

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

761340Orig1s000

REMS

Risk Evaluation and Mitigation Strategy (REMS) Document

EPYSQLI (eculizumab-aagh) REMS

I. Administrative Information

Risk: Serious meningococcal infections
Application Number: BLA 761340
Application Holder: Samsung Bioepis Co., Ltd.
Initial REMS Approval: 7/2024

II. REMS Goal

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

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

III. REMS Requirements

Samsung Bioepis Co., Ltd. must ensure that healthcare providers, patients, healthcare settings, pharmacies, and wholesalers-distributors comply with the following requirements:

1. Healthcare providers who prescribe EPYSQLI must:

To become certified to prescribe	1. Review the drug's Prescribing Information. 2. Review the following: Healthcare Provider Safety Brochure, Patient Safety Card, and Patient Guide. 3. Enroll by completing and submitting the Prescriber Enrollment Form to the REMS.
Before treatment initiation	4. Assess the patient for unresolved meningococcal infection. 5. For patients with an unresolved serious meningococcal infection: Not initiate EPYSQLI. 6. Assess the patient's vaccination status for meningococcal serogroups A, C, W, Y, and B and vaccinate as needed according to the current Advisory Committee on Immunization Practices (ACIP) recommendations for

	meningococcal vaccinations in patients receiving a complement inhibitor.
	- For patients who are not up to date with meningococcal vaccines at least two weeks prior to initiation of treatment and who must start EPYSQLI urgently: Provide the patient with a prescription for antibacterial drug prophylaxis. - Counsel the patient using the Patient Safety Card and Patient Guide. Provide a copy of the materials to the patient. - Counsel the patient on the need to carry the Patient Safety Card.
During treatment	- Assess the patient for early signs and symptoms of meningococcal infection and evaluate immediately if infection is suspected. - Vaccinate patients as needed according to the current ACIP recommendations for meningococcal vaccinations for patients receiving a complement inhibitor.
At all times	Report adverse events suggestive of meningococcal infection, including the patient's clinical outcomes, to Samsung Bioepis Co., Ltd.
2. Patients who are prescribed EPYSQLI:	
Before treatment initiation	- Get meningococcal vaccines for serogroups A, C, W, Y, and B as directed by your prescriber. - Take antibiotics as directed by your prescriber if you have to start EPYSQLI right away. - Receive counseling from your prescriber using the Patient Safety Card and Patient Guide. - Get the Patient Safety Card and Patient Guide from your prescriber.
During treatment	Get additional meningococcal vaccines as directed by your prescriber.
At all times during treatment and for 3 months after the last dose	- Have the Patient Safety Card with you. - Inform your prescriber or get emergency medical care right away if you experience any of the following: fever; fever and a rash; fever with high heart rate; headache with

nausea or vomiting; headache and fever; headache with stiff neck or stiff back; confusion; eyes sensitive to light; muscle aches with flu-like symptoms.

3. Healthcare Settings and pharmacies that dispense EPYSQLI must:

To become certified to dispense	1. Designate an Authorized Representative to carry out the certification process and oversee implementation and compliance with the REMS on behalf of the healthcare setting or pharmacy. 2. Have the Authorized Representative review the Healthcare Provider Safety Brochure. 3. Have the Authorized Representative enroll by completing and submitting the Healthcare Setting and Pharmacy Enrollment Form to the REMS. 4. Train all relevant staff involved in dispensing EPYSQLI using the Healthcare Provider Safety Brochure. 5. 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 the current Advisory Committee on Immunization Practices (ACIP) recommendations including antibacterial drug prophylaxis, if needed, before treatment initiation and document the findings. 6. 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.
Before dispensing, first dose	7. Obtain authorization to dispense each prescription by contacting the REMS to verify the prescriber is certified. 8. 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, and document the findings through the processes and procedures established as a requirement of the REMS.
Before dispensing, up to 6 months after the first dose	9. Obtain authorization to dispense each prescription by contacting the REMS to verify the prescriber is certified. 10. For patients who are not initially up to date with

	meningococcal vaccines when starting treatment: Assess the patient's vaccination status for up to date meningococcal vaccines for serogroups A, C, W, Y, and B including antibacterial drug prophylaxis, if needed, and document the findings through the processes and procedures established as a requirement of the REMS.
Before dispensing, 6 months after the first dose and thereafter	11. Obtain authorization to dispense each prescription by contacting the REMS to verify the prescriber is certified.
To maintain certification to dispense	12. If the Authorized Representative changes, have a new Authorized Representative enroll by completing and submitting the Healthcare Setting and Pharmacy Enrollment Form to the REMS.
At all times	13. Report adverse events suggestive of meningococcal infection to Samsung Bioepis Co., Ltd. 14. Not distribute, transfer, loan, or sell EPYSQLI, except to certified healthcare settings and certified pharmacies. 15. Maintain records of staff's completion of REMS training. 16. Maintain records that all processes and procedures are in place and are being followed. 17. Comply with audits carried out by Samsung Bioepis Co., Ltd. or a third party acting on behalf of Samsung Bioepis Co., Ltd. to ensure that all processes and procedures are in place and are being followed.
4. Wholesalers-distributors that distribute EPYSQLI must:	
To be able to distribute	1. Establish processes and procedures to ensure that the drug is distributed only to certified healthcare settings and certified pharmacies. 2. Train relevant staff involved in EPYSQLI distribution on the REMS requirements.

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| At all times | <ol style="list-style-type: none">3. Distribute only to certified healthcare settings and certified pharmacies.4. Maintain records of all drug distribution.5. Comply with audits carried out by Samsung Bioepis Co., Ltd. or a third party acting on behalf of Samsung Bioepis Co., Ltd. to ensure that all processes and procedures are in place and are being followed. |
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Samsung Bioepis Co., Ltd. must provide training to healthcare providers who prescribe EPYSQLI.

The training includes the following educational materials: [Healthcare Provider Safety Brochure](#), [Patient Safety Card](#), and [Patient Guide](#). The training must be available online and in hardcopy format via mail.

Samsung Bioepis Co., Ltd. must provide training to healthcare settings and pharmacies that dispense EPYSQLI.

The training includes the following educational material: [Healthcare Provider Safety Brochure](#). The training must be available online and in hardcopy format via mail.

To support REMS operations, Samsung Bioepis Co., Ltd. must:

1. Establish and maintain a [REMS Website](#), www.EPYSQLIREMS.com. The [REMS Website](#) must include the capability to complete prescriber, and healthcare setting and pharmacy certification or enrollment online, and the option to print the Prescribing Information, Medication Guide, and REMS materials. All product websites for consumers and healthcare providers must include prominent REMS-specific links to the [REMS Website](#). The [REMS Website](#) must not link back to the promotional product website(s).
2. Make the [REMS Website](#) fully operational and all REMS materials available through the [REMS Website](#) and the Call Center by the date EPYSQLI is first commercially distributed.
3. Establish and maintain a REMS Call Center at 1-866-318-8144.
4. Establish and maintain a validated, secure database of all certified prescribers, and certified healthcare settings and pharmacies in the EPYSQLI REMS, and patient-specific information on vaccination and antibacterial drug prophylaxis.
5. Ensure that healthcare settings and pharmacies are able to obtain authorization to dispense by phone or online.
6. Ensure prescribers, healthcare settings, and pharmacies are able to enroll by fax and online.
7. Ensure that prescribers, healthcare settings, and pharmacies, are able to report vaccination and antibacterial drug prophylaxis information online and by fax.
8. Ensure prescribers, and healthcare settings and pharmacies are able to report adverse events suggestive of meningococcal infections by phone.

