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Quality ID #QMM17: Appropriate Follow-up Recommendations for Ovarian-Adnexal Lesions using the Ovarian-Adnexal Reporting and Data System (O-RADS)
- National Quality Strategy Domain: Effective Clinical Care
- Meaningful Measure Area: Appropriate Use of Healthcare

2021 COLLECTION TYPE:
MIPS CLINICAL QUALITY MEASURES (CQMS)

MEASURE TYPE:
Process – High Priority

DESCRIPTION:
The percentage of final reports for female patients receiving a transvaginal ultrasound (US) examination of the pelvis (including transabdominal/transvaginal exams) where a clinically relevant lesion is detected, in which the radiologist describes the lesion using O-RADS Lexicon Descriptors and subsequently makes the correct clinical management recommendation based on the O-RADS Risk Stratification and Management System.

INSTRUCTIONS:
This measure is to be submitted **each time** during the reporting period a female pelvic ultrasound reports a finding that qualifies for description and management under the O-RADS criteria. Measure performance focuses on the radiologist's inclusion in the report of appropriate use of O-RADS descriptors and a subsequent O-RADS appropriate recommendation for the treating clinician to assist in overall risk stratification and management.

Measure Submission Type:
The listed denominator criteria are used to identify the intended patient population. The numerator options included in this specification are used to submit the quality actions as allowed by the measure.

DENOMINATOR:
All final reports for US examination of the female pelvis performed transvaginal with/without a transabdominal portion that have a clinically relevant lesion.

Denominator Criteria (eligible cases):
All patients, regardless of age
Patient procedure during the performance period (CPT):
Pelvis: 76830
AND
ICD-10 code(s): N83.0, N83.01, N83.02, N83.201, N83.202, N83.209, N83.291, N83.292, N83.299, N83.2, N83.8, N88.8, C56, C79, D27, D27.1, D27.9, C56, R18.0, R18.8, R59.0, 620, 614

DENOMINATOR EXCLUSIONS: None

NUMERATOR:
Documented identification of clinically relevant lesion using appropriate O-RADS terminology AND subsequent recommendation of clinical management according to O-RADS criteria.

NUMERATOR NOTE: When referencing the O-RADS criteria, the radiologist ***must*** include O-RADS score, appropriate lexicon descriptors, and appropriate premenopausal or postmenopausal management for the patient. If a patient's recommendation is "N/A" or "None" according to the O-RADS criteria, the radiologist should state "No imaging follow-up required" in the final report. Reference to O-RADS criteria while describing lesion and making recommendations would also suffice.

Numerator Options:
Performance Met:
PM017: Clinically relevant lesion identified using O-RADS terminology AND appropriate O-RADS management recommendation made in the Final Report

OR

Performance Not Met:
PNM17: Clinically relevant lesion identified but O-RADS terminology not used OR O-RADS appropriate clinical management not made in the Final Report

OR

DENOMINATOR EXCEPTION
PE017: Documentation of medical reason(s) for not documenting O-RADS score (such as, patients with a limited life expectancy, no positive finding of ovarian/adnexal mass(es)**,** or if the cyst has ruptured).

RATIONALE:
Female pelvic ultrasound is a common examination that can result in identification of ovarian/adnexal lesions of varying sizes requiring clinical management. Therefore,

accurate characterization of ovarian and adnexal findings on sonography is required for optimal patient management and risk stratification [1]. It is important for the clinician to receive information to differentiate between lesions that are likely benign and those that require more advanced follow up and possible surgical management due to the risk of malignancy. The current lack of standardized terminology in gynecological imaging has led to inconsistent treatment recommendations, even within the same institution [2], potentially causing increased cost and inappropriate resource consumption [3].

The Ovarian-Adnexal Reporting and Data System (O-RADS) US risk stratification and management system was created using a standard lexicon to eliminate these inconsistencies by using classes such as descriptors of the overall lesion, lesion size, blood flow, and internal content [2]. By use of such standardized terminology, radiologists should be able to communicate a more correct diagnosis, accurately assess the risk of malignancy, and create optimal patient treatment plans [2]. The goal is to recreate the same positive impact on gynecologic imaging as BI-RADS had on breast imaging.

