

KATHY HOCHUL Governor JAMES V. McDONALD, M.D., M.P.H. Commissioner JOHANNE E. MORNE, M.S. Acting Executive Deputy Commissioner

January 25, 2024

Dear Colleague/Hospital Chief Executive Officer:

This letter contains information on how to address the current and ongoing shortage of erythromycin (0.5%) ophthalmic ointment for the prevention of ophthalmia neonatorum caused by *N. gonorrhoeae.*

Under Section 12.2 of Title 10 of the Compilation of Rules and Regulations of the State of New York, it is the duty of an attending physician, licensed midwife, licensed nurse, or other authorized provider in attendance at the delivery of a newborn to place into the eyes of the infant, on delivery, an agent effective for preventing purulent conjunctivitis, such as erythromycin eye ointment. Eye prophylaxis is a universal requirement because the treatment is safe and effective for the prevention of gonococcal infection of the eyes.

Due to the ongoing shortage of erythromycin (0.5%) ophthalmic ointment, the Department has adopted the following guidance from the American Academy of Pediatrics:

"If erythromycin ointment is not available, a birthing parent who is at risk for exposure to *N. gonorrhoeae** or who had no prenatal care, should be tested for *N. gonorrhoeae** or who had no prenatal care, should be tested for *N. gonorrhoeae* in the immediate peripartum setting using a nucleic acid amplification test (NAAT). If the birth parent's test is positive for gonorrheal infection or if the test result is pending at time of discharge with concerns for lack of follow-up, the neonate should receive ceftriaxone, 25 to 50 mg/kg of body weight, IV or IM, not to exceed 250 mg in a single dose; if ceftriaxone is unavailable or contraindicated, a single dose of ceftazidime or cefepime may be substituted".²⁻⁴

According to the American Academy of Pediatrics, at-risk birthing parents include "women < 25 years old, and those 25 years or older who have a new partner, more than one sex partner, a sex partner with concurrent partners, or a sex partner who has a sexually transmitted infection (STI), or live in a community with high rates of gonorrhea; practice inconsistent condom use when not in a mutually monogamous relationship; have a previous or coexisting STI; have a history of exchanging sex for money or drugs; or have a history of incarceration".^{1,2}

For further guidance, please see: <u>AAP Erythromycin Ointment Shortage</u>.

The Centers for Disease Control and Prevention recommends notifying your local health department of any challenges in procuring the product. Additional information regarding the availability of erythromycin (0.5%) ophthalmic ointment is available on the FDA Drug Shortage page.

Please be advised that the Department will not take any enforcement actions in situations where a documented erythromycin ointment shortage prevents a provider from complying with the directive in 10 NYCRR § 12.2 and where supplemental measures, as recommended by the American Academy of Pediatrics, are taken to minimize the risk of ophthalmia neonatorum.

However, hospitals and healthcare providers must make every effort to provide eye prophylaxis to newborns at risk for exposure to *N. gonorrhoeae*, as the consequences of not administering an effective prophylactic agent can be catastrophic.

Sincerely,

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References:

- ^{1.} US Preventive Services Task Force. Screening for Chlamydia and Gonorrhea: US Preventive Services Task Force Recommendation Statement. 2021 Sept 14;326(10):949-956
- ² Sexually Transmitted Infections Treatment Guidelines, 2021. Centers for Disease Control and Prevention. Available at: <u>www.cdc.gov/std/treatment-</u> <u>guidelines/gonorrhea-neonates.htm</u>
- ^{3.} Nolt D, O'Leary ST, Aucott SW; AAP Committee on Infectious Diseases, AAP Committee on Fetus and Newborn. Risks of Infectious Diseases in Newborns Exposed to Alternative Perinatal Practices. *Pediatrics*. 2022;149(2):e2021055554
- ^{4.} American Academy of Pediatrics. Gonococcal Infections. In: Kimberlin DW, Barnett ED, Lynfield R, Sawyer MH, eds. Red Book: 2021 Report of the Committee on Infectious Diseases. 32nd ed. American Academy of Pediatrics; 2021:338-344