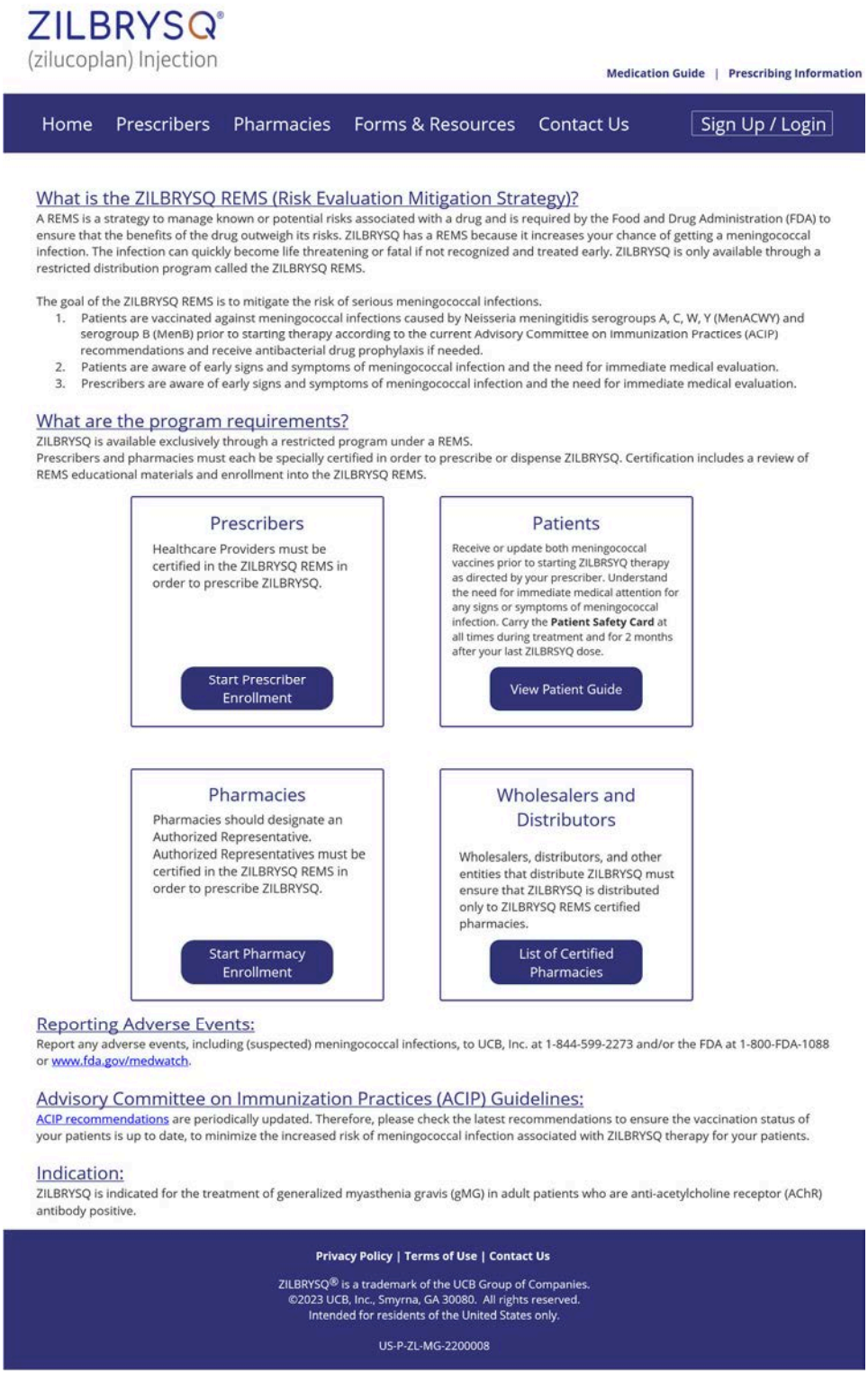
# 1. Pages

## 1.1. Home Page


ZILBRYSQ®
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What is the ZILBRYSQ REMS (Risk Evaluation Mitigation Strategy)?
A REMS is a strategy to manage known or potential risks associated with a drug and is required by the Food and Drug Administration (FDA) to ensure that the benefits of the drug outweigh its risks. ZILBRYSQ has a REMS because it increases your chance of getting a meningococcal infection. The infection can quickly become life threatening or fatal if not recognized and treated early. ZILBRYSQ is only available through a restricted distribution program called the ZILBRYSQ REMS.
The goal of the ZILBRYSQ REMS is to mitigate the risk of serious meningococcal infections.
1. Patients are vaccinated against meningococcal infections caused by Neisseria meningitidis serogroups A, C, W, Y (MenACWY) and serogroup B (MenB) prior to starting therapy according to the current Advisory Committee on Immunization Practices (ACIP) recommendations and receive antibacterial drug prophylaxis if needed.
2. Patients are aware of early signs and symptoms of meningococcal infection and the need for immediate medical evaluation.
3. Prescribers are aware of early signs and symptoms of meningococcal infection and the need for immediate medical evaluation.
What are the program requirements?
ZILBRYSQ is available exclusively through a restricted program under a REMS.
Prescribers and pharmacies must each be specially certified in order to prescribe or dispense ZILBRYSQ. Certification includes a review of REMS educational materials and enrollment into the ZILBRYSQ REMS.
