Update on CT Colonography

Judy Yee, MD, FACR
Professor and Vice Chair
University of California, San Francisco
Chief of Radiology, SF VA Medical Center
New CRC screening tests

Significant CTC efforts to date

USPSTF and Reimbursement ! ? !
TESTS THAT DETECT ADENOMATOUS POLYPS AND CANCER

- Flexible sigmoidoscopy every 5 yrs or
- Double contrast BE every 5 yrs or
- CT Colonography every 5 yrs or
- Colonoscopy every 10 yrs

TESTS THAT PRIMARILY DETECT CANCER

- FOBT or FIT annually
- Stool DNA test (interval unknown)

Colon cancer **PREVENTION** is the primary goal of CRC screening
TESTS THAT DETECT ADENOMATOUS POLYPS AND CANCER

TESTS THAT PRIMARILY DETECT CANCER
FDA Approves Exact Sciences’ Cologuard®; First and Only Stool DNA Noninvasive Colorectal Cancer Screening Test

First time in history a technology receives FDA approval and proposed national coverage by CMS on the same day

Screening test detects 92% of colorectal cancer

@ExactSciences' Cologuard has been approved by the @US_FDA to improve CRC screening rates

MADISON, Wisc., August 12, 2014 /PRNewswire/ — Exact Sciences Corp. (NASDAQ: EXAS) announced today that the U.S. Food and Drug Administration (FDA) has approved Cologuard, the company’s noninvasive, stool DNA colorectal cancer screening test. Cologuard is the first noninvasive screening test for colorectal cancer that analyzes both
Stool DNA Test

- Detects 9 DNA methylation and mutation biomarkers from cancer cells shed in the stool / detects hemoglobin in stool
- No dietary restrictions
- Takes about 2 weeks
- $600
- Recommended every 3 years
• 9989 participants

• **92%** sensitivity for detecting cancer (compared to ~74% for FIT)

• **87%** specificity
  (compared to 95% for FIT)
• 69% sensitivity for detecting polyps with high grade dysplasia (compared to ~46% for FIT)

• 42% sensitivity for detecting advanced pre-cancerous lesion (compared to 24% for FIT)
Press release

Epigenomics receives FDA approval for Epi proColon®

-First and only blood-based colorectal cancer screening test approved by the FDA

-Innovative, convenient and effective screening option for millions of eligible Americans

-Commercialization initiated with partner Polymedco

Berlin (Germany) and Germantown, MD (U.S.A.), April 13, 2016 – Epigenomics AG (Frankfurt Prime Standard: ECX, OTCQX: EPGNY), the German-American cancer molecular diagnostics company, today announced that the U.S. Food and Drug Administration (FDA) has approved the Company’s lead product, Epi proColon®, the first and only FDA-approved blood-based colorectal cancer screening test.
Septin 9 Biomarker

- Blood test detects methylated Septin 9 DNA, a biomarker for CRC.
- Shed into the bloodstream by CRC and detectable by Real-Time PCR.
Epi proColon vs OC

- 1,544 avg risk patients

New CRC screening tests

Significant CTC efforts to date

USPSTF and Reimbursement ! ? !
1994: CTC first introduced

1997 – 2007: Major Validation Trials

2008: ACS Endorsement in Joint Guidelines

2008: ACRIN 6664: National CTC Trial

2008: ACS Endorsement in Joint Guidelines

2008: ACS Endorsement in Joint Guidelines


2009- present: Radiation Dose, ECF, Validation in Medicare Age Pts

Private payer coverage/
Global dissemination

2013: FDA supports Screening CTC

2014:-2016 USPSTF Re-evaluation

Animal Models, SDCT – MDCT, CO2 Insufflator, Improved Workstations

Centers for Medicare & Medicaid Services

辐射剂量，ECF，验证在Medicare年龄患者

私人支付者的覆盖范围/
全球传播
Private Payer Coverage of CT Colonography

Coverage for **diagnostic** and **screening** CT colonography:

- CIGNA
- United Healthcare
- Unicare
- Anthem Blue Cross Blue Shield (CA, CO, CT, IN, KY, ME, MO, NV, NH, OH, VA, WI)
- Kaiser (MD, DE, PA, NJ, NY)
- BC/BS of Arkansas
- Carefirst BC/BS
- Georgia BC/BS
- Empire BC/BS
- BC/BS of North Carolina
- Independence BC
- BC/BS of Texas
- BC/BS of New Jersey
- Priority Health
- Johns Hopkins Healthcare
Executive Summary

“All members of the joint panels agreed that, given the risks and benefits identified, CTC should be one option for CRC screening of asymptomatic patients.”
Legislative Efforts

**H. R. 4632**

To amend title XVIII of the Social Security Act to cover screening computed tomography colonography as a colorectal cancer screening under the Medicare program.

IN THE HOUSE OF REPRESENTATIVES
FEBRUARY 25, 2016

Mr. WENSTRUP (for himself and Mr. DANNY K. DAVIS of Illinois) introduced the following bill, which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned.

A BILL

To amend title XVIII of the Social Security Act to cover screening computed tomography colonography as a colorectal cancer screening under the Medicare program.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the “CT Colonography Screening for Colorectal Cancer Act of 2016”.

SEC. 2. COVERAGE OF COMPUTED TOMOGRAPHY COLONOGRAPHY SCREENING AS A COLORECTAL CANCER SCREENING TEST UNDER MEDICARE.

**S. 2262**

To amend title XVIII of the Social Security Act to cover screening computed tomography colonography as a colorectal cancer screening test under the Medicare program.

IN THE SENATE OF THE UNITED STATES
NOVEMBER 10, 2015

Mr. INHOFE (for himself and Mr. NELSON) introduced the following bill; which was read twice and referred to the Committee on Finance.

A BILL

To amend title XVIII of the Social Security Act to cover screening computed tomography colonography as a colorectal cancer screening test under the Medicare program.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the “CT Colonography Screening for Colorectal Cancer Act of 2015”.

SEC. 2. COVERAGE OF COMPUTED TOMOGRAPHY COLONOGRAPHY SCREENING AS A COLORECTAL CANCER SCREENING TEST UNDER MEDICARE.
New CRC screening tests

Significant CTC efforts to date

USPSTF and Reimbursement ! ? !
# U. S. Preventive Service Task Force (USPSTF) Grading System

<table>
<thead>
<tr>
<th>Grade</th>
<th>Definition</th>
<th>Suggestions for Practice</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>The USPSTF recommends the service. There is high certainty that the net benefit is substantial.</td>
<td>Offer or provide this service.</td>
</tr>
<tr>
<td>B</td>
<td>The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.</td>
<td>Offer or provide this service.</td>
</tr>
<tr>
<td>C</td>
<td>The USPSTF recommends selectively offering or providing this service to individual patients based on professional judgment and patient preferences. There is at least moderate certainty that the net benefit is small.</td>
<td>Offer or provide this service for selected patients depending on individual circumstances.</td>
</tr>
<tr>
<td>D</td>
<td>The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.</td>
<td>Discourage the use of this service.</td>
</tr>
<tr>
<td>I</td>
<td>The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.</td>
<td>Read the clinical considerations section of USPSTF Recommendation Statement. If the service is offered, patients should understand the uncertainty about the balance of benefits and harms.</td>
</tr>
</tbody>
</table>
# Summary of Recommendations

