

REMS Training

ULTOMIRIS and SOLIRIS REMS Healthcare Setting (HCS) & Pharmacy Training

Please see accompanying full [Prescribing Information](#) for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.
Please see accompanying full [Prescribing Information](#) for SOLIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.

ALEXION
Astellera Pharmaceuticals Inc.

ULTOMIRIS
SOLIRIS

Thank you for joining today to review the ULTOMIRIS and SOLIRIS REMS Healthcare Setting (HCS) and Pharmacy training.

The purpose of this training is to describe the responsibilities of healthcare settings and pharmacies as key stakeholders in the ULTOMIRIS and SOLIRIS REMS program.

NOTE

**This deck is for supplemental training purposes only.
It does not replace the need for site-specific
Risk Evaluation and Mitigation Strategy (REMS) processes
and procedures, nor mandatory Healthcare Provider
Safety Brochure training required by REMS.**

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As an HCS/Pharmacy, What Do I Need to **KNOW?**



HCS/Pharmacy must be **REMS certified** to dispense product.

- Submit a **single enrollment form** to cover both ULTOMIRIS and SOLIRIS
- Enroll online at UltSolREMS.com or via fax, scan, or email



HCS/Pharmacy may visit REMS Portal (ie, UltSolREMS.com) to access **REMS-related resources** (ie, information and materials).



HCS/Pharmacy must have **processes and procedures** in place establishing how they assess patient's vaccination status for Advisory Committee on Immunization Practices (ACIP) compliance. Examples may include:

- Call Prescriber to assess patient's vaccination status
- Request Prescriber to assess ACIP compliance at each dispense
- Assess vaccination data in REMS Portal for ACIP compliance

Reminder: Details of process/workflow must be determined by HCS/Pharmacy



HCS/Pharmacy must designate an **Authorized Representative** and ensure all relevant staff are **trained** on established processes and procedures.



HCS/Pharmacy must **generate a REMS Dispense Authorization (RDA)** prior to each dispense.

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As a healthcare setting and pharmacy, **what exactly do you need to know?**

Healthcare settings and pharmacies must be Risk Evaluation and Mitigation Strategy (REMS)-certified in the ULTOMIRIS and SOLIRIS REMS program in order to dispense product. They will need to submit a single enrollment form which will cover both ULTOMIRIS and SOLIRIS. They can enroll online at UltSolREMS.com or they have the option to do so manually via fax, scan, or email.

Healthcare settings and pharmacies can access REMS-related resources, such as information and materials at UltSolREMS.com, which is a public-facing website, or on the REMS portal, which is password-protected.

As a requirement of the ULTOMIRIS and SOLIRIS REMS program, healthcare settings and pharmacies must designate an authorized representative to ensure that all relevant staff are trained on the established processes and procedures for that particular healthcare setting or pharmacy.

Healthcare settings and pharmacies must have processes in place to establish how the healthcare setting or pharmacy will assess vaccination status. This can include assessing vaccination data in the REMS portal for Advisory Committee on Immunization Practices (ACIP) compliance, calling the prescriber to assess a patient's vaccination status, or requesting the prescriber to assess ACIP compliance at each dispense.

It is important to note that the details of the processes at each individual healthcare setting and pharmacy location must be determined by that healthcare setting or pharmacy.

HCS/Pharmacy

Roles and Responsibilities

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Healthcare Setting/Pharmacy

Roles and Responsibilities

Designate an **Authorized Representative (AR)** to carry out the certification process and oversee implementation and compliance with the REMS on behalf of the healthcare setting or pharmacy.

- Authorized Representative will **review the Healthcare Provider Safety Brochure**.
- Authorized Representative **enrolls** by completing and submitting the **Healthcare Setting and Pharmacy Enrollment Form** to the REMS.
- Authorized Representative will **train** all relevant staff involved in dispensing ULTOMIRIS and SOLIRIS using the Healthcare Provider Safety Brochure and maintain a record of staff training.

Establish processes and procedures to assess the patient's vaccination status for up to date meningococcal vaccines for serogroups A, C, W, Y, and B according to current 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, before dispensing prescriptions up to 6 months after the first dose and document the findings.

Source: FDA-approved ULTOMIRIS and SOLIRIS REMS Document.

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What does it take for a healthcare setting or pharmacy to become certified in the REMS program?

There are a number of different activities that must be completed in order for the certification to be completed.

First and foremost, the healthcare setting or pharmacy must designate an **Authorized Representative (AR)** to carry out the certification process and oversee the implementation and compliance with the REMS program on behalf of that healthcare setting or pharmacy.

As an authorized representative, they must review the **Healthcare Provider Safety Brochure** and enroll in the REMS by completing the **Healthcare Setting and Pharmacy Enrollment Form** and submitting that to the REMS.

The Authorized Representative must also train all relevant staff involved in dispensing ULTOMIRIS and SOLIRIS, using the Healthcare Provider Safety Brochure and maintain a record of staff training.

The Authorized Representative must establish processes and procedures to assess the patient's vaccination status, according to the current ACIP recommendations. They must also include 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, the Authorized Representative must establish processes and procedures to assess the patient's vaccination status for up to date meningococcal vaccines, including antibacterial drug prophylaxis if needed, before dispensing prescriptions up to 6 months after the first dose. They must also document those findings.

Additional Roles and Responsibilities

- Report adverse events suggestive of meningococcal infections to Alexion Pharmaceuticals, Inc. by telephone at 1-844-259-6783. You are encouraged to report all other suspected adverse reactions to Alexion Pharmaceuticals, Inc. or the Federal Drug Administration (FDA) at www.fda.gov/medwatch or call 1-800-FDA-1088.
- Not distribute, transfer, loan, or sell ULTOMIRIS or SOLIRIS, except to other certified healthcare settings or 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 Alexion Pharmaceuticals, Inc. or a third party acting on behalf of Alexion Pharmaceuticals, Inc., to ensure that all processes and procedures are in place and are being followed.

Source: FDA-approved ULTOMIRIS and SOLIRIS REMS Document.

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Additional roles and responsibilities for healthcare settings and pharmacies:

- It is critical that healthcare settings and pharmacies report adverse events suggestive of meningococcal infections to Alexion;
- They must not distribute, transfer, loan, or sell ULTOMIRIS or SOLIRIS, except to another certified healthcare setting or pharmacy;
- They must maintain records of the staff's completion of REMS training and maintain records that all processes and procedures are in place and are being followed; and, ultimately,
- They must comply with audits carried out by Alexion, or a third party acting on Alexion's behalf, to ensure that all required processes and procedures are in place and are being followed.

How to **Enroll** a Healthcare Setting or Pharmacy

Easy as

1 ACCESS
UltSolREMS.com

2 REVIEW
required REMS materials

3 COMPLETE
and submit the Enrollment Form

The screenshot shows the UltSolREMS website interface. It features a navigation bar with 'ULTOMIRIS SOLIRIS' and a 'REMS' tab. The main content area is titled 'ULTOMIRIS and SOLIRIS Risk Evaluation and Mitigation Strategy (REMS)'. It includes a 'How to Enroll' section with a numbered list of steps: 1. Access UltSolREMS.com, 2. Review required REMS materials, and 3. Complete and submit the Enrollment Form. A red box highlights the 'How to Enroll' section.

The screenshot shows the 'ULTOMIRIS and SOLIRIS REMS HEALTHCARE SETTING AND PHARMACY ENROLLMENT FORM'. It includes sections for 'Instructions', 'Eligibility', 'Enrollment Information', 'Additional Healthcare Setting and Pharmacy Information', and 'Additional Healthcare Setting and Pharmacy Information'. The form contains various fields for user information, contact details, and checkboxes for enrollment type (Online or Paper).

What to Expect

Use your **HCS National Provider Identifier (NPI)** (not individual HCP NPI) and **verify** ship-to address **before** submitting

Email 1 REMS Certification Confirmed

- **Within minutes** for online enrollments
- Shortly after processing for paper enrollments

Email 2 Login Credentials & Portal Link

- Sent shortly after enrolling
- Set up login credentials within **5 days** for timely access

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How does enrollment take place? What does a healthcare setting or pharmacy need to do to enroll? This is very straightforward and easy as 1-2-3.

The first step is to access UltSolREMS.com.

The second step is to review those required REMS materials that we just reviewed.

The third step is to complete and submit the pre-enrollment form to the REMS. Before submitting the pre-enrollment form, please ensure that you use your healthcare setting's National Provider Identifier (NPI) and not an individual provider's NPI. It is also important to verify that your address on the enrollment form is your correct ship-to address prior to submitting the form.

After the enrollment form has been submitted, healthcare settings and pharmacies can expect to receive 2 emails, the first of which is a confirmation of successful REMS certification.

For online enrollments, this confirmation will be sent within minutes. For paper enrollments, a confirmation will be sent via e-mail shortly after the processing of that paper enrollment has taken place.

The second e-mail contains login credentials and a link to the REMS portal.

Following REMS Certification, the Authorized Representative Will Receive a Confirmation Email Including Login Credentials for the REMS Portal

After certification, you will receive an email with login credentials

Please set up your account within 5 days to ensure timely access to the portal

Mandatory Activities for HCS/Pharmacy in the REMS Portal

- 1 Enter Prescriber and Patient identifying information
- 2 Verify Prescriber REMS certification
- 3 Assess patient meningococcal vaccination status (ie, ACIP compliance) and use of antibacterial drug prophylaxis (as required) and document
- 4 Generate RDA

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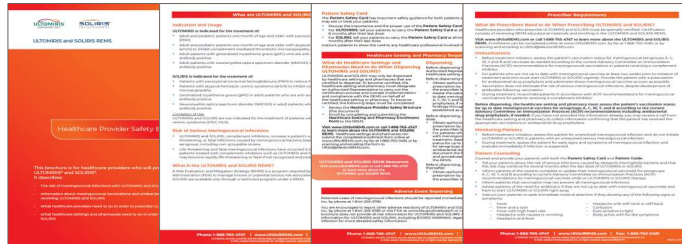
Following REMS certification, the Authorized Representative will receive a confirmation email with their login credentials for the REMS portal.

