Ask Dr. Miller

January 2013

The following questions were posed by NBCCEDP grantees:

Question #1: There have been several articles published regarding a bulletin that was sent to laboratories warning about inappropriate use of SurePath cervical test kits for HPV testing. Is anyone at CDC was aware of this issue?

Answer: We were aware that SurePath had not been approved by the FDA for use with HPV testing. But we were not aware of the bulletin and had not heard about the false-negative issue until these news articles were published. The exact extent and impact of this problem is unclear. There has been concerned raised among a few national organizations who will be looking further into this situation. We will continue to discuss the issue with our partner organizations. In the meantime, we recommend that you discuss this situation with your contract laboratories. The bulletin that was sent to the laboratories is attached for your review.

Question #2: As you know there are multiple states that have recently passed "Dense Breast" legislation requiring mammographers to notify women if they have dense breast tissue and recommend that these women discuss this issue with their physicians. We would like clarify the NBCCEDP position of reimbursement for screening breast ultrasound for dense breast tissue alone without clinical risk assessment and for screening ultrasound for dense breast tissue for women who are deemed high risk by a recognized clinical risk assessment tool.

Answer: Currently, there are no guidelines that recommend screening breast ultrasound. The NBCCEDP only supports guideline-recommended screening. Use of ultrasound as a tool for breast cancer screening is still in an investigational phase. As many states have passed similar legislation, we hope that physicians would not order additional tests just as a reflex to the law without doing a risk assessment and counseling the patient before deciding on a clinical pathway. Inefficient use of any tool may provide the patient with false degree of relief or concern. Any inappropriate use of BIRADS results or testing should be addressed with the provider. Your MAB can be of assistance with handling such issues.

CAPT Jacqueline W. Miller, MD, USPHS ● Medical Director, National Breast and Cervical Cancer Early Detection Program
Centers for Disease Control and Prevention ● Division of Cancer Prevention and Control ● JMiller5@cdc.gov

Question #3: One of our labs is billing for 3 units of HPV testing using CPT 87621. When reviewing the lab results, it appears two of the units are labeled as Cervista HPV 16/18 invader test, and the third unit is labeled as HPV DNA (high risk). Are we to be paying for the invader test, as well as the high risk test? Also, just curious, as far as I understand, the high risk test already looks for strains 16 and 18, so why is there another test to look for these?

Answer: The Cervista HR DNA panel does include HPV strains 16 and 18, along with 12 other high risk strains. The Cervista 16/18 looks at those specific strains only. If the HR test is positive, the 16/18 identifies if the woman is positive for these specific strains. Please refer to the ASCCP algorithms to review the management options for follow-up due to positive HPV HR test results. There has been no proven evidence that having this additional 16/18 test and possibly going to colposcopy earlier has benefit over the repeat testing option. Therefore, the NBCCEDP does not allow federal funds to be used for this test. Please refer to the NBCCEDP policy in the Program Guidance Manual.

Question #4: I recently attended a seminar on how to treat transgender-identified individuals in a health care setting. I was wondering if the CDC has addressed this within the NBCCEDP.

Answer: Following the Breast and Cervical Cancer Mortality Prevention Act that authorized the NBCCEDP and specifically states "women," the focus of the NBCCEDP is targeting women who are at risk for breast and cervical cancer. Currently, NBCCEDP federal funds may only be used to cover screening for female-to-male transgender individuals who have not yet undergone complete hysterectomy or bilateral mastectomy because these individuals are genetically female. We do not use federal funds for male-to-female individuals who are genetically male. Grantees may use other non-federal funds to screen this population.

Question #5: Do we need to revise our reimbursement rates based on the new CMS fee schedules each year?

Answer: Yes. Each year CMS releases updated fee schedules in January. Grantees should adjust their reimbursement rates based on the current CMS fee schedules. The fee schedules for 2013 have been updated and are available on the CMS Website. Please refer to the instructions on www.nbccedp.org in the CCW folder on how to access the schedules.