9. Ensure that once a report suggestive of meningococcal infection is received, Samsung Bioepis Co., Ltd., will follow up with the healthcare providers to obtain all required data. This requirement does not affect Samsung Bioepis Co., Ltd.'s other reporting and follow-up requirements under FDA regulations.
10. Provide the [Prescriber Enrollment Form](#), [Healthcare Provider Safety Brochure](#), [Patient Safety Card](#), [Patient Guide](#), Medication Guide and the EPYSQLI Prescribing Information to healthcare providers who (1) attempt to prescribe EPYSQLI and are not yet certified or (2) inquire about how to become certified.
11. Provide the [Healthcare Setting and Pharmacy Enrollment Form](#) and [Healthcare Provider Safety Brochure](#) to healthcare settings and pharmacies that (1) attempt to order/dispense and are not yet certified or (2) inquire about how to become certified.
12. Notify prescribers, and healthcare settings and pharmacies within 2 business days after they become certified in the REMS.
13. Provide certified prescribers access to the database of certified healthcare settings and pharmacies, and patient-specific information on vaccination and antibacterial drug prophylaxis.
14. Provide certified healthcare settings and pharmacies access to the database of certified prescribers, and patient-specific information on vaccination and antibacterial drug prophylaxis.
15. Provide authorized wholesalers-distributors a list of certified healthcare settings and pharmacies.

To ensure REMS participants' compliance with the REMS, Samsung Bioepis Co., Ltd. must:

16. Maintain adequate records to demonstrate that REMS requirements have been met, including, but not limited to records of: EPYSQLI distribution and dispensing; certification of prescribers, and healthcare settings and pharmacies; patient-specific information on vaccination and antibacterial drug prophylaxis; and audits of REMS participants. These records must be readily available for FDA inspections.
17. Verify annually that the designated Authorized Representative's name and contact information correspond to those of the current designated Authorized Representative for each healthcare setting and pharmacy. If different, the healthcare setting or pharmacy must be required to re-certify with a new Authorized Representative.
18. Establish and maintain a plan for addressing noncompliance with REMS requirements.
19. Monitor prescribers, and healthcare settings and pharmacies on an ongoing basis to ensure the requirements of the REMS are being met. Take corrective action if noncompliance is identified, including de-certification.
20. Audit certified healthcare settings and pharmacies no later than 180 calendar days after they receive their first shipment and a representative sample of certified healthcare settings and pharmacies annually thereafter, to ensure that all processes and procedures are in place, functioning, and comply with the REMS requirements.
21. Audit wholesalers-distributors no later than 180 calendar days after their first commercial distribution of EPYSQLI and annually thereafter to ensure that all processes and procedures are in place, functioning, and comply with the REMS requirements.

22. Take reasonable steps to improve operations of and compliance with the requirements of the EPYSQLI REMS based on monitoring and evaluation of the EPYSQLI REMS.

IV. REMS Assessment Timetable

Samsung Bioepis Co., Ltd. must submit REMS Assessments at 6 months, 12 months, and annually thereafter from the date of the initial approval of the REMS (07/19/2024). To facilitate inclusion of as much information as possible, while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 calendar days before the submission date for that assessment. Samsung Bioepis Co., Ltd. must submit each assessment so that it will be received by the FDA on or before the due date.

V. REMS Materials

The following materials are part of the EPYSQLI REMS:

Enrollment Forms

Prescriber:

1. [Prescriber Enrollment Form](#)

Healthcare Setting and Pharmacy:

2. [Healthcare Setting and Pharmacy Enrollment Form](#)

Training and Educational Materials

Prescriber:

3. [Healthcare Provider Safety Brochure](#)

Patient:

4. [Patient Safety Card](#)
5. [Patient Guide](#)

Healthcare Setting and Pharmacy:

6. [Healthcare Provider Safety Brochure](#)

Other Materials

7. [REMS Website](#)

VI. Statutory Elements

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

1. Elements to Assure Safe Use:
 - Healthcare providers who prescribe EPYSQLI are specially certified under 505-1(f)(3)(A)
 - Healthcare settings and pharmacies that dispense EPYSQLI are specially certified under 505-1(f)(3)(B)
 - EPYSQLI is dispensed to patients with evidence or other documentation of safe-use conditions under 505-1(f)(3)(D)
2. Implementation System
3. Timetable for Submission of Assessments

Prescriber Enrollment Form

Instructions

To become certified in the EPYSQLI REMS and prescribe EPYSQLI, prescribers must:

- 1) Review the EPYSQLI Prescribing Information, **Healthcare Provider Safety Brochure, Patient Safety Card and Patient Guide**.
- 2) Enroll by completing and submitting this **Prescriber Enrollment Form** to the REMS.
 - Online at www.EPYSQLIREMS.com
 - By fax at 1-866-318-0342

Prescriber Information *(all fields required unless otherwise indicated)*

First Name:

MI (opt):

Last Name:

National Provider Identifier (NPI) #:

Email:

Clinic/Practice Name:

Address Line 1:

Address Line 2:

City:

State:

Zip Code:

Office Phone Number (Ext opt):

Office Fax Number:

Credentials: ☐ MD ☐ DO ☐ APRN* ☐ PA ☐ PharmD

Medical Specialty (please select one): ☐ Hematology/Oncology ☐ Immunology
☐ Internal Medicine ☐ Nephrology ☐ Neurology
☐ Rheumatology ☐ Other (please specify):

Prescriber Delegate Information

A prescriber delegate is 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.

First Name:

Last Name:

Office Phone Number (Ext opt):

Email:

Credentials: ☐ MD ☐ DO ☐ APRN* ☐ PA ☐ PharmD

Prescriber Signature *(all fields required unless otherwise indicated)*

Prescriber Signature:

Date (MM/DD/YYYY):

* Includes Certified Nurse Practitioner (CNP), Clinical Nurse Specialist, (CNS), Certified Registered Nurse Anesthetist (CRNA), Certified Nurse-Midwife (CNM)

Prescriber Agreement

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

- I have read and understand the EPYSQLI Prescribing Information (PI), **Healthcare Provider Safety Brochure, Patient Safety Card, and Patient Guide.**
- I understand the:
 - » Risk of serious meningococcal infections associated with EPYSQLI.
 - » Early signs and symptoms of meningococcal infections and the need for immediate medical evaluation.
- I will enroll by completing and submitting this **Prescriber Enrollment Form** to the REMS.
- Before treatment initiation, I must:
 - » Assess the patient for unresolved meningococcal infection.
 - » For patients with an unresolved serious meningococcal infection: NOT initiate EPYSQLI.
 - » Assess the patient's vaccination status for meningococcal serogroups A, C, W, Y, and B and vaccinate as needed according to the current Advisory Committee on Immunization Practices (ACIP) recommendations for meningococcal vaccinations in patients receiving a complement inhibitor.
 - » For patients who are not up to date with meningococcal vaccines at least two weeks prior to initiation of treatment and who must start EPYSQLI urgently: Provide the patient with a prescription for antibacterial drug prophylaxis.

