

# Selected Genetic Tests For Cancer Diagnosis

Medical Evidence Development and  
Coverage Advisory Committee (MEDCAC)

May 1, 2013



# Definitions of Terms



## FISH:

- Fluorescence in-situ hybridization



## CUP:

- Cancer of unknown primary (site)



## ASCUS:

- Atypical squamous cells of unknown significance



## LSIL:

- Low-grade squamous intra-epithelial lesion



# Outcomes of Interest to CMS

- For FISH testing (ASCUS/LSIL):
  - Histologic confirmation of higher-grade cervical intraepithelial neoplasia ('CIN') on biopsy;
  - Overall survival;
  - Mortality;
  - Avoidance of harms of anti-tumor treatment;
  - Quality of life; and others.



# Outcomes of Interest to CMS

- For CUP testing:
  - Tumor recurrence;
  - Overall survival;
  - Mortality;
  - Avoidance of harms of anti-tumor treatment;
  - Quality of life; and others.



# MEDCAC Question #1

- 1. How confident are you that existing evidence is sufficient to confirm the clinical validity (defined as how reliably test results are associated with the presence of the disease or target condition) of each of the following?
  - a) DNA- or RNA-based testing (*'CUP testing'*) to predict tissue of origin for CUP.
  - b) FISH testing for cervical cancer/pre-cancer in patients with ASCUS or LSIL.

# Scale for voting on Q. 1:

1 Low Confidence	2	3 Intermediate Confidence	4	5 High Confidence
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- If the answer for either part of Question 1 is at least in the 'Intermediate' range (mean score is 2.5 or more) please vote on the corresponding part(s) of question 2.
- If not, please discuss questions 4-6.

# MEDCAC Question #2

- 2. How confident are you that there is sufficient evidence to determine whether genetic testing of tumor tissue ***affects*** health outcomes (including benefits and harms) for patients with cancer whose anticancer treatment strategy is guided by the results of each of the following?
  - a) DNA- or RNA-based testing to predict tissue of origin for CUP.
  - b) FISH testing for cervical cancer/pre-cancer in patients with ASCUS/LSIL.



# Scale for voting on Q. 2:

1 Low Confidence	2	3 Intermediate Confidence	4	5 High Confidence
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- If the answer for either part of Question 2 is at least in the 'Intermediate' range (i.e., mean score is 2.5 or more) please vote on the corresponding part(s) of question 3.
- If not, please discuss questions 4-6.



# MEDCAC Question #3

- 3. How confident are you that there is sufficient evidence to conclude that genetic testing of tumor tissue ***improves*** overall health outcomes (including benefits and harms) for patients with cancer whose anticancer treatment strategy is guided by the results of each of the following?
  - a) DNA- or RNA-based testing to predict tissue of origin for CUP.
  - b) FISH testing for cervical cancer/pre-cancer in patients with ASCUS/LSIL.

# Scale for voting on Q. 3:

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1 Low Confidence	2	3 Intermediate Confidence	4	5 High Confidence
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# MEDCAC Question 4

- 4. Please discuss whether the evidence as presented may be generalized based on each of the following factors:
  - a. Regulatory status of test (e.g., FDA approved/cleared vs. laboratory-developed test)?
  - b. Site of testing (e.g., university medical center or commercial laboratories vs. community based laboratories)?
  - c. Patient subgroups within the Medicare beneficiary population (e.g., age)?



# MEDCAC Question 5

- 5. Please identify and discuss any evidence gaps in assessing outcomes of interest to CMS for both
  - a. DNA- or RNA-based testing to predict tissue of origin for CUP, and
  - b. FISH testing for cervical cancer/pre-cancer in patients with ASCUS/LSIL.

# MEDCAC Question 6

- 6. Please comment on whether CMS should encourage development of additional evidence relevant to coverage determinations for
  - a. DNA- or RNA-based testing to predict tissue of origin for CUP, and
  - b. FISH testing for cervical cancer/pre-cancer in patients with ASCUS/LSIL.