College of American Pathologists

Pathology Performance Measures included in CMS 2014 PQRS

Breast Cancer Resection Pathology Reporting
Measure #99 – pT category (primary tumor) and pN category (regional lymph nodes) with histologic grade

Colorectal Cancer Resection Pathology Reporting
Measure #100 – pT category (primary tumor) and pN category (regional lymph nodes) with histologic grade

Barrett's Esophagus
Measure #249 – Esophageal biopsies with a diagnosis of Barrett's esophagus that also include a statement on dysplasia

Radical Prostatectomy Pathology Reporting
 Measure #250– Reports include the pT category, the pN category, the Gleason score and a statement about margin status

Immunohistochemical (IHC) Evaluation of HER2 for Breast Cancer Patients
Measure #251 – Quantitative HER2 evaluation by IHC uses the system recommended by the ASCO/CAP guidelines

Physician Performance Measures (Measures) and related data specifications developed by the College of American Pathologists are intended to facilitate quality improvement activities by physicians.

These Measures are intended to assist physicians in enhancing quality of care. They are designed for use by any physician who manages the care of a patient for a specific condition or for diagnosis or prevention. These Measures are not clinical guidelines and do not establish a standard of medical care. The College has not tested its Measures for all potential applications.

Measures are subject to review and may be revised or rescinded at any time by the College. They may not be altered without the prior written approval of the College of American Pathologists. Measures developed by the College of American Pathologists, while copyrighted, can be reproduced and distributed, without modification, for noncommercial purposes, e.g., use by health care providers in connection with their practices. Commercial use of the Measures is not permitted absent a license agreement between the user and the College of American Pathologists**.** Commercial use is defined as the sale, license, or distribution of the Measures for commercial gain, or incorporation of the Measures into a product or service that is sold, licensed or distributed for commercial gain**.**
The College of American Pathologists is not responsible for any harm to any party resulting from the use of these Measures.

THE MEASURES ARE PROVIDED "AS IS" WITHOUT WARRANTY OF ANY KIND

Limited proprietary coding is contained in the Measure specifications for convenience. Users of the proprietary code sets should obtain all necessary licenses from the owners of these code sets. The College of American Pathologists disclaims all liability for use or accuracy of any Current Procedural Terminology (CPT®) or other coding contained in the specifications.

THE SPECIFICATIONS ARE PROVIDED "AS IS" WITHOUT WARRANTY OF ANY KIND.

Measure #99: Breast Cancer Resection Pathology Reporting
pT category (primary tumor) and pN category (regional lymph nodes) with histologic grade

This measure may be used as an Accountability measure

Measure Description

Clinical Performance Measure
Numerator: Reports that include the pT category, the pN category and the histologic grade **Denominator:** All breast cancer resection pathology reports (excluding biopsies) **Denominator Exclusions:** Documentation of medical reason(s) for not including the pT category, the pN category or the histologic grade (eg; re-excision without residual tumor; non-carcinomas) **Measure:** Percentage of breast cancer resection pathology reports that include the pT category (primary tumor), the pN category (regional lymph nodes) and the histologic grade
The following clinical recommendation statements are quoted <u>verbatim</u> from the referenced clinical guidelines and represent the evidence base for the measure: Patient management and treatment guidelines promote an organized approach to providing quality care. The (American College of Surgeons Commission on Cancer) CoC requires that 90% of pathology reports that include a cancer diagnosis contain the scientifically validated data elements outlined in the surgical case summary checklist of the College of American Pathologists (CAP) publication Reporting on Cancer Specimens[i] . All invasive breast carcinomas, with the exception of medullary carcinoma should be graded. The grading system used must be specified in the report; the Nottingham combined histologic grade (Elston-Ellis modification of Scarff-Bloom-Richardson grading system) is recommended. Within each stage grouping there is a relation between histologic grade and outcome[ii] TNM staging information is included in factors proven to be of prognostic import and useful in clinical patient management.[iii]
Rationale for the measure: Therapeutic decisions for breast cancer management are stage driven and cannot be made without a complete set of pathology descriptors. Incomplete cancer resection pathology reports may result in misclassification of patients, rework and delays, and suboptimal management. The College of American Pathologists (CAP) has produced evidence-based checklists of essential pathologic parameters that are recommended to be included in cancer resection pathology reports. These checklists have been endorsed as a voluntary standard by National Quality Forum (NQF) and are considered the reporting standard by the

Commission on Cancer (CoC) of the American College of Surgeons (ACS).

The CAP recently conducted a structured audit of breast cancer pathology report adequacy at 86 institutions. Overall, 35% of eligible reports were missing at least one of the ten CAP-recommended breast cancer elements. Cancer Care Ontario (CCO) conducted a similar study in 2005 and found that 25% of breast cancer pathology reports did not include all of the information required by the CAP standards.

While the exact percentage of breast cancer resection pathology reports that are missing the pT category, the pN category and the histologic grade is unknown, these are essential elements in breast cancer treatment decisions and should be included in every pathology report when possible.

Data capture and calculations:
Calculation for Performance
For performance purposes, this measure is calculated by creating a fraction with the following components: Numerator, Denominator, and Denominator Exclusions.