- » Counsel the patient using the **Patient Safety Card** and **Patient Guide**. Provide a copy of the materials to the patient.
- » Counsel the patient on the need to carry the **Patient Safety Card** at all times and during and for 3 months after their last dose of EPYSQLI.
- During treatment, I must:
 - » Assess the patient for early signs and symptoms of meningococcal infection and evaluate immediately if infection is suspected.
 - » Vaccinate patients as needed according to the current ACIP recommendations for meningococcal vaccinations for patients receiving a complement inhibitor.
- At all times, I must:
 - » Report adverse events suggestive of meningococcal infection, including the patient's clinical outcomes to Samsung Bioepis Co., Ltd. by phone at 1-800-806-0716.
- I understand that if I do not maintain compliance with the requirements of the EPYSQLI REMS, I will no longer be able to prescribe EPYSQLI.
- I understand that Samsung Bioepis Co., Ltd. or its agents or contractors may use and disclose my information in accordance with the Samsung Bioepis Privacy Notice, including to support the administration of the EPYSQLI REMS.
- I understand that EPYSQLI REMS and its agents or contractors may contact me to support the administration of the EPYSQLI REMS.

Healthcare Setting and Pharmacy Enrollment Form

Instructions

To become certified in the EPYSQLI REMS and dispense EPYSQLI, the healthcare setting and pharmacy that dispenses these products must designate an Authorized Representative to carry out the certification process and oversee implementation and compliance with the REMS on behalf of the healthcare setting and pharmacy. The Authorized Representative must:

- 1) Review the **Healthcare Provider Safety Brochure**.
- 2) Enroll by completing and submitting this **Healthcare Setting and Pharmacy Enrollment Form** to the REMS.
 - Online at www.EPYSQLIREMS.com
 - By fax at 1-866-318-0342

REMS Healthcare Setting or Pharmacy Information

- ☐ Initial healthcare setting or pharmacy enrollment
- ☐ Change of information for enrolled healthcare setting or pharmacy
- ☐ Change of Authorized Representative

Authorized Representative Information *(all fields required unless otherwise indicated)*

First Name:	MI (opt):	Last Name:
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Title/Position: ☐ Pharmacist ☐ Nurse ☐ Other (please specify):

Authorized Representative National Provider Identifies (NPI):

Office Phone Number:	Office Fax Number:
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Email:

Preferred Method of Communication: ☐ Email ☐ Phone
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Dispensing Healthcare Setting and Pharmacy Information
(all fields required unless otherwise indicated)

Name of the institution:

Address Line 1:

Address Line 2 (opt):

City:

State:

Zip Code:

Office Phone Number (Ext opt):

Office Fax Number:

Email:

Institution National Provider Identifier (NPI):

Institution type: ☐ Hospital ☐ Infusion Site/Outpatient Clinic ☐ Physician Practice
☐ Specialty Pharmacy/Infusion Provider ☐ Other (please specify):

For each additional healthcare setting and pharmacy where EPYSQLI will be delivered, dispensed, and administered within your healthcare system for which the same Authorized Representative will be responsible, you will need to complete this section.

Additional Dispensing Healthcare Setting and Pharmacy Information
(all fields required unless otherwise indicated)

Name of the institution:

Address Line 1:

Address Line 2 (opt):

City:

State:

Zip Code:

Office Phone Number (Ext opt):

Office Fax Number:

Email:

Institution National Provider Identifier (NPI):

Institution type: ☐ Hospital ☐ Infusion Site/Outpatient Clinic ☐ Physician Practice
☐ Specialty Pharmacy/Infusion Provider ☐ Other (please specify):

Authorized Representative Agreement

As the healthcare setting and pharmacy Authorized Representative, to become certified to dispense, I must:

- Review the **Healthcare Provider Safety Brochure**.
- Enroll by completing and submitting this Healthcare Setting and Pharmacy Enrollment Form to the REMS
- Train all relevant staff involved in dispensing EPYSQLI using the **Healthcare Provider Safety Brochure**.
- 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 the current Advisory Committee on Immunization Practices (ACIP) recommendations including antibacterial drug prophylaxis, if needed, before treatment initiation and document the findings.
- For patients who are not up to date with meningococcal vaccines when starting treatment: Establish processes and procedures to assess the patient's vaccination status for up to date meningococcal vaccines including antibacterial drug prophylaxis, if needed, before dispensing prescriptions up to 6 months after the first dose and document the findings.

Before dispensing the first dose, all healthcare setting and pharmacy staff must:

- Obtain authorization to dispense each prescription by contacting the REMS to verify the prescriber is certified.
- 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 and document the findings through the processes and procedures established as a requirement of the REMS.

Before dispensing, up to 6 months after dispensing the first dose, all healthcare setting or pharmacy staff must:

- Obtain authorization to dispense each prescription by contacting the REMS to verify the prescriber is certified.
- For patients who are not initially up to date with meningococcal vaccines when starting treatment: Assess the patient's vaccination status for up to date meningococcal vaccines for serogroups A, C, W, Y, and B including antibacterial drug prophylaxis, if needed, and document the findings through the processes and procedures established as a requirement of the REMS.

Before dispensing, 6 months after the first dose and thereafter, all healthcare setting or pharmacy staff must:

- Obtain authorization to dispense each prescription by contacting the REMS to verify the prescriber is certified.

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

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

At all times, my healthcare setting or pharmacy staff must:

- Report adverse events suggestive of meningococcal infections to Samsung Bioepis Co., Ltd. by phone at 1-800-806-0716
- Not distribute, transfer, loan, or sell EPYSQLI, except to 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 Samsung Bioepis Co., Ltd. or a third party acting on behalf of Samsung Bioepis Co., Ltd. to ensure that all processes and procedures are in place and are being followed.

Authorized Representative Signature *(all fields required unless otherwise indicated)*

Signature:

Date (MM/DD/YYYY) :

EPYSQLI®

EPYSQLI REMS

Healthcare Provider Safety Brochure

**This brochure provides information
for healthcare providers who will prescribe or
dispense EPYSQLI**

It describes:

- What is EPYSQLI?
 - What is the EPYSQLI REMS?
 - Prescriber Requirements
 - Healthcare Setting and Pharmacy Requirements
 - EPYSQLI REMS Resources
 - Adverse Event Reporting
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What is EPYSQLI?