There are mandatory activities that are required for healthcare settings and pharmacies within the REMS portal. We will go through each of these in detail, but at a glance:

- 1) The healthcare setting or pharmacy needs to enter prescriber- and patient-identifying information, which is very important
- 2) They need to verify prescriber REMS certification
- 3) They need to assess patient meningococcal vaccination status to ensure compliance with ACIP and use of antibacterial drug prophylaxis as required, and document these findings
- 4) And, finally, they need to generate the REMS Dispense Authorization prior to each dispense

Review All REMS Materials and Complete the REMS Enrollment Form

Healthcare Provider Safety Brochure



Enrollment Form

Healthcare Settings and Pharmacies can access REMS educational materials and Enrollment Form via

- Accessing [UltSolREMS.com](https://ultsolrems.com)
- Calling the REMS Call Center at (888) 765-4747

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There are 2 REMS resources for healthcare settings and pharmacies: on the left is the **Healthcare Provider Safety Brochure** and on the right is the **Enrollment Form**.

Healthcare settings and pharmacies can access these materials on [UltSolREMS.com](https://ultsolrems.com) or by calling the REMS call center at (888) 765-4747. Healthcare settings and pharmacies need to review all of the materials, and complete and submit the Enrollment Form.

Audits and Corrective and Preventive Actions (CAPAs)

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Audits and CAPAs

As part of the ULTOMIRIS and SOLIRIS REMS, Alexion (or a third party on its behalf) may conduct **periodic audits** to verify that certified sites have required processes and procedures in place.

FDA Requirements

01

Why are audits required?

REMS audits ensure your HCS/Pharmacy complies with FDA-approved REMS requirements, verifying practices and documentation meet established standards for the safe and effective use of ULTOMIRIS and SOLIRIS.

How often will I be audited?

Your initial audit is scheduled within 180 days of REMS certification. Subsequent audits occur periodically, based on random selection and/or previous REMS non-compliance and audit outcomes.

What authority governs audits?

Audits are independently conducted by the REMS Administrator, on behalf of Alexion. This independence ensures transparency, objectivity, and an unbiased process as required by the FDA.

What Is an Audit?

02

How will my audit be conducted?

Audits are conducted via a targeted questionnaire on the REMS portal. The AR is notified by email, logs into the portal, completes the questionnaire, and uploads supporting documentation.

How will we be notified?

The AR receives an email notification when an audit questionnaire is assigned. You have 45 days to complete and submit. Email reminders are sent throughout. Check spam filters for audit emails from the REMS Administrator.

What records should we have ready?

Written REMS processes and procedures; dispensing and transfer records and training records (names, dates, and materials used) for all staff—including the full Healthcare Provider Safety Brochure training.

What Is a CAPA?

03

What is a CAPA?

A CAPA is a structured response to audit findings. It identifies the root cause of a compliance gap and outlines corrective and preventive steps. CAPAs are classified as Minor, Major, or Critical.

What happens if we receive a CAPA?

Minor findings: submit a CAPA plan within 30 business days.

Major findings: submit a CAPA plan within 30 business days.

Critical findings: submit a CAPA plan within 15 business days.

How do we close a CAPA?

Submit evidence of completed CAPA plan actions to the auditor by the assigned due date. Once the auditor approves the evidence and verifies that all actions are implemented, the audit is officially closed.

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REMS Dispense Authorization (RDA)

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An RDA Is Required for Every Single Dispense of ULTOMIRIS/SOLIRIS

What is an RDA?

- The RDA is a required step for every single dispense of ULTOMIRIS and SOLIRIS. The REMS portal will provide a unique RDA code for each dispense after a series of questions are answered.

Who generates the RDA?

- The HCS/Pharmacy must generate an RDA for every dispense. The RDA can be generated by the Authorized Representative or any other staff member with an account on the REMS portal.

What is required for an RDA to be generated?

- The REMS portal will verify that the Prescriber is certified in the REMS. The REMS portal will also ask for information on a patient's current vaccination status for those on therapy for less than 6 months.

How long is an RDA valid?

- The RDA is valid for a specific dispense. If that dispense does not occur, the RDA must be canceled in the REMS portal.

What are the requirements for new patients?

- Assess and document meningococcal vaccination status (A, C, W, Y, and B) before the first dispense. "Unknown" status is accepted for new patients only. Continue assessing vaccination status at each dispense for the first 6 months if the patient was not up to date at initiation.

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Let's review some key questions and answers about the **RDA**.

What is an RDA? The RDA is a required step for every single dispense of ULTOMIRIS and SOLIRIS. Within this REMS, "dispense" means providing the product for a patient's treatment, including when it will be administered in the healthcare setting. The REMS portal will provide a unique RDA code for each dispense after a series of questions are answered.

Who generates the RDA? The healthcare setting and pharmacy will generate an RDA for every dispense. The RDA can be generated by the authorized representative or any other staff member with an account on the REMS portal.

What is required for an RDA to be generated? The REMS portal will verify that the Prescriber is certified in the REMS. The REMS portal will also ask for information on a patient's current vaccination status for those on therapy for less than 6 months.

How long is an RDA valid? The RDA is valid for a specific dispense: one RDA, one dispense. If that dispense does not occur, the RDA must be canceled in the REMS portal.

What are the requirements for new patients? Assess and document meningococcal vaccination status (A, C, W, Y, and B) before the first dispense. "Unknown" status is accepted for new patients only. Continue assessing vaccination status at each dispense for the first 6 months if the patient was not up to date at initiation.

REMS Portal Activities: HCS/Pharmacy

Understanding Dispense Requirements

Before first dispense, assess patient's vaccination status 01	Subsequent dispenses up to 6 months 02	Dispenses after 6 months 03
If up to date with meningococcal vaccines* - Document findings - Obtain authorization (ie, RDA) from REMS, which includes verifying prescriber REMS certification If not up to date with meningococcal vaccines† - Document findings - Obtain authorization (ie, RDA) from REMS, which includes verifying prescriber REMS certification - At next dispense, assess patient's vaccination status for up to date meningococcal vaccines	If initially up to date with meningococcal vaccines* at first dispense, - Obtain authorization (ie, RDA) from REMS, which includes verifying prescriber REMS certification If not up to date with meningococcal vaccines† at first dispense, - Assess patient's vaccination status - Document findings - Obtain authorization (ie, RDA) from REMS, which includes verifying prescriber REMS certification	Obtain authorization (ie, RDA) from REMS by verifying prescriber REMS certification This authorization is obtained by generating an RDA and answering all associated questions

*Up to date with meningococcal vaccines for serogroups A, C, W, Y, and B according to the current Advisory Committee on Immunization Practices (ACIP) recommendations, including antibacterial drug prophylaxis, if needed.

†Examples include patients who have received only the first dose in their vaccination series.

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Let's examine the REMS requirements for RDA generation. These requirements adjust based on a patient's time on therapy.

Before the first dispense, the healthcare setting or pharmacy will assess the patient's vaccination status. If the patient is up to date with their meningococcal vaccines, in accordance with the current ACIP guidelines, the healthcare setting or pharmacy will document the finding, and they will obtain the REMS Dispense Authorization or RDA, which includes verifying prescriber REMS certification.

If the patient is not up to date with their meningococcal vaccines, the finding will be documented, the RDA will be obtained, which includes verifying prescriber REMS certification, and at the next dispense, the healthcare setting or pharmacy will assess the patient's vaccination status for up-to-date meningococcal vaccines.

Looking at subsequent dispenses up to 6 months, if initially up to date with meningococcal vaccines at the first dispense, an RDA will be obtained, which includes verifying prescriber REMS certification. If not up to date with meningococcal vaccines at the first dispense, the healthcare setting or pharmacy must assess the patient's vaccination status, document the finding, and subsequently obtain authorization, which includes again verifying prescriber REMS certification.

After 6 months of dispensing, the healthcare setting or pharmacy must obtain authorization from REMS by verifying prescriber REMS certification.

RDA Release and Exceptions



The REMS Portal will allow product to be dispensed in the following situations:

- The prescriber is REMS certified, or it is an emergency situation



Emergency situation is defined as a situation requiring hospitalization

- An exception to prescriber certification and HCS/pharmacy certification will only be made in an emergency situation, whereby a patient is hospitalized and in urgent need of product at the time the prescriber places the order
- REMS certification will be diligently pursued by the REMS Administrator following product shipment
- Vaccination information is incomplete or unknown*
- ACIP assessment is incomplete or unknown*

REMS Administrator can be contacted at 888-765-4747 with any questions



The REMS Portal will NOT allow product to be dispensed when:

- The prescriber is **NOT REMS certified** and it is **NOT an emergency situation**

*The REMS Administrator may follow up for more detail on specific cases.

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The REMS portal will allow product to be dispensed when either the prescriber is REMS certified, or the prescriber is not REMS certified but it is an emergency situation. Once again, this carve-out is when hospitalization is required—that is how an emergency situation within the ULTOMIRIS and SOLIRIS REMS program is defined. Dispenses can also occur, ie, RDAs can be generated, in situations where vaccination information is incomplete or unknown, or if ACIP assessment is incomplete or unknown. In these situations, the REMS administrator may follow up for more detail on specific cases.

