

## NATIONAL QUALITY FORUM—Evidence (subcriterion 1a)

**Measure Number** (if previously endorsed): 727

**Measure Title:** Gastroenteritis Admission Rate (PDI 16)

**IF the measure is a component in a composite performance measure, provide the title of the**

**Composite Measure here:** [Click here to enter composite measure #/ title](#)

**Date of Submission:** [Click here to enter a date](#)

### Instructions

- **For composite performance measures:**
  - A separate evidence form is required for each component measure unless several components were studied together.
  - If a component measure is submitted as an individual performance measure, attach the evidence form to the individual measure submission.
- Respond to all questions as instructed with answers immediately following the question. All information needed to demonstrate meeting the evidence subcriterion (1a) must be in this form. An appendix of supplemental materials may be submitted, but there is no guarantee it will be reviewed.
- If you are unable to check a box, please highlight or shade the box for your response.
- Maximum of 10 pages (includes questions/instructions; minimum font size 11 pt; do not change margins).  
**Contact NQF staff if more pages are needed.**
- Contact NQF staff regarding questions. Check for resources at [Submitting Standards webpage](#).

**Note:** The information provided in this form is intended to aid the Steering Committee and other stakeholders in understanding to what degree the evidence for this measure meets NQF's evaluation criteria.

### 1a. Evidence to Support the Measure Focus

The measure focus is evidence-based, demonstrated as follows:

- **Health outcome:** <sup>3</sup> a rationale supports the relationship of the health outcome to processes or structures of care. Applies to patient-reported outcomes (PRO), including health-related quality of life/functional status, symptom/symptom burden, experience with care, health-related behavior.
- **Intermediate clinical outcome:** a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence <sup>4</sup> that the measured intermediate clinical outcome leads to a desired health outcome.
- **Process:** <sup>5</sup> a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence <sup>4</sup> that the measured process leads to a desired health outcome.
- **Structure:** a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence <sup>4</sup> that the measured structure leads to a desired health outcome.
- **Efficiency:** <sup>6</sup> evidence not required for the resource use component.

### Notes

**3.** Generally, rare event outcomes do not provide adequate information for improvement or discrimination; however, serious reportable events that are compared to zero are appropriate outcomes for public reporting and quality improvement.

**4.** The preferred systems for grading the evidence are the U.S. Preventive Services Task Force (USPSTF) [grading definitions](#) and [methods](#), or Grading of Recommendations, Assessment, Development and Evaluation ([GRADE](#)) [guidelines](#).

**5.** 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 multistep process, the step with the strongest evidence for the link to the desired outcome should be selected as the focus of measurement. Note: A measure focused only on collecting PROM data is not a PRO-PM.

**6.** Measures of efficiency combine the concepts of resource use and quality (see NQF's [Measurement Framework: Evaluating Efficiency Across Episodes of Care](#); [AQA Principles of Efficiency Measures](#)).

**1a.1. This is a measure of:** *(should be consistent with type of measure entered in De.1)*

Outcome

- ☒ Health outcome: Click here to name the health outcome
- ☐ Patient-reported outcome (PRO): Click here to name the PRO  
*PROs include HRQoL/functional status, symptom/symptom burden, experience with care, health-related behaviors*
- ☐ Intermediate clinical outcome (e.g., lab value): Click here to name the intermediate outcome
- ☐ Process: Click here to name the process
- ☐ Structure: Click here to name the structure
- ☐ Other: Click here to name what is being measured

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**HEALTH OUTCOME/PRO PERFORMANCE MEASURE** *If not a health outcome or PRO, skip to [1a.3](#)*

**1a.2. Briefly state or diagram the path between the health outcome (or PRO) and the healthcare structures, processes, interventions, or services that influence it.**

Gastroenteritis is a leading infectious disease of childhood acute infections and leading cause of hospitalization. Many cases of gastroenteritis can be prevented by vaccination with the Rotavirus vaccine and through hygienic practices. Most cases of mild to moderate gastroenteritis can be treated in the outpatient arena. Early treatment focuses on oral rehydration.