EPYSQLI is indicated for the treatment of:

- Patients with paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis.
- Patients with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy.

Limitation of Use

- EPYSQLI is not indicated for the treatment of patients with Shiga toxin *E.coli* related hemolytic uremic syndrome (STEC-HUS).

Risk of Serious Meningococcal Infections

- EPYSQLI, a complement inhibitor, increases a patient's susceptibility to serious, life-threatening, or fatal infections caused by meningococcal bacteria (septicemia and/or meningitis) in any serogroup, including non-groupable strains.
- Life-threatening and fatal meningococcal infections have occurred in both vaccinated and unvaccinated patients treated with complement inhibitors such as EPYSQLI.
- The initiation of EPYSQLI is contraindicated in patients with unresolved serious *Neisseria meningitidis* infection.
- Complete or update meningococcal vaccination (for serogroups A, C, W, Y, and B) at least 2 weeks prior to administering the first dose of EPYSQLI, according to current Advisory Committee on Immunization Practices (ACIP) recommendations for patients receiving a complement inhibitor.
- If urgent EPYSQLI therapy is indicated in a patient who is not up to date with meningococcal vaccines according to ACIP recommendations, provide the patient with antibacterial drug prophylaxis and administer meningococcal vaccines as soon as possible.
- Vaccination does not eliminate the risk of serious meningococcal infections, despite development of antibodies following vaccination.
- Closely monitor patients for early signs and symptoms of meningococcal infection and evaluate patients immediately if infection is suspected. Promptly treat known infections.
- Inform patients of these signs and symptoms and instruct patients to seek immediate medical care if these signs and symptoms occur.

- Meningococcal infection may become rapidly life-threatening or fatal if not recognized and treated early.
- Consider interruption of EPYSQLI in patients who are undergoing treatment for serious meningococcal infection, depending on the risks of interrupting treatment in the disease being treated.

What is the EPYSQLI REMS?

A Risk Evaluation and Mitigation Strategy (REMS) is a program required by the Food and Drug Administration (FDA) to help ensure that the benefits of a drug outweigh its risks.

Because of the risk of serious meningococcal infections, EPYSQLI is available only through the EPYSQLI REMS, a restricted distribution program.

Prescriber Requirements

What do Prescribers Need to do When Prescribing EPYSQLI?

Healthcare providers who prescribe EPYSQLI must be specially certified. To become certified in the EPYSQLI REMS and prescribe EPYSQLI, prescribers must:

- Review the EPYSQLI Prescribing Information.
- Review the **Healthcare Provider Safety Brochure** (this document).
- Review the **Patient Safety Card**.
- Review the **Patient Guide**.
- Complete and submit the **Prescriber Enrollment Form** to the EPYSQLI REMS.
 - online to the EPYSQLI REMS www.EPYSQLIREMS.com.
 - by fax at 1-866-318-0342

Prescribers will be notified within 2 business days when their certification in the EPYSQLI REMS is complete and they can prescribe EPYSQLI.

Before initiating a patient's EPYSQLI treatment, prescribers must:

- Assess the patient for unresolved meningococcal infection and not initiate EPYSQLI in any patient with these infections.

- Assess the patient's vaccination status for meningococcal serogroups A, C, W, Y, and B and vaccinate as needed according to the current Advisory Committee on Immunization Practices (ACIP) recommendations for meningococcal vaccinations in patients receiving a complement inhibitor.
- For patients who are not up to date with meningococcal vaccines at least two weeks prior to initiation of treatment and who must start EPYSQLI urgently: Provide the patient with a prescription for antibacterial drug prophylaxis.
- Counsel the patient using the **Patient Safety Card** and **Patient Guide**. Provide a copy of the materials to the patient.
 - The **Patient Guide** provides information for your patients about the risk of serious meningococcal infections including:

- The need to complete or update their meningococcal vaccines for serotypes A, C, W, Y, and B at least two weeks prior to receiving the first dose of EPYSQLI or receive antibacterial drug prophylaxis if EPYSQLI must be initiated immediately, and they have not previously been vaccinated.
- Additional vaccines may be necessary during treatment with EPYSQLI.
- Meningococcal vaccines do not prevent all meningococcal infections.

- The **Patient Safety Card** has important safety information for both patients and any healthcare providers that may see or treat your patient. It describes the following signs and symptoms which, if experienced, should prompt the patient to seek immediate medical evaluation:

- fever
- fever and a rash
- fever with high heart rate
- headache with nausea or vomiting
- headache and fever
- headache with stiff neck or stiff back
- confusion
- eyes sensitive to light
- muscle aches with flu-like symptoms

- Counsel the patient on the need to carry the **Patient Safety Card**. Instruct your patient to show the card to any healthcare provider involved in their care.
- Instruct the patient to carry the **Patient Safety Card** at all times and for 3 months after their last dose.

During EPYSQLI treatment, prescribers must:

- Assess the patient for early signs and symptoms of meningococcal infection and evaluate immediately if infection is suspected.
- Vaccinate patients as needed according to the ACIP recommendations for meningococcal vaccinations for patients receiving a complement inhibitor.

At all times, prescribers must:

- Report adverse events suggestive of meningococcal infection, including the patient's clinical outcomes to Samsung Bioepis Co., Ltd. by phone at 1-800-806-0716.
- Comply with the EPYSQLI REMS requirements to maintain certification to prescribe.

Before dispensing, certified healthcare settings and pharmacies must assess the patient's vaccination status for up to date meningococcal vaccines for serogroups A, C, W, Y, and B according to the current ACIP recommendations including antibacterial drug prophylaxis, if needed. If you have not provided this information already, you may receive a call from the healthcare setting and pharmacy to collect information confirming that the patient has received the appropriate vaccinations or antibacterial drug prophylaxis.

Healthcare Setting and Pharmacy Requirements

What do Healthcare Settings and Pharmacies Need to do When Dispensing EPYSQLI?

EPYSQLI may only be dispensed by healthcare settings and pharmacies that are certified to dispense. To become certified, the healthcare setting and pharmacy must designate an Authorized Representative to carry out the certification process and oversee implementation and compliance with the REMS on behalf of the healthcare setting or pharmacy. To become certified, the Authorized Representative must:

- Review the **Healthcare Provider Safety Brochure** (this document).
- Complete and submit the **Healthcare Setting and Pharmacy Enrollment Form** to the REMS:
 - online to the EPYSQLI REMS www.EPYSQLIREMS.com.
 - by fax at 1-866-318-3142

By completing the Healthcare Setting and Pharmacy Enrollment Form, the Authorized Representative agrees to:

- Train all relevant staff involved in dispensing EPYSQLI using the **Healthcare Provider Safety Brochure**.
- 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 the current Advisory Committee on Immunization Practices (ACIP) recommendations including antibacterial drug prophylaxis, if needed, before treatment initiation and document the findings.