<table>
<thead>
<tr>
<th>Population</th>
<th>Recommendation</th>
<th>Grade (What’s This?)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adults, beginning at age 50 years and continuing until age 75 years</td>
<td>The USPSTF recommends screening for colorectal cancer using fecal occult blood testing, sigmoidoscopy, or colonoscopy in adults, beginning at age 50 years and continuing until age 75 years. The risks and benefits of these screening methods vary.</td>
<td>A</td>
</tr>
<tr>
<td>Adults age 76 to 85 years</td>
<td>The USPSTF recommends against routine screening for colorectal cancer in adults 76 to 85 years of age. There may be considerations that support colorectal cancer screening in an individual patient.</td>
<td>C</td>
</tr>
<tr>
<td>Adults older than age 85 years</td>
<td>The USPSTF recommends against screening for colorectal cancer in adults older than age 85 years.</td>
<td>D</td>
</tr>
<tr>
<td>Computed Tomographic Colonography and Fecal DNA testing as screening modalities</td>
<td>The USPSTF concludes that the evidence is insufficient to assess the benefits and harms of computed tomographic colonography and fecal DNA testing as screening modalities for colorectal cancer.</td>
<td>I</td>
</tr>
</tbody>
</table>
# Draft: Recommendation Summary

<table>
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<tr>
<td>Adults ages 50 to 75 years</td>
<td>The USPSTF recommends screening for colorectal cancer starting at age 50 years and continuing until age 75 years. The risks and benefits of different screening methods vary.</td>
<td>A</td>
</tr>
</tbody>
</table>
| Adults ages 76 to 85 years | The decision to screen for colorectal cancer in adults ages 76 to 85 years should be an individual one, taking into account the patient’s overall health and prior screening history.  
  - Adults in this age group who have never been screened for colorectal cancer are more likely to benefit.  
  - Screening would be most appropriate among adults who: 1) are healthy enough to undergo treatment if colorectal cancer is detected, and 2) do not have comorbid conditions that would significantly limit life expectancy. | C      |
Screening for Colorectal Cancer

The goal of screening is to reduce the number of people who die from cancer. Getting screened—and treated early, if cancer is found—reduces the risk of dying from this disease.

Evidence clearly shows that several different types of screening tests reduce deaths from colorectal cancer, including:

- **Stool tests:** In these screening tests, stool is collected and sent to a lab. The lab can use several different types of tests to check for the presence of blood, which can be a sign of CRC or of noncancerous growths that can become CRC.
- **Flexible sigmoidoscopy combined with stool testing:** A procedure to look inside the rectum and sigmoid (lower) colon for abnormalities using a sigmoidoscope (a thin, flexible tube) that is inserted into the rectum. This procedure can be done every ten years with stool testing (described above) performed every year.
- **Colonoscopy:** A procedure to look inside the rectum and colon for abnormalities. A colonoscope (a thin, tube-like instrument with a light and lens for viewing) is inserted through the rectum into the colon. During this procedure, any abnormal tissue seen may also be sampled and removed. Colonoscopy is also used, when required, as a follow-up diagnostic test to other tests listed here.

**Alternative tests with less evidence may also be useful in select circumstances, including:**

- **CT colonography:** A procedure that uses a series of x-rays called computed tomography to take a series of pictures of the colon. A computer puts the pictures together to create detailed images that may show abnormalities on the inside surface of the colon.
- **Multi-targeted stool DNA testing:** A test of a stool sample that looks for DNA mutations that may indicate the presence of abnormalities; additionally, like other stool tests, it also looks for the presence of hidden blood.
DRAFT
USPSTF Concerns

• Accuracy for detection of cancers
  (shift from cancer prevention ???)
• Optimum screening interval
• Extracolonic findings
• (Radiation)
To USPSTF committee members:

Thank you for the opportunity to comment on this draft statement.

The Society of Computed Body Tomography and Magnetic Resonance (SCBT-MR) extends a strong endorsement for CT colonography as an effective, minimally invasive exam for detection of colorectal neoplasia, with the potential to improve patient outcomes established since 1997. The risk of CRC is over 800 members and improves patient care through appropriate investor education. The SCBT-MR sponsors an in-depth coverage on a range of critical topics to provide answers for important clinical breakthroughs.

Overview
We respectfully ask the USPSTF to clarify the recommended test for colorectal cancer screening. CTC at 5-year intervals meets the criteria for an appropriate screening test.

“In our base-case analysis, CT colonography scores recommended strategies with age to begin screening. Selection of a 10-year interval for colonoscopy provided 81-96% of the lifetime-years gained with CRC requiring 2,000-3,599 fewer colonoscopies per 10,000 persons.

