This form contains the measure information submitted by stewards. Blank fields indicate no information was provided. Attachments also may have been submitted and are provided to reviewers. The sub-criteria and most of the footnotes from the evaluation criteria are provided in Word comments and will appear if your cursor is over the highlighted area (or in the margin if your Word program is set to show revisions in balloons). Hyperlinks to the evaluation criteria and ratings are provided in each section.

TAP/Workgroup (if utilized): Complete all yellow highlighted areas of the form. Evaluate the extent to which each sub-criterion is met. Based on your evaluation, summarize the strengths and weaknesses in each section.

Note: If there is no TAP or workgroup, the SC also evaluates the sub-criteria (yellow highlighted areas).

Steering Committee: Complete all pink highlighted areas of the form. Review the workgroup/TAP assessment of the sub-criterion, noting any areas of disagreement; then evaluate the extent to which each major criterion is met; and finally, indicate your recommendation for the endorsement. Provide the rationale for your ratings.

Evaluation ratings of the extent to which the criteria are met

C = Completely (unquestionably demonstrated to meet the criterion)
P = Partially (demonstrated to partially meet the criterion)
M = Minimally (addressed BUT demonstrated to only minimally meet the criterion)
N = Not at all (NOT addressed; OR incorrectly addressed; OR demonstrated to NOT meet the criterion)
NA = Not applicable (only an option for a few sub-criteria as indicated)

### MEASURE DESCRIPTIVE INFORMATION

**De.1 Measure Title:** Acute Otitis Externa: Topical therapy

**De.2 Brief description of measure:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were prescribed topical preparations

**De.3 Type of Measure:** process

**De.4 National Priority Partners Priority Area:** population health

**De.5 IOM Quality Domain:** effectiveness, equity

**De.6 Consumer Care Need:** Getting Better

### CONDITIONS FOR CONSIDERATION BY NQF

<table>
<thead>
<tr>
<th>Four conditions must be met before proposed measures may be considered and evaluated for suitability as voluntary consensus standards:</th>
<th>NQF Staff</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. The measure is in the public domain or an intellectual property (measure steward agreement) is signed. Public domain only applies to governmental organizations. All non-government organizations must sign a measure steward agreement even if measures are made publicly and freely available.</td>
<td>A Y N</td>
</tr>
</tbody>
</table>

Rating: C=Completely; P=Partially; M=Minimally; N=Not at all; NA=Not applicable
A.1 Do you attest that the measure steward holds intellectual property rights to the measure and the right to use aspects of the measure owned by another entity (e.g., risk model, code set)? Yes
A.2 Indicate if Proprietary Measure (as defined in measure steward agreement): No
A.3 Measure Steward Agreement: agreement signed and submitted
A.4 Measure Steward Agreement attached: Yes

B. The measure owner/steward verifies there is an identified responsible entity and process to maintain and update the measure on a schedule that is commensurate with the rate of clinical innovation, but at least every 3 years. Yes, information provided in contact section

C. The intended use of the measure includes both public reporting and quality improvement. Purpose: public reporting, quality improvement Accountability

D. The requested measure submission information is complete. Generally, measures should be fully developed and tested so that all the evaluation criteria have been addressed and information needed to evaluate the measure is provided. Measures that have not been tested are only potentially eligible for a time-limited endorsement and in that case, measure owners must verify that testing will be completed within 12 months of endorsement.

D.1 Testing: No, testing will be completed within 12 months
D.2 Have NQF-endorsed measures been reviewed to identify if there are similar or related measures? Yes

(for NQF staff use) Have all conditions for consideration been met? Met

Staff Notes to Steward (if submission returned):

Staff Notes to Reviewers (issues or questions regarding any criteria):

TAP/Workgroup Reviewer Name:

Steering Committee Reviewer Name:

1. IMPORTANCE TO MEASURE AND REPORT

Extent to which the specific measure focus is important to making significant gains in health care quality (safety, timeliness, effectiveness, efficiency, equity, patient-centeredness) and improving health outcomes for a specific high impact aspect of healthcare where there is variation in or overall poor performance. Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria.

1a. High Impact

(for NQF staff use) Specific NPP goal:

1a.1 Demonstrated High Impact Aspect of Healthcare: affects large numbers
1a.2

1a.3 Summary of Evidence of High Impact: "AOE is one of the most common infections encountered by clinicians. The annual incidence of AOE is between 1:100 and 1:250 of the general population, with regional variations based on age and geography; lifetime incidence is up to 10%. The direct cost of AOE is unknown, but the ototopical market in the United States is approximately 7.5 million annual prescriptions with total sales of $310 million. Additional medical costs include physician visits and prescriptions for analgesics and systemic medications, such as antibiotics, steroids, or both. The indirect costs of AOE have not been calculated but are likely to be substantial because of severe and persistent otalgia that limits activities."

1b. Opportunity for Improvement

1b.1 Benefits (improvements in quality) envisioned by use of this measure: Topical preparations should be used to treat AOE as they are active against the most common bacterial pathogens in AOE, Pseudomonas aeruginosa and Staphylococcus aureus. Topical preparations have demonstrated efficacy in the treatment of AOE with resolution in about 65-90% of patients.