The only time the REMS portal will not allow product to be dispensed is when the prescriber is not REMS-certified and it is not an emergency situation. At that point, there will be a hard stop in the REMS portal if the prescriber is not certified, and it's confirmed not to be an emergency situation.

The REMS administrator can be contacted at 888-765-4747 with any questions.

REMS Responsibilities for Vaccination Data

	REMS REQUIREMENTS	ADDITIONAL CONTEXT
Before treatment initiation, Prescribers must:	Assess the patient's vaccination status for meningococcal serogroups A, C, W, Y, and B.	Assess patient vaccination status.
	Vaccinate as needed according to the current ACIP recommendations for meningococcal vaccinations in patients receiving a complement inhibitor. For patients who are not up to date with meningococcal vaccines at least two weeks prior to initiation of treatment and who must start ULTOMIRIS or SOLIRIS urgently; Provide the patient with a prescription for antibacterial drug prophylaxis.	Vaccinate and prescribe antibacterial drug prophylaxis, if needed, in accordance with ACIP.
	Counsel the patient using the Patient Safety Card and Patient Guide. Provide a copy of the materials to the patient.	Counsel patients using Patient Safety Card and Patient Guide.
Before dispensing, all Healthcare Setting or Pharmacy staff must:	Obtain authorization to dispense each prescription by contacting the REMS to verify the prescriber is certified.	Authorization to dispense and contacting the REMS is achieved via the RDA generation step in the REMS portal.
	Assess the patient's vaccination status for up to date meningococcal vaccines for serogroups A, C, W, Y, and B including antibacterial drug prophylaxis, if needed.	Determine ACIP compliance (Yes, No, Unknown ²) by reviewing available vaccination information.
	And document the findings through the processes and procedures established as a requirement of the REMS.	- Enter assessment outcome by answering RDA questions. - Dispense may proceed upon successful generation of RDA code. - REMS administrator may follow up if vaccine data is inconsistent with RDA responses and/or if clinical context for ACIP assessment is needed. - The follow-up may include a request for missing information to better understand the patient's clinical situation.
PLEASE NOTE: An RDA code can be generated and product can be dispensed regardless of vaccination status assessment (ACIP compliance = Yes, No, Unknown)*. Vaccine data can be added to the portal before or after dispense.		
²Unknown status is available for new patients only. Source: FDA-approved ULTOMIRIS and SOLIRIS REMS Document. Please see accompanying full Prescribing Information for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections. Please see accompanying full Prescribing Information for SOLIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.		

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There are specific requirements for prescribers and HCS when it comes to vaccination data. The column on the left shows the exact REMS requirements as documented in the Healthcare Provider (HCP) Safety Brochure. These requirements were attested to at time of certification.

Let's start with Prescribers. Prescribers must assess patient vaccination status. They must vaccinate and prescribe antibacterial drug prophylaxis, if it is needed, in accordance with ACIP. They must also counsel patients using the Patient Safety Card and the Patient Guide.

Next are the Healthcare Settings and Pharmacies. Before dispensing SOLIRIS or ULTOMIRIS, they must obtain an authorization to dispense and verify the prescriber is certified during the RDA generation step. They must determine ACIP compliance by reviewing available vaccination information. Once determined, they must enter the assessment outcome by answering the RDA questions. The Dispense can proceed upon successful generation of the RDA code. If vaccination information is inconsistent with RDA responses or if clinical context is needed, the REMS administrator may follow up with the HCS to better understand the patient's clinical situation.

An important reminder here is that an RDA code can be generated and product can be dispensed regardless of the vaccination status assessment. Vaccine data can be added to the portal before or after dispense.

Managing and Entering Vaccine and Prophylactic Antibiotic Data



Vaccine data may be already available in the REMS portal for some patients via prescriber, vaccination site, or patient support program (ie, OneSource™)



Upon entering patient's name and date of birth in the portal, available information will be displayed for HCS/Pharmacy reference. Data can be downloaded



Vaccine data, if not available, may be provided by HCS/Pharmacy or Prescriber to REMS through **data entry in REMS portal** or by **emailing required data to REMS Administrator within 48 hours of RDA generation**

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When we refer to **Vaccination and Prophylactic Antibiotic Data** within the REMS portal, it is important to note that vaccine data may already be available in the portal. This vaccination data could have been entered previously by a prescriber, through a vaccination site, or through a patient support program, such as OneSource™.

This vaccination data could have been entered previously by the prescriber, through a vaccination site. **Vaccine data for some OneSource patients may already be available in the portal as well.**

When healthcare settings and pharmacies proceed to the REMS Dispense Authorization section of the REMS portal, they will see any vaccination data that is available. When they enter the patient's name on the portal, the available vaccine information will be displayed. These data can also be downloaded by clicking on the Microsoft Excel icon.

If vaccination data is unavailable, it can be provided to the REMS through data entry in the REMS portal. There is some flexibility in getting that vaccination data to the REMS administrator for appropriate documentation. Healthcare settings and pharmacies can manually enter vaccine data into the REMS portal for that respective patient, or they can email the required data to the REMS administrator within 48 hours of RDA generation.

Ordering Product

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REMS Requirements Related to Ordering Product



Ordering Product

- The only REMS requirement for Alexion to ship product is that the **location receiving the product is certified in the REMS program**
 - REMS requirements are outlined on slides 13-14
- **No patient vaccination information** is required at the time of order from Alexion
- In **Emergency situations* only**, a shipment will be allowed to a non-certified HCS
 - Process can be found on slide 15
- All sites ordering ULTOMIRIS or SOLIRIS **must have** REMS processes and procedures in place and comply with the REMS requirements

*Emergency situations are defined as situations requiring hospitalization.
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Ordering Product

When you order product, the only requirement for Alexion to ship is that the location receiving the product is certified in the REMS program; no patient vaccination information is required at the time of the order. All sites ordering ULTOMIRIS or SOLIRIS must have REMS processes and procedures in place and comply with the REMS requirements, which are outlined in further detail on slides 13-14. There is an emergency carve-out, described on slide 15, that allows shipments to non-certified healthcare settings or pharmacies in emergency situations only.

How to Order From Alexion

Contact Alexion 01	Verify Order Information 02	Verify REMS Certification 03
- Place order via electronic delivery interchange (EDI), fax, or email (PDF) - Include the following order information: Site Name, Prescriber Name & NPI, Drug, and Quantity - Call Alexion at 888-765-4747, option 3 to notify or request an emergent order	- Identifying information for both patient* and prescriber* will be requested for the order Patient Information*: Patient Initials, Date of Birth, Diagnosis Prescriber Information*: Prescriber Name, Prescriber NPI # Site Information: Ordering Site Name, Address - If emergency use, Alexion will call site to confirm patient is hospitalized	- Prior to shipment, Alexion will verify that site is certified in the REMS by reviewing Site Ship-To Information as enrolled with REMS Administrator - REMS ID, Facility NPI # associated with REMS, and Fax # may be requested to verify the order The REMS Portal is used to enroll sites, maintain their certification, and confirm they meet REMS requirements before product is shipped - Product can only be shipped to REMS-certified sites. Any site receiving product, even if not dispensing, must comply with all REMS requirements and will be audited

*For free drug eligibility verification purposes only.

Please see accompanying full [Prescribing Information](#) for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.
Please see accompanying full [Prescribing Information](#) for SOLIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.

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Here is how you order ULTOMIRIS or SOLIRIS:

The first step is to contact Alexion. Orders can be placed via electronic delivery interchange (EDI), fax, or email and should include the site name, prescriber name and NPI, drug, and quantity. For emergent orders, call 888-765-4747, option 3.

Once the order is received, Alexion will verify all necessary patient, prescriber, and site information. For emergent orders, Alexion will contact the site to confirm the patient is hospitalized.

Prior to shipment, Alexion will verify that the site is certified in the REMS. Information such as the REMS ID, facility NPI, and fax number may be requested to confirm the order. Product can only be shipped to REMS-certified sites, and any site receiving product is subject to audit.

The REMS Portal is used to enroll sites, maintain their certification, and confirm they meet REMS requirements before product is shipped. Product can only be shipped to REMS-certified sites. Any site receiving product, even if not dispensing, must comply with all REMS requirements and will be audited.

REMS Portal 101

Please see accompanying full [Prescribing Information](#) for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.
Please see accompanying full [Prescribing Information](#) for SOLIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.

All About the REMS Portal

The REMS Portal is your one-stop shop for all required aspects of REMS compliance—**certification, RDA creation, vaccination tracking, audits, and more.**

[Click a card to view that section](#)

Portal Landing & Navigation

Slides 23-24

Dashboard overview with alerts, notifications, and quick links to daily tasks.

Patient Management

Slides 25-33

Add and manage patients, document prophylaxis, and record vaccination history.

HCS & Pharmacy Management

Slides 34-39

Manage sites, staff, and multilocation compliance from one dashboard.

RDA Generation Process

Slides 40-48

Step-by-step workflow to create a REMS Dispense Authorization.

Audit Tracking

Slides 49-51

Receive audit notifications.

Certified Participant Locator & My Profile

Slides 52-59

Find certified sites by name or location and manage your account.

Please see accompanying full [Prescribing Information](#) for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.
Please see accompanying full [Prescribing Information](#) for SOLIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.

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REMS Portal

Portal Landing & Navigation

Please see accompanying full [Prescribing Information](#) for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.
Please see accompanying full [Prescribing Information](#) for SOLIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.