Prescribers
Healthcare Providers must be certified in the ZILBRYSQ REMS in order to prescribe ZILBRYSQ.
Start Prescriber Enrollment
Patients
Receive or update both meningococcal vaccines prior to starting ZILBRSYQ therapy as directed by your prescriber. Understand the need for immediate medical attention for any signs or symptoms of meningococcal infection. Carry the Patient Safety Card at all times during treatment and for 2 months after your last ZILBRSYQ dose.
View Patient Guide
Pharmacies
Pharmacies should designate an Authorized Representative.
Authorized Representatives must be certified in the ZILBRYSQ REMS in order to prescribe ZILBRYSQ.
Start Pharmacy Enrollment
Wholesalers and Distributors
Wholesalers, distributors, and other entities that distribute ZILBRYSQ must ensure that ZILBRYSQ is distributed only to ZILBRYSQ REMS certified pharmacies.
List of Certified Pharmacies
Reporting Adverse Events:
Report any adverse events, including (suspected) meningococcal infections, to UCB, Inc. at 1-844-599-2273 and/or the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.
Advisory Committee on Immunization Practices (ACIP) Guidelines:
ACIP recommendations are periodically updated. Therefore, please check the latest recommendations to ensure the vaccination status of your patients is up to date, to minimize the increased risk of meningococcal infection associated with ZILBRYSQ therapy for your patients.
Indication:
ZILBRYSQ is indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive.
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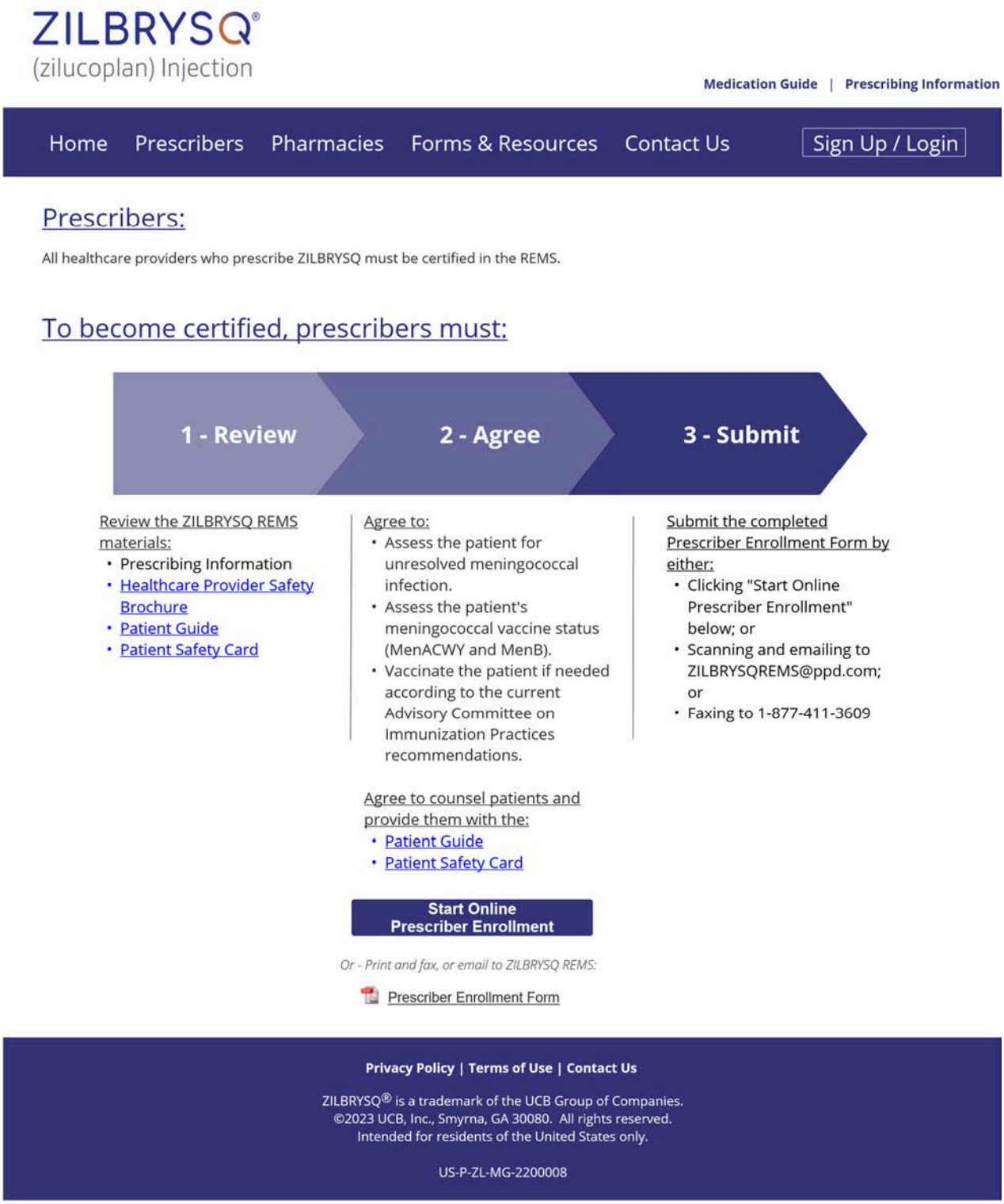
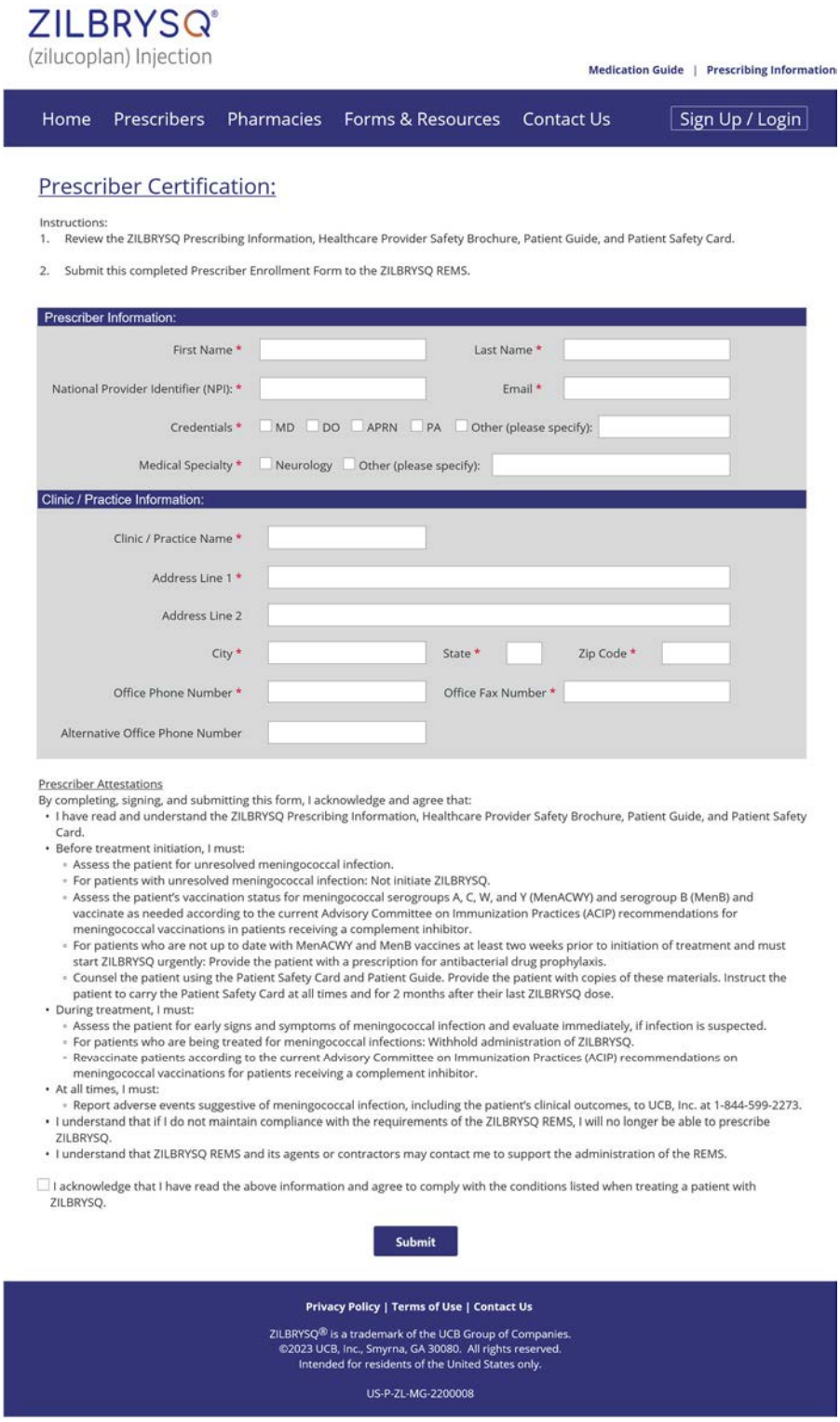
## 1.2. Prescriber



