

Risk Evaluation and Mitigation Strategies (REMS)

Medications and Requirements Chart

Chart Legend:

- Columns with an “✓” under the designated roles indicate requirements for that role related to the REMS programs
- For medications that are on LH Formulary (including with restrictions), the medication name is linked further in the document to more detailed REMS requirements pertaining to healthcare facilities/pharmacies, prescribers, and/or patients

NOTE: In some instances, a patient may be on a REMS medication and go to a hospital that is not REMS certified. Specific requirements to continue patients on their REMS medications can be seen in the prescribing information and additional information is found at the link below. A pertinent excerpt from that link is also copied below: [Roles of Different Participants in REMS | FDA](#)

EXCERPT: “Even if your hospital/health care setting isn’t certified to dispense a REMS drug, a patient who is on a REMS medication may be admitted to your hospital or to your emergency department. For example, if you work in an emergency department, you may be treating a patient who experienced a serious adverse event related to a drug he or she is already taking that has REMS requirements. Patients on a REMS drug may also be admitted to your hospital for an unrelated reason and may need to continue treatment on their REMS drug. If you work in an inpatient setting, it may be important for you to understand that your hospital may not stock certain REMS medications. The approved prescribing information is a good resource for medication information as well as information about specific requirements to continue that patient on a REMS medication. Approved prescribing information can be found at [Drugs@FDA: FDA-Approved Drugs](#) or [DailyMed](#). Information about REMS requirements can be found at [Approved Risk Evaluation and Mitigation Strategies \(REMS\)](#), in product labeling, or on REMS-specific websites.

Medication Generic (Brand)	Link to REMS site	Sites enrolled	Formulary status	Portal access	Certification/Enrollment requirements			Required pharmacist education	Comments
					Pharmacy	Prescriber	Patient		
Eculizumab (Soliris®)	✓	LEH/RCH, LGS, LMP, LSC, LCI	NF	✓	✓	✓	✓	✓	SLM/E+ for Rx education
Eculizumab-aagh (Epysqli®)	✓	LEH/RCH, LGS, LSC							
Ravulizumab-cwvz (Ultomiris®)	✓	LEH/RCH, LGS, LMP, LSC, LCI	NF	✓	✓	✓	✓	✓	SLM/E+ for Rx education

Definitions:

- Risk evaluation and mitigation strategy (REMS): a drug safety program that the food and drug administration (FDA) requires for certain medications with serious safety concerns

- REMS dispense authorization (RDA): A number generated through REMS portal to verify that all safe use conditions have been met before dispensing certain medications
- Elements to assure safe use (ETASU): REMS requirements that must be performed before the medication can be prescribed, dispensed or received. Additional examples can be found [here](#).

Eculizumab (Soliris®) and Eculizumab-aagh (Epysqli®)

This medication is **Inpatient Non-formulary and Restricted to Outpatient Use**. Inpatient use requires approval by a physician department leader (i.e. Medical Director or Chair, or hospital CMO) collaborating with a pharmacy leader – See [Non-Formulary, Restricted to Outpatient Medication process](#).

Receipt of an INPATIENT or OUTPATIENT (Day Treatment Unit or Infusion Center) order:

1. Verify Provider Enrollment by accessing the associated REMS page:
Eculizumab (Soliris®): <https://ultsolrems.com>
Eculizumab-aagh (Epysqli®): <https://www.epysqlirems.com>
 - If provider is not enrolled, pharmacist must contact the provider to enroll.
 - Provider will need to email or fax the Prescriber Enrollment Form available on the REMS site.
 - Do not proceed until provider enrollment is confirmed.
2. Collect patient information: Name, DOB, MRN, indication, dose, ordering physician from EHR and/or REMS portal.
 - Review or enter patient information and vaccination information into REMS portal.
 - Ensure patient has received meningococcal vaccinations for serogroups A, C, W, Y, and B based on vaccination recommendations according to the current Advisory Committee on Immunization Practices (ACIP) recommendations.
 - If meningococcal vaccinations are not fully up to date, ensure antibacterial drug prophylaxis is initiated before treatment
 - Update vaccination history, as applicable, based on EHR or provider supplied documentation.
 - Document findings in EHR and portal.

