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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 meningococcemia, even if the patient's symptoms initially appear mild, and irrespective of the patient's meningococcal vaccine or antimicrobial prophylaxis status.

For More 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

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