## 1.3. Prescriber Certification



ZILBRYSQ®
(zilucoplan) Injection

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Prescriber Certification:

Instructions:
1. Review the ZILBRYSQ Prescribing Information, Healthcare Provider Safety Brochure, Patient Guide, and Patient Safety Card.
2. Submit this completed Prescriber Enrollment Form to the ZILBRYSQ REMS.

Prescriber Information:

First Name * Last Name *
National Provider Identifier (NPI): * Email *
Credentials * MD DO APRN PA Other (please specify):
Medical Specialty * Neurology Other (please specify):

Clinic / Practice Information:

Clinic / Practice Name *
Address Line 1 *
Address Line 2
City * State * Zip Code *
Office Phone Number * Office Fax Number *
Alternative Office Phone Number

Prescriber Attestations
By completing, signing, and submitting this form, I acknowledge and agree that:
- I have read and understand the ZILBRYSQ Prescribing Information, Healthcare Provider Safety Brochure, Patient Guide, and Patient Safety Card.
- Before treatment initiation, I must:
  - Assess the patient for unresolved meningococcal infection.
  - For patients with unresolved meningococcal infection: Not initiate ZILBRYSQ.
  - Assess the patient's vaccination status for meningococcal serogroups A, C, W, and Y (MenACWY) and serogroup B (MenB) and vaccinate as needed according to the current Advisory Committee on Immunization Practices (ACIP) recommendations for meningococcal vaccinations in patients receiving a complement inhibitor.
  - For patients who are not up to date with MenACWY and MenB vaccines at least two weeks prior to initiation of treatment and must start ZILBRYSQ urgently: Provide the patient with a prescription for antibacterial drug prophylaxis.
  - Counsel the patient using the Patient Safety Card and Patient Guide. Provide the patient with copies of these materials. Instruct the patient to carry the Patient Safety Card at all times and for 2 months after their last ZILBRYSQ dose.
- During treatment, I must:
  - Assess the patient for early signs and symptoms of meningococcal infection and evaluate immediately, if infection is suspected.
  - For patients who are being treated for meningococcal infections: Withhold administration of ZILBRYSQ.
  - Revaccinate patients according to the current Advisory Committee on Immunization Practices (ACIP) recommendations on meningococcal vaccinations for patients receiving a complement inhibitor.
- At all times, I must:
  - Report adverse events suggestive of meningococcal infection, including the patient's clinical outcomes, to UCB, Inc. at 1-844-599-2273.
- I understand that if I do not maintain compliance with the requirements of the ZILBRYSQ REMS, I will no longer be able to prescribe ZILBRYSQ.
- I understand that ZILBRYSQ REMS and its agents or contractors may contact me to support the administration of the REMS.

I acknowledge that I have read the above information and agree to comply with the conditions listed when treating a patient with ZILBRYSQ.

