

Quality ID #146 (NQF 0508): Radiology: Inappropriate Use of “Probably Benign” Assessment Category in Screening Mammograms – National Quality Strategy Domain: Efficiency and Cost Reduction

2018 OPTIONS FOR INDIVIDUAL MEASURES:
REGISTRY ONLY

MEASURE TYPE:
Process

DESCRIPTION:
Percentage of final reports for screening mammograms that are classified as “probably benign”

INSTRUCTIONS:
This measure is to be submitted **each time** a screening mammogram is performed during the performance period. It is anticipated that eligible clinicians who provide the professional component of diagnostic imaging studies for screening mammograms will submit this measure.

Measure Submission:
The listed denominator criteria is used to identify the intended patient population. The numerator options included in this specification are used to submit the quality actions allowed by the measure. The quality-data codes listed do not need to be submitted for registry submissions; however, these codes may be submitted for those registries that utilize claims data.

DENOMINATOR:
All final reports for screening mammograms

***DENOMINATOR NOTE:** *Signifies that this CPT Category I code is a non-covered service under the Medicare Part B Physician Fee Schedule (PFS). These non-covered services should be counted in the denominator population for registry-based measures.*

Denominator Criteria (Eligible Cases):
Diagnosis for screening mammogram (ICD-10-CM): Z12.31
AND
Patient procedure during the performance period (CPT or HCPCS): 77067

NUMERATOR:
Final reports classified as “probably benign”

Numerator Instructions:
INVERSE MEASURE - A lower calculated performance rate for this measure indicates better clinical care or control. The “Performance Not Met” numerator option for this measure is the representation of the better clinical quality or control. Submitting that numerator option will produce a performance rate that trends closer to 0%, as quality increases. For inverse measures, a rate of 100% means all of the denominator eligible patients did not receive the appropriate care or were not in proper control.

A lower percentage, with a definitional target approaching 0%, indicates appropriate assessment of screening mammograms.

The mammogram assessment category (corresponding CPT Category II 33xxF code for assessment categories”) to be submitted is the final assessment for the screening mammographic study. If a diagnostic mammographic study follows the screening exam, the assessment category for the screening exam should be submitted with the corresponding CPT Category II code, i.e. 3340F for Mammogram assessment category of “incomplete: need additional imaging evaluation,” documented. Of note, the performance tags indicating

'Performance Met' and 'Performance Not Met' are included to highlight what is being measured and submitted and not to encourage the use and documentation of "probably benign".

Definition:

"Probably Benign" Classification – Mammography Quality Standards Act (MQSA) assessment category of "probably benign"; Breast Imaging-Reporting and Data System (BI-RADS®) category 3; or Food and Drug Administration (FDA)-approved equivalent assessment category

Numerator Options:

- | | |
|------------------------------------|---|
| <p><i>Performance Met:</i></p> | Mammogram assessment category of "probably benign," documented (3343F) |
| <p>OR</p> | |
| <p><i>Performance Not Met:</i></p> | Mammogram assessment category of "incomplete: need additional imaging evaluation," documented (3340F) |
| <p>OR</p> | |
| <p><i>Performance Not Met:</i></p> | Mammogram assessment category of "negative," Documented (3341F) |
| <p>OR</p> | |
| <p><i>Performance Not Met:</i></p> | Mammogram assessment category of "benign," Documented (3342F) |
| <p>OR</p> | |
| <p><i>Performance Not Met:</i></p> | Mammogram assessment category of "suspicious," Documented (3344F) |
| <p>OR</p> | |
| <p><i>Performance Not Met:</i></p> | Mammogram assessment category "highly suggestive of malignancy," documented (3345F) |
| <p>OR</p> | |
| <p><i>Performance Not Met:</i></p> | Mammogram assessment category of "known biopsy proven malignancy," documented (3350F) |

RATIONALE:

The "probably benign" assessment category is reserved for findings that have a high probability (≥98%) chance of being benign and should not be used as a category for indeterminate findings. Inappropriate designation of findings as "probably benign" can result in unnecessary follow-up of lesions that could have been quickly classified or delayed diagnosis and treatment of cancerous lesions. Published guidance documents emphasize the need to conduct a complete diagnostic imaging evaluation before making a probably benign (Category 3) assessment; making it inadvisable to use the probably benign categorization when interpreting a screening mammogram. Immediate completion of a diagnostic imaging evaluation for abnormal screening mammograms eliminates potential anxiety that women would endure with the short interval follow-up that is recommended for "probably benign" findings.