**1a.2.1. State the rationale supporting the relationship between the health outcome (or PRO) to at least one healthcare structure, process, intervention, or service (i.e., influence on outcome/PRO).**

Access to outpatient care may prevent illness through improved education about prevention, improved vaccination rates, and early access to treatment and/or treatment advice.

Clinical practice guidelines suggest that prevention of gastroenteritis is preventable; and hence, hospitalizations for gastroenteritis are preventable.

*Note: For health outcome/PRO performance measures, no further information is required; however, you may provide evidence for any of the structures, processes, interventions, or service identified above.*

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**INTERMEDIATE OUTCOME, PROCESS, OR STRUCTURE PERFORMANCE MEASURE**

**1a.3. Briefly state or diagram the path between structure, process, intermediate outcome, and health outcomes.** Include all the steps between the measure focus and the health outcome.

**1a.3.1. What is the source of the systematic review of the body of evidence that supports the performance measure?**

- ☐ Clinical Practice Guideline recommendation – **complete sections [1a.4](#), and [1a.7](#)**
- ☐ US Preventive Services Task Force Recommendation – **complete sections [1a.5](#) and [1a.7](#)**
- ☐ Other systematic review and grading of the body of evidence (e.g., Cochrane Collaboration, AHRQ Evidence Practice Center) – **complete sections [1a.6](#) and [1a.7](#)**
- ☐ Other – **complete section [1a.8](#)**

*Please complete the sections indicated above for the source of evidence. You may skip the sections that do not apply.*

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## 1a.4. CLINICAL PRACTICE GUIDELINE RECOMMENDATION

### 1a.4.1. Guideline citation (including date) and URL for guideline (if available online):

NGC:008846 Cincinnati Children's Hospital Medical Center. Evidence-based care guideline for prevention and management of acute gastroenteritis (AGE) in children aged 2 months to 18 years. Cincinnati (OH): Cincinnati Children's Hospital Medical Center; 2011 Dec 21. 21 p. [116 references]

Other clinical practice guidelines:

NGC:007073 Cortese MM, Parashar UD, Centers for Disease Control and Prevention (CDC). Prevention of rotavirus gastroenteritis among infants and children: recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR Recomm Rep. 2009 Feb 6;58(RR-2):1-25. [122 references]

### 1a.4.2. Identify guideline recommendation number and/or page number and quote verbatim, the specific guideline recommendation.

#### Major Recommendations

The strength of the recommendation (strongly recommended, recommended, or no recommendation) and the quality of the evidence (1a–5) are defined at the end of the "Major Recommendations" field.

#### Prevention

1. It is recommended that infants be immunized against rotavirus according to the Advisory Committee on Immunization Practices (ACIP) recommendations, including during mild acute gastroenteritis (AGE) (Soares-Weiser et al., 2010 [1a]; Staat et al., 2011 [3a]; Committee on Infectious Diseases & American Academy of Pediatrics [AAP], 2009 [5]; Cortese & Parashar, 2009 [5]). See Appendix 1 in the original guideline document.
2. It is recommended that families be instructed on the benefit of:
  - Hand hygiene in the prevention of transmission of AGE in the home and at day care (Ejemot et al., 2008 [1a]), and
  - Breastfeeding as a protective practice against severe AGE in infants (Lamberti et al., 2011 [1a]; Dennehy et al., 2006 [4a]; Van der Wielen & Van Damme, 2008 [5]).

**Note:** Overall evidence demonstrates a protective effect of probiotics against AGE in children. Due to lack of specific evidence of cause of diarrhea, organism(s), dosage, and product availability, a specific recommendation for the use of probiotics in prevention of AGE is unable to be made (Sazawal et al., 2006 [1a]; Hojsak et al., "Lactobacillus GG in the prevention of nosocomial," 2010 [2a]; Hojsak et al., "Lactobacillus GG in the prevention of gastrointestinal," 2010 [2a]; Lin et al., 2009 [2b]).