Submit

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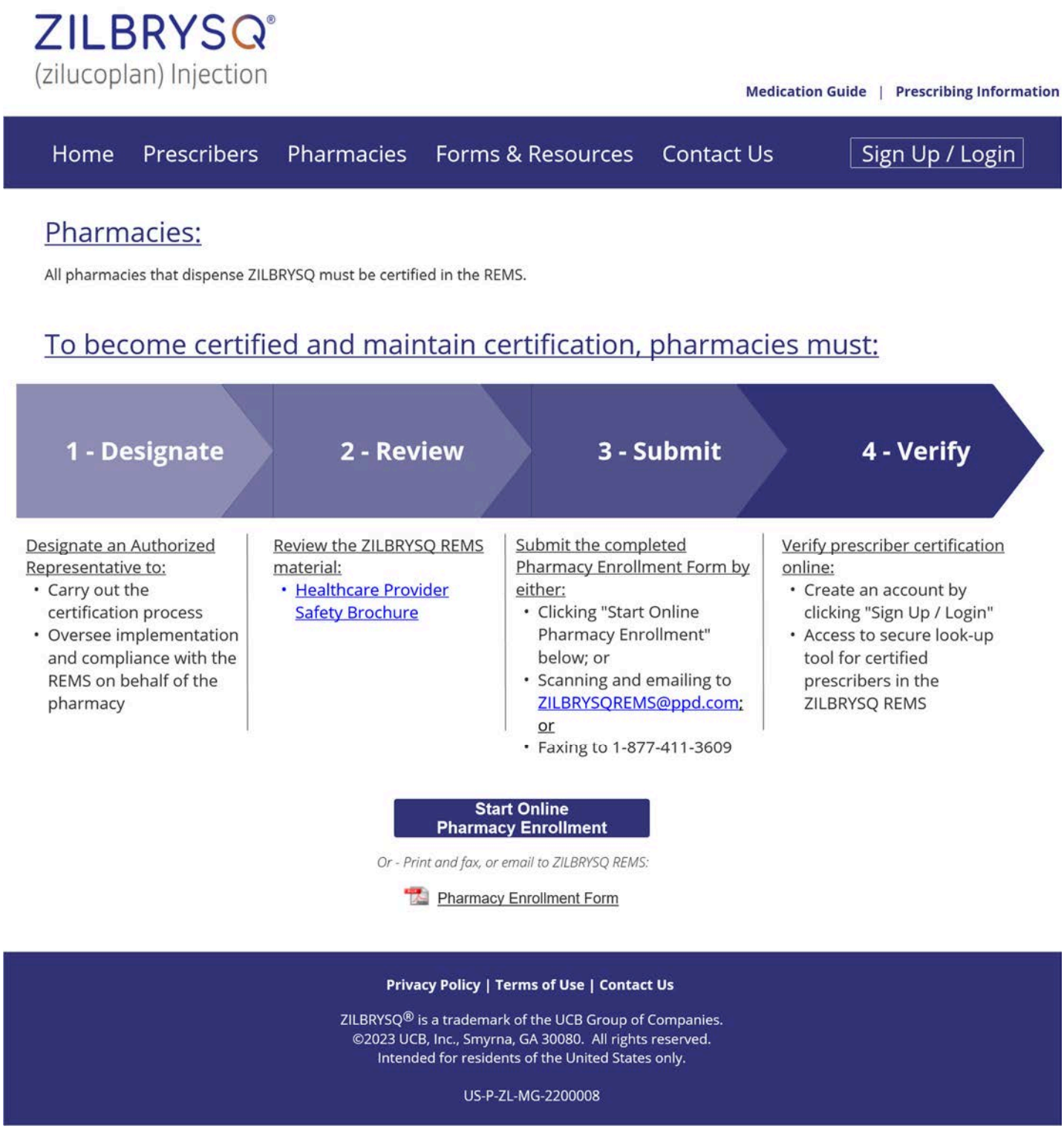
## 1.4. Pharmacy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Sign Up / Login
Pharmacies:
All pharmacies that dispense ZILBRYSQ must be certified in the REMS.
To become certified and maintain certification, pharmacies must:
1 - Designate
2 - Review
3 - Submit
4 - Verify
Designate an Authorized Representative to:
• Carry out the certification process
• Oversee implementation and compliance with the REMS on behalf of the pharmacy
Review the ZILBRYSQ REMS material:
• Healthcare Provider Safety Brochure
