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CDC Health Advisory

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Patients Receiving Eculizumab (Soliris®) at High Risk for Invasive Meningococcal Disease Despite Vaccination

Summary

Eculizumab (Soliris®) recipients have a 1,000 to 2,000-fold greater risk of invasive meningococcal disease compared to the general U.S. population. The Food and Drug Administration (FDA)-approved prescribing information for eculizumab includes a black box warning for increased risk of meningococcal disease, and the Advisory Committee on Immunization Practices (ACIP) recommends meningococcal vaccination for all patients receiving eculizumab. Recent data show that some patients receiving eculizumab who were vaccinated with the recommended meningococcal vaccines still developed meningococcal disease, most often from nongroupable *Neisseria meningitidis*, which rarely causes invasive disease in healthy individuals.

Background

Eculizumab is most commonly prescribed for treatment of 2 rare blood disorders: atypical hemolytic uremic syndrome (aHUS) and paroxysmal nocturnal hemoglobinuria (PNH). Through a request for data on meningococcal disease cases reported to state health departments, the U.S. Centers for Disease Control and Prevention (CDC) identified 16 cases of meningococcal disease in eculizumab recipients in the United States from 2008 through 2016; 11 (69%) of these were caused by nongroupable *N. meningitidis*. Meningococcal conjugate (MenACWY) vaccine targets serogroups A, C, W, and Y, and provides no protection against nongroupable *N. meningitidis*. Serogroup B meningococcal (MenB) vaccines are licensed specifically for protection against serogroup B meningococcal disease. Researchers have not assessed the extent of any potential cross protection for nongroupable *N. meningitidis* strains.

Recommendations for Healthcare Providers

Healthcare Providers:

- Could consider antimicrobial prophylaxis for the duration of eculizumab therapy to potentially reduce the risk of meningococcal disease.
- Should continue meningococcal vaccination of all patients who receive eculizumab.
- Should administer meningococcal vaccines at least 2 weeks prior to administering the first dose of eculizumab, unless the risks of delaying eculizumab therapy outweigh the risks of developing a meningococcal infection, according to the product label.
- Should maintain a high index of suspicion for meningococcal disease in patients taking eculizumab who present with any symptoms consistent with either meningitis or meningococemia, even if the patient's symptoms initially appear mild, and irrespective of the patient's meningococcal vaccine or antimicrobial prophylaxis status.

Resources for Additional Information

Managing the Risk of Meningococcal Disease among Patients Who Receive Eculizumab Therapy

<https://www.cdc.gov/meningococcal/clinical/eculizumab.html>

Signs and Symptoms of Meningococcal Disease

<https://www.cdc.gov/meningococcal/about/symptoms.html>

Food and Drug Administration. Soliris® (eculizumab) product label

https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/125166s417lbl.pdf

Atypical Hemolytic Uremic Syndrome (aHUS) <https://rarediseases.org/rare-diseases/atypical-hemolytic-uremic-syndrome/>

Paroxysmal Nocturnal Hemoglobinuria (PNH) <http://www.aamds.org/diseases/pnh>

Child and Adolescent Indications Schedule: Vaccines That Might Be Indicated for Persons Aged 0

through 18 Years Based On Medical Indications <https://www.cdc.gov/vaccines/schedules/hcp/imz/child-indications.html>

Adult Immunization Schedule by Medical and Other Indications Recommended Immunization Schedule for Adults Aged 19 Years or Older by Medical Conditions and Other Indications, United States, 2017

<https://www.cdc.gov/vaccines/schedules/hcp/imz/adult-conditions.html>

References

McNamara LA, Topaz N, Wang X, Hariri S, Fox L, MacNeil J. High risk for invasive meningococcal disease among patients receiving eculizumab (Soliris®) despite receipt of meningococcal vaccination.

MMWR Morb Mortal Wkly Rep. Epub ahead of print. 2017.

https://www.cdc.gov/mmwr/volumes/66/wr/mm6627e1.htm?s_cid=mm6627e1_w

DHEC contact information for reportable diseases and reporting requirements

Reporting of Invasive Meningococcal Disease is consistent with South Carolina Law requiring the reporting of diseases and conditions to your state or local public health department. (State Law # 44-29-10 and Regulation # 61-20) as per the DHEC 2017 List of Reportable Conditions available at: <http://www.scdhec.gov/Library/CR-009025.pdf>

Federal HIPAA legislation allows disclosure of protected health information, without consent of the individual, to public health authorities to collect and receive such information for the purpose of preventing or controlling disease. (HIPAA 45 CFR §164.512).

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<u>Lowcountry</u> 4050 Bridge View Drive, Suite 600 N. Charleston, SC 29405 Fax: (843) 953-0051	<u>Midlands</u> 2000 Hampton Street Columbia, SC 29204 Fax: (803) 576-2993	<u>Pee Dee</u> 145 E. Cheves Street Florence, SC 29506 Fax: (843) 661-4859	<u>Upstate</u> 200 University Ridge Greenville, SC 29602 Fax: (864) 282-4373
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For information on reportable conditions, see http://www.scdhec.gov/Health/FHPF/ReportDiseasesAdverseEvents/ReportableConditionsInSC/		<u>DHEC Bureau of Disease Control</u> Division of Acute Disease Epidemiology 2100 Bull St • Columbia, SC 29201 Phone: (803) 898-0861 • Fax: (803) 898-0897 Nights / Weekends: 1-888-847-0902	

Categories of Health Alert messages:

Health Alert	Conveys the highest level of importance; warrants immediate action or attention.
Health Advisory	Provides important information for a specific incident or situation; may not require immediate action.
Health Update	Provides updated information regarding an incident or situation; unlikely to require immediate action.
Info Service	Provides general information that is not necessarily considered to be of an emergent nature.