#### Assessment

##### Clinical Assessment

3. It is recommended that the history and physical examination be the primary basis for the diagnosis of AGE (Porter et al., 2003 [3a]; Local Consensus, 2011 [5]; King et al., 2003 [5b]).
4. It is recommended that weight on presentation be documented as a baseline to guide rehydration therapy if needed (Steiner, DeWalt, & Byerley, 2004 [1b]; Snaith, Peutrell, & Ellis, 2008 [4b]).

**Note:** Acute weight loss based on a recent, documented pre-illness weight, as might be available in the office setting, is the most reliable measure of dehydration status on presentation (Steiner, DeWalt, & Byerley, 2004 [1b]).

5. It is recommended that clinical assessment be initially performed for the presence and degree of dehydration (none, some or severe) (Steiner, DeWalt, & Byerley, 2004 [1b]; Duggan et al., 1996 [2a]; King et al., 2003 [5b]). See Table 2 in the original guideline document for a Clinical Dehydration Scale (CDS), valid for children under age 5 years (Friedman et al., 2004 [2a]).

**Note 1:** Although the CDS is the tool with the most published evidence of validity, other clinical signs and symptoms have been shown to be helpful in diagnosing degree of dehydration, and severe dehydration can exist even in the absence of a toxic appearance (Gorelick, Shaw, & Murphy, 1997 [3a]). See Appendix 2 and Appendix 3 in the original guideline document for additional tools and information regarding clinical assessment for dehydration.

**Note 2:** A meta-analysis of clinical signs and symptoms of dehydration in children identified abnormal capillary refill time as the most useful individual sign for predicting some dehydration (likelihood ratio [LR], 4.1; 95% confidence interval: 1.7, 9.8) against a gold standard of rehydration weight. As capillary refill time is not included in the CDS, it is prudent to include it in the routine assessment for dehydration (Steiner, DeWalt, & Byerley, 2004 [1b]).

##### Laboratory Studies

6. It is recommended that laboratory tests **not** be routinely performed in children with signs and symptoms of AGE; e.g., serum electrolytes, tests for specific pathogens, and urinary indices (Steiner, DeWalt, & Byerley, 2004 [1b]; Steiner, Nager, & Wang, 2007 [3b]; Local Consensus, 2011 [5]).

**Note 1:** Serum electrolytes are sometimes useful in assessing children with dehydration and who require intravenous (IV) fluids. In the absence of evidence-based criteria to direct selective electrolyte screening, clinical judgment regarding when to obtain electrolyte studies is superior to routine screening in protecting children from unnecessary testing (Steiner, DeWalt, & Byerley, 2004 [1b]; Wathen, MacKenzie, & Bothner, 2004 [3b]; Parkin et al., 2010 [4b]; Local Consensus, 2011 [5]; Rhee & Silverstein, 2005 [5]; Steiner, DeWalt, & Byerley, 2005 [5]; Tarini & Mendoza, 2005 [5]).

**Note 2:** Consider obtaining stool testing if there is a specific pathogen community outbreak; or for children who are less than 3 months of age, have grossly bloody stools, are immunocompromised, septic, toxic, or who have a history of foreign travel (Guarino et al., 2008 [5a]). A specific pathogen community outbreak may trigger health department testing requirements prior to return to day care (Ohio Administrative Code, 2009 [5]).

