**National Quality Forum—Evidence (subcriterion 1a)**

**Measure Number** (*if previously endorsed*)**:** 0108

**Measure Title**: Follow-Up Care for Children Prescribed ADHD Medication (ADD)

**IF the measure is a component in a composite performance measure, provide the title of the Composite Measure here:** N/A

**Date of Submission**: 4/2/2020

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| **Instructions**  *Complete 1a.1 and 1a.2 for all measures. If instrument-based measure, complete 1a.3.*  *Complete* ***EITHER 1a.2, 1a.3 or 1a.4*** *as applicable for the type of measure and evidence.*  *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.*   * 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. * Contact NQF staff regarding questions. Check for resources at [Submitting Standards webpage](http://www.qualityforum.org/Measuring_Performance/Submitting_Standards.aspx). |

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| **Note: The information provided in this form is intended to aid the Standing 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:   * Outcome: [**3**](#Note3) Empirical data demonstrate a relationship between the outcome and at least one healthcare structure, process, intervention, or service. If not available, wide variation in performance can be used as evidence, assuming the data are from a robust number of providers and results are not subject to systematic bias. * Intermediate clinical outcome: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#Note4)that the measured intermediate clinical outcome leads to a desired health outcome. * Process: [**5**](#Note5) a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#Note4) 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 [**4**](#Note4) that the measured structure leads to a desired health outcome. * Efficiency: [**6**](#Note6) evidence not required for the resource use component. * For measures derived from patient reports, evidence should demonstrate that the target population values the measured outcome, process, or structure and finds it meaningful. * Process measures incorporating Appropriate Use Criteria: See NQF’s guidance for evidence for measures, in general; guidance for measures specifically based on clinical practice guidelines apply as well.   **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 Grading of Recommendations, Assessment, Development and Evaluation [(GRADE) guidelines](http://www.gradeworkinggroup.org) and/or modified GRADE.  **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](http://www.qualityforum.org/Publications/2010/01/Measurement_Framework__Evaluating_Efficiency_Across_Patient-Focused_Episodes_of_Care.aspx); [AQA Principles of Efficiency Measures](http://www.aqaalliance.org/files/PrinciplesofEfficiencyMeasurementApril2006.doc)). |

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

Outcome

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.* (*A PRO-based performance measure is not a survey instrument. Data may be collected using a survey instrument to construct a PRO measure.)*

Intermediate clinical outcome (*e.g., lab value*): Click here to name the intermediate outcome

Process: Follow-Up Care for Children Prescribed ADHD Medication

Appropriate use measure: Click here to name what is being measured

Structure: Click here to name the structure

Composite: Click here to name what is being measured

**1a.2** **LOGIC MODEL** Diagram or briefly describe the steps between the healthcare structures and processes (e.g., interventions, or services) and the patient’s health outcome(s). The relationships in the diagram should be easily understood by general, non-technical audiences. Indicate the structure, process or outcome being measured.

Children newly prescribed attention-deficit hyperactivity disorder (ADHD) medication >> timely follow-up visits occur >> medication effectiveness and any adverse effects are assessed >> dose is adjusted if needed >> treatment adherence and health outcomes are improved

**1a.3** **Value and Meaningfulness:**  **IF** this measure is derived from patient report, provide evidence that the target population values the measured ***outcome, process, or structure*** and finds it meaningful. (Describe how and from whom their input was obtained.)