REMS Portal Dashboard: Portal Landing & Navigation

Click each **hot spot** for more info

ULTIMIRIS Prescribing Information

Dashboard

My Patients

Date of Birth (MM/DD/YYYY) Patient ID Prescriber Show Bookmarked Patients Only

Patient Name	Date of Birth	Patient ID	HCS/Rx Rems ID	HCS/Rx Name	Product	Most Recent RDA	RDA Code	Prescriber Name
Grace Brewer	01/15/1980	100001	0000011111	ABC Pharmacy	ULTIMIRIS	05/15/2025	1234567890	Bob Johnson
Shawn Harding	02/20/1985	100002	0000011111	ABC Pharmacy	ULTIMIRIS	05/10/2025	1234567890	Bob Johnson
Phillip Lucas	01/15/1980	100003	0000011111	ABC Pharmacy	ULTIMIRIS	01/15/1980	1234567890	Bob Johnson
Donna Combs	04/25/1975	100004	0000011111	ABC Pharmacy	SOLIRIS	01/15/1980	1234567890	Bob Johnson
Christine Fowler	05/30/1965	100005	0000011111	ABC Pharmacy	ULTIMIRIS	01/15/1980	1234567890	Bob Johnson
Richard Arroyo	06/18/1992	100006	0000022222	XVZ Pharmacy	SOLIRIS	01/15/1980	1234567890	Bob Johnson
Katherine Gray	07/12/1988	100007	0000022222	XVZ Pharmacy	ULTIMIRIS	01/15/1980	1234567890	Bob Johnson
Verity Chandler	08/05/1970	100008	0000022222	XVZ Pharmacy	ULTIMIRIS	01/15/1980	1234567890	Bob Johnson

Page 1 of 1 | Total Records: 10

Icon Legend

View Details Bookmark Patient/Prescriber View RDA Details Generate New RDA Generate RDA Cancel RDA Add Staff Member Remove Staff

Enroll a new HCS / Pharmacy Download History Timeline View Table View Edit Begin Audit Questionnaire

Notifications

Audit Questionnaire Assigned
Please submit the audit questionnaire.
Authorized Representative: Steve Meru

REMINDER: Add vaccination entry
Patient Grace Brewer due for vaccines on October 15, 2025.

Most Recent RDAs

Grace Brewer
Date of Birth: 01/15/1980
Prescriber: Bob Johnson
RDA Generated: 05/15/2025

Shawn Harding
Date of Birth: 02/20/1985
Prescriber: Bob Johnson
RDA Generated: 05/10/2025

Continue to Next Section

REMS Portal

Patient Management

Please see accompanying full [Prescribing Information](#) for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.
Please see accompanying full [Prescribing Information](#) for SOLIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.



Patients

HCS / Pharmacy REMS ID: 1234567890

Enter Date of Birth **OR** Patient ID.

Date of Birth (MM/DD/YYYY)

01/15/1980

Patient ID

100001

Quick Links

 GENERATE NEW ROAD

 ADD STAFF MEMBER

ENROLL A NEW HCS / PHARMACY

ACIP RECOMMENDATIONS

▼ Icon Legend

[View Details](#)
[Bookmark Patient/Prescriber](#)
[View RDA Details](#)
[Generate New RDA](#)
[Generate RDA](#)
[Cancel RDA](#)
[Add Staff Member](#)
[Remove Staff](#)

Continue to Next Section ➞

Please see accompanying full [Prescribing Information](#) for ULMOMIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections. Please see accompanying full [Prescribing Information](#) for SOLIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.

Patients

HCS / Pharmacy REMS ID: 1234567890

Enter Date of Birth OR Patient ID.

Date of Birth (MM/DD/YYYY)

01/15/1980

Patient ID

100001

SEARCH

First Name	Last Name	Date of Birth	Patient ID	Gender	Zip Code	Most Recent RDA	Product	HCS/Rx REMS ID	HCS/Rx Name
Grace	Brewer	01/15/1980	100001	Female	11223	05/15/2025	ULTOMIRIS	0000011111	Main Street Location

Page 1 of 1 | Total Records: 1

If you do not see the patient in the grid above, you may add the patient at this time.

ADD PATIENT

Quick Links

- GENERATE NEW RDA
- ADD STAFF MEMBER
- ENROLL A NEW HCS / PHARMACY
- ACIP RECOMMENDATIONS

Icon Legend

- View Details
- Bookmark Patient/Prescriber
- View RDA Details
- Generate New RDA
- Generate RDA
- Cancel RDA
- Add Staff Member
- Remove Staff
- Enroll a new HCS / Pharmacy
- Download History
- Timeline View
- Table View
- Edit
- Begin Audit Questionnaire

Please see accompanying full [Prescribing Information](#) for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.
Please see accompanying full [Prescribing Information](#) for SOLIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.

REMS Portal: Patient Management

[← Back](#)
[Next →](#)

[ULTOMIRIS Prescribing Information](#)
[ULTOMIRIS Medication Guide](#)
[SOLIRIS Prescribing Information](#)
[SOLIRIS Medication Guide](#)

ABC Pharmacy - 100 Main Street

Steve Meru

1

Add Patient

Select Location

Main Street Location

First Name

Grace

Last Name

Brewer

Date of Birth (MM/DD/YYYY)

01/15/1980

Gender

☐ Male
☒ Female
☐ Other
☐ Prefer Not to Provide

ZIP Code

11023

Indication

☐ Paroxysmal nocturnal hemoglobinuria (PNH)
☐ Atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy (TMA)
☒ Generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody positive
☐ Neuromyelitis optica spectrum disorder (NMOSD) who are anti-aquaporin-4 (AQP4) antibody positive
☐ Other (please specify)

CANCEL

ADD

2

Add Patient

Prior to adding a new patient, please review the patient list below. If your patient is shown below, please select the patient from grid and continue. If not please tick the check box and continue to add the patient.

Patient Name	Patient ID	Date of Birth (MM/DD/YYYY)
Gracy Brewer	100001	01/15/1980
Grace Brewer	100012	01/15/1990

☐ I have verified the above list and the patient I am trying to add is not in the above list.

CANCEL

CONTINUE

The **Add Patient** window lets users enter patient information, including location, first and last name, date of birth, gender, ZIP code, and indication before adding the patient

The **Add Patient** window prompts users to review the existing patient list and verify that the patient to be added is not already listed, and then continue

Please see accompanying full [Prescribing Information](#) for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.

Please see accompanying full [Prescribing Information](#) for SOLIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.

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Patient: Grace Brewer

HCS / Pharmacy REMS ID: 1234567890

Patient Details

EDIT PATIENT DETAILS

First Name: Grace Last Name: Brewer Date of Birth: 01/15/1980
Gender: Female Zip Code: 11223 Patient ID: 100001

Indication: Generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody positive.
First RDA Date: 01/15/1980

Quick Links

- GENERATE NEW RDA
- DOWNLOAD PATIENT HISTORY
- ACIP RECOMMENDATIONS

Antibacterial Drug Prophylaxis

EDIT ANTIBACTERIAL DRUG PROPHYLAXIS

Was the patient prescribed antibacterial drug prophylaxis? Yes Antibacterial drug prophylaxis prescription start date: 06/30/2025

Vaccination History

ADD VACCINATION REMINDER ADD VACCINATION RECORD

Vaccine Type	Brand	Dose Date	Administered prior to ULTOMIRIS or SOLIRIS?
MenB	Bexsero®	02/20/2025	Yes
MenACWY	Menveo®	02/20/2025	Yes
MenB	Bexsero®	01/18/2024	Yes
MenACWY	Menveo®	01/18/2024	Yes

Patient History

Date	Event	Details
08/15/2025	RDA Generated	ULTOMIRIS (ABC Pharmacy - 100 Main Street - Suite 210)
07/15/2025	RDA Canceled	ULTOMIRIS (ABC Pharmacy - 100 Main Street - Suite 210)
06/30/2025	Antibacterial Drug	Prescribed Antibacterial Drug Prophylaxis
06/15/2025	RDA Generated	ULTOMIRIS (XYZ Pharmacy - 101 Broad Street - STE 200)
05/15/2025	RDA Generated	ULTOMIRIS (XYZ Pharmacy - 101 Broad Street - STE 200)
02/20/2025	Vaccine Administered	MenB, Bexsero®
02/20/2025	Vaccine Administered	MenACWY, Menveo®
01/18/2024	Vaccine Administered	MenB, Bexsero®
01/18/2024	Vaccine Administered	MenACWY, Menveo®

Icon Legend

- View Details
- Bookmark Patient/Prescriber
- View RDA Details
- Generate New RDA
- Generate RDA
- Cancel RDA
- Add Staff Member
- Remove Staff
- Enroll a new HCS / Pharmacy
- Download History
- Timeline View
- Table View
- Edit
- Begin Audit Questionnaire

Please see accompanying full [Prescribing Information](#) for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.
Please see accompanying full [Prescribing Information](#) for SOLIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.

Continue to Next Section →

+ Patient: Brian Brewer

HCS / Pharmacy REMS ID: 123-4567890

Patient Details | Quick Links | Patient History

First Name: Brock Last Name: Brewer
Gender: Female Zip Code: 1223

Indication: Generalized myasthenia gravis (gMG) who are anti-acetylcholine antibody positive.
First RGA Date: 01/15/2020

Antibacterial Drug Prophylaxis

Was the patient prescribed antibacterial drug prophylaxis? Yes

Vaccination History

Vaccine Type	Brand	Date
Mening	Brevax [®]	02/20/20
MeningACWY	Menveo [®]	02/20/20
Mening	Brevax [®]	05/16/20
MeningACWY	Menveo [®]	05/16/20

Edit Patient Details

*First Name: Brock *Last Name: Brewer
*Date of Birth (MM/DD/YYYY): 01/15/1993
*Gender: Male (selected) Female Other Prefer Not to Provide
*ZIP Code: 1223
*Indication:
☐ Paroxysmal nocturnal hemoglobinuria (PNH)
☐ Atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy (TMA)
☒ Generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody positive
☐ Neuromyelitis optica spectrum disorder (NMOSD) who are anti-aquaporin-4 (AQP4) antibody positive
☐ Other (please specify)

CANCEL SAVE

The **Edit Patient Details** window lets users update patient information, including gender and indication.