1b.2 Summary of data demonstrating performance gap (variation or overall poor performance) across providers:
Recent PQRI data show opportunities for improvement in this area. 2008 PQRI data. Mean performance rate: 36.21%. National clinical performance rates: 10th percentile: 6.25%; 25th percentile: 14.29%; 50th percentile: 42.86%; 75th percentile: 86.67%; 90th percentile: 100.00%.

Performance of physicians who participate in 2008 PQRI is found to vary. As a result, opportunities for improvement exists for these early participants. In addition, continued reporting and tracking of measure performance and variation is required as familiarity with PQRI increases and an increasing number of physicians participate.

Despite their limited utility, many patients with acute otitis externa receive oral antibiotics, often in addition to topical therapy.

-A 1999 study analyzed data from the 1993 National Ambulatory Medical Care Survey in order to examine AOE treatment patterns in the United States. Systemic medications were prescribed at approximately 55% of visits. Patients received prescriptions for both topical and systemic medications at 39.8% of visits. Many of the oral antibiotics prescribed are not active against the most common bacterial pathogens in OE - Staphylococcus aureus or Pseudomonas aeruginosa. [1]

-A recent examination of antimicrobial prescribing in children with otitis externa found that inappropriate antimicrobial prescribing for OE occurs frequently among children. Approximately, 39% of visits resulted in a prescription for topical antibiotics, and 25% of visits resulted in a prescription for oral antibiotics. [2]

1b.3 Citations for data on performance gap:


1b.4 Summary of Data on disparities by population group:
We are not aware of any publications/evidence outlining disparities in this area.

1b.5 Citations for data on Disparities:

1c. Outcome or Evidence to Support Measure Focus

1c.1 Relationship to Outcomes (For non-outcome measures, briefly describe the relationship to desired outcome. For outcomes, describe why it is relevant to the target population): Topical preparations for the initial treatment of AOE lead to the clinical resolution of the condition.

1c.2-3. Type of Evidence: evidence based guideline

1c.4 Summary of Evidence (as described in the criteria; for outcomes, summarize any evidence that healthcare services/care processes influence the outcome):
Topical preparations are recommended as initial therapy for diffuse, uncomplicated AOE because of safety, efficacy, and excellent clinical and bacteriologic outcomes in comparative studies.

Reference:
Clinicians should use topical preparations for initial therapy of diffuse, uncomplicated AOE.

**Rating of strength/quality of evidence (also provide narrative description of the rating and by whom):**

Grade B

**Method for rating evidence:**

Evidence quality for grades of evidence

Grade A: Well-designed randomized controlled trials or diagnostic studies performed on a population similar to the guideline’s target population

Grade B: Randomized controlled trials or diagnostic studies with minor limitations; overwhelmingly consistent evidence from observational studies

Grade C: Observational studies (case control and cohort design)

Grade D: Expert opinion, case reports, reasoning from first principles (bench research or animal studies)

**Grade X:** Exceptional situations where validating studies cannot be performed and there is a clear preponderance of benefit over harm

**Summary of Controversy/Contradictory Evidence:** None

**Citations for Evidence (other than guidelines):**

**Quote the Specific guideline recommendation (including guideline number and/or page number):**

Clinicians should use topical preparations for initial therapy of diffuse, uncomplicated AOE. (Aggregate evidence quality - Grade B) (AAO-HNSF)


**Rating of strength of recommendation (also provide narrative description of the rating and by whom):**

**Recommendation**

**Method for rating strength of recommendation (If different from USPSTF system, also describe rating and how it relates to USPSTF):**

Strong recommendation - A strong recommendation means the benefits of the recommended approach clearly exceed the harms (or that the harms clearly exceed the benefits in the case of a negative recommendation) and that the quality of the supporting evidence is excellent (Grade A or B). In some clearly identified circumstances, strong recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits strongly outweigh the harms. Implication: Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.

Recommendation - A recommendation means the benefits exceed the harms (or that the harms clearly exceed the benefits in the case of a negative recommendation), but the quality of evidence is not as strong (Grade B or C). In some clearly identified circumstances, recommendations may be made based on lesser evidence when high-quality evidence is impossible to obtain and the anticipated benefits outweigh the harms. Implication: Clinicians should also generally follow a recommendation but should remain alert to new information and sensitive to patient preferences.

Option - An option means that either the quality of evidence that exists is suspect (Grade D) or that well-done studies (Grade A, B, or C) show little clear advantage to one approach versus another. Implication:
Clinicians should be flexible in their decision making regarding appropriate practice, although they may set bounds on alternatives; patient preference should have a substantial influencing role.

No recommendation - No recommendation means there is both a lack of pertinent evidence (Grade D)* and an unclear balance between benefits and harms. Implication: Clinicians should feel little constraint in their decision making and be alert to new published evidence that clarifies the balance of benefit versus harm; patient preference should have a substantial influencing role.

1c.14 Rationale for using this guideline over others:
It is the PCPI policy to use guidelines, which are evidence-based, applicable to physicians and other healthcare providers, and developed by a national specialty organization or government agency. In addition, the PCPI has now expanded what is acceptable as the evidence base for measures to include documented quality improvement (QI) initiatives or implementation projects that have demonstrated improvement in the quality of care.