Submit the completed Pharmacy Enrollment Form by either:
• Clicking "Start Online Pharmacy Enrollment" below; or
• Scanning and emailing to ZILBRYSQREMS@ppd.com; or
• Faxing to 1-877-411-3609
Verify prescriber certification online:
• Create an account by clicking "Sign Up / Login"
• Access to secure look-up tool for certified prescribers in the ZILBRYSQ REMS
Start Online Pharmacy Enrollment
Or - Print and fax, or email to ZILBRYSQ REMS:
Pharmacy Enrollment Form
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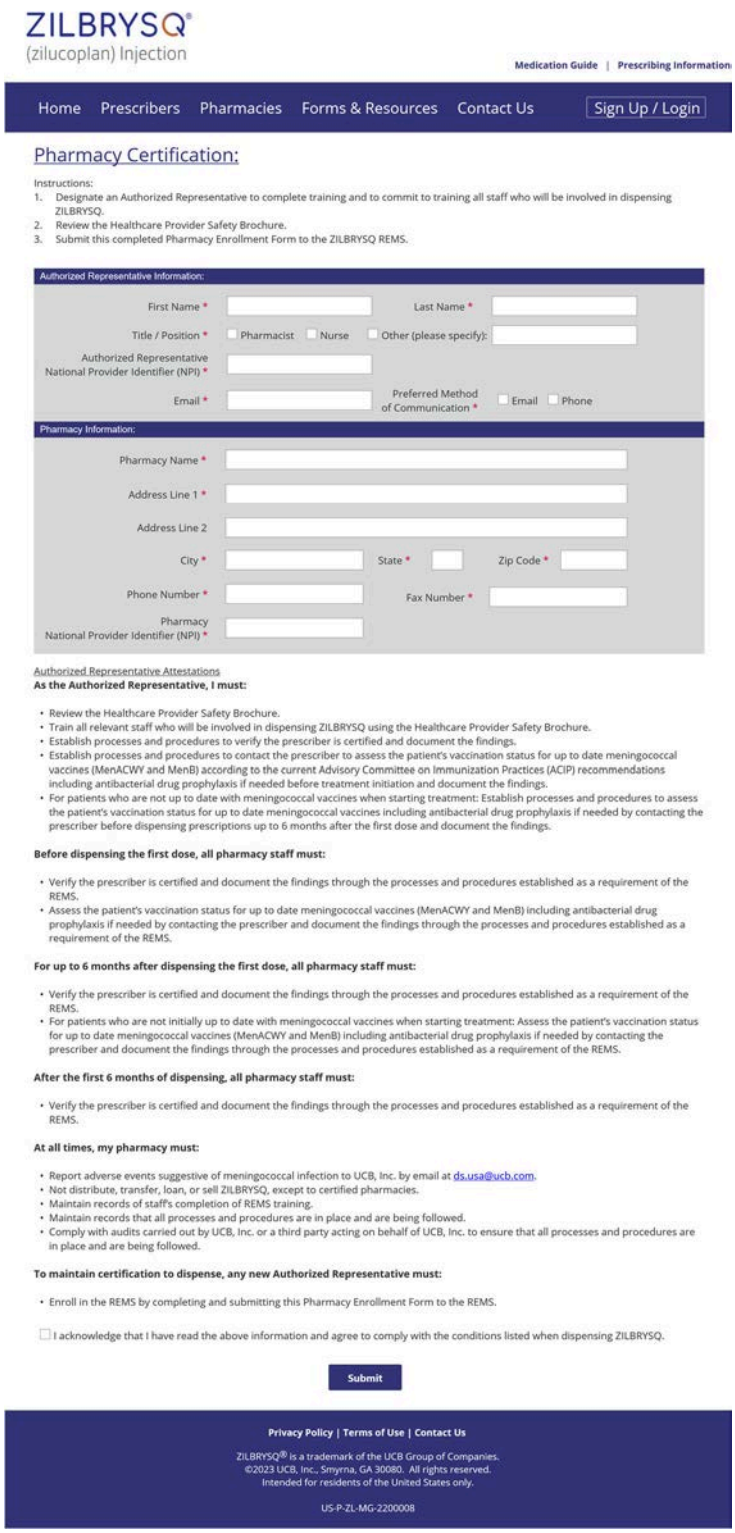
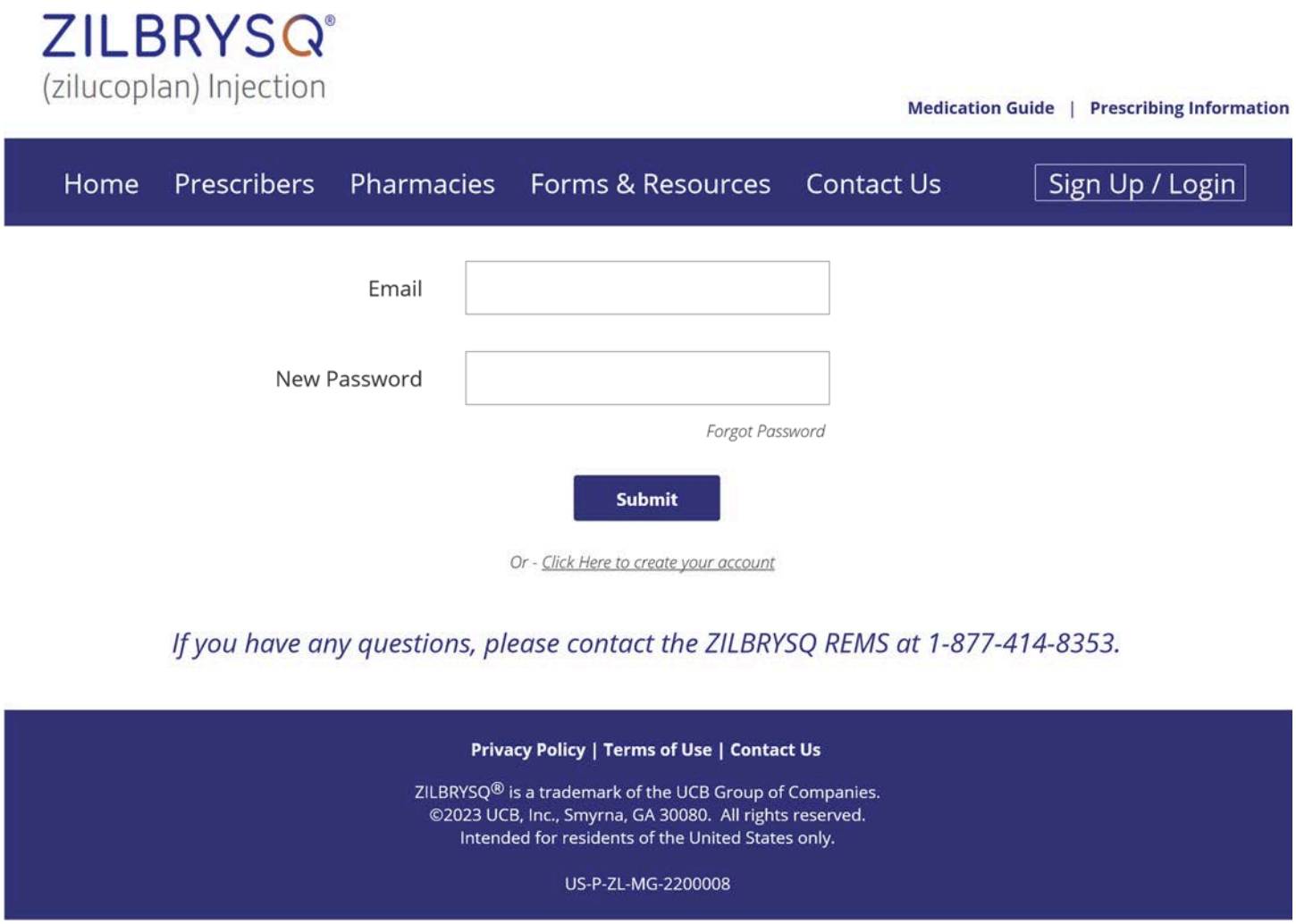
## 1.5. Pharmacy Certification