### **Management**

#### **Rehydration: Some or No Dehydration**

7. It is recommended that children with some or no dehydration, including those with recurrent vomiting, be managed by frequent phone or office/urgent care follow up and, on occasion, emergency department encounters (Local Consensus, 2011 [5]; Guarino et al., 2008 [5a]).
8. It is recommended, for the child with some or no dehydration:
  - Use of the child's preferred, usual, and age appropriate diet and fluids (Brown, Peerson, & Fontaine, 1994 [1b]; Fayad et al., 1993 [2a]; Alarcon et al., 1992 [2b]; Margolis et al., 1990 [2b]), and
  - Offer commercial oral rehydration solution (ORS), if tolerated and if losses exceed intake, until an adequate degree of rehydration is achieved (Hartling et al., 2006 [1a]; Fonseca, Holdgate, & Craig, 2004 [1a]). See Table 3 in the original guideline document for suggested directions for use. See Appendix 4 in the original guideline document for information on specific ORS options.
  - Offer about 10 mL/kg of ORS for each loose stool or vomiting episode (Armon et al., 2001 [5a]).
9. It is recommended that the following **not** be used:
  - Restrictive or progressive diets (Alarcon et al., 1991 [2b]; Margolis et al., 1990 [2b]; Khin et al., 1985 [2b]; Placzek & Walker-Smith, 1984 [2b])
  - A clear liquid diet (King et al., 2003 [5b]) (see Appendix 4 in the original guideline document)
  - Diluted milk or formula (Brown, Peerson, & Fontaine, 1994 [1b])
  - Lactose-free formula, unless previously-known lactose intolerance is present (Brown, Peerson, & Fontaine, 1994 [1b])

#### **Rehydration When Intravenous (IV) Therapy Is Chosen**

10. It is recommended,
  - When unable to replace the estimated fluid deficit and keep up with the on-going losses using oral feedings alone, and/or
  - For severely dehydrated children,  
That a bolus of IV isotonic solution (i.e. lactated Ringer's solution or normal saline) be administered until signs of dehydration have been reversed.  
Suggested initial therapy:
    - 20mL/kg body weight bolus over 30 to 60 minutes with reassessment and repeat if necessary (Hartling et al., 2006 [1a]; Fonseca, Holdgate, & Craig, 2004 [1a]; Nager & Wang, 2010 [2b]; Neville et al., 2006 [2b]; Spandorfer et al., 2005 [2b]; King et al., 2003 [5b]; Khanna et al., 2009 [5]).

**Note 1:** Two small studies by a single author demonstrated that initial bolus therapy at a rate of 50 mL/kg body weight is a viable alternative (Nager & Wang, 2010 [2b]; Nager & Wang, 2002 [2b]).

**Note 2:** Nasogastric (NG) as compared to IV rehydration is as efficacious, is no more labor intensive, and is associated with fewer complications (Rouhani et al., 2011 [1b]). For the purposes of this guideline NG may be substituted for IV rehydration, but due to its infrequent use at Cincinnati Children's Hospital Medical Center (CCHMC), it is not otherwise mentioned in this document. It is appropriate to involve the family in the decision regarding the selection of IV versus NG for fluid replacement.

#### **Oral and IV Fluids After Initial Rehydration Bolus**

11. It is recommended that the child treated with IV fluids continue, as soon as tolerated, with:
  - A preferred, usual, and age appropriate diet and fluids, which may include commercial ORS (Fayad et al., 1993 [2a]; Cohen et al., 1995 [2b]; Fox et al., 1990 [2b]; Hjelt et al., 1989 [2b]; Khin et al., 1985 [2b]), and
  - About 10 mL/kg of ORS for each loose stool or vomiting episode (Armon et al., 2001 [5a]).
12. It is recommended that ongoing reassessment of hydration status and tolerance of oral rehydration therapy (ORT) be used to guide the need for and choice of IV fluids after initial isotonic bolus:
  - For the hydrated child able to tolerate oral rehydration therapy, discontinue IV therapy
  - For the child not fully hydrated upon reassessment, give additional isotonic fluids as a bolus
  - For the hydrated child unable to tolerate sufficient oral rehydration therapy to replace losses

- Give half-normal saline with 5% dextrose at a maintenance volume plus calculated replacement for losses
- After child begins to urinate (or if serum electrolytes are known to be normal) add 20 mEq/L potassium chloride (Kannan et al., 2010 [2a]; Neville et al., 2010 [2a]; Montanana et al., 2008 [2a]; Yung & Keeley, 2009 [2b]; Drysdale et al., 2010 [4a]; Hanna & Saberi, 2010 [4a]; Snaith, Peutrell, & Ellis, 2008 [4b]; Holliday & Segar, 1957 [5])

**Note 1:** Patients with abnormal plasma sodium levels or abnormal kidney function are excluded from the target population for this guideline and from all of the cited studies for this recommendation. Individual consideration for these patients is particularly important regarding maintenance fluids.