2a. MEASURE SPECIFICATIONS

S.1 Do you have a web page where current detailed measure specifications can be obtained?
S.2 If yes, provide web page URL:

2a. Precisely Specified

2a.1 Numerator Statement (Brief, text description of the numerator - what is being measured about the target population, e.g. target condition, event, or outcome):
Patients who were prescribed topical preparations

2a.2 Numerator Time Window (The time period in which cases are eligible for inclusion in the numerator):
Once within the denominator time window

2a.3 Numerator Details (All information required to collect/calculate the numerator, including all codes, logic, and definitions):
EHR specifications for this measure are under development

Claims Specifications
CPT Category II code: 4130F - Topical preparations (including OTC) prescribed for acute otitis externa

2a.4 Denominator Statement (Brief, text description of the denominator - target population being measured):
All patients aged 2 years and older with a diagnosis of AOE

2a.5 Target population gender: Male, Female
2a.6 Target population age range: Aged 2 years and older

2a.7 Denominator Time Window (The time period in which cases are eligible for inclusion in the denominator):
Each episode* of AOE within a 12 month period.

*An episode of AOE is defined as a 30-day period from onset of Acute Otitis Externa (as indicated by the

Rating: C=Completely; P=Partially; M=Minimally; N=Not at all; NA=Not applicable
2a.8 Denominator Details (All information required to collect/calculate the denominator - the target population being measured - including all codes, logic, and definitions):
EHR specifications for this measure are under development

Claims Specifications
ICD-9-CM Diagnosis Codes: 380.10, 380.11, 380.12, 380.13, 380.22

AND
CPT codes: 99201, 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215, 99241, 99242, 99244, 99245, 99382, 99383, 99384, 99385, 99386, 99387, 99392, 99393, 99394, 99395, 99396, 99397

2a.9 Denominator Exclusions (Brief text description of exclusions from the target population):
Documentation of medical reason(s) for not prescribing topical preparations (eg, coexisting acute otitis media, tympanic membrane perforation)
Documentation of patient reason(s) for not prescribing topical preparations (eg, patient refusal)

2a.10 Denominator Exclusion Details (All information required to collect exclusions to the denominator, including all codes, logic, and definitions):
EHR specifications for this measure are under development

Claims Specifications
Documentation of medical reason(s) for not prescribing topical preparations (eg, coexisting acute otitis media, tympanic membrane perforation)
Append modifier to CPT Category II code: 4130-1P
OR
Drug allergy or other adverse effects
ICD-9-CM diagnosis codes: 995.27 AND E946.0, E946.6, E946.8

Documentation of patient reason(s) for not prescribing topical preparations
Append modifier to CPT Category II code: 4130F-2P

2a.11 Stratification Details/Variables (All information required to stratify the measure including the stratification variables, all codes, logic, and definitions):
Stratification by insurance coverage (commercial, Medicare and Medicaid) is recommended by some implementers

2a.12-13 Risk Adjustment Type: no risk adjustment necessary

2a.14 Risk Adjustment Methodology/Variables (List risk adjustment variables and describe conceptual models, statistical models, or other aspects of model or method):

2a.15-17 Detailed risk model available Web page URL or attachment:

2a.18-19 Type of Score: rate/proportion
2a.20 Interpretation of Score: better quality = higher score
2a.21 Calculation Algorithm (Describe the calculation of the measure as a flowchart or series of steps):
See sample calculation algorithm attached

2a.22 Describe the method for discriminating performance (e.g., significance testing):

2a.23 Sampling (Survey) Methodology If measure is based on a sample (or survey), provide instructions for obtaining the sample, conducting the survey and guidance on minimum sample size (response rate):

2a.24 Data Source (Check the source(s) for which the measure is specified and tested)
Electronic administrative data/claims, electronic Health/Medical Record, paper medical record/flowsheet,

Comment [k9]: 11 Risk factors that influence outcomes should not be specified as exclusions.
12 Patient preference is not a clinical exception to eligibility and can be influenced by provider interventions.
special or unique data

2a.25 Data source/data collection instrument (identify the specific data source/data collection instrument, e.g., name of database, clinical registry, collection instrument, etc.);

2a.26-28 Data source/data collection instrument reference web page URL or attachment:

2a.29-31 Data dictionary/code table web page URL or attachment:

2a.32-35 Level of Measurement/Analysis (Check the level(s) for which the measure is specified and tested)

Clinicians: Individual, Clinicians: Group

2a.36-37 Care Settings (Check the setting(s) for which the measure is specified and tested)

Ambulatory Care: Office, Ambulatory Care: Clinic, Ambulatory Care: Hospital Outpatient

2a.38-41 Clinical Services (Healthcare services being measured, check all that apply)

Clinicians: Physicians (MD/DO), Clinicians: PA/NP/Advanced Practice Nurse

<table>
<thead>
<tr>
<th>TESTING/ANALYSIS</th>
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2b. Reliability testing

2b.1 Data/sample (description of data/sample and size):

2b.2 Analytic Method (type of reliability & rationale, method for testing):

2b.3 Testing Results (reliability statistics, assessment of adequacy in the context of norms for the test conducted):

<table>
<thead>
<tr>
<th>2b</th>
<th>C</th>
<th>P</th>
<th>M</th>
<th>N</th>
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</table>

2c. Validity testing

2c.1 Data/sample (description of data/sample and size):

2c.2 Analytic Method (type of validity & rationale, method for testing):

It is the consensus of the PCPI Measures Implementation and Evaluation Committee that face and content validity of PCPI measures can be assumed to be established once they have progressed beyond the Public Comment period by virtue of the specialized expertise of the PCPI work group members who are involved in identifying and drafting performance measures within a topical domain as well, as the rigorous, structured discussions that are prescribed according to PCPI protocols for work group conduct.