**NA.**

**\*\*RESPOND TO ONLY ONE SECTION BELOW -EITHER 1a.2, 1a.3 or 1a.4) \*\***

**1a.2** **FOR OUTCOME MEASURES including PATIENT REPORTED OUTCOMES - Provide empirical data demonstrating the relationship between the outcome (or PRO) to at least one healthcare structure, process, intervention, or service.**

**1a.3.****SYSTEMATIC REVIEW(SR) OF THE EVIDENCE (for intermediate outcome, PROCESS, or STRUCTURE PERFORMANCE measures, including those that are instrument-based) If the evidence is not based on a systematic review go to section 1a.4) If you wish to include more than one systematic review, add additional tables.**

**What is the source of the systematic review of the body of evidence that supports the performance measure? A systematic review is a scientific investigation that focuses on a specific question and uses explicit, prespecified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies. It may include a quantitative synthesis (meta-analysis), depending on the available data. (IOM)**

Clinical Practice Guideline recommendation (with evidence review)

☐ US Preventive Services Task Force Recommendation

☐ Other systematic review and grading of the body of evidence (*e.g., Cochrane Collaboration, AHRQ Evidence Practice Center*)

☐ Other

**Table 1: American Academy of Pediatrics Guidelines**

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| **Source of Systematic Review:**   * **Title** * **Author** * **Date** * **Citation, including page number** * **URL** | * ADHD: Clinical Practice Guideline for the Diagnosis, Evaluation, and Treatment of Attention-Deficit/Hyperactivity Disorder in Children and Adolescents * American Academy of Pediatrics (AAP) * 2019 * ADHD: Clinical Practice Guideline for the Diagnosis, Evaluation, and Treatment of Attention-Deficit/Hyperactivity Disorder in Children and Adolescents. Subcommittee On Attention-Deficit/Hyperactivity Disorder. September 30, 2019, peds.2019;144; DOI: 10.1542/peds.2019-2528 * https://pediatrics.aappublications.org/content/pediatrics/144/4/e20192528.full.pdf |
| Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the SR. | American Academy of Pediatrics Clinical Practice Guideline for the Diagnosis, Evaluation and Treatment of ADHD in Children and Adolescents  *Key Action Statement (KAS) 1:* The pediatrician or other primary care clinicians (PCC) should initiate an evaluation for ADHD for any child or adolescent age 4 years to the 18th birthday who presents with academic or behavioral problems and symptoms of inattention, hyperactivity, or impulsivity. *Grade B: Strong Recommendation*  *KAS 4:* ADHD is a chronic condition; therefore, the PCC should manage children and adolescents with ADHD in the same manner that they would children and youth with special health care needs, following the principles of the chronic care model and the medical home. *Grade B: Strong Recommendation*  *KAS 5b*: For elementary and middle school-aged children (age 6 years to the 12th birthday) with ADHD, the PCC should prescribe FDA-approved medications for ADHD, along with parent training in behavior management (PTBM) and/or behavioral classroom intervention (preferably both PTBM and behavioral classroom interventions). Educational interventions and individualized instructional supports, including school environment, class placement, instructional placement, and behavioral supports, are a necessary part of any treatment plan and often include an IEP or a rehabilitation plan (504 plan). *Grade A: Strong Recommendation* |
| Grade assigned to the **evidence** associated with the recommendation with the definition of the grade | The grade assigned by the AAP to the evidence supporting the listed Clinical Practice Guidelines for the Diagnosis, Evaluation and Treatment of ADHD in Children and Adolescents were A and B.  Grade A: Meta-analysis, systematic reviews of RCTs or diagnostic studies with minor limitations; overwhelmingly consistent evidence from observational studies  Grade B: RCTs or diagnostic studies with minor limitations; overwhelmingly consistent evidence from observational studies |
| Provide all other grades and definitions from the evidence grading system |  |
| Grade assigned to the **recommendation** with definition of the grade | The AAP assigned the categorization of Strong Recommendation to the listed Clinical Practice Guidelines for the Diagnosis, Evaluation and Treatment of ADHD in Children and Adolescents.  Strong Recommendation: A strong recommendation means that the committee believes that the benefits of the recommended approach clearly exceed the harms of that approach (or, in the case of a strong negative recommendation, that the harms clearly exceed the benefits) and that the quality of the evidence supporting this approach is either excellent or impossible to obtain. Clinicians should follow such guidance unless a clear and compelling rationale for acting in a contrary manner is present |