Numerator (A) Includes:
- Reports that include the pT category, the pN category and the histologic grade

Denominator (PD) Includes:
- Breast cancer resection pathology reports (excluding biopsies)

Denominator Exclusions (C) Include:
- Documentation of medical reason(s) for not including the pT category, the pN category or the histologic grade

INSTRUCTIONS[1]: This measure is to be reported **each time** a breast cancer resection surgical pathology examination is performed during the reporting period for breast cancer patients. Each unique CPT Category I code submitted on the claim will be counted for denominator inclusion. It is anticipated that **clinicians who examine breast tissue specimens following resection** in a laboratory or institution will submit this measure. Independent laboratories (ILs) and independent diagnostic testing facilities (IDTFs), using indicator Place of Service 81, are **not** included in PQRS. If the specimen is not primary breast tissue (eg, liver, lung), report only CPT II code **3250F**.

Measure Reporting via Claims: ICD-9-CM/ICD-10-CM diagnosis codes and CPT codes are used to identify patients who are included in the measure's denominator. CPT Category II codes are used to report the numerator of the measure.
When reporting the measure via claims, submit the appropriate ICD-9-CM/ICD-10-CM diagnosis codes, CPT codes, and the appropriate CPT Category II code **OR** the CPT Category II code **with** the modifier. The modifiers allowed for this measure are: 1P- medical reasons, 8P- reason not otherwise specified. All measure-specific coding should be reported on the claim(s) representing the eligible encounter.

Measure Reporting via Registry: ICD-9-CM/ICD-10-CM diagnosis codes and CPT codes are used to identify patients who are included in the measure's denominator. The listed numerator options are used to report the numerator of the measure. The quality-data codes listed do not need to be submitted for registry-based submissions; however, these codes may be submitted for those registries that utilize claims data.

---

[1] CMS 2014 PQRS Individual measure claims registry specification supporting documents http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/MeasuresCodes.html

Measure Specifications – *Breast Cancer Resection Pathology Reporting- pT category and pN category with histologic grade*

A. Administrative claims data

Administrative claims data collection requires users to identify the eligible population (denominator) and numerator using codes recorded on claims or billing forms (electronic or paper). Users report a rate based on all patients in a given practice for whom data are available and who meet the eligible population/denominator criteria.

Note: Patients with multiple pathology reports related to the same breast tumor will be counted only once. Pathology reports for the same breast neoplasm addressed in previous pathology reports up to six months following the index resection pathology report will not be included in assessing this clinical performance measure.

(Note: The specifications listed below are those needed for performance calculation.)

Denominator (Eligible Population): All breast cancer resection pathology reports (excluding biopsies)

ICD-9 diagnosis codes: 174.0, 174.1, 174.2, 174.3, 174.4, 174.5, 174.6, 174.7, 174.8, 174.9, 175.0, 175.9

AND

CPT service codes: 88307, 88309

After October 1, 2014

ICD-10 diagnosis codes: C50.011, C50.012, C50.019, C50.021, C50.022, C50.029, C50.111, C50.112, C50.119, C50.121, C50.122, C50.129, C50.211, C50.212, C50.219, C50.221, C50.222, C50.229, C50.311, C50.312, C50.319, C50.321, C50.322, C50.329, C50.411, C50.412, C50.419, C50.421, C50.422, C50.429, C50.511, C50.512, C50.519, C50.521, C50.522, C50.529, C50.611, C50.612, C50.619, C50.621, C50.622, C50.629, C50.811, C50.812, C50.819, C50.821, C50.822, C50.829, C50.911, C50.912, C50.919, C50.921, C50.922, C50.929

AND

CPT service codes: 88307, 88309

Denominator Exclusion: Documentation of medical reason(s) for not including the pT category, the pN category or the histologic grade (eg; re-excision without residual tumor; non-carcinomas)

- **Append modifier to CPT Category II code** (in development): **3260F-1P**

Numerator: Reports that include the pT category, the pN category and the histologic grade

- **Report the CPT Category II code** (in development) **designated for this numerator:**

5

3260F – pT (primary tumor), pN (regional lymph node), and histologic grade documented in pathology report

- o Use the -8P modifier when pT (primary tumor), pN (regional lymph node), and histologic grade **not** documented in pathology report; reason not otherwise specified

Or

3250F – Specimen site other than anatomic location of primary tumor

**Measure #100: Colorectal Cancer Resection Pathology Reporting
pT category (primary tumor) and pN category (regional lymph nodes) with histologic grade**

This measure may be used as an Accountability measure

Measure Description

Clinical Performance Measure
Numerator: Reports that include the pT category, the pN category and the histologic grade
Denominator: All colon and rectum cancer resection pathology reports
Denominator Exclusions: Documentation of medical reason(s) for not including the pT category, the pN category or the histologic grade (eg; non-carcinomas; anal canal)
Measure: Percentage of colon and rectum cancer resection pathology reports that include the pT category (primary tumor), the pN category (regional lymph nodes) and the histologic grade

The following clinical recommendation statements are quoted <u>verbatim</u> from the referenced clinical guidelines and represent the evidence base for the measure:

Patient management and treatment guidelines promote an organized approach to providing quality care. The (American College of Surgeons Committee on Cancer) CoC requires that 90% of pathology reports that include a cancer diagnosis contain the scientifically validated data elements outlined in the surgical case summary checklist of the College of American Pathologists (CAP) publication Reporting on Cancer Specimens.[i]

Surgical resection is the primary therapy for most colorectal carcinomas, and the most important prognostic indicators are related to the pathologic findings in the resection specimen. The anatomic extent of disease is by far the most important prognostic factor in colorectal cancer. Pathologic staging depends on pathologic documentation of the anatomic extent of disease, whether or not the primary tumor has been completely removed. If a biopsied tumor is not resected for any reason (eg, when technically unfeasible) and if the highest T and N categories or the M1 category of the tumor can be confirmed microscopically, the criteria for pathologic classification and staging have been satisfied without total removal of the primary cancer.[iv]

Rationale for the measure:

Therapeutic decisions for colorectal cancer management are stage driven and cannot be made without a complete set of pathology descriptors. Incomplete cancer resection pathology reports may result in misclassification of patients, rework and delays, and suboptimal management. The College of American Pathologists (CAP) has produced evidence-based checklists of essential pathologic parameters that are recommended to be included in cancer resection pathology reports. These checklists have been endorsed as a voluntary standard by National Quality Forum (NQF) and are considered the reporting standard by the Commission on Cancer (CoC) of the American College of Surgeons (ACS).