**Note 2:** The grade of the body of evidence is high for not using less than 0.45% saline during the first 24 hours of IV fluid therapy for children with normal kidney function (Kannan et al., 2010 [2a]; Yung & Keeley, 2009 [2b]; Hanna & Saberi, 2010 [4a]).

#### **Inpatient Management**

13. It is recommended that a child be admitted for inpatient care when:

- The child is severely dehydrated
- The child has intractable vomiting
- The child is unable to maintain hydration orally due to vomiting or diarrhea losses
- Caregivers cannot provide adequate care at home and/or there are social or logistical concerns (Local Consensus, 2011 [5]; Guarino et al., 2008 [5a]).

14. It is recommended, if the child requires IV fluids for more than 24 hours, or if reassessment reveals evidence of fluid or electrolyte imbalance, that selection and adjustment of IV fluid and rate of administration be based on sound principles and ongoing reassessment including:

- Frequent clinical assessment
- Daily weights, and
- Regular electrolyte monitoring as clinically indicated, at minimum every 2 to 3 days (Neville et al., 2005 [3b]; Drysdale et al., 2010 [4a]; Moritz & Ayus, 2010 [5]; Holliday, Ray, & Freidman, 2007 [5]; Guarino et al., 2008 [5a]).

**Note:** Strict intake and output measurements (I/O) are ideal to guide therapy. However, standardized measured daily weights are less burdensome to obtain and are sufficient to guide therapy, while inaccurate I/O measurements are inadequate (Drysdale et al., 2010 [4a]; Snaith, Peutrell, & Ellis, 2008 [4b]).

#### **Adjunct Therapy**

There is a growing body of literature establishing the effectiveness of selected probiotics as an adjunct to rehydration therapy in simple AGE. Proven efficacy is organism- and dose-dependent and there is no evidence of efficacy for most probiotic products (see Appendix 5 in the original guideline document for product information). In developed countries, *Lactobacillus rhamnosus* GG (LGG) given in a daily dose of 10 billion colony forming units per day (CFU/day) has proven efficacy, particularly in rotavirus, to reduce the duration of diarrhea, the risk of protracted diarrhea and the duration of hospitalization (Szajewska et al., 2007 [1a]; Guarino et al., 2008 [5a]).

15. It is recommended to talk to parents before making a decision about probiotic use. If a family chooses to use a probiotic, it is important to assure selection of an effective product (see Appendix 5 in the original guideline document).

To obtain best efficacy:

- Use a dose of at least 10 billion CFU/day of LGG (see Appendix 5 in the original guideline document regarding product availability)
- Start treatment as soon as possible
- Treat for a total of 5 to 7 days (Szajewska, Skorka, & Dylag, 2007 [1a]; Szajewska et al., 2007 [1a]; Guandalini et al., 2000 [2a]; Local Consensus, 2011 [5]; Guarino et al., 2008 [5a]; Harris et al., 2008 [5a]).

**Note:** Parameters influencing the family's decision to use probiotics may include:

- Cost
- Evidence of benefit
- Likelihood of rotavirus origin
- Transmission concerns
- Safety

(Allen et al., 2010 [1a]; Szajewska et al., 2007 [1a]; Guandalini et al., 2000 [2a]). See Appendix 5 in the original guideline document for elaboration of these parameters.