## 1.6. Log In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Sign Up / Login
Email
New Password
Forgot Password
Submit
Or - Click Here to create your account
If you have any questions, please contact the ZILBRYSQ REMS at 1-877-414-8353.
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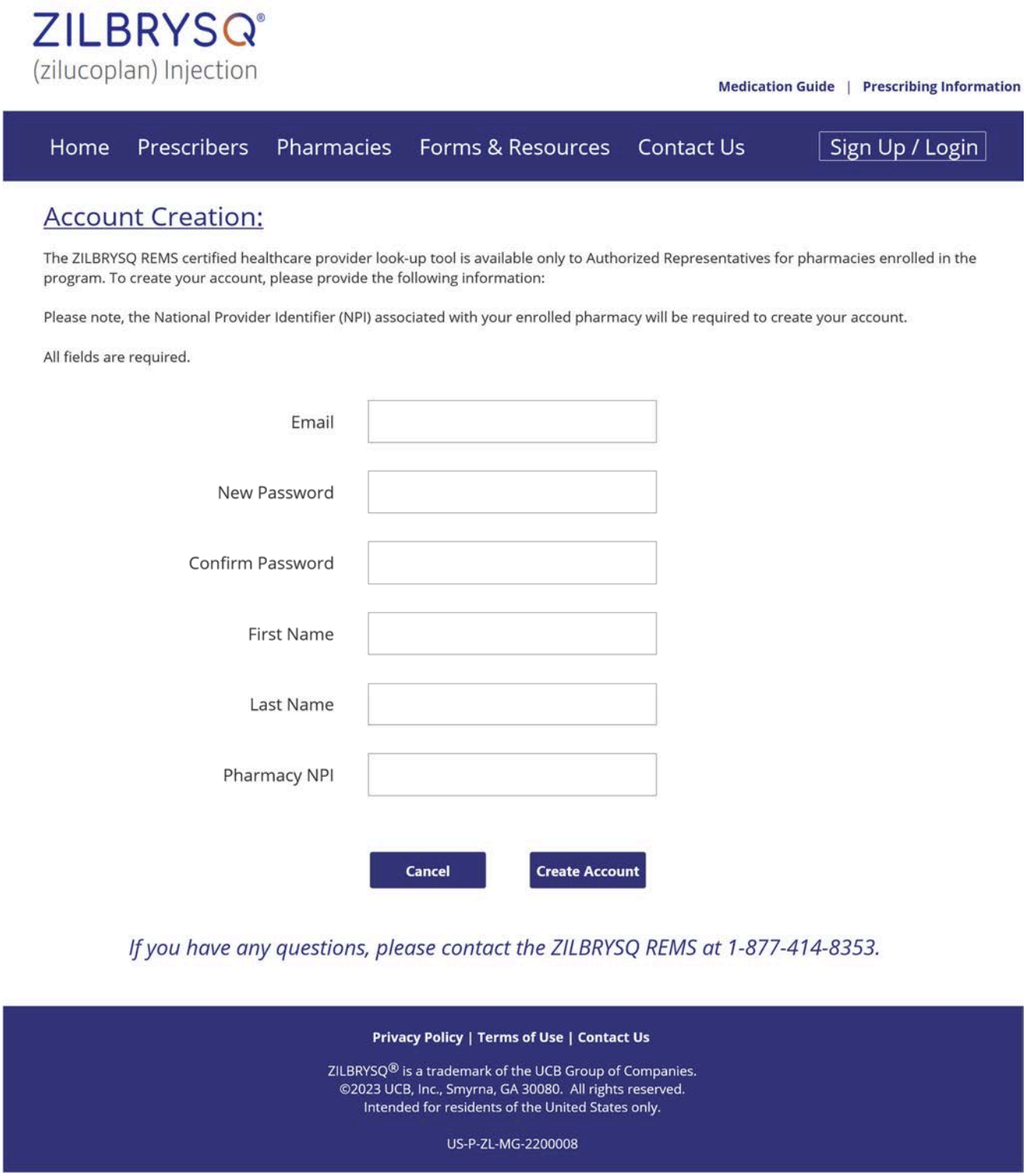
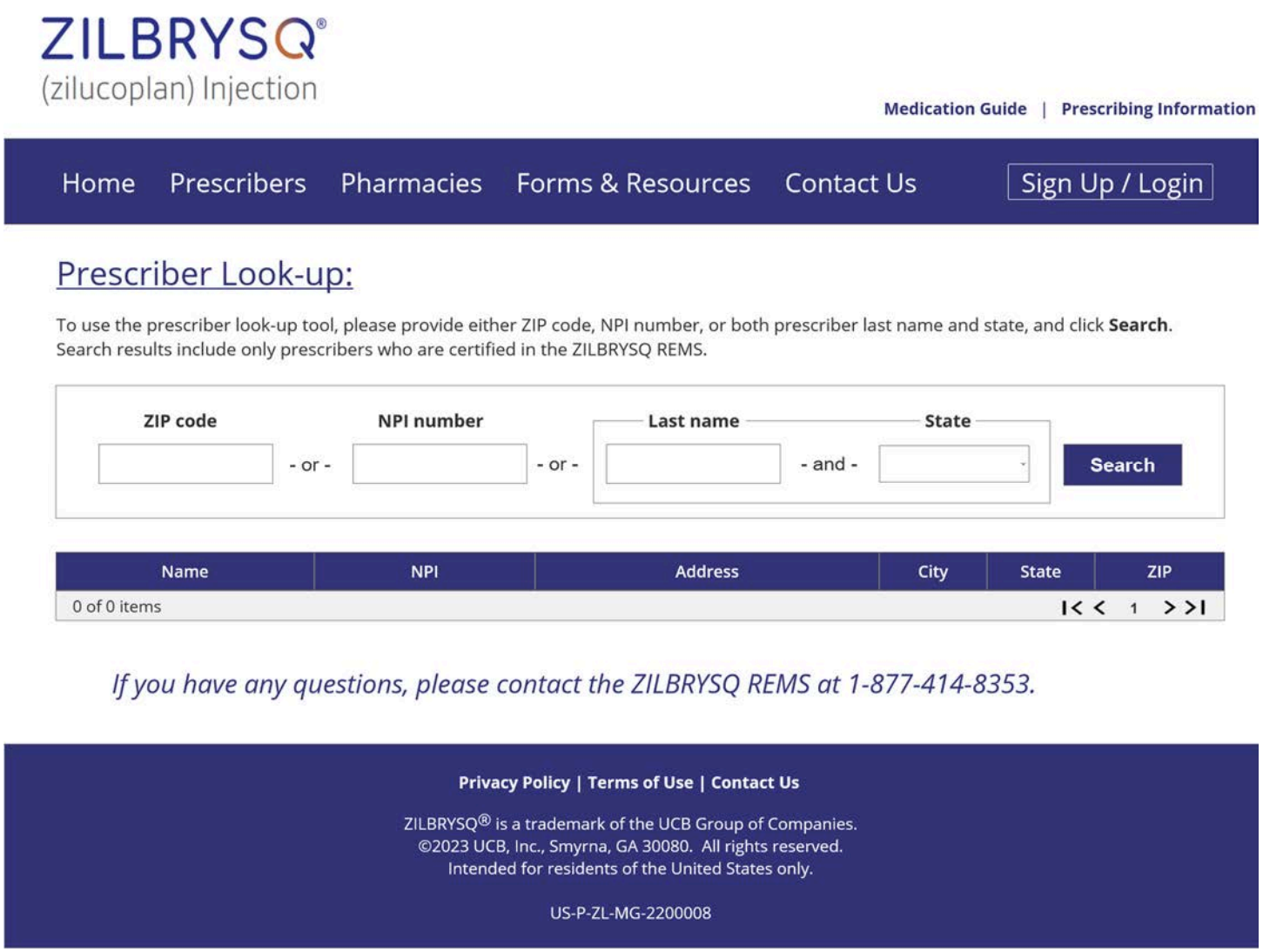
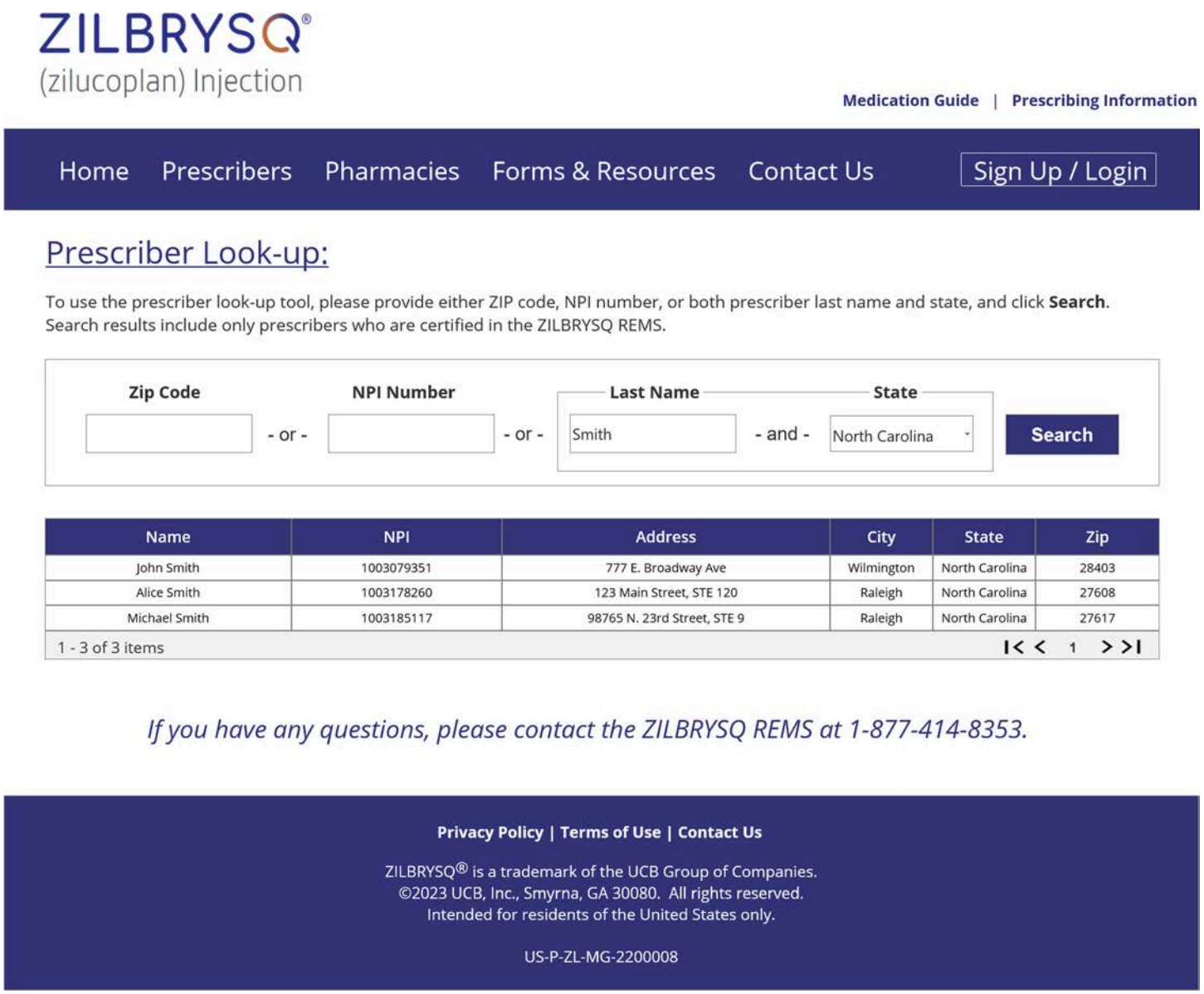
## 1.7. Create an Account