The CAP recently conducted a structured audit of colorectal cancer pathology report adequacy at 86

institutions. Overall, 34% of eligible reports were missing at least one of the ten CAP-recommended colorectal cancer elements. Cancer Care Ontario (CCO) conducted a similar study in 2005 and found that 31% of colorectal cancer pathology reports did not include all of the information required by the CAP standards.

While the exact percentage of colorectal cancer resection pathology reports that are missing the pT category, the pN category and the histologic grade is unknown, these are essential elements in colorectal cancer treatment decisions and should be included in every pathology report when possible.

Data capture and calculations:
Calculation for Performance
For performance purposes, this measure is calculated by creating a fraction with the following components: Numerator and Denominator.

Numerator (A) Includes:
- Reports that include the pT category, the pN category and the histologic grade

Denominator (PD) Includes:
- Colon and rectum cancer resection pathology reports (excluding biopsies)

Denominator Exclusions (C) Include:
- Documentation of medical reason(s) for not including the pT category, the pN category or the histologic grade

---

INSTRUCTIONS[2]: This measure is to be reported **each time** a colorectal cancer resection surgical pathology examination is performed during the reporting period for colorectal cancer patients. Each unique CPT Category I code submitted on the claim will be counted for denominator inclusion. It is anticipated that **clinicians who examine colorectal tissue specimens following resection** in a laboratory or institution will submit this measure. Independent Laboratories (ILs) and Independent Diagnostic Testing Facilities (IDTFs), using indicator Place of Service 81, are not included in PQRS. If the specimen is not primary colorectal tissue (eg, liver, lung), report only **G8723**.

Measure Reporting via Claims: ICD-9-CM/ICD-10-CM diagnosis codes and CPT codes are used to identify patients who are included in the measure's denominator. Quality-data codes are used to report the numerator of the measure.
When reporting the measure via claims, submit the appropriate ICD-9-CM/ICD-10-CM diagnosis codes, CPT codes, and the appropriate quality-data code. All measure-specific coding should be reported on the claim(s) representing the eligible encounter.

Measure Reporting via Registry: ICD-9-CM/ICD-10-CM diagnosis codes and CPT codes are used to identify patients who are included in the measure's denominator. The listed numerator options are used to report the numerator of the measure.

The quality-data codes listed do not need to be submitted for registry-based submissions; however, these codes may be submitted for those registries that utilize claims data.

---

[2] CMS 2014 PQRS Individual measure claims registry specification supporting documents http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/MeasuresCodes.html

Measure Specifications – *Measure #2: Colorectal Cancer Resection Pathology Reporting- pT category and pN category with histologic grade*

A. Administrative claims data

Administrative claims data collection requires users to identify the eligible population (denominator) and numerator using codes recorded on claims or billing forms (electronic or paper). Users report a rate based on all patients in a given practice for whom data are available and who meet the eligible population/denominator criteria.

(Note: The specifications listed below are those needed for <u>performance calculation</u>.)

<u>Denominator (Eligible Population)</u>: All colon and rectum cancer resection pathology reports (excluding biopsies)

ICD-9 diagnosis codes: 153.0, 153.1, 153.2, 153.3, 153.4, 153.5, 153.6, 153.7, 153.8, 153.9, 154.0, 154.1, 154.8

AND

CPT service code: 88309

After October 1, 2014

ICD-10 diagnosis codes: C18.0, C18.1, C18.2, C18.3, C18.4, C18.5, C18.6, C18.7, C18.8, C18.9, C19, C20, C21.2, C21.8

AND

CPT service code: 88309

<u>Denominator Exclusion:</u> Documentation of medical reason(s) for not including the pT category, the pN category or the histologic grade (eg; non-carcinomas; anal canal)

- **Use G code**: **G8722**

<u>Numerator</u>: Reports that include the pT category, the pN category and the histologic grade

- **Report the G code designated for this numerator:**

G8721 – pT (primary tumor), pN (regional lymph node), and histologic grade documented in pathology report

Or

G8723 – Specimen site other than anatomic location of primary tumor

Or

G8724 – pT (primary tumor), pN (regional lymph node), and histologic grade **not** documented in pathology report; reason not specified

Measure #249 Esophageal biopsies with a diagnosis of Barrett's esophagus that also include a statement on dysplasia

This measure may be used as an Accountability measure

<u>Measure Description:</u> This is a physician-specific measure based on esophageal biopsies with a diagnosis of Barrett's esophagus that also include a statement about dysplasia