#### **Other Therapy**

16. It is recommended that antiemetics **not** be routinely used in the management of children with AGE (Fedorowicz, Jagannath, & Carter, 2011 [1a]; Szajewska, Gieruszczak-Bialek, & Dylag, 2007 [1a]).

**Note 1:** On 9/15/2011, the U.S. Food and Drug Administration (FDA) notified the healthcare community that ondansetron may increase the risk of developing prolongation of the QT interval of the electrocardiogram. Patients at risk for adverse outcomes include those with underlying heart conditions, such as congenital long QT syndrome, those who are predisposed to low levels of potassium and magnesium in the blood, and those taking other medications that lead to QT prolongation (Mehta, Sanatani, & Whyte, 2010 [2b]; FDA, 2011 [5]; McKechnie & Froese, 2010 [5]).

**Note 2:** Shared decision making may be employed in the consideration of ondansetron use in children with vomiting. Discussion points may include:

- Its use may decrease vomiting during the first hours after presentation
  - Its use may decrease the need for IV fluids in the emergency department
  - Its use may reduce hospitalization rates in those patients who require IV fluids
  - Its use may increase diarrheal episodes
  - It has a relatively high cost
  - Most studies of ondansetron use in children with AGE have
  - Been performed only on mildly dehydrated children
  - Received funding from the manufacturer of ondansetron
  - Its use may increase risk for long QT interval (Fedorowicz, Jagannath, & Carter, 2011 [1a]; DeCamp et al., 2008 [1a]; Szajewska, Gieruszczak-Bialek, & Dylag, 2007 [1a]; Yilmaz, Yildizdas, & Sertdemir, 2010 [2a]; FDA, 2011 [5]).
17. It is recommended that antimicrobial therapies **not** be used except for cases of culture-proven pathology (Barbara et al., 2000 [3a]; Szajewska & Dziechciarz, 2010 [5]). See AAP Red Book for specifics (AAP, 2009 [5]).
18. It is recommended that antidiarrheal agents **not** be routinely used in the management of children with AGE (King et al., 2003 [5b]; Khanna et al., 2009 [5]).

#### **Discharge Criteria**

19. It is recommended that for children receiving care in a hospital setting, prompt discharge be considered when the following levels of recovery are reached:
- Sufficient rehydration achieved as indicated by weight gain and/or clinical status
  - IV fluids not required
  - Oral intake equals or exceeds losses
  - Medical follow up is available via telephone or office visit
  - Adequate family teaching has occurred, including:
    - Hand hygiene at home, day care and elsewhere (see Recommendation #2 above) for prevention of AGE transmission
    - Expected course of illness
    - Prevention of dehydration
    - Signs of dehydration (Local Consensus, 2011 [5])

#### **Return to Social Life**

20. It is recommended that a child with diarrhea of infectious or unknown cause return to day care only when transmission can be reliably prevented, preferably after the diarrhea has ceased (Local Consensus, 2011 [5]; Ohio Administrative Code, 2009 [5]). At minimum:
- Stools are more formed
  - Stools are not leaking out of the diaper
  - Frequency of diaper changes are able to be handled by day care staff
  - For the toilet trained child, the child can make it to the bathroom without soiling
  - Good hand hygiene is practiced by day care staff

**Note:** Negative testing for certain pathogens may be required by law or by the day care facility (Local Consensus, 2011 [5]; Ohio Administrative Code, 2009 [5]).

**1a.4.3. Grade assigned to the quoted recommendation with definition of the grade:**

**Table of Evidence Levels**

Quality Level	Definition
1a <sup>†</sup> or 1b <sup>†</sup>	Systematic review, meta-analysis, or meta-synthesis of multiple studies
2a or 2b	Best study design for domain
3a or 3b	Fair study design for domain
4a or 4b	Weak study design for domain
5	Other: general review, expert opinion, case report, consensus report, or guideline

<sup>†</sup>a = good quality study; b = lesser quality study

**1a.4.4. Provide all other grades and associated definitions for recommendations in the grading system.** (Note: If separate grades for the strength of the evidence, report them in section 1a.7.)