Street - Suite 200
01/2020 Antibacterial Drug Prescribed Antibacterial Drug Prophylaxis
01/2020 RGA Generated ULTIMIRIS JvXZ Pharmacy - 1st Broad Street - STE 200
01/2020 RGA Generated ULTIMIRIS JvXZ Pharmacy - 1st Broad Street - STE 200
01/2020 Vaccine Administered MenB, Brevax[®]
01/2020 Vaccine Administered MenACWY, Menveo[®]
01/2020 Vaccine Administered MenB, Brevax[®]
01/2020 Vaccine Administered MenACWY, Menveo[®]
Page 2 of 2 | 3rd Broad St.

Icon Legend

- View Details
- Bookmark Patient/Prescriber
- View RGA Details
- Generate New RGA
- Generate RGA
- Cancel RGA
- Add Staff Member
- Remove Staff
- Enroll a new HCS / Pharmacy
- Download History
- Timeline View
- Table View
- Edit
- Begin Audit Questionnaire

Continue to Next Section

The screenshot displays the SOLIRIS patient record for Grace Brewer. A modal window titled "Edit Antibacterial Drug Prophylaxis" is open, asking if the patient was prescribed antibacterial drug prophylaxis. The user has selected "No". The window also prompts for the start date (MM/DD/YYYY), which is currently set to 06/30/2025. The background shows the patient's details, including name, date of birth, and a list of vaccinations. A yellow callout box highlights the window title and the purpose of the edit function.

Edit Antibacterial Drug Prophylaxis

*Was the patient prescribed antibacterial drug prophylaxis?
☒ Yes ☐ No ☐ Unknown

If available, please provide patient's antibacterial drug prophylaxis Prescription Start Date (MM/DD/YYYY)
 06/30/2025

CANCEL SAVE

Dashboard PATIENTS REMS DISPENSE AUTHORIZATIONS HEALTHCARE SETTING AND PHARMACY MANAGEMENT AUDIT QUESTIONNAIRE CERTIFIED PARTICIPANT LOCATOR MY PROFILE

1 Patient: Grace Brewer HCS / Pharmacy REMS ID: 1234567890

2

Add Vaccination Record

* Indicates Required Field

* Vaccination Type: * Brand:

Dose Date (MM/DD/YYYY): Exact Date Unknown: ☐

Dose administered prior to ULTOMIRIS or SOLIRIS: ☐ Yes ☐ No

CANCEL ADD

The **Add Vaccination Record** window lets users select the vaccination type and brand, enter the dose date or mark it as unknown, and indicate whether the dose was given before ULTOMIRIS or SOLIRIS

Add Vaccination Reminder

Reminder Date:

This is a reminder for future vaccination doses for a patient. It is not a reminder for RDA generation OR product shipments.

CANCEL SAVE REMINDER

Vaccination History

Vaccine Type	Brand	Dose Date	Administered prior to ULTOMIRIS or SOLIRIS?
MenB	Bexsero®	02/20/2025	Yes
MenACWY	Menveo®	02/20/2025	Yes
MenB	Bexsero®	01/16/2024	Yes
MenACWY	Menveo®	01/16/2024	Yes

1

2

Icon Legend

View Details Bookmark Patient/Prescriber View RDA Details Generate New RDA Generate RDA Cancel RDA Add Staff Member

Enroll a new HCS / Pharmacy Download History Timeline View Table View Edit Begin Audit Questionnaire

CONTINUE TO NEXT SECTION

Please see accompanying full [Prescribing Information](#) for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections. Please see accompanying full [Prescribing Information](#) for SOLIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.

The **Edit Vaccination Record** window lets users update the vaccination type, brand, whether the exact date is unknown, the exact dose date, and whether the dose was given before ULMOTMIRIS or SOLIRIS, and then save the changes

1 Patient: Grace Brewer

HCS / Pharmacy REMS ID: 123-4567890

Edit Vaccination Record

* Indicates Required Field

* Vaccination Type :
MenACWY
-- Please Select --
MenB
MenB
MenACWY
SOLIRIS? :
☒ Yes ☐ No

* Brand :
-- Please Select --
Exact Date Unknown : ☐

* Dose Date (MM/DD/YYYY) :
01/16/2024

* Dose administered prior to ULMOTMIRIS or SOLIRIS :
☒ Yes ☐ No

CANCEL SAVE

Vaccination History

Vaccine Type	Brand	Dose Date	Administered prior to ULMOTMIRIS or SOLIRIS?
MenB	Boxano®	02/20/2025	Yes
MenACWY	Menveo®	02/25/2025	Yes
MenB	Boxano®	01/16/2024	Yes
MenACWY	Menveo®	01/16/2024	Yes

Icon Legend

View Details | Bookmark Patient/Prescriber | View RGA Details | Generate New RGA | Generate RGA | Cancel RGA | Add Staff Member | Remove Staff

Enroll a new HCS / Pharmacy | Download History | Timeline View | Table View | Edit | Begin Audit Questionnaire

Continue to Next Section →

Please see accompanying full [Prescribing Information](#) for ULMOTMIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections. Please see accompanying full [Prescribing Information](#) for SOLIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.

REMS Portal

HCS & Pharmacy Management

Please see accompanying full [Prescribing Information](#) for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.
Please see accompanying full [Prescribing Information](#) for SOLIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.



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HCS / Pharmacy Management

About All Staff

About tab provides a summary of HCS/Pharmacy information, including REMS status, location details, and identifiers

HCS / Pharmacy REMS ID: 1234567890

Selected Location: Main Street Location

HCS / Pharmacy Information

EDIT HCS / PHARMACY INFORMATION

Name: Community Hospital of the Greater City-City Area

Nick Name: Community Hospital

REMS ID: 0000000000

Phone: (000) 000-0000

Address: 123 Main St., King Of Prussia, PA 19406

NPI: 0000000000

REMS Status: Certified

Fax: (000) 000-0000

Active AR Information

First Name: Steve

Last Name: Meru

Title: Pharmacy Manager

Email: Steve.Meru@communityhospital.com

Phone: (000) 000-0000

Fax: (000) 000-0000

REMS ID: 1134567890

Legend

- View Details
- Bookmark Patient/Prescriber
- View RDA Details
- Generate RDA
- Regenerate RDA
- Cancel RDA
- Add Staff Member
- Remove Staff
- Enroll a new HCS/Pharmacy
- Download Patient History
- Timeline View
- Table View
- Edit
- Begin Audit Questionnaire

Please see accompanying full [Prescribing Information](#) for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.
Please see accompanying full [Prescribing Information](#) for SOLIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.

Continue to Next Section

DASHBOARD PATIENTS REMS DISPENSE AUTHORIZATIONS HCS / PHARMACY MANAGEMENT AUDIT QUESTIONNAIRE CAPA CERTIFIED PARTICIPANT LOCATOR MY PROFILE

HCS / Pharmacy Management About tab provides a summary of HCS/Pharmacy information, including REMS status, location details, and identifiers

HCS / Pharmacy REMS ID: 1234567890

About All Staff

Selected Location: Main Street Location

HCS / Pharmacy Information

Name: Community Hospital of the Greater City Area

Phone: (000) 000-0000

REMS Status: Certified

Active AR Information

First Name: Steve

Email: Steve.Merul@communityhospital.com

REMS ID: 1234567890

Legend

Edit HCS / Pharmacy Information

*NPI
0000000000

*Name
Community Hospital of the Greater City Area

Nickname:
Community Hospital

*REMS ID
0000000000

*Address 1
123 Main St

Address 2

*City
King Of Prussia

*State
PA

*ZIP Code
19406

*Phone
000-000-0000

*Fax
000-000-0000

REMS Status: CERTIFIED

CANCEL SAVE

The **Edit HCS/Pharmacy Information** window lets users update details such as name, nickname, phone number, and fax number before saving

Please see accompanying full [Prescribing Information](#) for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.
Please see accompanying full [Prescribing Information](#) for SOLIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.

Healthcare Setting and

About

All Staff

The **All Staff** tab displays all personnel for the selected location, and users can use "Add New Staff" to add new team members who need REMS access

HCS / Pharmacy REMS ID: 1234567890

Selected Location: ABC Pharmacy - 100 Main Street - Suite 210

Staff Information

ADD NEW STAFF

Name	Email
Madeline Andersen	Madeline.Andersen@communityhospital.com
Tina Donaldson	Tina.Donaldson@communityhospital.com
Max Graham	Max.Graham@communityhospital.com
Whitney Lawson	Whitney.Lawson@communityhospital.com
Lissa Evans	Lissa.Evans@communityhospital.com

Page 1 of 1 | Total Records: 5

Icon Legend

View Details Bookmark Patient/Prescriber View RDA Details Generate New RDA Generate RDA Cancel RDA Add Staff Member Remove Staff
Enroll a new HCS / Pharmacy Download History Timeline View Table View Edit Begin Audit Questionnaire

Please see accompanying full [Prescribing Information](#) for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.
Please see accompanying full [Prescribing Information](#) for SOLIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.

DASHBOARD PATIENTS REMS DISPENSE AUTHORIZATIONS HEALTHCARE SETTING AND PHARMACY MANAGEMENT AUDIT QUESTIONNAIRE CERTIFIED PARTICIPANT LOCATOR MY PROFILE

ULTOMIRIS Prescribing Information ULTIMIRIS Medication Guide

REMS ID: 1234567890

1

Add Staff

Please enter the staff's email address below and click "Search".