To Members of the USPSTF,
Re: Draft Recommendation Statement for CRC Colonoscopy

The Society of Abdominal Radiology (SAR) and ACR have jointly submitted their recommendations for colorectal cancer screening.

To Members of the USPSTF,
Re: Draft Recommendation Statement for CRC Colonoscopy

To: Members of the USPSTF,

The Society of Abdominal Radiology (SAR) and ACR have jointly submitted their recommendations for colorectal cancer screening.

November 2, 2015

Submitted Electronically

United States Preventive Services Taskforce
Agency for Healthcare Research and Quality
540 Gaither Road
Rockville, MD 20850

Re: Draft USPSTF Recommendations on Colorectal Cancer Screening

Dear Chairman Su and Task Force Members,

The American College of Radiology (ACR) has a long history of advocating for quality in colorectal cancer screening and has emphasized the importance of early detection. Therefore, the ACR strongly urges the United States Preventive Services Task Force (USPSTF) to consider Colonoscopy (CTC) colonography as a recommended screening test for colorectal cancer (CRC). Provided are comprehensive comments and robust evidence to support CTC as a recommended colorectal cancer screening test.

CRC is the second most common cancer diagnosed in the United States and the third leading cause of cancer death even though it has a 90% 5-year survival rate when detected early. Over 140,000 Americans are diagnosed with colorectal cancer (CRC) every year, and nearly 50,000 men and women die due to late detection. Less than half of affected 50 years of age and older are compliant with recommended screening in the United States with the existing USPSTF recommended screening options. Providing patients with additional effective screening tools for CRC will promote early detection and will save thousands of lives and help close the gap in CRC screening rates between whites and minority populations. The time is now for CT colonography to be recognized as an approved screening test.
## Colorectal Cancer: Screening

**Release Date: June 2016**

### Recommendation Summary

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<th>Population</th>
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<tbody>
<tr>
<td>Adults aged 50 to 75 years</td>
<td>The USPSTF recommends screening for colorectal cancer starting at age 50 years and continuing until age 75 years. The risks and benefits of different screening methods vary. See the Clinical Considerations section and the Table for details about screening strategies.</td>
<td>A</td>
</tr>
</tbody>
</table>
| Adults aged 76 to 85 years | The decision to screen for colorectal cancer in adults aged 76 to 85 years should be an individual one, taking into account the patient’s overall health and prior screening history.  
- Adults in this age group who have never been screened for colorectal cancer are more likely to benefit.  
- Screening would be most appropriate among adults who 1) are healthy enough to undergo treatment if colorectal cancer is detected and 2) do not have comorbid conditions that would significantly limit their life expectancy. | C                    |
7 tests evaluated:
- colonoscopy
- flexible sigmoidoscopy
- CT colonography
- gFOBT
- FIT
- stool DNA
- blood Septin biomarker

The designations “recommended” and “alternative” were removed.