**1a.4.5. Citation and URL for methodology for grading recommendations** (if different from 1a.4.1):

**1a.4.6. If guideline is evidence-based (rather than expert opinion), are the details of the quantity, quality, and consistency of the body of evidence available (e.g., evidence tables)?**

☐ Yes → **complete section 1a.7**

☐ No → **report on another systematic review of the evidence in sections 1a.6 and 1a.7; if another review does not exist, provide what is known from the guideline review of evidence in 1a.7**

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**1a.5. UNITED STATES PREVENTIVE SERVICES TASK FORCE RECOMMENDATION**

**1a.5.1. Recommendation citation** (including date) and **URL for recommendation** (if available online):

**1a.5.2. Identify recommendation number and/or page number and quote verbatim, the specific recommendation.**

**1a.5.3. Grade assigned to the quoted recommendation with definition of the grade:**

**1a.5.4. Provide all other grades and associated definitions for recommendations in the grading system.** (Note: the grading system for the evidence should be reported in section 1a.7.)

**1a.5.5. Citation and URL for methodology for grading recommendations** (if different from 1a.5.1):

**Complete section 1a.7**

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**1a.6. OTHER SYSTEMATIC REVIEW OF THE BODY OF EVIDENCE**

**1a.6.1. Citation** (including date) and **URL** (if available online):

**1a.6.2.** Citation and URL for methodology for evidence review and grading (if different from 1a.6.1):

Complete section [1a.7](#)

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**1a.7. FINDINGS FROM SYSTEMATIC REVIEW OF BODY OF THE EVIDENCE SUPPORTING THE MEASURE**

*If more than one systematic review of the evidence is identified above, you may choose to summarize the one (or more) for which the best information is available to provide a summary of the quantity, quality, and consistency of the body of evidence. Be sure to identify which review is the basis of the responses in this section and if more than one, provide a separate response for each review.*

**1a.7.1.** What was the specific structure, treatment, intervention, service, or intermediate outcome addressed in the evidence review?

**1a.7.2.** Grade assigned for the quality of the quoted evidence with definition of the grade:

**1a.7.3.** Provide all other grades and associated definitions for strength of the evidence in the grading system.

**1a.7.4.** What is the time period covered by the body of evidence? (provide the date range, e.g., 1990-2010). Date range: [Click here to enter date range](#)

**QUANTITY AND QUALITY OF BODY OF EVIDENCE**

**1a.7.5.** How many and what type of study designs are included in the body of evidence? (e.g., 3 randomized controlled trials and 1 observational study)

**1a.7.6.** What is the overall quality of evidence across studies in the body of evidence? (discuss the certainty or confidence in the estimates of effect particularly in relation to study factors such as design flaws, imprecision due to small numbers, indirectness of studies to the measure focus or target population)

**ESTIMATES OF BENEFIT AND CONSISTENCY ACROSS STUDIES IN BODY OF EVIDENCE**

**1a.7.7.** What are the estimates of benefit—magnitude and direction of effect on outcome(s) across studies in the body of evidence? (e.g., ranges of percentages or odds ratios for improvement/decline across studies, results of meta-analysis, and statistical significance)

**1a.7.8.** What harms were studied and how do they affect the net benefit (benefits over harms)?

**UPDATE TO THE SYSTEMATIC REVIEW(S) OF THE BODY OF EVIDENCE**

**1a.7.9.** If new studies have been conducted since the systematic review of the body of evidence, provide for each new study: 1) citation, 2) description, 3) results, 4) impact on conclusions of systematic review.

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**1a.8 OTHER SOURCE OF EVIDENCE**

*If source of evidence is NOT from a clinical practice guideline, USPSTF, or systematic review, please describe the evidence on which you are basing the performance measure.*

**1a.8.1** What process was used to identify the evidence?

**1a.8.2.** Provide the citation and summary for each piece of evidence.