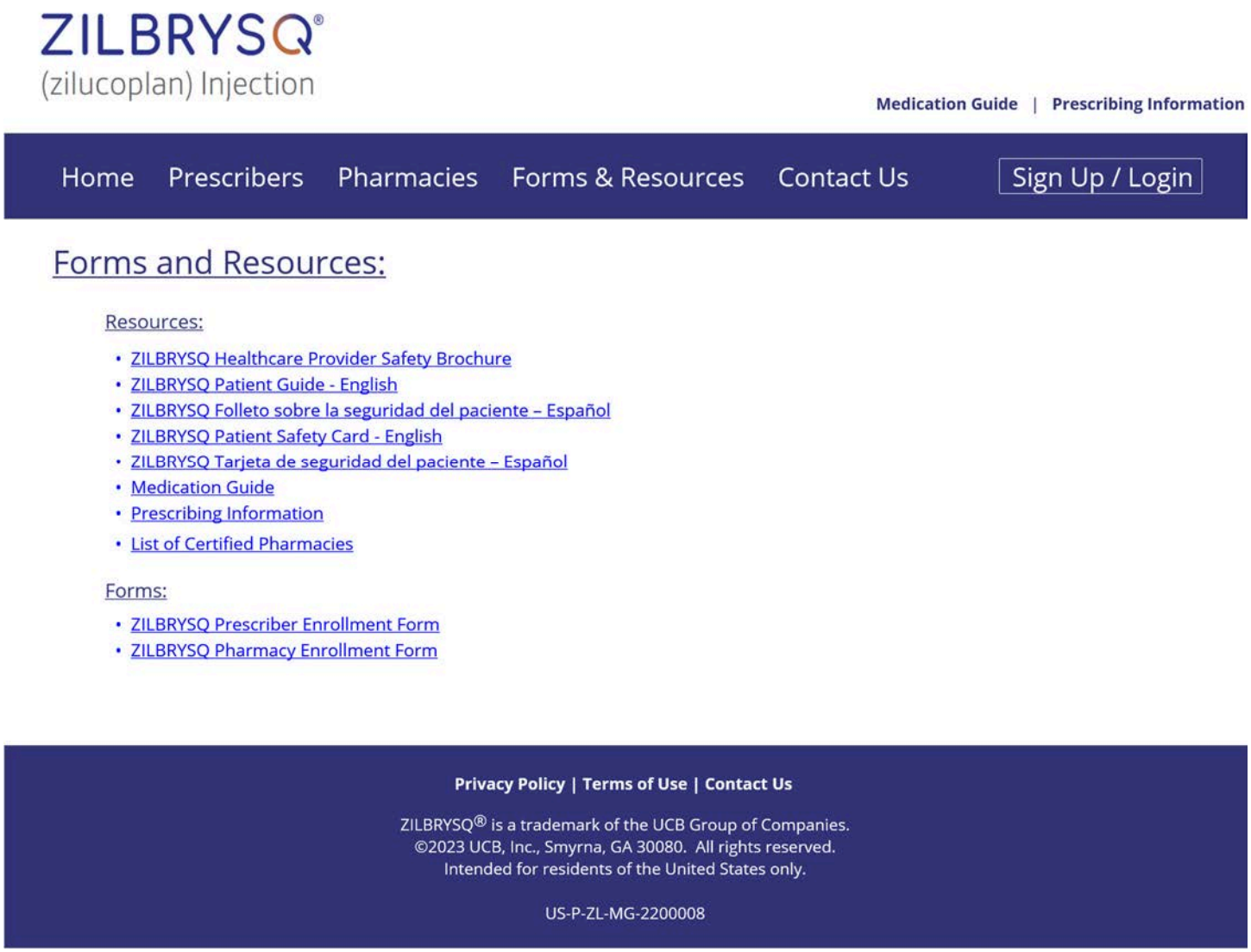
## 1.8. Pharmacy - Prescriber Look-up - Landing



