Ask Dr. Miller

October 2012

The following questions were posed by NBCCEDP grantees:

Question #1: We are in the process of contracting with a lab for processing our Pap tests. Are College of American Pathologists (CAP) accreditation and Clinical Laboratory Improvement Act (CLIA) certification both still required?

Answer: I am not aware of CDC ever having a CAP accreditation requirement. CAP accreditation typically goes beyond the basic requirements of CLIA. CDC requires CLIA certification. NBCCEDP policy states that all cervical cytology interpretation must be performed by a qualified laboratory that meets the standards and regulations described by CMS under CLIA.

Question #2: The Medicare reimbursement rate for HPV testing in our state is $28. However, the lab charges in our state are as high as $80 in some geographic locations. Can we accommodate the new screening guidelines using HPV testing by charging our women the difference between the reimbursement rate and the actual lab charge?

Answer: In your contract with the labs, there should be an agreement that the lab will accept your reimbursement rate (which cannot be higher than the Medicare rate) for all tests performed on BCCP patients. Therefore, even though their charge may be higher, the lab doesn't get paid entire charge. The program only pays the Medicare allowable amount and the rest of the charge is written off by the lab. The woman should not be charged the difference. This should be the same case for any other tests where the charge is higher than your fee schedule.

Question #3: The U.S. Food and Drug Administration (FDA) has approved an ultrasound device for use in combination with mammography for breast cancer screening in women with dense breast tissue. The device, known as the Automated Breast Ultrasound System (ABUS), was developed to provide clinicians with an additional resource for screening women with dense breasts. The current indication is limited to use in women who have a negative mammogram and no symptoms of breast cancer. Is CDC aware of this new ultrasound tool? Is CDC planning to cover this service? Is it too early?

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Answer: CDC is aware of this new tool, but we are not planning to cover it as this point. It is too early to know its real benefit. Also, it is not currently included in any national recommendations as an adjunct to screening. As always, CDC's goal is to provide high-quality and cost-efficient cancer screening services. We will continue to follow the science as the technology for cancer tests continues to advance.

Question #4: A 36 year old woman new to BCCP had a negative Pap result, but positive HPV test. The provider recommended another Pap test in 5 years. Is this appropriate follow-up?

Answer: No, the recommendation for women who have negative cytology but positive HPV DNA test is repeat co-testing in 12 months if this was her first co-test. If this was her second follow-up co-test, she should be referred for colposcopy. There is a section in the March 2012 ACS/ASCCP/ASCP recommendation paper that specifically describes this scenario. This case should be reviewed with your MAB as this may require specific communication or professional development with the provider.

Question #5: We have a few clients with a final diagnosis of CIN2 by colposcopy with biopsy and endocervical curettage. Their records indicate that no treatment was necessary. Is this appropriate care?

Answer: The ASCCP has stated that CIN2 may be observed in some women because the data shows that CIN2 may regress, especially among "young women and adolescents". This is a gray zone because they didn't clearly define a cut-off age for young women. So while this care may be appropriate, these women are being followed closely. The 2006 ASCCP recommendations state that these women should have repeat colposcopy with biopsy every 6 months for 24 months. If regression does not occur then they should be treated.