Clinical Performance Measure
<u>**Numerator:**</u> Esophageal biopsy reports with the histologic finding of Barrett's mucosa that contain a statement about dysplasia (present, absent, or indefinite.) <u>**Denominator:**</u> All esophageal biopsy reports that document the presence of Barrett's mucosa. <u>**Denominator Exclusions:**</u> Esophageal biopsy reports with malignant neoplasms; documentation of medical reason for not reporting the histologic finding of Barrett's mucosa, e.g. absences of metaplasia (and therefore not commenting on dysplasia). **Measure:** Percentage of patients with esophageal biopsy reports for Barrett's esophagus that contain a statement about dysplasia.
The following clinical recommendation statements are quoted <u>verbatim</u> from the referenced clinical guidelines and represent the evidence base for the measure: The diagnosis of Barrett's esophagus requires systematic biopsy of the abnormal-appearing esophageal mucosa to document intestinal metaplasia and to detect dysplasia.[3,4]
Rationale for the measure: Endoscopy is the technique of choice used to identify suspected Barrett's esophagus and to diagnose complications of GERD.   Biopsy must be added to confirm the presence of Barrett's epithelium and to evaluate for dysplasia (PQRI measure #62, ACG, 2005).[5]

---

[3] Sampliner RE and the practice parameters committee of the American College of Gastroenterology. Updated practice guidelines on the diagnosis, surveillance and therapy of Barrett's esophagus. Amer J Gastroentrol 97:1888-1895, 2002
[4] Wang, K.K. and Sampliner, RE. Updated Guidelines 2008 for the Diagnosis, Surveillanceand Therapy of Barrett's Esophagus, Am J Gastroenterol 2008;103:788–797
[5] Ibid.

11

There is a rapidly rising incidence of adenocarcinoma of the esophagus in the United States. A diagnosis of Barrett's esophagus increases a patient's risk for esophageal adenocarcinoma by 30 to 125 times that of people without Barrett's esophagus (although this risk is still small 0.4% to 0.5% per year). Esophageal adenocarcinoma is often not curable, partly because the disease is frequently discovered at a late stage and because treatments are not effective.[6] A diagnosis of Barrett's esophagus could allow for appropriate screening of at risk patients as recommended by the American College of Gastroenterology[7].

Standard endoscopy with biopsy currently is the most reliable means of establishing a diagnosis of Barrett's esophagus.[8] The definitive diagnosis of Barrett's esophagus requires a pathologist's review of an esophageal biopsy. Dysplasia is the first step in the neoplastic process, and information about dysplasia is crucial for clinical decision-making directing therapy.[9] The presence and grade of dysplasia cannot be determined by routine endoscopy[10], and pathologist' review of a biopsy is essential for recognition of dysplasia.[11] Endoscopic surveillance detects curable neoplasia in patients with Barrett's esophagus.[12]

Data capture and calculations:

Calculation for Performance
For performance purposes, this measure is calculated by creating a fraction with the following components: Numerator, Denominator, and Denominator Exclusions.

Numerator (A) Includes:
- Esophageal biopsy reports with the histologic finding of Barrett's mucosa that contain a statement about dysplasia (present, absent or indefinite)

Denominator (PD) Includes:
- All esophageal biopsy reports that document the presence of Barrett's mucosa.

Denominator Exclusions (C) Include: Esophageal biopsy reports with malignant neoplasms; esophageal biopsy reports noting absence of intestinal metaplasia - documentation of medical reason for not reporting the histologic finding of Barrett's mucosa, e.g. absences of metaplasia (and therefore not commenting on dysplasia).

---

[6] Barrett's Esophagus, National Digestive Diseases Information Clearinghouse, HHS www.digestive.niddk.nih.gov

[7] Sampliner RE and the practice parameters committee of the American College of Gastroenterology. Updated practice guidelines on the diagnosis, surveillance and therapy of Barrett's esophagus. Amer J Gastroentrol 97:1888-1895, 2002.

[8] Sharma, P. et al., A Critical Review of the Diagnosis and Mangement of Barrett's Esophagus: The AGA Chicago Workshop. GasteroEnterology 2004;127:310-330.

[9] CAP 06 AP118 The Nuance of Inflammation in the Gastrointestinal Tract: How to Become Your Gastroenterologist's Best Friend, Robert E Petras, MD, FCAP, FACG
http://www.cap.org/apps/docs/annual_meeting/cap_06/course_materials/inflammation_in_the_gastrointestinal_tract.pdf

[10] Sharma, P. et al., A Critical Review of the Diagnosis and Mangement of Barrett's Esophagus: The AGA Chicago Workshop. GasteroEnterology 2004;127:310-330.

[11] Sampliner RE and the practice parameters committee of the American College of Gastroenterology. Updated practice guidelines on the diagnosis, surveillance and therapy of Barrett's esophagus. Amer J Gastroentrol 97:1888-1895, 2002.

[12] Sharma, P. et al., A Critical Review of the Diagnosis and Mangement of Barrett's Esophagus: The AGA Chicago Workshop. GasteroEnterology 2004;127:310-330.

INSTRUCTIONS[13]:

This measure is to be reported **each time** a patient's surgical pathology report demonstrates Barrett's Esophagus; however, only one QDC per date of service for a patient is required. This measure may be reported by eligible professionals who perform the quality actions described in the measure based on the services provided and the measure-specific denominator coding.

Measure Reporting via Claims:

ICD-9-CM/ICD-10-CM diagnosis codes, CPT codes, and patient demographics are used to identify patients who are included in the measure's denominator. CPT Category II codes or quality-data codes are used to report the numerator of the measure.

When reporting the measure via claims, submit the listed ICD-9-CM/ ICD-10-CM diagnosis codes, CPT codes, and the appropriate CPT Category II code **OR** quality-data code **OR** the CPT Category II code **with** the modifier. The modifiers allowed for this measure are: 1P- medical reasons, 8P- reason not otherwise specified. All measure-specific coding should be reported on the claim(s) representing the eligible encounter.