*Email
Joyce.Patrick@communityhospital.com

SEARCH

CANCEL ADD

The **Add Staff** window lets users enter a staff member's email, search for their information, and add them with the required authorization

2

Add Staff

Please enter the staff's email address below and click "Search".

*Email
Joyce.Patrick@communityhospital.com

SEARCH

Please enter or update the information below for this Staff user.

*First Name
Joyce

*Last Name
Patrick

By the healthcare setting and pharmacy, authorized representative, grant administrative rights to the Staff user listed above to manage REMS Dispense Authorization (SDMs) and provide vaccination status/antibacterial drug prophylaxis information to the REMS on my behalf.

Once a staff member is added, the staff member will immediately receive an email notification with steps to create a login account in the ULTIMIRIS.com.

CANCEL ADD

The **Add Staff** window lets users search for a staff member by email, enter or update their first and last name, and add them, after which the staff member receives an email to create their account

Icon Legend

View Details Bookmark Patient/Prescriber View RDA Details Generate New RDA

Enroll a new HCS / Pharmacy Download History Timeline View Table View Edit Begin Audit Questionnaire

Remove Staff

Page 1 of 1 | Total Records: 5

Please see accompanying full [Prescribing Information](#) for ULTIMIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.
Please see accompanying full [Prescribing Information](#) for SOLIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.

DASHBOARD PATIENTS REMS DISPENSE AUTHORIZATIONS HEALTHCARE SETTING AND PHARMACY MANAGEMENT AUDIT QUESTIONNAIRE CERTIFIED PARTICIPANT LOCATOR MY PROFILE

Healthcare Settings

1

Edit Staff

*Email
Joyce.Patrick@communityhospital.com

Please enter or update the information below for this Staff user.

*First Name
Joyce

*Last Name
Patrick

CANCEL SAVE

The **Edit Staff** window lets users search for a staff member by email, update their first and last name, and save the changes

2

Remove Staff

Are you sure want to remove staff association?

Email
Steve.Meru@communityhospital.com

Name
Joyce Patrick

CANCEL REMOVE

The **Remove Staff** window asks the user to confirm removing a staff association by showing the staff member's email and name before removal

Icon Legend

View Details Bookmark Patient/Prescriber View RDA Details Generate New RDA Generate RDA Enroll a new HCS / Pharmacy Download History Timeline View Table View Edit Begin Audit Questionnaire

Please see accompanying full [Prescribing Information](#) for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.
Please see accompanying full [Prescribing Information](#) for SOLIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.

REMS Portal

RDA Generation Process

Please see accompanying full [Prescribing Information](#) for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.
Please see accompanying full [Prescribing Information](#) for SOLIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.



DASHBOARD PATIENTS **REMS DISPENSE AUTHORIZATIONS** HEALTHCARE SETTING AND PHARMACY MANAGEMENT AUDIT QUESTIONNAIRE CERTIFIED PARTICIPANT LOCATOR MY PROFILE

REMS Dispense Authorizations (RDAs)

HCS / Pharmacy REMS ID: 1234567890

Patient ID: _____ Prescriber: _____ Date of Birth (MM/DD/YYYY): _____ Show Bookmarked Patients Only: ☐ No ☒ Yes

	Name	Date of Birth	Patient ID	Product	Prescriber NPI	Prescriber Name	RDA Generated	RDA Code	RDA Generated By	Status				
					Grace Brewer	01/15/1980	100001	ULTOMIRIS	1234567890	Bob Johnson	08/15/2025	0123456789	Steve Menu	RDA Car...
					Shawn Harding	02/20/1985	100002	ULTOMIRIS	1234567890	Bob Johnson	05/00/1970	0123456789	Steve Menu	
					Philip Lucas	01/15/1980	100003	ULTOMIRIS	1234567890	Bob Johnson	05/00/1970	0123456789	Steve Menu	
					Dennis Combs	04/25/1975	100004	SOLIRIS	1234567890	Bob Johnson	05/00/1970	0123456789	Steve Menu	
					Christine Fowler	05/30/1965	100005	ULTOMIRIS	1234567890	Bob Johnson	05/00/1970	0123456789	Steve Menu	
					Richard Arroyo	06/18/1992	100006	SOLIRIS	1234567890	Bob Johnson	05/00/1970	0123456789	Steve Menu	
					Katherine Gray	07/12/1988	100007	ULTOMIRIS	1234567890	Bob Johnson	05/00/1970	0123456789	Steve Menu	
					Venly Chandler	06/05/1970	100008	ULTOMIRIS	1234567890	Bob Johnson	05/00/1970	0123456789	Steve Menu	

Page 1 of 11 | Total Records: 11

Icon Legend

- View Details
- Bookmark Patient/Prescriber
- View RDA Details
- Generate New RDA
- Generate RDA
- Cancel RDA
- Add Staff Member
- Remove Staff
- Enroll a new HCS / Pharmacy
- Download History
- Timeline View
- Table View
- Edit
- Begin Audit Questionnaire

Quick Links

- GENERATE NEW RDA**
- ADD STAFF MEMBER
- ENROLL A NEW HCS / PHARMACY
- ACIP RECOMMENDATIONS

Please see accompanying full [Prescribing Information](#) for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections. Please see accompanying full [Prescribing Information](#) for SOLIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.

Click **hot spot** for more info

1 Create an RDA from this screen (ie, generate new REMS Dispense Authorization)

Generate RDA

Continue to Next Section

Generate REMS Dispense Authorizations (RDAs)

1 Select Location 2 Select Patient 3 Select Prescriber 4 Dispense Information 5 Completion

CONTINUE

CANCEL

Select Location

Enter Location OR NPI:

Location

NPI

SEARCH

Location	Address	NPI	REMS ID
ABC Pharmacy	100 Main Street - Suite 210 Philadelphia, PA 99999	1234567890	1234567899
XYZ Pharmacy	101 Broad Street - STE 200 Philadelphia, PA 99999	1234567891	1234567891
Test Specialty Pharmacy	123 Maple Street Philadelphia, PA 99999	1234567892	1234567892

Selection Summary

Select a location to continue.

Selection Summary is the box on the right that shows a quick overview of the choices you've made (location, patient, prescriber, etc.) before continuing with the RDA generation process.

Icon Legend

View Details Bookmark Page

Enroll a new HCS / Pharmacy

Download History

Timeline View

Table View

Edit

Begin Audit Questionnaire

Cancel RDA

Add Staff Member

Remove Staff

The **Location** selection step lets users search by location or NPI, view matching results, and choose the correct site to begin generating an RDA

Continue to Next Section

Please see accompanying full [Prescribing Information](#) for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.
Please see accompanying full [Prescribing Information](#) for SOLIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.

Generate REMS Dispense Authorizations (RDAs)

1 Select Location 2 **Select Patient** 3 Select Prescriber 4 Dispense Information 5 Completion

CONTINUE

CANCEL

Search and Select a Patient

Enter Date of Birth OR Patient ID.

Date of Birth (MM/DD/YYYY)

Patient ID

01/15/1980

100001

SEARCH

CLEAR

Patient Name	Patient ID	Date of Birth (MM/DD/YYYY)
Grace Brewer	100001	01/15/1980

If you do not see the patient in the grid above, you may add the patient at this time.

ADD PATIENT

Selection Summary

Select a patient to continue.

Location: ABC Pharmacy

Address: 100 Main Street - Suite 210, Philadelphia, PA 99999

NPI: 1234567890

REMS ID: 1234567899

The **Search and Select a Patient** selection step lets users search patients by date of birth or patient ID, view matching results, and choose the correct patient to begin generating an RDA. If the patient is not shown, you may also add the patient at this time.

Icon Legend

View Details Bookmark Patient/Prescriber View RDA Details Generate New RDA Generate RDA Cancel RDA Add Staff Member Remove Staff
Enroll a new HCS / Pharmacy Download History Timeline View Table View Edit Begin Audit Questionnaire

Continue to Next Section

Please see accompanying full [Prescribing Information](#) for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.
Please see accompanying full [Prescribing Information](#) for SOLIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.

Generate REMS Dispense Authorizations (RDAs)

1 Select Location 2 Select Patient 3 **Select Prescriber** 4 Dispense Information 5 Completion

CONTINUE

CANCEL

Search and Select a Prescriber

Enter NPI OR Prescriber Name.

NPI

3334567890

Prescriber Name

John Peter

SEARCH

CLEAR

Prescriber Name

Prescriber NPI

Prescriber REMS Status

No Records Found

10

20

30

40

50

60

70

80

90

100

Page 1 of 1 | Total Records: 0

If you do not see the prescriber in the grid above, you may add the prescriber at this time. You may also call the ULTOMIRIS and SOLIRIS REMS Call Center at 1-888-765-4747 if you need additional information.

ADD PRESCRIBER

Selection Summary

Select a prescriber to continue.

Location: ABC Pharmacy

Address: 100 Main Street - Suite 210, Philadelphia, PA 99999

NPI: 1234567890

REMS ID: 1234567899

The **Search and Select a Prescriber** selection step lets users search prescribers by NPI or name, view matching results, and choose the correct patient to begin generating an RDA. If the prescriber is not shown, you may also add the prescriber at this time.

Icon Legend

View Details Bookmark Patient/Prescriber View RDA Details Generate New RDA Generate RDA Cancel RDA Add Staff Member Remove Staff
Enroll a new HCS / Pharmacy Download History Timeline View Table View Edit Begin Audit Questionnaire

Continue to Next Section

Please see accompanying full [Prescribing Information](#) for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections. Please see accompanying full [Prescribing Information](#) for SOLIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.

