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

DATE:	July 7, 2017
TO:	Health Alert Network
FROM:	Rachel Levine, MD, Acting Secretary of Health
SUBJECT:	**Patients Receiving Eculizumab (Soliris®) at High Risk for Invasive Meningococcal Disease Despite Vaccination**
DISTRIBUTION:	Statewide
LOCATION:	Statewide
STREET ADDRESS:	Statewide
COUNTY:	Statewide
MUNICIPALITY:	Statewide
ZIP CODE:	Statewide

This transmission is a "Health Advisory" provides important information for a specific incident or situation; may not require immediate action.

HOSPITALS: PLEASE SHARE WITH ALL MEDICAL, PEDIATRIC, INFECTION CONTROL, NURSING AND LABORATORY STAFF IN YOUR HOSPITAL

EMS COUNCILS: PLEASE DISTRIBUTE AS APPROPRIATE

FQHCs: PLEASE DISTRIBUTE AS APPROPRIATE

LOCAL HEALTH JURISDICTIONS: PLEASE DISTRIBUTE AS APPROPRIATE

PROFESSIONAL ORGANIZATIONS: PLEASE DISTRIBUTE TO YOUR MEMBERSHIP

The Pennsylvania Department of Health (PADOH) is forwarding the following advisory to healthcare providers, **"**Patients Receiving Eculizumab (Soliris®) at High Risk for Invasive Meningococcal Disease Despite Vaccination" from the Centers for Disease Control and Prevention (CDC). If you have any questions or concerns, please call PADOH at 1-877-PA-HEALTH (1-877-724-3258) or your local health department.

This is an official

CDC HEALTH ADVISORY

Distributed via the CDC Health Alert Network
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CDCHAN-00404

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

The Centers for Disease Control and Prevention (CDC) protects people's health and safety by preventing and controlling diseases and injuries; enhances health decisions by providing credible information on critical health issues; and promotes healthy living through strong partnerships with local, national, and international organizations.

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.
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This information is current as of July 7, 2017 but may be modified in the future.