Measure Reporting via Registry:

ICD-9-CM/ICD-10-CM diagnosis codes, CPT codes, and patient demographics are used to identify patients who are included in the measure's denominator. The listed numerator options are used to report the numerator of the measure.

The quality-data codes listed do not need to be submitted for registry-based submissions; however, these codes may be submitted for those registries that utilize claims data.

---

[13] CMS 2014 PQRS Individual measure claims registry specification supporting documents
http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/MeasuresCodes.html

Measure Specifications – *Measure #1: Esophageal biopsies with a diagnosis of Barrett's Esophagus that also include a statement about dysplasia*

B. Administrative claims data

Administrative claims data collection requires users to identify the eligible population (denominator) and numerator using codes recorded on claims or billing forms (electronic or paper). Users report a rate based on all patients in a given practice for whom data are available and who meet the eligible population/denominator criteria.

(Note: The specifications listed below are those needed for <u>performance calculation</u>.)

Denominator (Eligible Population): All esophageal biopsy reports that document the presence of Barrett's mucosa.

- ➤ **CPT codes:**
  - CPT code – 88305 *Level IV – Surgical pathology, gross and microscopic examination*

  AND

- ➤ **ICD-9 codes:**
  - 530.85 *Barrett's esophagus*

After October 1, 2014

- ➤ **CPT codes:**
  - CPT code – 88305 *Level IV – Surgical pathology, gross and microscopic examination*

  AND

- ➤ **ICD-10 codes:**
  - K22.70, K22.710, K22.711, K22.719

Denominator Exclusion: Documentation of medical reason for not reporting the histologic finding of Barrett's mucosa (eg, malignant neoplasm or absence of intestinal metaplasia). [For patient with appropriate exclusion criteria, report 3125F with modifier 1P]

Numerator: Esophageal biopsy reports with the histologic finding of Barrett's mucosa that contain a statement about dysplasia (present, absent, or indefinite.)

- **3125F** Esophageal biopsy report with a statement about dysplasia (present, absent, or indefinite)
    - o Use the -8P modifier when the pathology report does <u>not </u>include a statement about dysplasia (present, absent, or indefinite)

Revised February 17, 2014

o Use the -1P modifier when the pathology report documents medical reason(s) for not reporting the histological finding of Barrett's mucosa (eg, malignant neoplasm or absence of intestinal metaplasia)

Or

- **G8797** – Specimen site other than anatomic location of esophagus

Performance Measure: 3125F
                                     CPT codes 88305 and ICD-9 codes 530.85

Radical Prostatectomy

Measure #250 – the pT category, the pN category, Gleason score and a statement about margin status

This measure may be used as an Accountability measure

Measure Description: This is a measure based on whether radical prostatectomy pathology report includes the pT category, the pN category, the Gleason score and a statement about margin status.

Clinical Performance Measure
Numerator: Radical prostatectomy pathology reports that include the pT category, the pN category, the Gleason score and a statement about margin status **Denominator:** All radical prostatectomy pathology reports **Denominator Exclusions:** Documentation of medical reason for exclusion (e.g. specimen originated from other malignant neoplasms, secondary site prostatic carcinomas, and transurethral resections of the prostate (TURP)   **Measure:** Percentage of radical prostatectomy pathology reports that include the pT category, the pN category, the Gleason score and a statement about margin status.
The following clinical recommendation statements are quoted <u>verbatim</u> from the referenced clinical guidelines and represent the evidence base for the measure: Patient management and treatment guidelines promote an organized approach to providing quality care. The (American College of Surgeons Committee on Cancer) CoC requires that 90% of pathology reports that include a cancer diagnosis contain the scientifically validated data elements outlined in the surgical case summary checklist of the College of American Pathologists (CAP) publication *Reporting on Cancer Specimens*.[14] The College regards the reporting elements in the "Surgical Pathology Cancer Case Summary (Checklist)" portion of the protocols as essential elements of the pathology report. However, the manner in which these elements are reported is at the discretion of each specific pathologist, taking into account clinician preferences, institutional policies, and individual practice.[15]

---

[14] American College of Surgeons Commission on Cancer. *Cancer Program Standards 2004 Revised Edition*. Available at: http://www.facs.org/cancer/coc/cocprogramstandards.pdf. Accessed August 29, 2006

[15] Prostate gland, Protocol applies to invasive carcinomas of the prostate gland. College of American Pathologists. Revised January 2005. Available at: http://www.cap.org/apps/docs/cancer_protocols/2006/prostate06_pw.doc Accessed April 6, 2007.

Pathologic staging is usually performed after surgical resection of the primary tumor. Pathologic staging depends on pathologic documentation of the anatomic extent of disease, whether or not the primary tumor has been completely removed.[16]

Rationale for the measure:

Therapeutic decisions for prostate cancer management are stage driven and cannot be made without a complete set of pathology descriptors. Incomplete pathology reports for prostate cancer may result in misclassification of patients, rework and delays, and suboptimal management. The College of American Pathologists Cancer Committee has produced an evidence-based protocol/checklist of essential pathologic parameters that are recommended to be included in prostate cancer resection pathology reports. Conformance of pathology reports with the CAP checklist is a requirement for Cancer Center certification by the ACS.