Additional Info from Society of Radiologist in Ultrasound (SRU):
Updated SRU Consensus Conference Statements and Recommendations - Unnecessary follow-up of simple cysts increases the chance of surgical intervention as slow or uncertain growth can lead to recommendations for surgical removal even in the absence of malignant findings. Once an adnexal cyst demonstrates sonographic features indicating a negligible risk of malignancy, imaging follow-up may still be reasonable for those cysts large enough to merit surveillance to distinguish a growing benign neoplasm from a nonneoplastic cyst. However, it is also reasonable to rely on clinical follow-up alone (patient symptoms and physical examination) once a cyst has been well-characterized as simple, with US follow-up used as the clinician feels indicated. A thorough patient assessment is required to make specific recommendations for surgical intervention based on careful review of a patient's symptoms, age, medical profile, and US findings.
https://doi.org/10.1148/radiol.2019191354

An example of the O-RADS system is outlined as follows:

O-RADS Score	Risk Category [IOTA Model]	Lexicon Descriptors		Management	
				Pre-menopausal	Post-menopausal
0	Incomplete Evaluation [N/A]	N/A		Repeat study or alternate study	
1	Normal Ovary [N/A]	Follicle defined as a simple cyst ≤ 3 cm		None	N/A
		Corpus Luteum ≤ 3cm			
2	Almost Certainly Benign [< 1%]	Simple cyst	≤ 3 cm	N/A	None
			> 3 cm to 5 cm	None	Follow up in 1 year. *
			> 5 cm but < 10 cm	Follow up in 8 - 12 weeks	
		Classic Benign Lesions	See **Figure 3** for separate descriptors	See **Figure 3** for management strategies	
		Non-simple unilocular cyst, smooth inner margin	≤ 3 cm	None	Follow up in 1 year * If concerning, US specialist or MRI
			> 3 cm but < 10 cm	Follow-up in 8 - 12 weeks If concerning, US specialist	US specialist or MRI
3	Low Risk Malignancy [1-<10%]	Unilocular cyst ≥ 10 cm (simple or non-simple)		US specialist or MRI Management by gynecologist	
		Typical dermoid cysts, endometriomas, hemorrhagic cysts ≥ 10 cm			
		Unilocular cyst, any size with irregular inner wall <3 mm height			
		Multilocular cyst < 10 cm, smooth inner wall, CS = 1-3			
		Solid smooth, any size, CS = 1			
4	Intermediate Risk [10- < 50%]	Multilocular cyst, no solid component	≥ 10 cm, smooth inner wall, CS = 1-3	US specialist or MRI Management by gynecologist with GYN-oncologist consultation or solely by GYN-oncologist	
			Any size, smooth inner wall, CS = 4		
			Any size, irregular inner wall and/or irregular septation, any color score		
		Unilocular cyst with solid component	Any size, 0-3 papillary projections, CS = any		
		Multilocular cyst with solid component	Any size, CS = 1-2		
		Solid	Smooth, any size, CS = 2-3		
5	High Risk [≥ 50%]	Unilocular cyst, any size, ≥ 4 papillary projections, CS = any		GYN-oncologist	
		Multilocular cyst with solid component, any size, CS = 3-4			
		Solid smooth, any size, CS = 4			
		Solid irregular, any size, CS = any			
		Ascites and/or peritoneal nodules**			

Figure 2: Image shows Ovarian-Adnexal Reporting and Data System (O-RADS) US risk stratification and management system. * = At a minimum, at least 1-year follow-up showing stability or decrease in size is recommended with consideration of annual follow-up of up to 5 years, if stable. However, there is currently a paucity of evidence for defining optimal duration or interval of timing for surveillance. ** = Presence of ascites with category 1–2 lesion, must consider other malignant or nonmalignant etiologies of ascites. CS = color score, GYN = gynecologic, IOTA = International Ovarian Tumor Analysis, N/A = not applicable. Adapted, with permission, from the American College of Radiology.