- For patients who are not up to date with meningococcal vaccines when starting treatment: Establish processes and procedures to assess the patient's vaccination status for up to date meningococcal vaccines including antibacterial drug prophylaxis, if needed, before dispensing prescriptions up to 6 months after the first dose and document the findings.

Before dispensing the first dose, all healthcare setting and pharmacy staff must:

- Obtain authorization to dispense each prescription by contacting the REMS to verify the prescriber is certified.
- 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, and document the findings through the processes and procedures established as a requirement of the REMS.

Before dispensing, up to 6 months after the first dose, the healthcare setting and pharmacy staff must:

- Obtain authorization to dispense each prescription by contacting the REMS to verify the prescriber is certified.
- For patients who are not initially up to date with meningococcal vaccines when starting treatment: Assess the patient's vaccination status for up to date meningococcal vaccines for serogroups A, C, W, Y, and B including antibacterial drug prophylaxis, if needed, and document the findings through the processes and procedures established as a requirement of the REMS.

Before dispensing, 6 months after the first dose and thereafter, the healthcare setting and pharmacy staff must:

- Obtain authorization to dispense each prescription by contacting the REMS to verify the prescriber is certified.

At all times, all healthcare setting and pharmacy staff must:

- Report adverse events suggestive of meningococcal infection to Samsung Bioepis Co., Ltd. By phone at 1-800-806-0716.
- Not distribute, transfer, loan, or sell EPYSQLI, except to certified healthcare settings and 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 Samsung Bioepis Co., Ltd. or a third party acting on behalf of Samsung Bioepis Co., Ltd., to ensure that all processes and procedures are in place and are being followed.

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

- Enroll by completing and submitting the **Healthcare Setting and Pharmacy Enrollment Form** to the REMS.

EPYSQLI REMS Resources

Visit www.EPYSQLIREMS.com or call 1-866-318-8144 to learn more about the EPYSQLI REMS.

Adverse Event Reporting

Report adverse events suggestive of meningococcal infections including the patient's clinical outcomes, immediately to Samsung Bioepis Co., Ltd. by phone at 1-800-806-0716.

You are encouraged to report other adverse reactions of EPYSQLI to Samsung Bioepis Co., Ltd. by phone at 1-800-806-0716 or the FDA at www.fda.gov/medwatch or call 1-800-FDA-1088.

This brochure does not provide all risk information for EPYSQLI. Please see Prescribing Information for EPYSQLI, including BOXED WARNING regarding serious meningococcal infections for more detailed safety information.





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SAMSUNG BIOEPIS

Patients receiving EPYSQLI should carry this card at all times during treatment and for 3 months after the last dose of EPYSQLI.
Show this card to any healthcare provider involved in your health care.

Patient Name	
Prescriber Name	
Prescriber Phone Number	
Emergency Contact Number	

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EPYSQLI®

**PATIENT
SAFETY CARD**

Important Safety Information for Patients Taking EPYSQLI (eculizumab-aagh)

EPYSQLI can increase your chance of getting **serious meningococcal infections**. **These infections may quickly become life-threatening or cause death if not recognized and treated early.** If you experience any of the following signs and symptoms of serious meningococcal infection, you should immediately call your healthcare provider or seek emergency medical care, preferably in a major emergency medical care center:

- Fever
- Fever and a rash
- Fever with high heart rate
- Headache with nausea or vomiting
- Headache and fever
- Headache with stiff neck or stiff back
- Confusion
- Eyes sensitive to light
- Muscle aches with flu-like symptoms

Get emergency medical care right away if you have any of these signs or symptoms and show this card to any healthcare provider who treats you.

Your risk of meningococcal infection may continue for several weeks after your last dose of EPYSQLI. Carry this card with you at all times during treatment and for 3 months after your last dose of EPYSQLI.

Information for the Treating Healthcare Provider

This patient has been prescribed EPYSQLI (eculizumab-aagh) therapy, which increases the patient's susceptibility to meningococcal infections (*Neisseria meningitidis*) or other general infections.

- Meningococcal infections may become rapidly life-threatening or fatal if not recognized and treated early.
- **Closely monitor patients for early signs and symptoms of serious meningococcal infections and evaluate immediately if infection is suspected. Promptly treat known infections.**
- Contact the healthcare provider who prescribed EPYSQLI (listed below) as soon as possible if the patient has signs and symptoms of serious meningococcal infection.

For more information about EPYSQLI, please refer to the Prescribing Information. Report adverse events suggestive of meningococcal infections at 1-800-806-0716.

EPYSQLI[®] 

PATIENT GUIDE

If you have any questions about your health or medicines,
talk to your healthcare provider

To report side effects, contact Samsung Bioepis Co., Ltd.
at 1-800-806-0716,
or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

What is EPYSQLI?

EPYSQLI is a medicine that affects your immune system. EPYSQLI can lower the ability of your immune system to fight infections.

EPYSQLI (eculizumab-aagh) is a prescription medicine used to treat

- Patients with paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis.
- Patients with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy.

What are the serious risks of EPYSQLI?

EPYSQLI increases your chance of getting serious and life-threatening meningococcal infections.

Meningococcal infections may quickly become life-threatening and cause death if not recognized and treated early.

Call your healthcare provider or get emergency medical care right away if you get any of these signs and symptoms of a serious meningococcal infection:

- Fever
- Fever and a rash
- Fever with high heart rate
- Headache with nausea or vomiting
- Headache and fever
- Headache with stiff neck or stiff back
- Confusion
- Eyes sensitive to light
- Muscle aches with flu-like symptoms

Patient Card

You will receive a **Patient Safety Card** from your healthcare provider. The **Patient Safety Card** covers the risk of serious meningococcal infection while taking EPYSQLI.

- Your risk of serious meningococcal infections may continue for several weeks after your last dose of EPYSQLI.
- Carry this card at all times during treatment and for 3 months after your last dose of EPYSQLI.
- **Show this card to any healthcare provider who treats you. This will help them diagnose and treat you quickly.**
- Get treatment right away for any symptoms of a meningococcal infection even if you do not have your card on you.



Getting Your Meningococcal Vaccines

- Complete or update your meningococcal vaccine(s) at least 2 weeks before your first dose of EPYSQLI.
- If you have not completed your meningococcal vaccines and EPYSQLI must be started right away, you should receive the required vaccine(s) as soon as possible.
- If you have not been vaccinated and EPYSQLI must be started right away, you should also receive antibiotics to take for as long as your healthcare provider tells you.
- If you had a meningococcal vaccine in the past, you might need additional vaccine(s) before you start EPYSQLI. Your healthcare provider will decide if you need additional meningococcal vaccine(s).
- Meningococcal vaccines do not prevent all meningococcal infections.
- Keep your vaccination records in a safe place and notify your healthcare provider that you have been vaccinated.
- Your healthcare provider and the certified healthcare setting or pharmacy may contact you to verify your vaccination records before your medicine is provided for you.

What is the EPYSQLI REMS?