The protocol recommends the use of the TNM Staging System for carcinoma of the prostate of the American Joint Committee on Cancer (AJCC) and the International Union Against Cancer (UICC).[17] [18] The radical prostatectomy checklist also includes extraprostatic extension.[19]

In a study of cancer recurrence following radical prostatectomy, it was noted that "The relatively high proportion of patients who have biopsy-proven local recurrence who have organ-confined disease is probably inaccurate and, in large part, reflects undersampling and underrecognition of extraprostatic extension."[20]

The CAP Q probes data (2006) indicates that 11.6% of prostate pathology reports had missing elements. Extent of invasion (pTNM) was most frequently missing (52.1% of the reports missing elements), and extraprostatic extension was the second most frequently missing (41.7% of the reports missing elements). Margin status was missing in 8.3% of reports.

A sampling from prostate cancer cases in 2000 through 2001[21] from the College of Surgeons National Cancer Data Base found only 48.2% of surgical pathology reports for prostate cancer documented pathologic stage similar to the more recent data from the CAP Q probes study. The NCDB data showed the Gleason score was present 86.3% of the time, slightly less than the 100% compliance found in the CAP Q probes study and that margin status was present in 84.9% of reports.

Data capture and calculations:

---

[16] Ibid.

[17] Greene FL, Page DL, Fleming ID, et al, eds. *AJCC Cancer Staging Manual.* 6th ed. New York: Springer; 2002.

[18] Sobin LH, Wittekind C. *UICC TNM Classification of Malignant Tumours.* 6th ed. New York: Wiley-Liss; 2002.

[19] Prostate gland, Protocol applies to invasive carcinomas of the prostate gland. College of American Pathologists. Revised January 2005. Available at: http://www.cap.org/apps/docs/cancer_protocols/2006/prostate06_pw.doc Accessed April 6, 2007.

[20] Ripple, M., et al., Needle biopsy of recurrent adenocarcinoma of the prostate after radical prostatectomy. Mod Pathol 2000;13(5):521–527

[21] Spencer, BA, et al. Variations in Quality of Care for Men with Early-Stage Prostate Cancer. J Clin Onclol 26:3735-3742.

Calculation for Performance

For performance purposes, this measure is calculated by creating a fraction with the following components: Numerator, Denominator, and Denominator Exclusions.

Numerator (A) Includes:
- Radical prostatectomy pathology reports that include the pT category, the pN category, the Gleason score and a statement about margin status.

Denominator (PD) Includes:
- All radical prostatectomy pathology reports

Denominator Exclusions (C) Include:
- Documentation of medical reason for exclusion (e.g. specimen originated from other malignant neoplasms, secondary site prostatic carcinomas, and transurethral resections of the prostate (TURP)

INSTRUCTIONS[22]:

This measure is to be reported **each time** a radical prostatectomy surgical pathology examination is performed during the reporting period for prostate patients. Each unique CPT Category I code or quality-data code submitted on the claim will be counted for denominator inclusion. It is anticipated that **clinicians who examine prostate tissue specimens following resection** in a laboratory or institution will submit this measure. Independent Laboratories (ILs) and Independent Diagnostic Testing Facilities (IDTFs), using indicator Place of Service 81, are not included in PQRS. If the specimen is not primary prostate tissue (e.g., breast, lung), report only **G8798**.

Measure Reporting via Claims:

ICD-9-CM/ICD-10-CM diagnosis codes, CPT codes, and patient demographics are used to identify patients who are included in the measure's denominator. CPT Category II codes or quality-data codes are used to report the numerator of the measure.

When reporting the measure via claims, submit the listed ICD-9-CM /ICD-10-CM diagnosis codes, CPT codes, and the appropriate CPT Category II code **OR** quality-data codes **OR** the CPT Category II code **with** the modifier. The modifiers allowed for this measure are: 1P- medical reasons, 8P- reason not otherwise specified. All measure-specific coding should be reported on the claim(s) representing the eligible encounter.

Measure Reporting via Registry:

ICD-9-CM/ICD-10-CM diagnosis codes, CPT codes, and patient demographics are used to identify patients who are included in the measure's denominator. The listed numerator options are used to report the numerator of the measure.

---

[22] CMS 2014 PQRS Individual measure claims registry specification supporting documents
http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/MeasuresCodes.html

The quality-data codes listed do not need to be submitted for registry-based submissions; however, these codes may be submitted for those registries that utilize claims data.

Measure Specifications – *Measure #250: Pathology Report content for Radical Prostatectomy*

C. Administrative claims data

Administrative claims data collection requires users to identify the eligible population (denominator) and numerator using codes recorded on claims or billing forms (electronic or paper). Users report a rate based on all patients in a given practice for whom data are available and who meet the eligible population/denominator criteria.

(Note: The specifications listed below are those needed for <u>performance calculation</u>.)

Denominator (Eligible Population): All radical prostatectomy pathology reports

➢ **CPT code:**

- 88309 - *Level VI - Surgical pathology, gross and microscopic examination*
AND

➢ **ICD-9 code:**

- 185 – *malignant neoplasm of prostate*

After October 1, 2014:

➢ **CPT code:**

- 88309 - *Level VI - Surgical pathology, gross and microscopic examination*
AND

➢ **ICD-10 code:**

- C61

Denominator Exclusion: Documentation of medical reason for exclusion (e.g. specimen originated from other malignant neoplasms, secondary site prostatic carcinomas, or transurethral resections of the prostate (TURP) [For patient with appropriate exclusion criteria, report 3267F with modifier 1P.]

Numerator: Radical prostatectomy pathology reports that include the pT category, the pN category, Gleason score and a statement about margin status

➢ Report the following CPT Category II code to confirm the inclusion of the designated elements in a radical prostatectomy pathology report:

- **3267F** –pathology report includes pT category, pN category, Gleason score and statement

about margin status
- o Use the -8P modifier when the pathology report does <u>not</u> include pT category, pN category, Gleason score and statement about margin status
- o Use the -1P modifier to Category II code **3267F** to report documented circumstances that appropriately exclude patients from the denominator.