No current MIPS measure addresses this need for effective description of ovarian/adnexal lesions and subsequent management. Without appropriate upfront lesion management recommendations by radiologists as provided by O-RADS, studies have shown that downstream consumption of resources tends to increase and create a wide variability in care [3]. In this way, use of this measure will decrease health care expenditures and result in cost savings to the US health system [3] as well as potentially lead to improved patient outcomes.

MEASURE TESTING AND GAP ANALYSIS:

200 ultrasound reports for findings of ovarian mass were reviewed. Findings were stratified by age, positive or negative findings, and whether a recommendation was made or not. Below are details of the gap analysis.

Table #1 shows the overall findings. In premenopausal women (under 50 years of age) there were 58 positive findings of ovarian masses/cysts. Of those 25 (43%) did not include a recommendation. Furthermore, of the ones that did include

recommendations, the recommendations were quite inconsistent as demonstrated in Table #2 below.

In postmenopausal women (50 years and older) there were 103 positive finding of ovarian masses/cysts and, of those, 94 (91%) did not include a recommendation.

TABLE #1

FINDINGS	# FOUND	AGE
No ovarian mass	16	under 50
Ovarian masses w/o recommendations	25	under 50
Ovarian masses w/recommendations	33	under 50
No ovarian mass	23	50 +
Ovarian masses w/o recommendation	94	50 +
Ovarian masses w/recommendations	9	50 +
TOTAL	200	All Ages

Table#2 shows the inconsistency in recommendations for the premenopausal group. Small finding such as these in premenopausal patients are fairly common and most certainly benign, therefore, typically should not lead to follow-up imaging.

TABLE #2

Actual Recommendation	**SIZE (cm)**	**AGE**	**Recommendation Had O-RADS been Used**
3 month follow-up is recommended	1.9	20	No follow-up
A follow-up pelvic US is recommended 6 to 12 weeks to document stability vs resolution	2.2	32	No follow-up
A follow-up US after 6 weeks may confirm that it has resolved or that it is smaller	2.2	38	No follow-up
Follow-up as clinically recommended	2.5*	35	No follow-up
A follow-up transabdominal and endovaginal pelvic US in 6 weeks time is recommended to assure stability or resolution	2.7	43	No follow-up
Consider follow-up sonography in 4 to 6 months	2.7	43	No follow-up
Consider 6 week follow-up for further evaluation	2.8	30	No follow-up
Follow-up US after menses is suggested	3.1	49	No follow-up unless non-simple cyst
6 week US follow-up recommended	3.2	35	No follow-up unless non-simple cyst
Follow-up pelvic ultrasound 2 - 3 months recommended to reevaluate	3.2	33	No follow-up unless non-simple cyst

* There was an abd/transvag US 1 day earlier without any recommendation at all for this patient