| Provide all other grades and definitions from the recommendation grading system | **American Academy of Pediatrics Grading System**   * Recommendation**:** A recommendation means that the committee believes that the benefits exceed the harms (or, in the case of a negative recommendation, that the harms exceed the benefits), but the quality of the evidence on which this recommendation is based is not as strong. Clinicians also generally should follow such guidance but also should be alert to new information and sensitive to patient preferences * Option: An option means either that the evidence quality that exists is suspect or that well-designed, well-conducted studies have demonstrated little clear advantage to one approach versus another. Options offer clinicians flexibility in their decision-making regarding appropriate practice, although they may set boundaries on alternatives. Patient preference should have a substantial role in influencing clinical decision-making, particularly when policies are expressed as options.   No Recommendation: No recommendation is made when there is both a lack of pertinent evidence and an unclear balance between benefits and harms. Clinicians should feel little constraint in their decision-making when addressing areas with insufficient evidence. Patient preference should have a substantial role in influencing clinical decision-making. |
| Body of evidence:   * Quantity – how many studies? * Quality – what type of studies? | Guidelines from the American Academy of Pediatrics (Wolraich et al. 2011) cite a randomized control trial of 600 children diagnosed with ADHD ages 7-9 years old, as well as a prospective observational cohort study of 34 children. It also cites two systematic literature reviews and the chronic care model (Bodenheimer, Wagner, & Grumbach 2002). The action statement also received a grade of B, which indicates high quality evidence including randomized controlled trials.  The evidence supporting the AAP guidelines received a grade of B, indicating that the guideline is supported by strong evidence consisting of randomized controlled trials and that there is a preponderance of benefit compared to harm. Additionally, the AAP guideline is based on 15 randomized controlled trials in addition to multiple controlled and uncontrolled trials, all providing evidence of the efficacy of continuous medication treatment and exploring side effects and other aspects of ADHD medication use that require monitoring. |
| Estimates of benefit and consistency across studies | The evidence supporting the guidelines demonstrate the benefits of consistent treatment, side-effect monitoring and medication adjustment for children and adolescents with ADHD. Timely follow-up visits ensure children and adolescents on AHDH medications receive these services. Both the AAP and AACAP guidelines are based on the Multi-Modal Treatment Study of Children with ADHD (MTA) (in addition to other studies). In the MTA study, children with ADHD were randomized to four groups: algorithmic medication treatment alone, psychosocial treatment alone, a combination of algorithmic medication management and psychosocial treatment, and community treatment. Algorithmic medication treatment consisted of monthly appointments in which the dose of medication was titrated according to parent and teacher rating scales. Children in all four treatment groups demonstrated benefits to treatment in terms of reduced symptoms of ADHD compared to baseline. The two groups that received algorithmic medication management showed a superior outcome with regard to ADHD symptoms compared with those that received intensive behavioral treatment alone or community treatment (MTA Cooperative Group, 1999a [rct]). Once the study treatments ceased at 14 months, the combined and medication groups lost some of their treatment gains, in part because of medication discontinuation and in part because the medication was now being given in the community with less careful monitoring and dose adjustment (MTA Cooperative Group, 2004a [rct], 2004b [rct]). |
| What harms were identified? | The American Academy of Pediatrics provided an analysis of net benefit and concluded that there is a preponderance of benefit over harm because of the opportunity to assess adverse effects of medication and to sustain treatment. |
| Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR? | There have been no new studies that contradict the current body of evidence. |