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

EPYSQLI has a REMS because EPYSQLI can increase your chance of getting serious meningococcal infections. Meningococcal infections may quickly become life-threatening and cause death if not recognized and treated early.

If you have questions about the EPYSQLI REMS, you can call the EPYSQLI REMS or visit the REMS Website.

- **Phone: 1-866-318-8144**
 - » Monday - Friday 8:00am - 8:00pm Eastern Time
- **www.EPYSQLIREMS.com**

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EPYSQLI Risk Evaluation and Mitigation Strategy (REMS)

What is the EPYSQLI REMS?

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

What is the goal of the EPYSQLI REMS?

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

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

EPYSQLI is indicated for the treatment of:

- Patients with paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis.
- Patients with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy.

Limitation of Use

EPYSQLI is not indicated for the treatment of patients with Shiga toxin E. coli related hemolytic uremic syndrome (STEC-HUS).

Reporting Adverse Events

Report adverse events suggestive of meningococcal infections including the patient's clinical outcomes, immediately to Samsung Bioepis Co., Ltd. by phone at 1-800-806-0716.

You are encouraged to report other adverse reactions of EPYSQLI to Samsung Bioepis Co., Ltd. by phone at 1-800-806-0716 or report to the FDA at www.fda.gov/medwatch or call 1-800-FDA-1088.

For EPYSQLI REMS Information call:
PHONE: 1-866-318-0342
FAX: 1-866-318-8144

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Prescriber

Requirements for Prescribers

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

Healthcare providers (HCPs) who prescribe EPYSQLI must be specially certified.

Prescriber Certification

Enrollment in the EPYSQLI REMS allows HCPs to be able to prescribe EPYSQLI. Certification in the EPYSQLI REMS includes the following steps:

1

Review the following:

- EPYSQLI Prescribing Information
- Healthcare Provider Safety Brochure
- Patient Safety Card
- Patient Guide

2

Enroll in the EPYSQLI REMS. Submit the completed **Prescriber Enrollment Form**:

- Online
- By fax at 1-866-318-8144

Resources for Healthcare Providers

[Prescriber Enrollment Form](#)[Healthcare Provider Safety Brochure](#)[Patient Safety Card](#)[Patient Guide](#)

Patient Counseling

Prescribers must:

- Counsel the patients using both the **Patient Safety Card** and **Patient Guide**. Provide a copy of the materials to the patient.
 - The **Patient Guide** provides information for your patients about the risk of serious meningococcal infections including:
 - The need to complete or update their meningococcal vaccines for serotypes A, C, W, Y, and B at least 2 weeks prior to receiving the first dose of EPYSQLI or receive antibacterial drug prophylaxis if EPYSQLI must be initiated immediately, and they have not previously been vaccinated.
 - Additional vaccines may be necessary during treatment with EPYSQLI.
 - Meningococcal vaccines do not prevent all meningococcal infections.
 - The **Patient Safety Card** has important safety information for both patients and any healthcare providers that may see or treat your patient. It describes the signs and symptoms which, if experienced, should prompt the patient to seek immediate medical care.
- Counsel the patient on the need to carry the **Patient Safety Card**. Instruct your patient to show the card to any healthcare provider involved in their care.
 - Instruct the patient to carry the **Patient Safety Card** at all times and for 3 months after their last dose.

For EPYSQLI REMS Information call:
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FAX: 1-866-318-8144

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Prescriber Online Enrollment

Instructions

To become certified in the EPYSQLI REMS and prescribe EPYSQLI, prescribers must:

1. **Review** the EPYSQLI Prescribing Information, **Healthcare Provider Safety Brochure**, **Patient Safety Card**, and **Patient Guide**.
2. **Enroll** by completing and submitting this **Prescriber Enrollment Form** to the REMS.
 - Online at www.EPYSQLIREMS.com
 - By fax at 1-866-318-8144

Prescriber Enrollment Form

Please enter your National Provider Identifier (NPI) # and click "Continue".

* fields required

Prescriber Information

* National Provider Identifier (NPI) #

[Continue](#)

For EPYSQLI REMS Information call:

PHONE: 1-866-318-0342

FAX: 1-866-318-8144

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Reference ID: 5416363

Prescriber Online Enrollment

Instructions

To become certified in the EPYSQLI REMS and prescribe EPYSQLI, prescribers must:

1. Review the EPYSQLI Prescribing Information, **Healthcare Provider Safety Brochure**, **Patient Safety Card**, and **Patient Guide**.
2. Enroll by completing and submitting this **Prescriber Enrollment Form** to the REMS.
 - Online at www.EPYSQLIREMS.com
 - By fax at 1-866-318-8144

Prescriber Enrollment Form

Please enter your National Provider Identifier (NPI) # and click "Continue".

* fields required

Prescriber Information

* National Provider Identifier (NPI) #

1234567890

Continue

* First Name

Steve

MI

* Last Name

Meru

* Email

* Clinic/Practice Name

* Address Line 1

831 Broadway

Address Line 2

* City

Philadelphia

* State

PA

* Zip Code

* Office Phone Number

Ext

* Fax Number

* Credentials

☐ MD

☐ DO

☐ APRN*

☐ PA

☐ PharmD

* Medical Specialty (please select one)

☐ Hematology/Oncology

☐ Immunology

☐ Internal Medicine

☐ Nephrology

☐ Neurology

☐ Rheumatology

☐ Other (please specify)

Prescriber Delegate Information

A prescriber delegate is 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.

First Name

Last Name

Office Phone Number

Ext

Credentials

☐ MD

☐ DO

☐ APRN*

☐ PA

☐ PharmD

*Includes Certified Nurse Practitioner (CNP), Clinical Nurse Specialist, (CNS), Certified Registered Nurse Anesthetist (CRNA), Certified Nurse-Midwife (CNM)

Prescriber Agreement

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

- I have read and understand the EPYSQLI Prescribing Information (PI), **Healthcare Provider Safety Brochure**, **Patient Safety Card**, and the **Patient Guide**.
- I understand the:
 - Risk of serious meningococcal infections associated with EPYSQLI.
 - Early signs and symptoms of meningococcal infections and the need for immediate medical evaluation.
- I will enroll by completing and submitting this **Prescriber Enrollment Form** to the REMS.
- Before treatment initiation, I must:
 - Assess the patient for unresolved meningococcal infection.
 - For patients with unresolved meningococcal infection: NOT initiate EPYSQLI.
 - Assess the patient's vaccination status for meningococcal serogroups A, C, W, Y, and B and vaccinate as needed according to the current Advisory Committee on Immunization Practices (ACIP) recommendations for meningococcal vaccinations in patients receiving a complement inhibitor.
 - For patients who are not up to date with meningococcal vaccines at least two weeks prior to initiation of treatment and who must start EPYSQLI urgently: Provide the patient with a prescription for antibacterial drug prophylaxis.
 - Counsel the patient using the **Patient Safety Card** and **Patient Guide**. Provide a copy of the materials to the patient.
 - Counsel the patient on the need to carry the **Patient Safety Card** at all times and during and for 3 months after their last dose.
- During treatment, I must:
 - Assess the patient for early signs of meningococcal infection and evaluate immediately if infection is suspected.
 - Vaccinate patients as needed according to the ACIP recommendations for meningococcal vaccinations for patients receiving a complement inhibitor.
- At all times, I must:
 - Report adverse events suggestive of meningococcal infection, including the patient's clinical outcomes to Samsung Bioepis Co., Ltd. by phone at 1-800-806-0716.
- I understand that if I do not maintain compliance with the requirements of the EPYSQLI REMS, I will no longer be able to prescribe EPYSQLI.
- I understand that EPYSQLI REMS and its agents or contractors may contact me to support the administration of the EPYSQLI REMS.