FINDINGS The USPSTF concludes with high certainty that screening for colorectal cancer in average-risk, asymptomatic adults aged 50 to 75 years is of substantial net benefit. Multiple screening strategies are available to choose from, with different levels of evidence to support their effectiveness, as well as unique advantages and limitations, although there are no empirical data to demonstrate that any of the reviewed strategies provide a greater net benefit. Screening for colorectal cancer is a substantially underused preventive health strategy in the United States.
<table>
<thead>
<tr>
<th>Screening Method</th>
<th>Frequency</th>
<th>Evidence of Efficacy</th>
<th>Other Considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Stool-Based Tests</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>gFOBT</td>
<td>Every year</td>
<td>RCTs with mortality end points: High-sensitivity versions (eg, Hemoccult SENSA) have superior test performance characteristics than older tests (eg, Hemoccult II)</td>
<td>Does not require bowel preparation, anesthesia, or transportation to and from the screening examination (test is performed at home)</td>
</tr>
<tr>
<td>FIT</td>
<td>Every year</td>
<td>Test characteristic studies: Improved accuracy compared with gFOBT Can be done with a single specimen</td>
<td>Does not require bowel preparation, anesthesia, or transportation to and from the screening examination (test is performed at home)</td>
</tr>
<tr>
<td>FIT-DNA</td>
<td>Every 1 or 3 y</td>
<td>Test characteristic studies: Specificity is lower than for FIT, resulting in more false-positive results, more diagnostic colonoscopies, and more associated adverse events per screening test Improved sensitivity compared with FIT per single screening test</td>
<td>There is insufficient evidence about appropriate longitudinal follow-up of abnormal findings after a negative diagnostic colonoscopy; may potentially lead to overly intensive surveillance due to provider and patient concerns over the genetic component of the test</td>
</tr>
<tr>
<td><strong>Direct Visualization Tests</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Colonoscopy</td>
<td>Every 10 y</td>
<td>Prospective cohort study with mortality end point</td>
<td>Requires less frequent screening Screening and diagnostic follow-up of positive findings can be performed during the same examination</td>
</tr>
<tr>
<td>CT colonography*</td>
<td>Every 5 y</td>
<td>Test characteristic studies</td>
<td>There is insufficient evidence about the potential harms of associated extracolonic findings, which are common</td>
</tr>
<tr>
<td>Flexible sigmoidoscopy</td>
<td>Every 5 y</td>
<td>RCTs with mortality end points: Modeling suggests it provides less benefit than when combined with FIT or compared with other strategies</td>
<td>Test availability has declined in the United States</td>
</tr>
<tr>
<td>Flexible sigmoidoscopy with FIT*</td>
<td>Flexible sigmoidoscopy every 10 y plus FIT every year</td>
<td>RCT with mortality end point (subgroup analysis)</td>
<td>Test availability has declined in the United States Potentially attractive option for patients who want endoscopic screening but want to limit exposure to colonoscopy</td>
</tr>
</tbody>
</table>
Screening for colorectal cancer is a substantially underused preventive health strategy in the United States. In addition, there are no empirical data to suggest that any of the strategies provide a greater net benefit. Accordingly, the best screening test is the one that gets done, and the USPSTF concludes that maximizing the total proportion of the eligible population that receives screening will result in the greatest reduction in colorectal cancer deaths.
People can choose their colon cancer screening method: U.S. panel

BY ANDREW M. SEAMAN

(Reuters Health) - U.S. adults should choose the type of colon cancer screening they feel most comfortable with, the government-backed U.S. Preventive Services Task Force now advises.

The updated recommendation, directed at people ages 50 to 75 years, is a departure from the influential panel's 2008 guidance, which said people in that age group should be screened on a specific time table using one of four tests.

AMIC applauds USPSTF confirmation of CT colonography as an effective colon cancer screening option

Washington, D.C. - The Access to Medical Imaging Coalition (AMIC) today applauded the United States Preventive Services Task Force (USPSTF) for confirming that computed tomography (CT) colonography is an effective colorectal cancer screening option. In the final recommendation issued yesterday, USPSTF assigned an "A" grade to colorectal cancer (CRC) screening in those ages 50-75 years and provided a list of recognized screening exams, which included CT colonography.

"We are pleased that USPSTF has recognized the numerous benefits of CT colonography for Medicare patients," said Tim Trylsa, executive director of AMIC. "CTC is the least invasive available procedure for detecting cancerous polyps, which makes it a more appealing procedure to patients who may otherwise avoid getting screened early, when cancer is most treatable—highlighting that that the most effective screening method is the one that is used. CT colonography especially meets a need among minorities where screening rates are historically lower and we now hope that the Centers for Medicare & Medicaid Services will recognize its benefits and expand access to this life-saving technology for populations that need it most.”
Next Step
National Coverage Determination

- Determines national CMS coverage of a service
- Authorized by the Social Security Act
- Can be internally or externally triggered

- Binding on all Medicare Administrative Contractors, fiscal intermediaries, quality improvement organizations, HMO’s, competitive medical plans and health care prepayment plans