**Table 2: American Academy of Child and Adolescent Psychiatry Guidelines**

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| **Source of Systematic Review:**   * **Title** * **Author** * **Date** * **Citation, including page number** * **URL** | Practice parameter for the assessment and treatment of children and adolescents with attention-deficit/hyperactivity disorder.  American Academy of Child and Adolescent Psychiatry (AACAP)  2007  Practice Parameter for the Assessment and Treatment of Children and Adolescents With Attention-Deficit/Hyperactivity Disorder  Pliszka, Steven. Journal of the American Academy of Child & Adolescent Psychiatry , Volume 46 , Issue 7 , 894 – 921.  <http://www.jaacap.com/article/S0890-8567(09)62182-1/abstract> |
| Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the SR. | Overall Guideline  The key to effective long-term management of the patient with ADHD is continuity of care with a clinician experienced in the treatment of ADHD. The frequency and duration of follow-up sessions should be individualized for each family and patient, depending on the severity of ADHD symptoms; the degree of comorbidity of other psychiatric illness; the response to treatment; and the degree of impairment in home, school, work, or peer-related activities. The clinician should establish an effective mechanism for receiving feedback from the family and other important informants in the patient’s environment to be sure symptoms are well controlled and side effects are minimal. Although this parameter does not seek to set a formula for the method of follow-up, significant contact with the clinician should typically occur two to four times per year in cases of uncomplicated ADHD and up to weekly sessions at times of severe dysfunction or complications of treatment.  Specific Recommendations  Recommendation 6: A Well-Thought-Out and Comprehensive Treatment Plan Should Be Developed for the Patient With ADHD. The treatment plan should be reviewed regularly and modified if the patient’s symptoms do not respond. Minimal Standard [MS]  Recommendation 9. During a Psychopharmacological Intervention for ADHD, the Patient Should Be Monitored for Treatment-Emergent Side Effects. Minimal Standard [MS]  Recommendation 12. Patients Should Be Assessed Periodically to Determine Whether There Is Continued Need for Treatment or If Symptoms Have Remitted. Treatment of ADHD Should Continue as Long as Symptoms Remain Present and Cause Impairment. Minimal Standard [MS] |
| Grade assigned to the **evidence** associated with the recommendation with the definition of the grade | The grade assigned by AACAP to the evidence supporting the listed Practice Parameters for the Assessment and Treatment of Children and Adolescents with ADHD varied by study and included [rct] and [ut]:  • [rct] Randomized, controlled trial is applied to studies in which subjects are randomly assigned to two or more treatment conditions.  • [ut] Uncontrolled trial is applied to studies in which subjects are assigned to one treatment condition |
| Provide all other grades and definitions from the evidence grading system | The grades assigned by the AACAP to evidence supporting the Practice Parameters for the Assessment and Treatment of Children and Adolescents with ADHD noted the strength of the study by listing the study type. Other studies used to support the guidelines included:  • [rct] Randomized, controlled trial is applied to studies in which subjects are randomly assigned to two or more treatment conditions.  • [ct] Controlled trial is applied to studies in which subjects are nonrandomly assigned to two or more treatment conditions.  • [ut] Uncontrolled trial is applied to studies in which subjects are assigned to one treatment condition.  • [cs] Case series/report is applied to a case series or a case report. |
| Grade assigned to the **recommendation** with definition of the grade | AACAP assigned a grade of [MS] Minimal Standard to the listed Practice Parameters for the Assessment and Treatment of Children and Adolescents with ADHD.  [MS] Minimal Standard is applied to recommendations that are based on rigorous empirical evidence (e.g., randomized, controlled trials) and/or overwhelming clinical consensus. Minimal standards apply more than 95% of the time (i.e., in almost all cases). |
| Provide all other grades and definitions from the recommendation grading system | American Academy of Child and Adolescent Psychiatry Grading System  [CG] Clinical Guideline is applied to recommendations that are based on strong empirical evidence (e.g., nonrandomized, controlled trials) and/or strong clinical consensus. Clinical guidelines apply approximately 75% of the time (i.e., in most cases).  [OP] Option is applied to recommendations that are acceptable based on emerging empirical evidence (e.g., uncontrolled trials or case series/reports) or clinical opinion, but lack strong empirical evidence and/or strong clinical consensus.  [NE] Not Endorsed is applied to practices that are known to be ineffective or contraindicated. |