Authorized Representative Signature

Use your mouse or touchpad to sign.



Cancel

Clear Signature

Submit

*** Medical Specialty**

☐ Hematology/Oncology ☐ Immunology ☐ Internal Medicine ☐ Nephrology ☐ Neurology ☐ Rheumatology ☒ Other (please specify)

*** Medical Specialty Other**



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Online Prescriber Enrollment

Thank you for submitting your information to enroll in the EPYSQLI REMS.

You will receive an enrollment confirmation via email with instructions on how to create an online account.

For questions regarding the EPYSQLI REMS, call 1-866-318-0342.

For EPYSQLI REMS Information call:

PHONE: 1-866-318-0342

FAX: 1-866-318-8144

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Healthcare Setting and Pharmacy

Requirements for Healthcare Settings and Pharmacies

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

To become certified in the EPYSQLI REMS and dispense EPYSQLI, the healthcare setting and pharmacy that dispenses EPYSQLI must designate an Authorized Representative to carry out the certification process and oversee the implementation and compliance with the REMS on behalf of the healthcare setting and pharmacy.

Healthcare Settings and Pharmacies Certification

For a healthcare setting and pharmacy to become certified, the Authorized Representative must complete the following steps:

1

Review the [Healthcare Provider Safety Brochure](#)

2

Enroll in the EPYSQLI REMS by completing and submitting the [Healthcare Setting and Pharmacy Enrollment Form](#) to the EPYSQLI REMS

- Online
- By fax at 1-866-318-8144

Resources for Healthcare Settings and Pharmacies

[Healthcare Setting and
Pharmacy Enrollment
Form](#)[Healthcare Provider
Safety Brochure](#)

For EPYSQLI REMS Information call:
PHONE: 1-866-318-0342
FAX: 1-866-318-8144

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Online Healthcare Setting and Pharmacy Enrollment

Instructions

To become certified in the EPYSQLI REMS and dispense EPYSQLI, the healthcare setting and pharmacy that dispenses this product must designate an Authorized Representative to carry out the certification process and oversee implementation and compliance with the REMS on behalf of the healthcare setting and pharmacy. The Authorized Representative must:

1. **Review** the **Healthcare Provider Brochure**
2. **Enroll** by completing and submitting this **Healthcare Setting and Pharmacy Enrollment Form** to the REMS.
 - Online at www.EPYSQLIREMS.com
 - By fax at 1-866-318-8144

Healthcare Setting and Pharmacy Enrollment Form

Please enter the Institution National Provider Identifier (NPI) and click "Continue" to begin.

* fields required

Dispensing Healthcare Setting and Pharmacy Information

* Institution National Provider Identifier (NPI)

[Continue](#)

For EPYSQLI REMS Information call:

PHONE: 1-866-318-0342

FAX: 1-866-318-8144

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Online Healthcare Setting and Pharmacy Enrollment

Instructions

To become certified in the EPYSQLI REMS and dispense EPYSQLI, the healthcare setting and pharmacy that dispenses this product must designate an Authorized Representative to carry out the certification process and oversee implementation and compliance with the REMS on behalf of the healthcare setting and pharmacy. The Authorized Representative must:

1. Review the [Healthcare Provider Brochure](#)
2. Enroll by completing and submitting this [Healthcare Setting and Pharmacy Enrollment Form](#) to the REMS.
 - Online at [www.EPYSQLIREMS.com](#)
 - By fax at 1-866-318-6344

Healthcare Setting and Pharmacy Enrollment Form

Please enter the Institution National Provider Identifier (NPI) and click "Continue" to begin.

*Fields required

Dispensing Healthcare Setting and Pharmacy Information

*Institution National Provider Identifier (NPI)

1234567890

Continue

*Enrollment Type

- ☒ Initial healthcare setting or pharmacy enrollment ☐ Change of information for enrolled healthcare setting or pharmacy
☐ Change of Authorized Representative

*Name of the Institution

AIC Pharmacy

*Address Line 1

Address Line 2

*City

*State

*Zip Code

*Phone Number

Ext

*Fax Number

*Email

*Confirm Email

Institution Type

- ☒ Hospital ☐ Infusion Site/Outpatient Clinic ☐ Physician Practice ☐ Specialty Pharmacy/Infusion Provider

For each additional healthcare setting and pharmacy where EPYSQLI will be delivered, dispensed, and administered within your healthcare system for which the same Authorized Representative will be responsible, click "Add Another Healthcare Setting and Pharmacy".

Add Another Healthcare Setting and Pharmacy

Authorized Representative Information

*First Name

HE

*Last Name

*Title/Position

- ☒ Pharmacist ☐ Nurse ☐ Other (please specify)

*Authorized Representative National Provider Identifier (NPI)

*Office Phone Number

Ext

*Office Fax Number

*Email

*Preferred Method of Communication

- ☒ Email ☐ Phone

Authorized Representative Attestations

As the healthcare setting and pharmacy Authorized Representative, to become certified to dispense, I must:

- Review the [Healthcare Provider Brochure](#).
- Enroll by completing and submitting this [Healthcare Setting and Pharmacy Enrollment Form](#) to the REMS.
- Train all relevant staff involved in dispensing EPYSQLI using the [Healthcare Provider Brochure](#).
- Establish processes and procedures to contact the prescriber to assess the patient's vaccination status for up to date meningococcal vaccines for serogroups A, C, W, Y, and B according to the current Advisory Committee on Immunization Practices (ACIP) recommendations in patients receiving a complement inhibitor, 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.

Before dispensing the first dose, all healthcare settings or pharmacy staff must:

- Obtain authorization to dispense each prescription by contacting the REMS to verify the prescriber is certified.
- 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, and document the findings through the processes and procedures established as a requirement of the REMS.

Before dispensing, up to 6 months after dispensing the first dose, all healthcare setting or pharmacy staff must:

- Obtain authorization to dispense each prescription by contacting the REMS to verify the prescriber is certified.
- For patients who are not initially up to date with meningococcal vaccines when starting treatment: Assess the patient's vaccination status for up to date meningococcal vaccines for serogroups A, C, W, Y, and B including antibacterial drug prophylaxis, if needed, and document the findings through the processes and procedures established as a requirement of the REMS.