National Coverage Determination

- **Minimum 9 month process:**
  - **First 6 months:**
    1) preliminary discussion
    2) assignment to a benefit category
    3) generation of a National Coverage request
    4) CMS staff review
    5) external technology assessment and/or Medicare Coverage Advisory Committee recommendations
    6) CMS staff review
    7) Draft Decision Memo posted

- **Following 3 months:**
  1) 30 day public comment period
  2) 60 day requirement to complete the Final Decision Memo

August 11, 2016

Submitted Electronically

Tamara S. Syrek Jensen, J.D.
Director, Coverage and Analysis Group
Centers for Medicare & Medicaid Services
Mail Stop C1-09-06
7500 Security Boulevard
Baltimore, MD 21244

By Online Submission

Re: National Coverage Reconsideration for Screening Computed Tomography Colonography (CTC) for Colorectal Cancer (CAG-00396N)

Dear Ms. Syrek Jensen,

The Colon Cancer Alliance (CCA), Colon Cancer Coalition (CCC), Prevent Cancer Foundation (PCF), Society of Abdominal Radiology (SAR), Society of Computed Body Tomography & Magnetic Resonance (SCBT-MR), American College of Radiology (ACR), Medical Imaging Technology Alliance (MITA), BRACCO, and iCAD, a Coalition representing colorectal cancer patients, diagnostic radiologists, radiation oncologists, nuclear medicine physicians, medical physicists, body and abdominal imagers, and manufacturers, formally request the opening of national coverage reconsideration for screening Computed Tomography Colonography (CTC) for colorectal cancer (CAG-00396N). The CCA, CCC, PCF, SAR, SCBT-MR, ACR, MITA, BRACCO, and iCAD, hereafter referred to as the “CTC Coalition,” agree with the recent United States Preventive Services Task Force (USPSTF) final recommendation of grade “A” for colorectal cancer screening in those age 50-75 years with a list of recognized screening exams including CTC.
CTC Coalition

- Colon Cancer Alliance (CCA)
- Colon Cancer Coalition (CCC)
- Prevent Cancer Foundation (PCF)
- Society of Abdominal Radiology (SAR)
- Society of Computed Body Tomography & Magnetic Resonance (SCBT-MR)
- American College of Radiology (ACR)
- Medical Imaging Technology Alliance (MITA)
- BRACCO
- iCAD
NCD Request

• Performance in senior patient cohorts
• Extracolonic findings
• Radiation dose

• CTC training
• Cost-effectiveness
• Increase in screening rates
3 Process Measures:
• bowel cleansing and distention
• technical adequacy screening CTC
• technical adequacy diagnostic CTC

3 Outcomes Measures:
• perforation rate
• true positives $\geq 10$ mm
• significant ECF
ACR   CTC Registry Update

• 10,280 exams registered
• 17 active facilities

• Fee waiver for all VA/DOD facilities (fee typically depends on # physicians and # sites, ≥ $500)

• New for 2016: revisit CTC data elements after C-RADS revision, possible electronic upload of data
<table>
<thead>
<tr>
<th>Procedure</th>
<th>Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>CT Colonography</td>
<td>9</td>
</tr>
<tr>
<td>DC Barium Enema</td>
<td>6</td>
</tr>
<tr>
<td>SC Barium Enema</td>
<td>4</td>
</tr>
<tr>
<td>MR Colonography</td>
<td>4</td>
</tr>
</tbody>
</table>

If CTC or DCBE cannot be performed

Scale: 1 (not appropriate) to 9 (more appropriate)
ACR CTC Resources Website

http://www.acr.org/Quality-Safety/Resources/CTC-Resources

- Policies, Statements
- Approp Criteria
- Research
  - ACRIN
  - JACR
- Education
- Practice Guidelines
- Registry
- Pt Information
  - radiologyinfo.org
- Private payer coverage
Summary Points

• CT Colonography is under an umbrella “A” rating by USPSTF
• Request for CMS NCD submitted
• Be aggressive in using your local reimbursement availability – probably better than you think
• Use ACR resources: NRDR, website, Appropriateness Criteria
Thank you

judy.yee@ucsf.edu