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NCCN Task Force Report: Evaluating the Clinical Utility of Tumor Markers in Oncology

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Kristina M. Gregory, RN, MSN, OCN, is our nurse planner for this educational activity.

Target Audience

This educational program is designed to meet the needs of oncologists, advanced practice nurses, and other clinical professionals who treat and manage patients with cancer.

Educational Objectives

After completion of this CME/CE activity, participants should be able to:

- Distinguish between a prognostic factor and a predictive factor as they apply to oncology
- Define the term "clinical utility" as it applies to the incorporation of tumor markers into clinical practice guidelines
- Describe the factors considered in the evaluation of the clinical utility of a tumor marker in oncology
- Describe the complementary roles played by pathologists and clinicians in ensuring accurate testing of tumor markers
- Explain the difference between the terms "laboratory certification" and "laboratory accreditation" as they apply to pathology laboratories performing tumor marker testing
- Describe the importance of pathologic expertise, internal quality control standards, and external quality assurance monitoring in determining the reliability of tumor marker testing
- Explain the significance of FDA approval as it applies to a diagnostic test
- Summarize initiatives for transitioning basic and translational research findings on tumor markers into clinical practice

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This publication may include the discussion of products for indications not approved by the FDA.

Participants are encouraged to consult the package inserts for updated information and changes regarding indications, dosages, and contraindications. This recommendation is particularly important with new or infrequently used products.

Activity Instructions

Participants will read all portions of this monograph, including all tables, figures, and references. To receive your continuing education credit and certificate, visit http://www.cvent.com/d/rcq8rk to complete the post-test and evaluation. A minimum passing score of 70% is required on the post-test to be eligible for credits. If a minimum score is not achieved, you will be sent an e-mail with the opportunity to retake the test.

All post-test scores must be received by midnight on November 25, 2012 in order to be eligible for credit.

It should take approximately 0.75 hours (45 minutes) to complete the activity as designed. There is no registration fee for this activity. Certificates for passing scores will be e-mailed within 15 business days of submission of post-test and evaluation.

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Disclosure of Affiliations and Significant Relationships

Dr. Febbo has disclosed that he has no financial interests, arrangements, or affiliations with the manufacturers of any products or devices discussed in this report or their competitors.

Dr. Ladanyi has disclosed that he has financial interests, arrangements, or affiliations with the manufacturers of any products or devices discussed in this report or their competitors. He is a speaker for Infinity Pharmaceuticals.

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Dr. De Marzo has disclosed that he has no financial interests, arrangements, or affiliations with the manufacturers of any products or devices discussed in this report or their competitors.

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Dr. Sgroi has disclosed that he has financial interests, arrangements, or affiliations with the manufacturers of any products or devices discussed in this report or their competitors. He receives patent compensation from bioTheranostics, Inc.

Post-test

1. In order for molecular test results to be used to determine patient care, the test must be:
   a. FDA-approved
   b. FDA-cleared
   c. Performed in a CLIA laboratory
   d. Any of the above
   e. All of the above

2. If a given test is approved or cleared by the FDA, this indicates that it has proven clinical utility. Is this statement true or false?
   a. True
   b. False

3. What is detected by the companion diagnostic recently FDA approved with vemurafenib for treatment of metastatic melanoma?
   a. *ALK* gene fusion
   b. *ESR1* overexpression
   c. *BRAF* V600 mutation
   d. *KRAS* mutation
   e. Serum PSA

4. A hypothetical test for determining somatic mutation in a newly identified gene has been shown to predict response to a new chemotherapy agent. If use of the test is required for prescription of the drug, and both are approved by the FDA, the test would be called a:
   a. Laboratory-developed test (LDT)
   b. CLIA-certified test
   c. Companion diagnostic
   d. CAP-certified test

5. Which of the following must have proven clinical validity?
   a. An LDT performed in a CLIA laboratory
   b. An FDA-cleared test
   c. An FDA-approved test
   d. A molecular test performed in a research laboratory
   e. a and b
   f. b and c
   g. a, b, c, and d
   h. a and d
   i. None of the above

6. The Clinical Laboratory Improvement Amendment (CLIA) of 1988 is administered by:
   a. FDA
   b. CMS
   c. CAP
   d. NCCN

7. What can be done to help prove clinical utility of a molecular test?
   a. Demonstrate that test performance is reproducible in 3 or more clinical laboratories.
   b. Demonstrate that test results predict response/lack of response to a given therapy.
   c. Demonstrate that test results show which subset of patients have the longest progression-free survival.
   d. Demonstrate that test results are statistically significant.

8. Which molecular test is predictive for response to trastuzumab?
   a. HER2*(ERBB2)* protein expression by immunohistochemistry
   b. ER-α*(ESR1)*/PgR(PR) protein expression by immunohistochemistry
   c. HER2*(ERBB2)* amplification by FISH
   d. a and b
   e. a and c
   f. a, b, and c

9. Which tests have proven clinical utility in NSCLC?
   a. *EGFR* mutation and *KRAS* mutation
   b. ERCC1 expression and *BRAF* mutation
   c. *ALK* gene fusion and *EGFR* mutation
   d. *ALK* gene fusion and *KRAS* mutation

10. Which molecular tests have proven clinical utility and outperform Gleason sum as a prognostic for localized prostate cancer?
    a. Baseline PSA level
    b. Urine PCA3 testing
    c. Circulating tumor cell analysis
    d. Gene expression analysis
    e. All of the above
    f. None of the above

11. *IDH1* and *IDH2* mutations have been detected in what types of cancers:
    a. AML
    b. NSCLC
    c. Glioma
    d. a and b
    e. a and c
    f. b and c
    g. None of the above

12. Which methods of testing have proven analytic validity for MSI/MMR assessment in colon cancer?
    a. PCR for MSI
    b. Flow cytometry for MSI
    c. Immunohistochemistry for MMR
    d. FISH for MMR
    e. a and b
    f. a and c
    g. b and c
    h. c and d

To Receive Credit

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