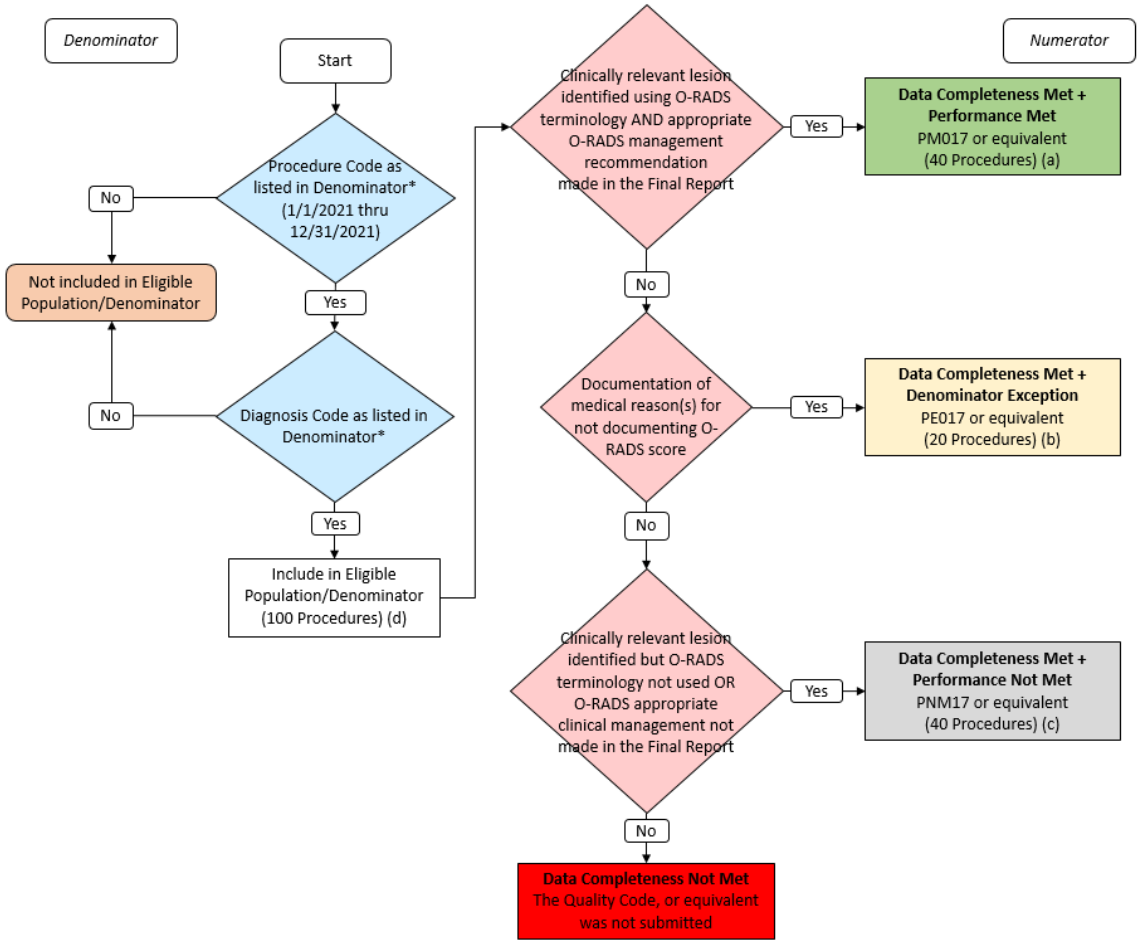
REFERENCES:

1. Andreotti et al. O-RADS US Risk Stratification and Management System: A Consensus Guideline from the ACR Ovarian-Adnexal Reporting and Data System Committee. Radiology 2020; 294:168–185.
2. Andreotti et al. Ovarian-Adnexal Reporting Lexicon for Ultrasound: A White Paper of the ACR Ovarian-Adnexal Reporting and Data System Committee. J Am Coll Radiol 2018;15:1415-1429.
3. Rosenkranz et al. Variation in Downstream Relative Costs Associated With Incidental Ovarian Cysts on Ultrasound. J Am Coll Radiol 2018;15:958-963.

Meaningful Measure Priority: Appropriate Use of Healthcare
NQS Domain: Effective Clinical Care
Measure type: Process- High Priority
Data Source: Registry, RIS/VR System, Contracted third party data capture systems.
Measure Steward: MSN Healthcare Solutions, LLC
Number of Multiple Performance Rates: 1
Inverse Measure: No
Proportion Measure Scoring: Yes
Continuous Measure Scoring: No
Risk adjustment: No
NQF Number: Not applicable
eCQM Number: Not applicable
High Priority Type: Care Coordination
Care Setting: Ambulatory Hospital, Hospital Inpatient, Outpatient Services, ED Services
Includes Telehealth: No

2021 Clinical Quality Measure Flow for Quality ID #QMM17: Appropriate Follow-up Recommendations for Ovarian-Adnexal Lesions using the O-RADS US Risk Stratification and Management System

Disclaimer: *Refer to the measure specification for specific coding and instructions to submit this measure*



** See the posted measure specification for specific coding and instructions to submit this measure.*

SAMPLE CALCULATIONS:

Data Completeness =

$$\frac{\text{Performance Met (a=40 procedures) + Denominator Exception (b=20 procedures) + Performance Not Met (c=40 procedures)}}{\text{Eligible Population / Denominator (d=100 procedures)}} = \frac{100 \text{ procedures}}{100 \text{ procedures}} = \mathbf{100.00\%}$$

Performance Rate =

$$\frac{\text{Performance Met (a=40 procedures)}}{\text{Data Completeness Numerator (100 procedures) - Denominator Exception (20 procedures)}} = \frac{40 \text{ procedures}}{80 \text{ procedures}} = \mathbf{50.00\%}$$

2021 Clinical Quality Measure Flow Narrative for Quality ID #QMM17: Appropriate Follow-up Recommendations for Ovarian-Adnexal Lesions using the Ovarian-Adnexal Reporting and Data System (O-RADS)

Disclaimer: *Refer to the measure specification for specific coding and instructions to submit this measure.*

1. Start with Denominator

2. Check Procedure Performed
    a. If Procedure Code as listed in Denominator equals NO, do not include in Eligible Population. Stop Processing.
    b. If Procedure Code as listed in Denominator equals YES, Proceed to Check Diagnosis Code.
3. Check Diagnosis Code
    a. If Diagnosis Code as listed in Denominator equals NO, do not include in Eligible Population. Stop Processing.
    b. If Diagnosis Code as listed in Denominator equals YES, include in Eligible Population.
4. Denominator Population:
    a. Denominator Population is all Eligible Procedures in the Denominator. Denominator is represented as Denominator in the Sample Calculation listed at the end of this document. Letter "d" equals 100 procedures in the Sample Calculation.
5. Start Numerator
6. Check Clinically relevant lesion identified using O-RADS terminology AND appropriate O-RADS management recommendation made in the Final Report:
    a. If Clinically relevant lesion identified using O-RADS terminology AND appropriate O-RADS management recommendation made in the Final Report 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 Clinically relevant lesion identified using O-RADS terminology AND appropriate O-RADS management recommendation made in the Final Report equals NO, proceed to check Documentation of medical reason(s) for not documenting O-RADS score
7. Check Documentation of medical reason(s) for not documenting O-RADS score:
    a. If Documentation of medical reason(s) for not documenting O-RADS score equals YES, include in Data Completeness Met and Denominator Exception.
    b. Data Completeness Met and Denominator Exception letter is represented in the Data Completeness and Performance Rate in the Sample Calculation listed at the end of this document. Letter "b" equals 20 procedures in the Sample Calculation.
    c. If Documentation of medical reason(s) for not documenting O-RADS score equals NO, Proceed to Clinically relevant lesion identified but O-RADS terminology not used OR O-RADS appropriate clinical management not made in the Final Report
8. Check Clinically relevant lesion identified but O-RADS terminology not used OR O-RADS appropriate clinical management not made in the Final Report
    a. If Clinically relevant lesion identified but O-RADS terminology not used OR O-RADS appropriate clinical management not made in the Final Report 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 and Performance Rate in the Sample Calculation listed at the end of this document. Letter “c” equals 40 procedures in the Sample Calculation
c. If Clinically relevant lesion identified but O-RADS terminology not used OR O-RADS appropriate clinical management not made in the Final Report equals NO, Proceed to Data Completeness Not Met.

9. Check Data Completeness Not Met
    a. If Data Completeness Not Met, the Quality Data Code or equivalent was not submitted. 0 procedures have been subtracted from the Data Completeness Numerator in the Sample Calculation

SAMPLE CALCULATIONS:

Data Completeness =

$$\frac{\text{Performance Met (a=40 procedures) + Denominator Exception (b=20 procedures) + Performance Not Met (c=40 procedures)}}{\text{Eligible Population / Denominator (d=100 procedures)}} = \frac{\text{100 procedures}}{\text{100 procedures}} = \mathbf{100.00\%}$$

Performance Rate =

$$\frac{\text{Performance Met (a=40 procedures)}}{\text{Data Completeness Numerator (100 procedures) - Denominator Exception (20 procedures)}} = \frac{\text{40 procedures}}{\text{80 procedures}} = \mathbf{50.00\%}$$