Or

- • **G8798** – Specimen site other than anatomic location of prostate

Performance Measure: 3267F
Claims using CPT code 88309 and ICD-9 code 185

Immunohistochemical (IHC) Evaluation for Breast Cancer Patients

Measure #251 – quantitative HER2 evaluation by IHC uses the system recommended by the ASCO/CAP guidelines

This measure may be used as an Accountability measure

Measure Description: This is a measure based on whether quantitative evaluation of HER2 by immunohistochemistry (IHC) uses the system recommended in the ASCO/CAP Guidelines for Human Epidermal Growth Factor Receptor 2 Testing in breast cancer

Clinical Performance Measure
Numerator: Breast cancer patients receiving quantitative breast tumor HER2 IHC evaluation using the ASCO/CAP recommended manual system or a computer-assisted system consistent with the optimal algorithm for HER2 testing as described in the ASCO/CAP guideline[23]*
Denominator: All breast cancer patients with quantitative breast tumor evaluation by HER2 IHC [defined by CPT codes *88360-quantitative tumor immunohistochemistry, manual; 88361-quantitative tumor immunohistochemistry, computer-assisted* plus ICD-9 codes for breast cancer]
Denominator Exclusions: None
Measure: Percentage of patients with quantitative breast tumor HER2 IHC evaluation using the ASCO/CAP recommended manual system or a computer-assisted system consistent with the optimal algorithm for HER2

---

[23] Wolff, A.C., et al. American Society of Clinical Oncology/College of American Pathologists Guideline Recommendations for Human Epidermal Growth Factor Receptor 2 Testing in Breast Cancer. *Arch Pathol Lab Med*. 2007;131:18-43

- **Positive HER2 test. (p.25)**
  Based on a literature review of clinical trials, international studies and protocols, expert consensus, and US Food and Drug Administration Panel findings, a positive HER2 test is defined as either IHC result of 3+ cell surface protein expression (defined as uniform intense membrane staining of > 30% of invasive tumor cells)
- **Equivocal HER2 test. (p.26)**
  The equivocal range for IHC consists of samples scored 2+, and this may include up to 15% of samples. An equivocal result (2+) is complete membrane staining that is either non-uniform or weak in intensity but with obvious circumferential distribution in at least 10% of cells. Very rarely, in the experience of panel members, invasive tumors can show intense, complete membrane staining of 30% or fewer tumor cells. These are also considered to be equivocal in this guideline.
- **Negative HER2 test. (p.27)**
  A negative HER2 test is defined as either an IHC result of 0 or 1+ for cellular membrane protein expression (no staining or weak, incomplete membrane staining in any proportion of tumor cells),....

testing as described in the ASCO/CAP guidelines

The following clinical recommendation statements are quoted <u>verbatim</u> from the referenced clinical guidelines and represent the evidence base for the measure:

"Positive HER2 test. – Based on a literature review of clinical trials, international studies and protocols, expert consensus, and US Food and Drug Administration Panel findings, a positive HER2 test is defined as either … uniform intense membrane staining of >30% of invasive tumor cells… or FISH result of amplified *HER2* gene copy number (average of > six gene copies/nucleus for test systems without internal control probe) or *HER2*/CEP 17 ratio of more than 2.2, where CEP 17 is a centromeric probe for chromosome 17 on which the *HER2* gene resides. The 30% [criterion] for a positive IHC is further discussed in Appendix G."[24]

From Appendix G:
"For IHC assays of HER2 protein expression, the original US Food and Drug Administration-approved interpretation guidelines provide insufficient specificity. Several experts, including those serving as central reviewers on clinical trials, have specified that a threshold of more than 30% of tumor (rather than the originally specified 10%) should show strong circumferential membrane staining for a positive result. This means that according to this guideline, strong circumferential staining of 30% or less of cells would be considered equivocal and be subjected to confirmatory FISH testing."[25]

Rationale for the measure:

Through a cooperative effort with the American Society of Clinical Oncologists (ASCO) and the CAP, new guidelines for Human Epidermal Growth Factor 2 testing in breast cancer were published in January 2007.

The ASCO/CAP Guideline recommendations for quantitative HER2 IHC evaluation were designed to enhance concordance with FISH assays for HER2 Amplified and Non-amplified tumor status. The recommendations are different from those provided by HER2 antibody manufacturers and compliance is likely to considerably less than 100%. Implementation of Guideline scoring would promote uniformity and quality among interpreting pathologists.

Data capture and calculations:

<u>**Calculation for Performance**</u>
For performance purposes, this measure is calculated by creating a fraction with the following components: Numerator, Denominator, and Denominator Exclusions.

---

[24] Wolff, A.C., et al. American Society of Clinical Oncology/College of American Pathologists Guideline Recommendations for Human Epidermal Growth Factor Receptor 2 Testing in Breast Cancer. *Arch Pathol Lab Med*. 2007;131:18-43
[25] Ibid.

Numerator (A) Includes:

Breast cancer patients receiving quantitative breast tumor HER2 IHC evaluation using the ASCO/CAP recommended manual system or a computer-assisted system consistent with the optimal algorithm for HER2 testing as described in the ASCO/CAP guideline

Denominator (PD) Includes:
All breast cancer patients with quantitative breast tumor evaluation by HER2 IHC

Denominator Exclusions (C) Include:
- None

INSTRUCTIONS[26]: This measure should be reported **each time** a quantitative HER2 IHC pathology examination is performed during the reporting period for patients with breast cancer; however, **only one QDC per date of service** for a patient is required. This measure may be reported by clinicians who perform the quality actions described in the measure based on the services provided and the measure-specific denominator coding.