CLINICAL RECOMMENDATION STATEMENTS:

A category 3, 4, or 5 assessment is not recommended for a screening mammogram, even though in some instances a highly suspicious abnormality may be identified that will warrant a recommendation for biopsy. Rather, all patients with screening abnormalities should be given a BI-RADS® category 0 assessment and recalled for further diagnostic studies. (ACR, 2013)

All the previously cited studies emphasize the need to conduct a complete diagnostic imaging evaluation before making a probably benign (category 3) assessment; hence it is recommended not to render such an assessment in interpreting a screening mammography examination. The practice of rendering category 3 assessments directly from screening examination also has been shown to result in adverse outcomes: 1) unnecessary follow-up of

many lesions that could have been promptly assessed as benign, and 2) delayed diagnosis of a small number of cancers that otherwise may have been smaller in size and less likely to be advanced in stage (ACR, 2013)

The use of assessment category 3, probably benign, has been clarified in the lexicon of the 2013 edition. It is emphasized that this is not an indeterminate category used simply when the radiologist is unsure whether to render a benign (BI-RADS® category 2) or suspicious (BI-RADS® category 4) assessment, but one that is reserved for specific imaging findings known to have a greater than essentially 0% but $\leq 2\%$ likelihood of representing malignancy. (ACR, 2013)

For mammography, there is robust literature describing three findings (noncalcified circumscribed solid mass, focal asymmetry and solitary group of punctate calcifications) that have likelihoods of malignancy in the defined ($\leq 2\%$) probably benign range, for which short interval (6-month) follow-up mammography and then periodic mammographic surveillance represents appropriate management. Use of assessment category 3 for mammographic findings other than these three should be considered only if the radiologist has personal experience to justify a watchful-waiting approach, preferably involving observation of a sufficient number of cases of an additional mammographic finding to suggest a likelihood of malignancy within the defined ($\leq 2\%$) probably-benign range. Two large-scale studies performed in the United States have validated that in the usual-care setting, category 3 assessments indeed are associated with a likelihood of malignancy of $<2\%$. (ACR 2013)

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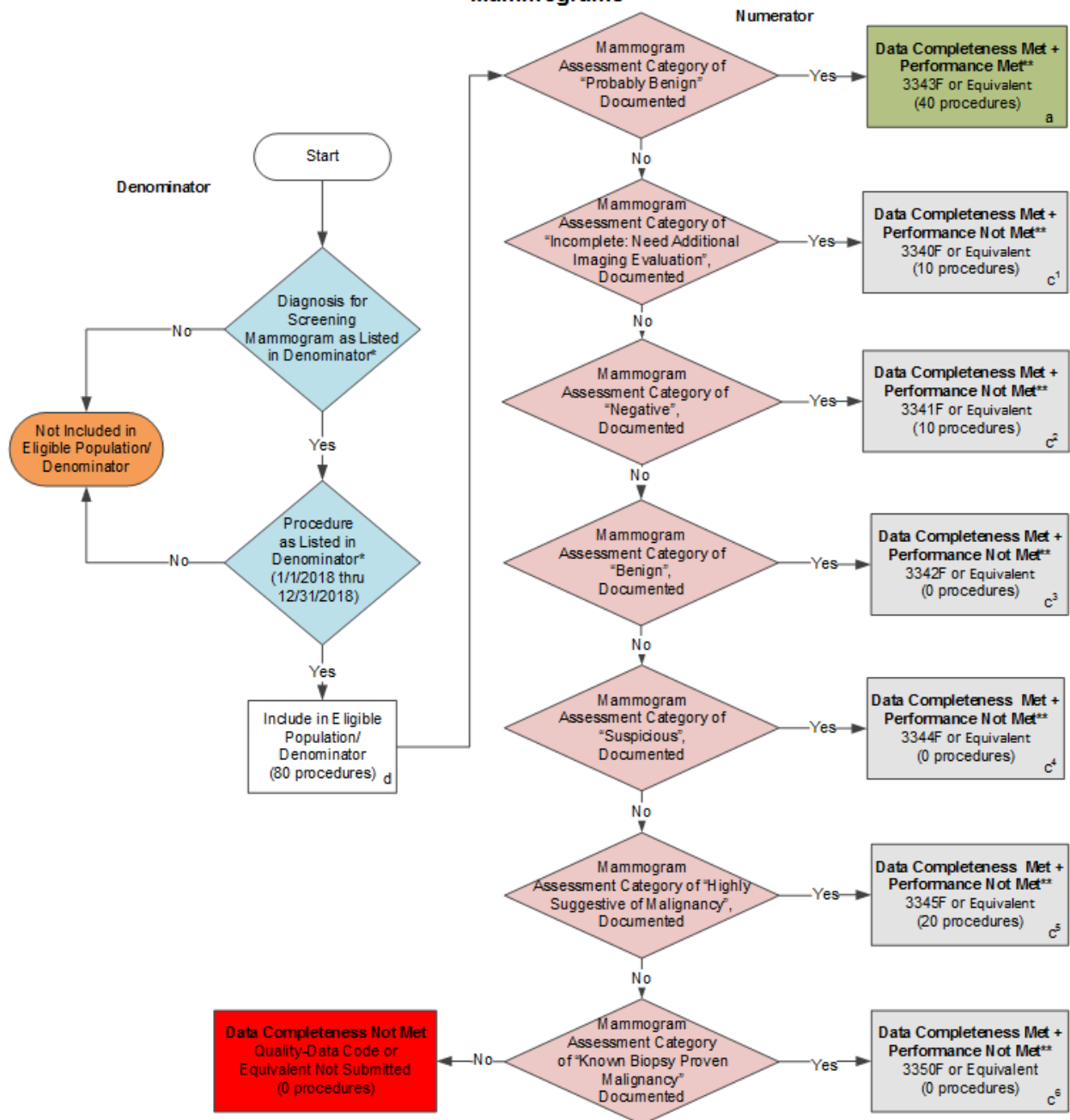
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2018 Registry Flow for Quality Data #146 NQF #0508: Radiology: Inappropriate Use of "Probably Benign" Assessment Category in Screening Mammograms