2c.3 Testing Results (statistical results, assessment of adequacy in the context of norms for the test conducted):

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<thead>
<tr>
<th>2c</th>
<th>C</th>
<th>P</th>
<th>M</th>
<th>N</th>
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</table>

2d. Exclusions Justified

2d.1 Summary of Evidence supporting exclusion(s):

The PCPI supports the consideration of exceptions (or exclusions) on a measure by measure basis. There must be a clear rationale to permit an exception for a medical, patient, or system reason, based on whether or not that reason is significant and occurs frequently enough. The PCPI also advocates for the systematic review and analysis of each physician’s exceptions data to identify practice patterns and opportunities for quality improvement. That is, while exceptions are removed from the denominator when calculating performance, rates of exceptions should be reported alongside performance rates. Denominator exceptions are included in this particular measure so that physicians can identify patients for whom topical therapy is not appropriate. The recommendation for initial topical therapy applies to the

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<th>2d</th>
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<th>P</th>
<th>M</th>
<th>N</th>
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</thead>
</table>

Rating: C=Completely; P=Partially; M=Minimally; N=Not at all; NA=Not applicable
otherwise healthy patient with diffuse AOE that is not complicated by osteitis, abscess formation, middle ear disease, or recurrent episodes of infection. Topical therapy should be supplemented by systemic antibiotics if the affected individual has a condition, especially diabetes that is associated with markedly increased morbidity, or HIV infection/AIDS with immune deficiency that could impair host defenses; if the infection has spread beyond the confines of the ear canal into the pinna, skin of the neck or face, or into deeper tissues such as occurs with malignant external otitis; or if there is good reason to believe that topical therapy cannot be delivered effectively."

2d.3 Data/sample (description of data/sample and size):

2d.4 Analytic Method (type analysis & rationale):

2d.5 Testing Results (e.g., frequency, variability, sensitivity analyses):

2e. Risk Adjustment for Outcomes/ Resource Use Measures

2e.1 Data/sample (description of data/sample and size):

2e.2 Analytic Method (type of risk adjustment, analysis, & rationale):

2e.3 Testing Results (risk model performance metrics):

2e.4 If outcome or resource use measure is not risk adjusted, provide rationale:

2f. Identification of Meaningful Differences in Performance

2f.1 Data/sample from Testing or Current Use (description of data/sample and size):

2f.2 Methods to identify statistically significant and practically/meaningfully differences in performance (type of analysis & rationale):

2f.3 Provide Measure Scores from Testing or Current Use (description of scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of statistically significant and meaningfully differences in performance):

2g. Comparability of Multiple Data Sources/Methods

2g.1 Data/sample (description of data/sample and size):

2g.2 Analytic Method (type of analysis & rationale):

2g.3 Testing Results (e.g., correlation statistics, comparison of rankings):

2h. Disparities in Care

2h.1 If measure is stratified, provide stratified results (scores by stratified categories/cohorts):

Rating: C=Completely; P=Partially; M=Minimally; N=Not at all; NA=Not applicable
2h.2 If disparities have been reported/identified, but measure is not specified to detect disparities, provide follow-up plans:
The PCPI and NCQA are currently developing a framework for stratifying measures to test for disparities.

TAP/Workgroup: What are the strengths and weaknesses in relation to the sub-criteria for Scientific Acceptability of Measure Properties?
Steering Committee: Overall, to what extent was the criterion, Scientific Acceptability of Measure Properties, met?
Rationale:

3. USABILITY

Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand the results of the measure and are likely to find them useful for decision making. (evaluation criteria)

3a. Meaningful, Understandable, and Useful Information

3a.1 Current Use: in use
3a.2 Use in a public reporting initiative (disclosure of performance results to the public at large) (If used in a public reporting initiative, provide name of initiative(s), locations, Web page URL(s). If not publicly reported, state the plans to achieve public reporting within 3 years):
This measure is used in the CMS PQRI program claims option for 2008, 2009 and 2010, and registry option for 2009 and 2010.
3a.3 If used in other programs/initiatives (If used in quality improvement or other programs/initiatives, name of initiative(s), locations, Web page URL(s). If not used for QI, state the plans to achieve use for QI within 3 years):
Testing of Interpretability (Testing that demonstrates the results are understood by the potential users for public reporting and quality improvement)
3a.4 Data/sample (description of data/sample and size):
3a.5 Methods (e.g., focus group, survey, QI project):
3a.6 Results (qualitative and/or quantitative results and conclusions):
3b/3c. Relation to other NQF-endorsed measures
3b.1 NQF # and Title of similar or related measures:
(for NQF staff use) Notes on similar/related endorsed or submitted measures:
3b. Harmonization
If this measure is related to measure(s) already endorsed by NQF (e.g., same topic, but different target population/setting/data source or different topic but same target population):
3b.2 Are the measure specifications harmonized? If not, why?
3c. Distinctive or Additive Value
3c.1 Describe the distinctive, improved, or additive value this measure provides to existing NQF-endorsed measures:

Comment [KP22]: 3a. Demonstration that information produced by the measure is meaningful, understandable, and useful to the intended audience(s) for both public reporting (e.g., focus group, cognitive testing) and informing quality improvement (e.g., quality improvement initiatives). An important outcome that may not have an identified improvement strategy still can be useful for informing quality improvement by identifying the need for and stimulating new approaches to improvement.