 Select Location —
 Select Patient —
 Select Prescriber —
 Dispense Information —
 Completion

▼ Icon Legend

2

Select Location — Select Patient — Select Prescriber — **Diagnosis Information** — Complete[illegible]

45

Generate REMS Dispense Authorizations (RDAs)

Generate REMS Dispense Authorizations (RDAs)

HCS / Pharmacy REMS ID: 1234567890

Select Patient

Select Prescriber

Select Dispense Information

Select Location

RDAs Complete

RDAs Dispense Authorization generated

RDAs Dispense Authorization

32323237

OK TO DISPENSE

RDAs requirements met.

GENERATE NEW RDA

Selection Summary

Prescriber: Bob Johnson

NPI: 0123456789

RDAs Status: CERTIFIED

Patient: Grace Brewer

Patient ID: 123456

Date of Birth: 01/15/1980

Most Recent RDA: 01/15/2023

Indication: Acquired hemolytic anemic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy (TMA)

Antibacterial Drug Prophylaxis

Was the patient administered

Date antibacterial drug prophylaxis administered: 04/03/2023

antibacterial drug prophylaxis?

Yes

Vaccination History

Vaccine Type	Brand	Drop Date	Administered prior to USCMMS or Not
✓ Hemophilus	Hemophilus	07/06/2024	Yes
✓ Hib	Brevinor	04/76/2024	Yes
✓ Hib/CACVY	Hemophilus	07/06/2023	Yes
✓ Hib	Brevinor	04/76/2023	Yes

Dispense Information:

Product to Dispense: US7144805

Is the patient up to date (a completed primary vaccination series) for immunization services for meningitis A, C, W, Y and B as per Advisory Committee on Immunization Practices (ACIP) recommendations?

Yes

The **RDA completion** page confirms that the REMS dispense authorization has been generated, displays the authorization number and dispense status, and shows a summary of prescriber, patient, prophylaxis, and vaccination details

at a prescriber to continue.

tion: ABC Pharmacy

ISSN: 100 Main Street - Suite 210, Philadelphia, PA 19106
215-567-8990
ID: 1234567899

Search and Select a Prescriber selection step lets you search prescribers by NPI or name, view matching results, and choose the correct patient to begin generating an RDA. If the prescriber is not shown, you may add the prescriber at this time.

Please see accompanying full [Prescribing Information](#) for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections. Please see accompanying full [Prescribing information](#) for SOLIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.

Generate RDA

The **Remove Bookmark** window lets users select the location tied to the bookmark and confirm its removal for the displayed patient

1 Select Location

2 Select Patient

3 Select Prescriber

4 Dispense Information

5 Completion

CONTINUE

CANCEL

Select Location

Enter Location OR NPI

Location

Location	Address
ABC Pharmacy	100 Main Street Philadelphia, PA
XYZ Pharmacy	101 Broad Street Philadelphia, PA
Test Specialty Pharmacy	123 Maple Street Philadelphia, PA

Selection Summary

ULTOMIRIS Prescribing Information

ULTOMIRIS Medication Guide

Grace Brewer

Patient ID: 100001

Date of Birth: 01/15/1980

Most Recent RDA: 05/15/2025

*Select Location

Main Street Location

CANCEL REMOVE

Icon Legend

View Details Bookmark Patient/Prescriber View RDA Details Generate New RDA Generate RDA Cancel RDA Add Staff Member Remove Staff

Enroll a new HCS / Pharmacy Download History Timeline View Table View Edit Begin Audit Questionnaire

Please see accompanying full [Prescribing Information](#) for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.
Please see accompanying full [Prescribing Information](#) for SOLIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.

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REMS Portal

Audit Tracking

Please see accompanying full [Prescribing Information](#) for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.
Please see accompanying full [Prescribing Information](#) for SOLIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.



Audit Questionnaire

HCS / Pharmacy REMS ID: 1234567890

Below is a list of Sample Stakeholder Audit Questionnaires for locations where you are the Authorized Representative.

- Download the list to spreadsheet format by clicking the Excel icon just above the column headers
- Search/Filter the list by entering information in the textbox below any column header
- Sort the list by clicking on any column header

Audit List

	Audit ID	ITEMS ID	HCS / Pharmacy Name	Audit Status	Audit Status Date	Response Due Date
	165	1234567890	Law Pharmacy	ACTIVE	12/02/2025 12:08 PM	01/16/2026
	209	1234567891	Law HCS	AUDIT CLOSED	12/02/2025 10:25 AM	10/26/2025
	4323	1234567892	vWUjHj ay3HD	UNDER REVIEW	12/02/2025 10:15 PM	10/26/2025
	3500	1234567893	Law Pharmacy	IN PROGRESS	09/11/2025 03:07 PM	01/16/2026
	4488	1234567894	hdiFD KKKKJRXZ	SUBMITTED	12/02/2025 04:42 AM	10/26/2025

▼ Icon Legend

- [View Details](#)
[Bookmark Patient/Prescriber](#)
[View RDA Details](#)
[Generate New RDA](#)
[Generate RDA](#)
[Cancel RDA](#)
[Add Staff Member](#)
[Remove Staff](#)

Please see accompanying full [Prescribing Information](#) for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections. Please see accompanying full [Prescribing information](#) for SOLIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.

Portal Landing & Navigation

Click **hot spot** for more info

The **portal header** or **notifications** are other ways to access audit updates

Continue to Next Section ➞

Links to
slide 24

Links to
slide 52

UNLOAD FILE

OR

Drag & Drop files here

I certify, as the Authorized Representative of my Healthcare Setting or Pharmacy in the ULTOMIRIS and SOLIRIS REMS, that I have completed this Audit Questionnaire to the best of my knowledge.

☐ Signature of Authorized Representative

CANCEL

SAVE AND QUIT

SUBMIT

- Save and Quit: Selecting "Save and Quit" will save all information entered. The audit questionnaire will display on your audit listing with a "Resume Audit Questionnaire" button.
- Submit: Selecting "Submit" will save all information entered. The audit questionnaire will display on your audit listing with a "View Audit Questionnaire" button.

Legend

[View Details](#)
[Bookmark Patient/Prescriber](#)
[View RCA Details](#)
[Generate RCA](#)
[Regenerate RCA](#)
[Cancel RCA](#)
[Add Staff Member](#)
[Remove Staff](#)
[Enroll a new HCS / Pharmacy](#)

[Download Patient History](#)
[Timeline View](#)
[Table View](#)
[Edit](#)
[Begin Audit Questionnaire](#)

The **Audit Questionnaire** page lets users complete the required REMS audit by entering authorized representative information, healthcare setting and pharmacy details, answering compliance questions, uploading files, and submitting the form

Continue to Next Section

Please see accompanying full [Prescribing Information](#) for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections. Please see accompanying full [Prescribing Information](#) for SOLIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.

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REMS Portal

Certified Participant Locator

Please see accompanying full [Prescribing Information](#) for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.
Please see accompanying full [Prescribing Information](#) for SOLIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.



Certified Participant Locator

HCS / Pharmacy REMS ID: 1234567890

Search By: ☒ Address ☐ Name ☐ NPI ☐ REMS ID

Please enter a street address, city, state, or zip code.

* Find a Participant Near

19422

Search Radius

Within 100 miles

SEARCH

Icon Legend

- View Details
- Bookmark Patient/Prescriber
- View RDA Details
- Generate New RDA
- Generate RDA
- Cancel RDA
- Add Staff Member
- Remove Staff
- Enroll a new HCS / Pharmacy
- Download History
- Timeline View
- Table View
- Edit
- Begin Audit Questionnaire

[Continue to Next Section](#)

Please see accompanying full [Prescribing Information](#) for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.
Please see accompanying full [Prescribing Information](#) for SOLIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.

The **search page** lets users look up **healthcare settings and pharmacies** or **healthcare providers** by address, name, NPI, or REMS ID, set a search radius, and view matching locations on an **interactive map** with details and directions

1

Dashboard | Alerts | REMS Dispute Authorizations | Healthcare Setting and Pharmacy Management | Audit Questionnaire | **Certified Participant Locator** | My Profile

Certified Participant Locator HCS / Pharmacy REMS ID: 1234567890

Search By: ☒ Address ☐ Name ☐ NPI ☐ REMS ID

Please enter a street address, city, state, or zip code.

*Find a Participant Near

Search Radius

Within 5 miles

Within 10 miles

Within 15 miles

Within 25 miles

Within 50 miles

Within 100 miles

SEARCH

2

Healthcare Providers | **Healthcare Settings and Pharmacies**

Map Satellite

Icon Legend

View Details | Bookmark Patient/Prescriber | View RDA Details | Generate New RDA

Enroll a new HCS / Pharmacy | Download History | Timeline View | Table View

Map

Andrew James

750 miles

James Anderson

750 miles

Bob Johnson

750 miles

Rita Evans

750 miles

Please see accompanying full [Prescribing Information](#) for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.
Please see accompanying full [Prescribing Information](#) for SOLIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.

REMS Portal

My Profile

Please see accompanying full [Prescribing Information](#) for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.
Please see accompanying full [Prescribing Information](#) for SOLIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.