SAMPLE CALCULATIONS:

Data Completeness=

$$\frac{\text{Performance Met (a=40 procedures)} + \text{Performance Not Met (c}^1\text{+c}^2\text{+c}^3\text{+c}^4\text{+c}^5\text{+c}^6\text{= 40 procedures)}}{\text{Eligible Population / Denominator (d=80 procedures)}} = \frac{80 \text{ procedures}}{80 \text{ procedures}} = 100.00\%$$

Performance Rate=**

$$\frac{\text{Performance Met (a=40 procedures)}}{\text{Data Completeness Numerator (80 procedures)}} = \frac{40 \text{ procedures}}{80 \text{ procedures}} = 50.00\%$$

*See the posted Measure Specifications for specific coding and instructions to submit this measure.
 **A lower calculated performance rate for this measure indicates better clinical care or control.
 NOTE: Submission Frequency- Procedure

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 The measure diagrams were developed by CMS as a supplemental resource to be used in conjunction with the measure specifications. They should not be used alone or as a substitution for the measure specification.

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2018 Registry Flow for Quality ID #146 NQF #0508:

Radiology: Inappropriate Use of "Probably Benign" Assessment Category in Screening Mammograms

Please refer to the specific section of the specification to identify the denominator and numerator information for use in submitting this Individual Specification. This flow is for registry data submission.

1. Start with Denominator
2. Check Patient Diagnosis:
 - a. If Diagnosis for Screening Mammogram as Listed in Denominator equals No, do not include in Eligible Patient Population. Stop Processing.
 - b. If Diagnosis for Screening Mammogram as Listed in Denominator equals Yes, proceed to Check Procedure Performed.
3. Check Procedure Performed:
 - a. If Procedure as Listed in the Denominator equals No, do not include in Eligible Patient Population. Stop Processing.
 - b. If Procedure as Listed in the Denominator equals Yes, include in the Eligible Population.
4. Denominator Population:
 - a. Denominator Population is all Eligible Patients in the denominator. Denominator is represented as Denominator in the Sample Calculation listed at the end of this document. Letter d equals 80 procedures in the Sample Calculation.
5. Start Numerator
6. Check Mammogram Assessment Category of "Probably Benign" Documented:
 - a. If Mammogram Assessment Category of "Probably Benign" Documented equals Yes, include in Data Completeness Met and Performance Met.
 - b. Data Completeness Met and Performance Met letter is represented in the Data Completeness and Performance Rate in the Sample Calculation listed at the end of this document. Letter a equals 40 procedures in the Sample Calculation.
 - c. If Mammogram Assessment Category of "Probably Benign" Documented equals No, proceed to Mammogram Assessment Category of "Incomplete: Need Additional Imaging Evaluation", Documented.
7. Check Mammogram Assessment Category of "Incomplete: Need Additional Imaging Evaluation", Documented:
 - a. If Mammogram Assessment Category of "Incomplete: Need Additional Imaging Evaluation", Documented equals Yes, include in Data Completeness Met and Performance Not Met.
 - b. Data Completeness Met and Performance Not Met letter is represented in the Data Completeness in the Sample Calculation listed at the end of this document. Letter c1 equals 10 procedures in the Sample Calculation.
 - c. If Mammogram Assessment Category of "Incomplete: Need Additional Imaging Evaluation", Documented equals No, proceed to Mammogram Assessment Category of "Negative" Documented.
8. Check Mammogram Assessment Category of "Negative", Documented:

- a. If Mammogram Assessment Category of "Negative" Documented equals Yes, include in Data Completeness Met and Performance Not Met.
 - b. Data Completeness Met and Performance Not Met letter is represented in the Data Completeness in the Sample Calculation listed at the end of this document. Letter c2 equals 10 procedures in the Sample Calculation.
 - c. If Mammogram Assessment Category of "Negative" Documented equals No, proceed to Mammogram Assessment Category of "Benign" Documented.
9. Check Mammogram Assessment Category of "Benign", Documented:
- a. If Mammogram Assessment Category of "Benign" Documented equals Yes, include in Data Completeness Met and Performance Not Met.
 - b. Data Completeness Met and Performance Not Met letter is represented in the Data Completeness in the Sample Calculation listed at the end of this document. Letter c3 equals 0 procedures in the Sample Calculation.
 - c. If Mammogram Assessment Category of "Benign" Documented equals No, proceed to Mammogram Assessment Category of "Suspicious" Documented.
10. Check Mammogram Assessment Category of "Suspicious", Documented:
- a. If Mammogram Assessment Category of "Suspicious" Documented equals Yes, include in Data Completeness Met and Performance Not Met.
 - b. Data Completeness Met and Performance Not Met letter is represented in the Data Completeness in the Sample Calculation listed at the end of this document. Letter c4 equals 0 procedures in the Sample Calculation.
 - c. If Mammogram Assessment Category of "Suspicious" Documented equals No, Proceed to Mammogram Assessment Category of "Highly Suggestive of Malignancy" Documented.
11. Check Mammogram Assessment Category of "Highly Suggestive of Malignancy", Documented:
- a. If Mammogram Assessment Category of "Highly Suggestive of Malignancy" Documented equals Yes, include in Data Completeness Met and Performance Not Met.
 - b. Data Completeness Met and Performance Not Met letter is represented in the Data Completeness in the Sample Calculation listed at the end of this document. Letter c5 equals 20 procedures in the Sample Calculation.
 - c. If Mammogram Assessment Category of "Highly Suggestive of Malignancy" Documented equals No, proceed to Mammogram Assessment Category of "Known Biopsy Proven Malignancy" Documented.
12. Check Mammogram Assessment Category of "Known Biopsy Proven Malignancy", Documented:
- a. If Mammogram Assessment Category of "Known Biopsy Proven Malignancy" Documented equals Yes, include in Data Completeness Met and Performance Not Met.
 - b. Data Completeness Met and Performance Not Met letter is represented in the Data Completeness in the Sample Calculation listed at the end of this document. Letter c6 equals 0 procedures in the Sample Calculation.

- c. If Mammogram Assessment Category of "Known Biopsy Proven Malignancy" Documented equals No, proceed to Data Completeness Not Met.

13. Check Data Completeness Not Met:

- a. If Data Completeness Not Met equals No, Quality Data Code or equivalent not submitted. 0 procedures have been subtracted from the Data Completeness Numerator in the Sample Calculation.

SAMPLE CALCULATIONS:

Data Completeness=

$$\frac{\text{Performance Met (a=40 procedures)} + \text{Performance Not Met (c}^1\text{+c}^2\text{+c}^3\text{+c}^4\text{+c}^5\text{+c}^6\text{ = 40 procedures)}}{\text{Eligible Population / Denominator (d=80 procedures)}} = \frac{80 \text{ procedures}}{80 \text{ procedures}} = 100.00\%$$

Performance Rate=**

$$\frac{\text{Performance Met (a=40 procedures)}}{\text{Data Completeness Numerator (80 procedures)}} = \frac{40 \text{ procedures}}{80 \text{ procedures}} = 50.00\%$$