Comment [KP23]: 3b. The measure specifications are harmonized with other measures, and are applicable to multiple levels and settings.

Comment [K24]: 16 Measure harmonization refers to the standardization of specifications for similar measures on the same topic (e.g., influenza immunization of patients in hospitals or nursing homes), or related measures for the same target population (e.g., eye exam and HbA1c for patients with diabetes), or definitions applicable to many measures (e.g., age designation for children) so that they are uniform or compatible, unless differences are dictated by the evidence. The dimensions of harmonization can include numerator, denominator, exclusions, and data source and collection instructions. The extent of harmonization depends on the relationship of the measures, the evidence for the specific measure focus, and differences in data sources.

Comment [KP25]: 3c. Review of existing endorsed measures and measure sets demonstrates that the measure provides a distinctive or additive value to existing NQF-endorsed measures (e.g., provides a more complete picture of quality for a particular condition or aspect of healthcare).
5. Competing Measures If this measure is similar to measure(s) already endorsed by NQF (i.e., on the same topic and the same target population), describe why it is a more valid or efficient way to measure quality:

<table>
<thead>
<tr>
<th>TAP/Workgroup: What are the strengths and weaknesses in relation to the sub-criteria for Usability?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steering Committee: Overall, to what extent was the criterion, Usability, met?</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Rationale:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. (evaluation criteria)</td>
</tr>
</tbody>
</table>

### 4. FEASIBILITY

4a. Data Generated as a Byproduct of Care Processes

<table>
<thead>
<tr>
<th>4a.1-2 How are the data elements that are needed to compute measure scores generated?</th>
</tr>
</thead>
<tbody>
<tr>
<td>data generated as byproduct of care processes during delivery, coding/abstraction performed by someone other than person obtaining original information,</td>
</tr>
</tbody>
</table>

4b. Electronic Sources

<table>
<thead>
<tr>
<th>4b.1 Are all the data elements available electronically? (elements that are needed to compute measure scores are in defined, computer-readable fields, e.g., electronic health record, electronic claims)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
</tr>
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<thead>
<tr>
<th>4b.2 If not, specify the near-term path to achieve electronic capture by most providers.</th>
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<tbody>
<tr>
<td>Electronic health record products are not uniform in ability to collect data in a standardized way at this time. Design decisions made by individual practices during the implementation of these measures can affect measure performance.</td>
</tr>
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</table>

4c. Exclusions

<table>
<thead>
<tr>
<th>4c.1 Do the specified exclusions require additional data sources beyond what is required for the numerator and denominator specifications?</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
</tr>
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</table>

<table>
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<tr>
<th>4c.2 If yes, provide justification.</th>
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</table>

4d. Susceptibility to Inaccuracies, Errors, or Unintended Consequences

<table>
<thead>
<tr>
<th>4d.1 Identify susceptibility to inaccuracies, errors, or unintended consequences of the measure and describe how these potential problems could be audited, if audited, provide results.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physicians have voluntarily reported on this measure as part of the PQRI program. We are not aware of any unintended consequences related to this measurement.</td>
</tr>
</tbody>
</table>

4e. Data Collection Strategy/Implementation

<table>
<thead>
<tr>
<th>4e.1 Describe what you have learned/modified as a result of testing and/or operational use of the measure regarding data collection, availability of data/missing data, timing/frequency of data collection, patient confidentiality, time/cost of data collection, other feasibility/implementation issues:</th>
</tr>
</thead>
</table>

| 4e.2 Costs to implement the measure (costs of data collection, fees associated with proprietary |

## Comments

- Comment [K26]: 5. Demonstration that the measure is superior to competing measures - new submissions and/or endorsed measures (e.g., is a more valid or efficient way to measure).
- Comment [KP27]: 4a. For clinical measures, required data elements are routinely generated concurrent with and as a byproduct of care processes during care delivery. (e.g., BP recorded in the electronic record, not abstracted from the record later by other personnel; patient self-assessment tools, e.g., depression scale; lab values, meds, etc.)
- Comment [KP28]: 4b. The required data elements are available in electronic sources. If the required data are not in existing electronic sources, a credible, near-term path to electronic collection by most providers is specified and clinical data elements are specified for transition to the electronic health record.
- Comment [KP29]: 4c. Exclusions should not require additional data sources beyond what is required for scoring the measure (e.g., numerator and denominator) unless justified as supporting measure validity.
- Comment [KP30]: 4d. Susceptibility to inaccuracies, errors, or unintended consequences and the ability to audit the data items to detect such problems are identified.
- Comment [KP31]: 4e. Demonstration that the data collection strategy (e.g., source, timing, frequency, sampling, patient confidentiality, etc.) can be implemented (e.g., already in operational use, or testing demonstrates that it is ready to put into operational use).
measures):