My Profile

Personal Details

First Name: Steve

Email: Steve.Meru@communityhospital.com

Phone: 000-000-0000

REMS ID: 1134567890

Last Name: Meru

Title: Pharmacy Manager

Fax: 000-000-0000

HCS / Pharmacy REMS ID: 1234567890

Quick Links

 GENERATE NEW RDA

 ADD STAFF MEMBER

ENROLL A NEW HCS / PHARMACY

ACIP RECOMMENDATIONS

Associated Dispensing HCS / Pharmacy

ENROLL A NEW HCS / PHARMACY

	Name	Nickname	NPI	BEMS ID	Address	Phone	Fax
	ABC Pharmacy	Community Hospital	1234567890	1234567899	100 Main Street - Suite 210 Philadelphia, PA 1910999	555-555-1212	555-555-3434
	XYZ Pharmacy	Community Hospital	1234567891	1234567891	101 Broad Street - STE 200 Philadelphia, PA 1910999	555-555-1212	555-555-3434
	Test Specialty Pharmacy	Community Hospital	1234567892	1234567892	123 Maple Street Philadelphia, PA 1910999	555-555-1212	555-555-3434

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Page 1 of 11 | Total Records: 11

▼ Icon Legend

[View Details](#)
[Bookmark Patient/Prescriber](#)
[View RDA Details](#)
[Generate New RDA](#)
[Generate RDA](#)
[Cancel RDA](#)
[Add Staff Member](#)
[Remove Staff](#)

Please see accompanying full [Prescribing Information](#) for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections. Please see accompanying full [Prescribing information](#) for SOLIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.

The **Edit Personal Detail** window lets users update their title, phone number, and fax number and save the changes

My Profile

Personal Details

First Name: Steve
Email: Steve.Menu@communityhospital.com
Phone: 000-000-0000
REMS ID: 1234567890

EDIT PERSONAL DETAILS

HCS / Pharmacy REMS ID: 1234567890

Quick Links

Associated Dispensing HCS / Pharmacy

Name	Hickname	ID	PH
ABC Pharmacy	Community Hospital	1234567890	
XYZ Pharmacy	Community Hospital	1234567890	
Test Specialty Pharmacy	Community Hospital	1234567890	

Icon Legend

View Details | Bookmark Patient/Prescriber | View RDA Details | Generate New RDA | Generate RDA | Cancel RDA | Add Staff Member | Remove Staff
Enroll a new HCS / Pharmacy | Download History | Timeline View | Table View | Edit | Begin Audit Questionnaire

Edit Personal Detail

*First Name: Steve
*Last Name: Menu
*Email: Steve.Menu@communityhospital.com
*Title: Pharmacy Manager
*Phone: (000) 000-0000
*Fax: (000) 000-0000

CANCEL

SAVE

Please see accompanying full [Prescribing Information](#) for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.
Please see accompanying full [Prescribing Information](#) for SOLIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.

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The **Edit Associated Dispensing HCS/Pharmacy** window lets users update pharmacy details such as name, nickname, phone number, and fax number, and save the changes

My Profile

Personal Details

First Name: Steve Last Name: [REDACTED]
Email: Steve.Menu@communityhospital.com Title: Pharmacist
Phone: 000-000-0000 Fax: 000-000-0000
REMS ID: 1234567890

Associated Dispensing HCS / Pharmacy

Name	Nickname	NPI	REMS ID
ABC Pharmacy	Community Hospital	1234567890	1234567890
XYZ Pharmacy	Community Hospital	1234567890	1234567890
Test Specialty Pharmacy	Community Hospital	1234567890	1234567890

Icon Legend

View Details Bookmark Patient/Prescriber View RDA Details Generate New RDA Generate RDA Cancel RDA Add Staff Member Remove Staff
Enroll a new HCS / Pharmacy Download History Timeline View Table View Edit Begin Audit Questionnaire

Edit Associated Dispensing Healthcare Setting / Pharmacy

* NPI
1234567890

* Name
Main Street Location

Nickname:
Community Hospital

* REMS ID
1234567890

* Address 1
123 Main St

* Address 2
[REDACTED]

* City
King Of Prussia

* State
-- Please Select --

* ZIP Code
19406

* Phone
000-000-0000

* Fax
000-000-0000

REMS Status: **CERTIFIED**

CANCEL SAVE

Please see accompanying full [Prescribing Information](#) for ULTIMIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.
Please see accompanying full [Prescribing Information](#) for SOLIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.



A Cross-Functional Team Is in Place to Support Customers' REMS Questions

For all Alexion needs, please reach out to the appropriate party:

REMS Logistics, Certifications, & Audits
Contact REMS Administrator at (888) 765-4747

Patient Support Services (including vaccination support)
Connect with OneSource™ Specialist or Patient Education Manager at (888) 765-4747

All other ULTOMIRIS or SOLIRIS needs
Connect with your regular Alexion contact

Report adverse events suggestive of meningococcal infections to Alexion Pharmaceuticals, Inc. at **1-844-259-6783**. You are encouraged to report all other suspected adverse reactions to Alexion Pharmaceuticals, Inc. or the FDA at www.fda.gov/medwatch

Where Should I Refer Any Questions?

ALEXION, the Alexion logo, ULTOMIRIS, and SOLIRIS are registered trademarks and OneSource is a trademark of Alexion Pharmaceuticals, Inc.
© 2025, Alexion Pharmaceuticals, Inc. All rights reserved.
Please see accompanying full [Prescribing Information](#) for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.
Please see accompanying full [Prescribing Information](#) for SOLIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.

In conclusion, we want to highlight who to reach out to, and where should you refer any questions.

If questions do occur, it is important to know there is a cross-functional team in place to support customers' REMS questions.

Any questions related to **REMS Logistics, Certifications & Audit** should be directed to UBC, the REMS administrator.

Patient Support Services (including vaccination support) should be directed to the OneSource specialist or Patient Education Manager.

And, finally, customers should connect with their regular Alexion contact for **All Other ULTOMIRIS or SOLIRIS Needs**.

This concludes today's Healthcare Setting and Pharmacy training on the ULTOMIRIS and SOLIRIS REMS. Thank you.

Terms to Know

Healthcare Setting (HCS) and Pharmacy	- Any location that receives or dispenses ULTOMIRIS and/or SOLIRIS - Must be certified in combined ULTOMIRIS and SOLIRIS REMS
Authorized Representative (HCS Only)	Representative responsible for carrying out the certification process and overseeing implementation of and compliance with the ULTOMIRIS and SOLIRIS REMS on behalf of the HCS
Healthcare Setting and Pharmacy Staff	An office contact or administrative support staff who is allowed access to the REMS portal, including the ability to create REMS Dispense Authorizations, by the Authorized Representative
Prescriber	- A healthcare provider who prescribes ULTOMIRIS and/or SOLIRIS - Must be certified in Combined ULTOMIRIS and SOLIRIS REMS to prescribe
Delegate (Prescriber Only)	- Another certified ULTOMIRIS and/or SOLIRIS prescriber to cover for prescriber during scheduled absence - Another certified prescriber in a multiple-provider practice where a patient may see any of the providers in the office
Designee (Prescriber Only)	An office contact or administrative support staff for the prescriber's office who will be able to enter patient vaccination and antibacterial drug prophylaxis information on the prescriber's behalf
REMS Dispense Authorization (RDA)	An authorization to dispense ULTOMIRIS or SOLIRIS that is required for each dispense
Advisory Committee on Immunization Practices (ACIP)	- Provides advice and guidance to the Director of the CDC regarding use of vaccines and related agents for control of vaccine-preventable diseases in the civilian population of the United States - Meningococcal recommendations: https://www.cdc.gov/acip-recs/hcp/vaccine-specific/meningococcal.html#cdc_generic_section_2-current-meningococcal-vaccine-recommendations

Please see accompanying full [Prescribing Information](#) for ULTOMIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.
Please see accompanying full [Prescribing Information](#) for SOLIRIS, including Boxed WARNING regarding serious and life-threatening or fatal meningococcal infections.

US/ALL/1047 V6 08/2026 61

There are important terms to know as we progress throughout our training today.

The **Healthcare Setting (HCS) and Pharmacy** is defined as any location that receives or dispenses ULTOMIRIS and/or SOLIRIS. As mentioned, they must be certified in the combined ULTOMIRIS and SOLIRIS REMS.

An **Authorized Representative (HCS Only)**, pertinent to the healthcare settings and pharmacies, are those individuals responsible for carrying out the certification process and overseeing the implementation of and compliance with the ULTOMIRIS and SOLIRIS REMS on behalf of that healthcare setting and pharmacy.

Healthcare Setting and Pharmacy Staff is an in-office contact or any administrative support staff granted access by the authorized representative to the REMS portal. That access includes the ability to create the REMS Dispense Authorizations.

A **Prescriber** is a healthcare provider who prescribes ULTOMIRIS and/or SOLIRIS. These providers must be certified in the combined ULTOMIRIS and SOLIRIS REMS program in order to prescribe product.

The next two terms are related to the prescriber:

The **Delegate (Prescriber Only)** could be another certified ULTOMIRIS or SOLIRIS prescriber who could cover for the prescriber during any scheduled absence. For example, if someone goes on vacation, they will have another prescriber in place who is also certified and who can cover in their absence. A delegate could also be another certified prescriber in a multiple-provider practice where a patient may see any of the doctors in the office. A delegate would cover both of those scenarios.

A **Designee (Prescriber Only)** is an in-office contact or administrative support staff for that certified prescriber's office who will enter information, such as patient vaccination information, details regarding antibacterial drug prophylaxis, etc, into the REMS portal on the prescriber's behalf.

A **REMS Dispense Authorization**, or RDA, is an authorization to dispense ULTOMIRIS or SOLIRIS. This is required for each patient dispense. RDAs are very important, and we'll go into much more detail about this in subsequent slides.

And, lastly, the **Advisory Committee on Immunization Practices**, or ACIP, provides advice and guidance to the Director of the CDC regarding the use of vaccines and related agents for the control of vaccine-preventable diseases in the U.S. civilian population.