| Body of evidence:   * Quantity – how many studies? * Quality – what type of studies? | Guidelines from the American Academy of Child and Adolescent Psychiatry (Pliszka 2007) cite two randomized control trials, one of which enrolled 600 children diagnosed with ADHD ages 7-9 years. The other study enrolled 103 children diagnosed with ADHD also ages 7-9. In addition to these large randomized control trials, each recommendation cited additional studies which provided further evidence examining treatment planning for children with ADHD, side effects associated with ADHD medications, medication adherence, and treatment adjustment.  Recommendation 6: Treatment Plan review and modification: 3 RCTs  Recommendation 9: Side Effect Monitoring: 4 RCTS, 1 CT, 1 UT  Recommendation 12: Periodic Assessment of Symptoms: 8 RCTs, 5 UTs  Overall, the quality of the evidence regarding follow-up care for children with a prescription for an ADHD medication is good. Guidelines from the American Academy of Pediatrics and the American Academy of Child and Adolescent Psychiatry cite the Multi-Modal Treatment Study of Children with ADHD (MTA). The 1999-published MTA study, sponsored by the National Institute of Mental Health, was a randomized control trial, multi-site study of nearly 600 elementary school children, 7-9 years of age who were diagnosed with ADHD and randomly assigned to one of four treatment modes: medication alone; psychosocial/behavioral treatment alone; a combination of both; or routine community care. The MTA study demonstrated that, on average, carefully monitored medication management with monthly follow-up is more effective than intensive behavioral treatment for ADHD symptoms, for periods lasting as long as 14 months. The quality of this study can be considered high due to the randomization and large sample size. The AACAP guideline is based on 15 randomized controlled trials in addition to multiple controlled and uncontrolled trials, all providing evidence of the efficacy of continuous medication treatment and exploring side effects and other aspects of ADHD medication use that require monitoring. |
| Estimates of benefit and consistency across studies | The evidence supporting the guidelines demonstrate the benefits of consistent treatment, side-effect monitoring and medication adjustment for children and adolescents with ADHD. Timely follow-up visits ensure children and adolescents on AHDH medications receive these services. Both the AAP and AACAP guidelines are based on the Multi-Modal Treatment Study of Children with ADHD (MTA) (in addition to other studies). In the MTA study, children with ADHD were randomized to four groups: algorithmic medication treatment alone, psychosocial treatment alone, a combination of algorithmic medication management and psychosocial treatment, and community treatment. Algorithmic medication treatment consisted of monthly appointments in which the dose of medication was titrated according to parent and teacher rating scales. Children in all four treatment groups demonstrated benefits to treatment in terms of reduced symptoms of ADHD compared to baseline. The two groups that received algorithmic medication management showed a superior outcome with regard to ADHD symptoms compared with those that received intensive behavioral treatment alone or community treatment (MTA Cooperative Group, 1999a [rct]). Once the study treatments ceased at 14 months, the combined and medication groups lost some of their treatment gains, in part because of medication discontinuation and in part because the medication was now being given in the community with less careful monitoring and dose adjustment (MTA Cooperative Group, 2004a [rct], 2004b [rct]). In terms of side-effect monitoring, the AACAP guidelines are based on four randomized controlled trials, one controlled trial and one uncontrolled trial. These trials found that it is prudent to monitor side effects in order to optimize patient outcomes. |
| What harms were identified? | N/A |
| Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR? | Numerous (>100) studies related to the care for patients with ADHD have been published since the publication of this guideline, none of which contradict the need for appropriate follow-up once treatment with medication begins. |

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**1a.4 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.4.1** **Briefly SYNTHESIZE the evidence that supports the measure.** A list of references without a summary is not acceptable.

**1a.4.2 What process was used to identify the evidence?**

**1a.4.3.** **Provide the citation(s) for the evidence.**