4e.3 Evidence for costs:

4e.4 Business case documentation:

<table>
<thead>
<tr>
<th>TAP/Workgroup: What are the strengths and weaknesses in relation to the sub-criteria for Feasibility?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steering Committee: Overall, to what extent was the criterion, Feasibility, met?</td>
</tr>
<tr>
<td>Rationale:</td>
</tr>
<tr>
<td>C</td>
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</table>

<table>
<thead>
<tr>
<th>RECOMMENDATION</th>
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<tbody>
<tr>
<td>(for NQF staff use) Check if measure is untested and only eligible for time-limited endorsement.</td>
</tr>
<tr>
<td>Time-limited</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Steering Committee: Do you recommend for endorsement?</th>
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</thead>
<tbody>
<tr>
<td>Comments:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CONTACT INFORMATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Co.1 Measure Steward (Intellectual Property Owner)</td>
</tr>
<tr>
<td>Co.1 Organization</td>
</tr>
<tr>
<td>American Medical Association</td>
</tr>
<tr>
<td>Co.2 Point of Contact</td>
</tr>
<tr>
<td>Mark</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Measure Developer if different from Measure Steward</th>
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<tr>
<td>Co.3 Organization</td>
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<tr>
<td>American Medical Association</td>
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<tr>
<td>Co.4 Point of Contact</td>
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<td>Mark</td>
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<tr>
<th>Co.5 Submitter If different from Measure Steward POC</th>
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<th>Co.6 Additional organizations that sponsored/participated in measure development</th>
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<tr>
<td>American Academy of Otolaryngology – Head and Neck Surgery (AAO-HNS) Foundation</td>
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<th>ADDITIONAL INFORMATION</th>
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<tr>
<td>Workgroup/Expert Panel involved in measure development</td>
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<tr>
<td>Ad.1 Provide a list of sponsoring organizations and workgroup/panel members’ names and organizations. Describe the members’ role in measure development.</td>
</tr>
<tr>
<td>Allan S. Lieberthal, MD, FAAP (Co-Chair) (pediatrics)</td>
</tr>
<tr>
<td>Richard M. Rosenfeld, MD, MPH (Co-Chair) (otolaryngology)</td>
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<tr>
<td>Brian L. Bachelder, MD (family medicine)</td>
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<tr>
<td>Steve I. Pelton, MD (pediatrics/pediatric infectious diseases)</td>
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<tr>
<td>Karen Jo Doyle, MD, PhD (otolaryngology)</td>
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<td>Peter S. Roland, MD (otolaryngology)</td>
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<tr>
<td>Cynthia P. Helstad, PhD, RN</td>
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<tr>
<td>Xavier Sevilla, MD (pediatrics)</td>
</tr>
<tr>
<td>Rahul Khare, MD, FACEP (emergency medicine)</td>
</tr>
<tr>
<td>David L. Witsell, MD, MHS (otolaryngology)</td>
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PCPI measures are developed through cross-specialty, multi-disciplinary work groups. All medical specialties and other health care professional disciplines participating in patient care for the clinical condition or topic under study must be equal contributors to the measure development process. In addition, the PCPI strives to include on its work groups individuals representing the perspectives of patients, consumers, private health plans, and employers. This broad-based approach to measure development ensures buy-in on the measures from all stakeholders and minimizes bias toward any individual specialty or stakeholder group. All work groups have at least two co-chairs who have relevant clinical and/or measure development expertise and who are responsible for ensuring that consensus is achieved and that all perspectives are voiced.

Ad.2 If adapted, provide name of original measure:
Ad.3-5 If adapted, provide original specifications URL or attachment

Measure Developer/Steward Updates and Ongoing Maintenance

Ad.6 Year the measure was first released: 2007
Ad.7 Month and Year of most recent revision:
Ad.8 What is your frequency for review/update of this measure? Every 3 years or as new evidence becomes available that materially affects the measures
Ad.9 When is the next scheduled review/update for this measure? 2010-03

Ad.10 Copyright statement/disclaimers: Physician Performance Measures (Measures) and related data specifications, developed by the Physician Consortium for Performance Improvement® (the Consortium), are intended to facilitate quality improvement activities by physicians.

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

Ad.11 -13 Additional Information web page URL or attachment: Attachment Sample Calculation Algorithm.doc

Date of Submission (MM/DD/YY): 05/10/2010
Clinical care processes typically include multiple steps: assess → identify problem/potential problem → choose/plan intervention (with patient input) → provide intervention → evaluate impact on health status. If the measure focus is one step in such a multi-step process, the step with the greatest effect on the desired outcome should be selected as the focus of measurement. For example, although assessment of immunization status and recommending immunization are necessary steps, they are not sufficient to achieve the desired impact on health status - patients must be vaccinated to achieve immunity. This does not preclude consideration of measures of preventive screening interventions where there is a strong link with desired outcomes (e.g., mammography) or measures for multiple care processes that affect a single outcome.