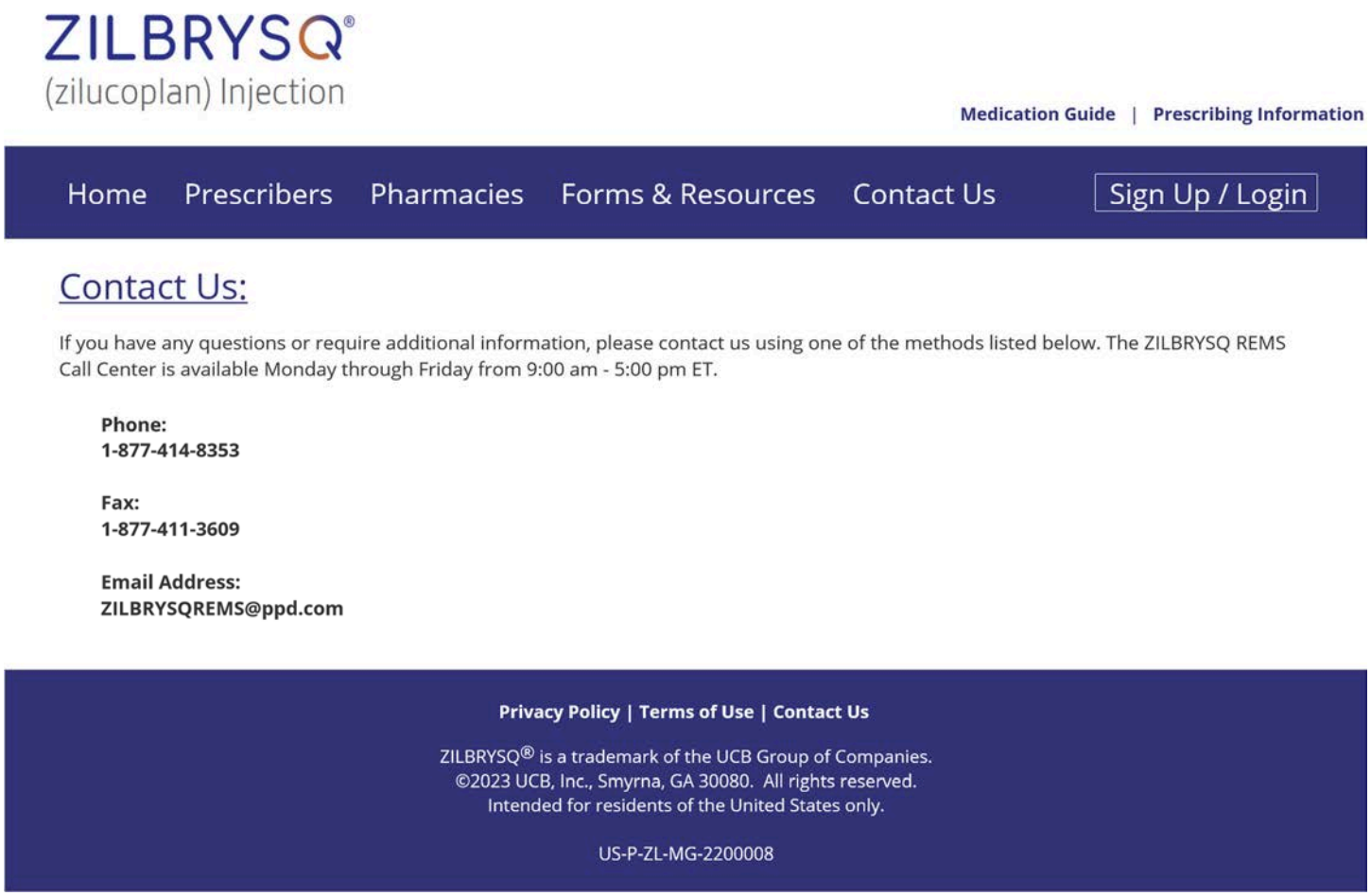
## 1.9. Pharmacy - Prescriber Look-up - Results



## 1.10. Forms & Resources



## 1.11. Contact Us



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**This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.**

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/s/

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TERESA J BURACCHIO
10/17/2023 11:13:55 AM