Before dispensing, 6 months after the first dose and thereafter, all healthcare setting or pharmacy staff must:

- Obtain authorization to dispense each prescription by contacting the REMS to verify the prescriber is certified.

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

- Enroll by completing and submitting this [Healthcare Setting and Pharmacy Enrollment Form](#) to the REMS.

At all times, my healthcare setting or pharmacy must:

- Report adverse events suggestive of meningococcal infections to Samsung Bioepis Co., Ltd. by phone at 1-800-806-0716.
- Not distribute, transfer, loan, or sell EPYSQLI, except to 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 Samsung Bioepis Co., Ltd. or a third party acting on behalf of Samsung Bioepis Co., Ltd. to ensure that all processes and procedures are in place and are being followed.

Authorized Representative Signature

Use your mouse or touchpad to sign.

Cancel

***Title/Position**

☐ Pharmacist ☐ Nurse ☒ Other (please specify)

***Title/Position Other**

Institution Type

☐ Hospital ☐ Infusion Site/Outpatient Clinic ☐ Physician Practice ☐ Specialty Pharmacy/Infusion Provider

Dispensing Healthcare Setting and Pharmacy Information

* Institution National Provider Identifier (NPI)

Continue

For each additional healthcare setting and pharmacy where EPYSQLI will be delivered, dispensed, and administered within your healthcare system for which the same Authorized Representative will be responsible, click "Add Another Healthcare Setting and Pharmacy".

Add Another Healthcare Setting and Pharmacy



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- [Healthcare Setting and Pharmacy](#)
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- [Resources](#)
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Online Healthcare Setting and Pharmacy Enrollment

Thank you for submitting your information to enroll in the EPYSQLI REMS.

You will receive an enrollment confirmation via email with instructions on how to create an online account.

For questions regarding the EPYSQLI REMS, call 1-866-318-0342.

For EPYSQLI REMS Information call:
PHONE: 1-866-318-0342
FAX: 1-866-318-8144

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Certified Healthcare Setting and Pharmacy Locator

Use the Online Locator tool to search for a specific location on a map view.



**Online Locator for Certified Healthcare
Settings and Pharmacies**

Enter a Name, NPI, State, or Zip Code to limit the search results.

Name, NPI, State, or Zip Code

Search

For EPYSQLI REMS Information call:
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Certified Healthcare Setting and Pharmacy Locator

Use the Online Locator tool to search for a specific location on a map view.

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Settings and Pharmacies](#)

Enter a Name, NPI, State, or Zip Code to limit the search results.

Name, NPI, State, or Zip Code

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Certified Healthcare Settings and Pharmacies

Name ↑	Address	City	State	ZIP Code	Phone	Institution Type
ABC Pharmacy	123 Main Street	Philadelphia	PA	99999	555 555-1212	Specialty Pharmacy/Infusion Provider
XYZ Hospital	831 Blank Lane	Philadelphia	PA	99999	555 555-3434	Hospital

For EPYSQLI REMS Information call:
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Certified Healthcare Setting and Pharmacy Locator

Enter a Street Address, City, State, or Zip Code, and click "Search".

* Street Address, City, State, or Zip Code

* Search Radius

10 miles

[Search](#)

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Certified Healthcare Setting and Pharmacy Locator

Enter a Street Address, City, State, or Zip Code, and click "Search".

* Street Address, City, State, or Zip Code

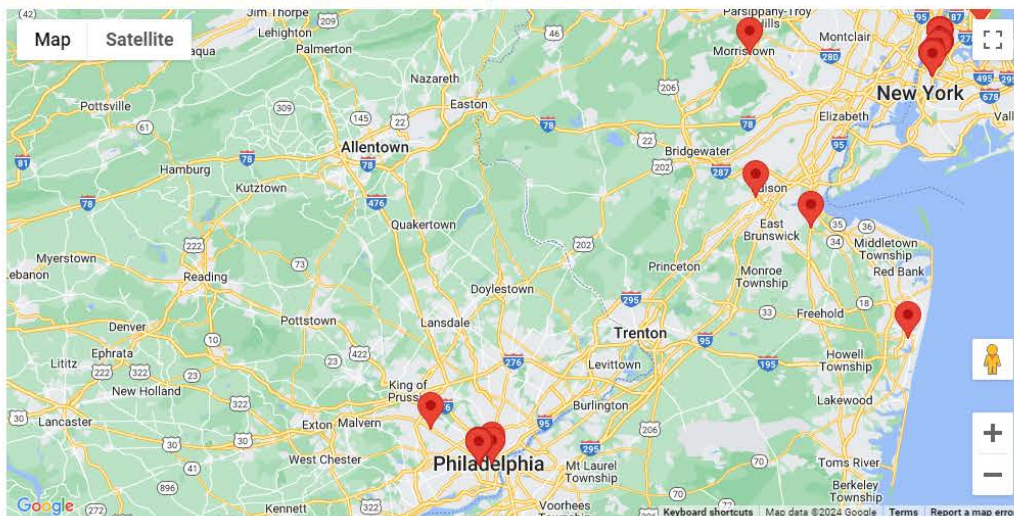
PA

* Search Radius

10 miles

Search

Certified Healthcare Setting and Pharmacy Locations



ABC PHARMACY

825 OLD LANCASTER RD
BRYN MAWR, PA 19010
610-555-4511

26.2 miles
[Directions](#)

BDD INFUSION CENTER

1220 BUTTONWOOD ST APT 505
PHILADELPHIA, PA 19123-3654
215-555-3740

27.9 miles
[Directions](#)

COUNTY FAMILY PRACTICE

925 CHESTNUT ST
PHILADELPHIA, PA 19107
215-555-8874

28.3 miles
[Directions](#)

CCC SPECIALTY PHARMACY

925 CHESTNUT ST
PHILADELPHIA, PA 19147
215-555-8874

28.3 miles
[Directions](#)

DDD SPECIALTY PHARMACY

3400 SPRUCE STREET
PHILADELPHIA, PA 19104-4204
215-555-0063

28.6 miles
[Directions](#)

JJJ HOSPITAL

3400 SPRUCE ST
PHILADELPHIA, PA 19104-4238
215-555-2400

28.6 miles
[Directions](#)

SSS INFUSION PROVIDER

3400 SPRUCE ST
PHILADELPHIA, PA 19104-4238
267-555-5175

28.6 miles
[Directions](#)

GGG HOSPITAL

3400 SPRUCE ST
PHILADELPHIA, PA 19104-4238
267-555-3491

28.6 miles
[Directions](#)



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Healthcare Setting and Pharmacy



Healthcare Provider Safety Brochure



Healthcare Setting and Pharmacy
Enrollment Form

Patient



Medication Guide



Patient Guide



Patient Safety Card

Advisory Committee on Immunization Practices (ACIP) recommendations can be found at
<https://www.cdc.gov/vaccines/hcp/acip-recs/index.html>.

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Phone

1-866-318-0342

FAX

1-866-318-8144

Hours of Operation

Monday - Friday
8:00 AM - 8:00 PM
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