Clinically necessary measure exclusions are identified and must be:

- supported by evidence of sufficient frequency of occurrence so that results are distorted without the exclusion;
- a clinically appropriate exception (e.g., contraindication) to eligibility for the measure focus;
- precisely defined and specified:
  - if there is substantial variability in exclusions across providers, the measure is specified so that exclusions are computable and the effect on the measure is transparent (i.e., impact clearly delineated, such as number of cases excluded, exclusion rates by type of exclusion); if patient preference (e.g., informed decision-making) is a basis for exclusion, there must be evidence that it strongly impacts performance on the measure and the measure must be specified so that the information about patient preference and the effect on the measure is transparent (e.g., numerator category computed separately, denominator exclusion category computed separately).
The AAO-HNS/AMA PCPI Acute Otitis Externa/Otitis Media with Effusion Work Group thanks the NQF Steering Committee for their thorough review and consideration of these measures. Based on your comments, we have provided clarification and rationales for the measures on which the Steering Committee had questions or recommended revisions. In addition, we have prepared a request for reconsideration of the measures that the Committee did not recommend for endorsement.

Given the tight timeframes of this project and the AMA PCPI protocol for the Work Group review/approval process, we have not yet confirmed Work Group consensus on these responses but expect to do so within the next week; we anticipate that we will be able to provide NQF with confirmation by April 30th.

ACP-009-10: Acute Otitis Externa - Topical therapy
ACP-011-10: Acute Otitis Externa - Systemic antimicrobial therapy – Avoidance of inappropriate use

Steering Committee Condition for Endorsement: Pair measures

Given that these measures address appropriate and inappropriate treatment of patients with AOE, the Work Group agrees that pairing them would be reasonable and would provide a more comprehensive perspective on the quality of care for AOE. Consistent with the definitions for paired/bundled* measures from the Institute for Healthcare Improvement and NQF, pairing the measures will result in a recommendation that these two measures be reported together and that neither of these measures be used independently. A performance score for each measure should be reported individually.

* (As the PCPI uses these terms presently, a “pair” is a “bundle” consisting of only two measures.)

With regard to the request for adding specificity to the ICD-9 coding and the exclusions, medical reasons for exclusion are intended to identify patients for whom the aspect of care is not appropriate. (“Patient reasons” for exclusion identify patient preferences.) Rather than attempt to specify an exhaustive list of explicit medical, patient, and system reasons for exclusion for each measure, the AMA PCPI relies on clinicians to link the exclusion with a documented reason for the decision to not prescribe or administer the therapy. In some cases, the AMA PCPI supports a list of examples which are not intended to be an all-inclusive list of reasons why a patient should be excluded, but are based on the experience and judgment of the Work Group and published evidence, where available. In order to address the concerns of the Steering Committee, the Work Group has agreed to update the measure worksheets as follows:

For ACP-009-10: medical reason(s) for not prescribing topical preparations (eg, coexisting acute otitis media, tympanic membrane perforation)

For ACP-011-10: medical reason(s) for prescribing systemic antimicrobial therapy (eg, coexisting diabetes, immune deficiency)

By way of background, the PCPI began to define exclusions (perhaps better called exceptions) using three broad categories (medical, patient, and system) to reflect the state of the art of physician-level measurement and to enable exception reporting to be feasible when the data source is claims. Our intent through our testing projects—and with the expanded use of EHRs—is to add specificity to these three categories. For example, through one testing project of measures focused on cardiology drugs, we learned that almost all medical exceptions fell into four subcategories:
• Clinical contraindication
• Drug allergy
• Drug intolerance
• Drug interaction

If we validate this finding with other types of measures (including these AOE/OME measures), we will seek clinical coding for these subcategories and add them to our measure specifications.

Additionally, when we validate specific reasons for exception that are codeable (such as the reasons added for measures 009 and 011 above, pending Work Group consensus), we will include them in specifications as well.

As to the request for additional information on testing for these measures: The paucity of testing data currently presented is consistent with the NQF policy defining eligibility for time-limited endorsement. As measure developers, we are committed to field testing the measures within the time-limited endorsement period and providing the project results to NQF as well as to our measure development Work Group.

The PCPI Testing Protocol outlines the comprehensive set of tests that should be conducted in different practice settings, using different data sources, for each performance measurement set. The PCPI recognizes that multiple testing projects may be needed to achieve the required test results for each measurement set. Moreover, testing and surveillance should be part of continued evaluation and updating of the measures. The protocol recommends tests in a variety of areas, including feasibility/implementation and reliability, and that testing be conducted in a variety of practice settings including (e.g., solo practices, large practices, academic practices, safety-net practices, single- and multi-specialty groups). The results of performance measure testing projects are used to inform the measure development workgroup as well as to improve the measures' clarity and specifications.

More specifically, as to measure 011 and the other “avoidance of inappropriate use” measures in the AOE/OME set, plans are in place for a project to identify cost savings associated with these measures by examining ICD-9 coding frequencies of reported exceptions. We expect to have results from this project available to share with NQF later in 2010.