Vaccinations: Ensure patient has plans to receive vaccines covering all serogroups listed above. These must be ordered and signed by the ordering provider.

- Assess vaccination status prior to initiation; patients should receive meningococcal vaccine(s) at least 2 weeks prior to treatment initiation.
- In unvaccinated patients, administer meningococcal vaccine(s) as soon as possible and initiate antibacterial prophylaxis.

Prophylaxis: All patients should also receive antibacterial prophylaxis when receiving C5 inhibitors.

Adults:

- Penicillin VK 500 mg PO twice daily
- In the case of penicillin allergy, Ciprofloxacin 500 mg daily or Azithromycin 500 mg daily may be used

Pediatrics:

- Penicillin VK:
 - ≤3 years: Oral: 125 mg twice daily

- >3-12 years: Oral: 250 mg twice daily
- > 12 years: Oral 500 mg twice daily
- Azithromycin:
 - 5 mg/kg/dose (maximum 500mg) PO daily
- 3. Generate REMS Dispense Authorization (RDA) for dispensing by accessing the REMS portal.
- 4. Drug procurement
 - Ordering via McKesson Plasma & Biologics by 1300, for next day. If ordered after 1300, will need to call manufacturer direct.
 - Evening/weekend emergent shipment: Contact site leadership to determine procurement.

Prior to each dispense for continuation of therapy:

1. Review patient vaccination status for meningococcal vaccines including antibacterial drug prophylaxis, if needed, before dispensing prescriptions.
 - If vaccine status is not up to date or antibacterial drug prophylaxis needed, do not dispense and contact provider.
2. If vaccination status is up to date and/or prophylaxis is provided with plan to complete vaccination, obtain authorization to dispense each prescription by accessing the REMS portal and generating RDA.

At all times for either INPATIENT or OUTPATIENT dispensing:

- Report adverse events suggestive of meningococcal infections to drug manufacturer or FDA MedWatch.
 - **Eculizumab (Soliris®)**: Alexion Pharmaceuticals, Inc. 1-844-259-6783
 - **Eculizumab-aagh (Epysqli®)**: Teva Pharmaceuticals 1-888-483-8279
 - **FDA**: www.fda.gov/medwatch or 1-800-FDA-1088
- Not distribute, transfer, loan, or sell eculizumab or eculizumab-aagh, 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 drug manufacturer or a third party acting on behalf of drug manufacturer, to ensure that all processes and procedures are in place and are being followed.

Ravulizumab-cwvz (Ultomiris®)

This medication is **Inpatient Non-formulary and Restricted to Outpatient Use**. Inpatient use requires approval by a physician department leader (i.e. Medical Director or Chair, or hospital CMO) collaborating with a pharmacy leader – See [Non-Formulary, Restricted to Outpatient Medication process](#).

Receipt of an INPATIENT or OUTPATIENT (Day Treatment Unit or Infusion Center) order:

1. Verify Provider Enrollment by accessing the associated REMS page:

Ravulizumab-cwvz (Ultomiris®): <https://ultsolrems.com>

 - If provider is not enrolled, pharmacist must contact the provider to enroll.
 - Provider will need to email or fax the Prescriber Enrollment Form available on the REMS site.
 - Do not proceed until provider enrollment is confirmed.

2. Collect patient information: Name, DOB, MRN, indication, dose, ordering physician from EHR and/or REMS portal.
 - Review or enter patient information and vaccination information into REMS portal.
 - Ensure patient has received meningococcal vaccinations for serogroups A, C, W, Y, and B based on vaccination recommendations according to the current Advisory Committee on Immunization Practices (ACIP) recommendations.
 - If meningococcal vaccinations are not fully up to date, ensure antibacterial drug prophylaxis is initiated before treatment
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- **FDA:** www.fda.gov/medwatch or 1-800-FDA-1088
- Not distribute, transfer, loan, or sell ravulizumab-cwvz, except to other certified healthcare settings or certified pharmacies.
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