Measure Reporting via Claims:
ICD-9-CM/ICD-10-CM diagnosis codes, CPT codes, and patient demographics are used to identify patients who are included in the measure's denominator. CPT Category II codes are used to report the numerator of the measure.

When reporting the measure via claims, submit the listed ICD-9-CM/ICD-10-CM diagnosis codes, CPT codes, and the appropriate CPT Category II code **OR** the CPT Category II code **with** the modifier. The modifiers allowed for this measure is: 8P- reason not otherwise specified. All measure-specific coding should be reported on the claim(s) representing the eligible encounter.

Measure Reporting via Registry:
ICD-9-CM/ICD-10-CM diagnosis codes, CPT codes, and patient demographics are used to identify patients who are included in the measure's denominator. The listed numerator options are used to report the numerator of the measure.

The quality-data codes listed do not need to be submitted for registry-based submissions; however, these codes may be submitted for those registries that utilize claims data.

---

[26] CMS 2014 PQRS Individual measure claims registry specification supporting documents
http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/MeasuresCodes.html

Measure Specifications – *Measure #4:* Quantitative HER2 evaluation by immunohistochemistry (IHC) uses the ASCO/CAP recommended system

---

D. Administrative claims data

Administrative claims data collection requires users to identify the eligible population (denominator) and numerator using codes recorded on claims or billing forms (electronic or paper). Users report a rate based on all patients in a given practice for whom data are available and who meet the eligible population/denominator criteria.

(Note: The specifications listed below are those needed for <u>performance calculation</u>.)

<u>Denominator (Eligible Population):</u> All breast cancer patients with quantitative breast tumor evaluation by HER2 IHC

> **ICD-9 diagnosis codes for breast cancer: 174.0, 174.1, 174.2, 174.3, 174.4, 174.5, 174.6, 174.7, 174.8, 174.9, 175.0, 175.9**

   AND

> **CPT codes: Quantitative IHC Evaluation – 88360 or 88361 (**The CPT descriptor for 88360 and 88361 is, "Morphometric analysis, tumor immunohistochemistry (eg, Her-2/neu, estrogen receptor/progesterone receptor), quantitative or semi-quantitative, each antibody.")

After October 1, 2014:

> **ICD-10 diagnosis codes for breast cancer:** C50.011, C50.012, C50.019, C50.021, C50.022, C50.029, C50.111, C50.112, C50.119, C50.121, C50.122, C50.129, C50.211, C50.212, C50.219, C50.221, C50.222, C50.229, C50.311, C50.312, C50.319, C50.321, C50.322, C50.329, C50.411, C50.412, C50.419, C50.421, C50.422, C50.429, C50.511, C50.512, C50.519, C50.521, C50.522, C50.529, C50.611, C50.612, C50.619, C50.621, C50.622, C50.629, C50.811, C50.812, C50.819, C50.821, C50.822, C50.829, C50.911, C50.912, C50.919, C50.921, C50.922, C50.929

   AND

> **CPT codes: Quantitative IHC Evaluation – 88360 or 88361 (**The CPT descriptor for 88360 and 88361 is, "Morphometric analysis, tumor immunohistochemistry (eg, Her-2/neu, estrogen receptor/progesterone receptor), quantitative or semi-quantitative, each antibody.")

<u>Denominator Exclusion:</u> None. [There are no performance exclusions for theses codes. Do not report modifier 1P, 2P, or 3P with this code.]

Numerator: Breast cancer patients receiving quantitative breast tumor HER2 IHC evaluation using the ASCO/CAP recommended manual system or a computer-assisted system consistent with the optimal algorithm for HER2 testing as described in the ASCO/CAP guideline

> ➢ Report one of the following CPT Category II codes to confirm the use of the recommended scoring system:

- **3394F** –Quantitative HER2 IHC evaluation consistent with scoring system defined in the ASCO/CAP guidelines
  - o Use the -8P modifier when the evaluation was not consistent with scoring system defined in the ASCO/CAP guidelines
- **3395F**– Quantitative non-HER2 IHC evaluation (eg, testing for estrogen or progesterone receptors, [ER/PR]) performed

Performance Measure: 3394F + 3395F
Claims identified by CPT code 88360 or 88361 and breast cancer ICD- 9 codes

---

[i] American College of Surgeons Commission on Cancer. Cancer Program Standards 2004 Revised Edition. Available at: http://www.facs.org/cancer/coc/cocprogramstandards.pdf. Accessed August 29, 3006

[ii] Breast, Protocol applies to all invasive carcinomas of the breast. College of American Pathologists. Revised January 2005. Available at: http://www.cap.org/apps/docs/cancer_protocols/2005/breast05_pw.pdf. Accessed August 29, 2006.

[iii] Fitzgibbons PL, Page DL, Weaver D, et al. Prognostic factors in breast cancer. College of American Pathologists consensus statement 1999. Arch Pathol Lab Med. 2000:124:966-978.

[iv] Colon and Rectum, Protocol applies to all invasive carcinomas of the colon and rectum. College of American Pathologists. Revised January 2005. Available at: http://www.cap.org/apps/docs/cancer_protocols/2005/colonrectum05_pw.pdf. Accessed August 29, 2006.