ACP-012-10: Otitis Media with Effusion - Antihistamines or decongestants – Avoidance of inappropriate use
ACP-013-10: Otitis Media with Effusion - Systemic corticosteroids – Avoidance of inappropriate use
ACP-015-10: Otitis Media with Effusion - Systemic antimicrobials – Avoidance of inappropriate use

Steering Committee Condition for Endorsement: Bundle measures

Given that these measures address the well-documented inappropriate treatment of patients with OME, the PCPI Work Group agrees that bundling them would be reasonable and would provide a more comprehensive perspective on the quality of care for OME. Consistent with the definitions for paired/bundled measures from the Institute for Healthcare Improvement and NQF, bundling the measures will result in a recommendation that these three measures be reported together and that none of these measures be used independently. A performance score for each measure should be reported individually.

Regarding the recommendation to “eventually endorse [these 3 measures] as a composite measure after maintenance review” – In preparing for maintenance review, the Work Group will consider the inclusion of these measures in a composite and provide its recommendations to NQF, given that a composite measure would yield a single score and the selection of a scoring methodology appropriate for the component measures requires careful consideration. The PCPI will soon initiate a
public comment period on a framework for incorporating composite measures into its portfolio; that guidance document will be helpful in considering composite measures for this clinical area.

**ACP-008-10: Otitis Media with Effusion – Hearing Testing**

**Pending Steering Committee Recommendation**

The Steering Committee requested additional information related to patient age criteria and care settings. After review of our measure submission form, we believe that these elements of the measure specifications were clearly and accurately defined, but will welcome the opportunity to provide any additional clarifications needed on the April 26 conference call.

Regarding our selection of the “special or unique data” field: Our intent in checking this data source was to indicate that “Hybrid data” – electronic data collection supplemented with medical record abstraction – may be used for the measure. The online submission form unfortunately does not provide a means to specify our intent in selecting that data source.

As a point of clarification, this data source was checked for all of the PCPI AOE/OME and Endoscopy measures submitted under this call for measures. Although the Steering Committee only called attention to this field selection for the Hearing Testing measure, the explanation provided above also applies to the other PCPI measures submitted for these topics.

As to the request for information on future validity testing for this measure: The paucity of testing data currently presented is consistent with the NQF policy defining eligibility for time-limited endorsement. As measure developers, we are committed to field testing the measure within the time-limited endorsement period and providing the project results to NQF as well as to our measure development Work Group.

The Steering Committee also requested statistics on the number of children with OME and whether hearing testing for these children is routine practice. Recent studies indicate that about 2.2 million diagnosed episodes of OME occur annually in the United States, yielding a combined direct and indirect annual cost estimate of $4.0 billion. In the first year of life, more than 50% of children will experience OME, increasing to more than 60% by age 2 years. The mean hearing loss with OME is 25-28 db HL (decibels hearing level) with about 20% exceeding 35 dB HL. For comparison, normal hearing is less than 20 dB HL.

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**Reconsideration Requests:**

**Measure #ACP-010-10: Acute Otitis Externa - Pain assessment**

Steering Committee Recommendation: Not recommended

Despite the Steering Committee’s concern regarding the potential redundancy of this measure in the emergency department setting, this measure would have a significant impact in the other settings for which it is specified including urgent and outpatient care. While there is a lack of research regarding practice patterns for this specific process of care for patients with AOE, 2008 PQRI data show a significant opportunity for improvement with a mean performance score of 33.95%. Pain relief remains a major goal in the management of AOE. Ongoing assessment of the severity of discomfort is essential for proper management.
Measure #ACP-021-10: Otitis Media with Effusion - Diagnostic evaluation – Assessment of tympanic membrane mobility

Steering Committee Recommendation: Not recommended

The Work Group respectfully disagrees with the Steering Committee’s assessment that this measure may not have a significant impact on outcomes. Correctly diagnosing middle ear effusion is essential for proper management. OME must be differentiated from AOM to avoid unnecessary antimicrobial use. OME is often characterized by a cloudy tympanic membrane with distinctly impaired mobility which can best be determined with pneumatic otoscopy or tympanometry. Furthermore, survey data indicate that current practice is not adherent to the guideline. Only about half of all respondents correctly identified tympanometry as the most accurate test to predict a normal middle ear. And between 75.5 and 82.1% of respondents (depending on specialty) correctly identified the best diagnostic tests for OME.

Thank you again for the opportunity to provide this information for the Steering Committee’s consideration.


Sample PCPI Calculation Algorithm

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

Numerator (A) Includes:
Number of patients meeting numerator criteria

Denominator (PD) Includes:
Number of patients meeting criteria for denominator inclusion

Denominator Exclusions (C) Include:
Number of patients with valid medical, patient or system exclusions (where applicable; will differ by measure)

Performance Calculation
\[
\frac{A}{PD - C}
\]

If a measure does not allow for exclusion(s), it is calculated by creating a fraction with the following components:
Numerator and Denominator.

Numerator (A) Includes:
Number of patients meeting measure criteria

Denominator (PD) Includes:
Number of patients meeting criteria for denominator inclusion

Overall Exclusion Calculation
\[
\frac{C}{PD}
\]

OR

Exclusion Calculation by Type
\[
\frac{C_1}{PD} \quad \frac{C_2}{PD} \quad \frac{C_3}{PD}
\]