Research Protocol for Prior Authorization Policies for Pediatric ADHD Medication Prescriptions

Prepared by the Policy Surveillance Program and the Centers for Disease Control and Prevention

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Prior Authorization Policies for Pediatric ADHD Medication Prescriptions

I. Date of Protocol: May 3, 2016

II. Scope: Compile state Medicaid prior authorization policies for the coverage of prescription medications used to treat children younger than age 18 years with attention-deficit/hyperactivity disorder (ADHD). This dataset is limited to Medicaid policies that require prior authorization for children younger than age 18 years for preferred and non-preferred ADHD medications. The Centers for Disease Control and Prevention (CDC) and the Policy Surveillance Program (PSP) collaborated to research and build this dataset.

III. Primary Data Collection:


b. Dates Covered in the Dataset: August 24, 2009–November 1, 2015. The effective date listed for each state is the date of the most recent version of the prior authorization policy coded. If more than one prior authorization form or official document was included in the legal text for a state, the effective date reflects the date of the most recently updated document.

c. Data Collection Methods:

- The team building this dataset included two legal researchers and one supervisor. One researcher was from CDC (researcher 1) and the other researcher was from PSP (researcher 2). The supervisor was from PSP. In addition, an epidemiology assistant from CDC’s Child Development Studies (CDS) team performed preliminary research for this dataset.
- The CDS epidemiology assistant performed the following research procedure during November 2014–June 2015. First, the epidemiology assistant conducted Internet searches for Medicaid prior authorization policies for each state and the District of Columbia that addressed the prescription of ADHD medications, stimulant medications, or psychotropic medications to children younger than age 6 years. The epidemiology assistant collected prior authorization forms, memoranda from state
Medicaid directors to prescribers, and drug utilization review board meeting notes. The epidemiology assistant performed a secondary search for the state’s preferred drug list (PDL). The epidemiology assistant then performed a cross-check with the Centers for Medicare and Medicaid Services’ Medicaid Drug Utilization Review State Comparison/Summary Report FFY 2013 Annual Report, in which each state was asked to report any program in place to monitor, manage, or control the use of stimulants or psychotropic medications. Finally, the epidemiology assistant contacted the state Medicaid office of each state for which evidence of a policy was collected to confirm the date that prior authorization was first implemented in that state.

- Researcher 1 did not repeat the research on the 17 states that the epidemiology assistant confirmed had prior authorization policies relevant to the dataset. Researcher 1 repeated the research on the other 33 states and the District of Columbia. During July 22–August 25, 2015, Researcher 1 conducted Internet searches for Medicaid prior authorization policies involving the prescription of ADHD medications, stimulant medications, or psychotropic medications to children younger than age 18 years in the 33 remaining jurisdictions. Researcher 1 collected prior authorization forms, memoranda from state Medicaid directors to prescribers, drug utilization review board meeting notes, and state PDLs.

- While conducting background research on September 16, 2015, researcher 1 discovered an additional state with prior authorization policies (Florida).

- During coding, both researchers performed a final research check by searching state Medicaid websites to ensure that policies effective as of November 1, 2015, had been collected and coded.

- After coding was completed, to ensure that all states with policies had been captured, the researchers checked all states marked as "no" for the existence of a publicly available policy. They also performed supplemental web research as needed on state Medicaid websites for states with policies for each type of medication (e.g., Florida has separate policies for stimulants and long-acting stimulants) to ensure that no additional policies were missed.

IV. Coding:

a. Development of Coding Scheme: The researchers developed questions based on initial research conducted by CDC. CDC provided an initial list of states with prior authorization policies and copies of those policies, which the researchers used to extract variables for the coding scheme. Coding questions were
developed and circulated to the supervisor and to a CDC epidemiologist, whose research focuses on childhood neurobehavioral and mental health conditions such as ADHD, for approval. When the questions were finalized, the researchers entered them into the LawAtlas Workbench for coding.

The researchers then performed a preliminary application of the coding scheme to 10 states’ policies. Each researcher coded the policies of five states and then redundantly coded the five remaining states’ policies. The supervisor performed quality control measures, described in greater detail in Section V, to determine any divergences between the researchers’ coding answers. The supervisor and researchers then discussed and resolved all divergences. Coding questions were edited for clarity when the wording of a question caused a divergence. This process was repeated after each of four rounds of coding.

b. Coding Methods:
   - The text coded was limited to “prior authorization policies,” as defined below. Statutes and regulations that were cited or cross-referenced in these policies were not coded or included in the legal text.
   - For all questions:
     - “Prior authorization policy” (hereafter “policy” or “policies”):
       1. This term is defined as a state Medicaid policy (administered via traditional fee-for-service and not solely through third parties, such as managed care organizations) that prevents children younger than age 18 years from receiving coverage for prescribed preferred and non-preferred ADHD medications without additional prescriber involvement. The documentation considered a policy in this dataset included a prior authorization form with criteria, a policy memo detailing that state’s prior authorization criteria, and/or a state Medicaid PDL that included prior authorization criteria.
       2. The states coded in this dataset were limited to states that included both preferred and non-preferred drugs within the scope of their Medicaid prior authorization policies. Therefore, a state that had a PDL with prior authorization criteria that applied only to non-preferred drugs for all children younger than age 18 years was coded as “no” for the question, “Does the state Medicaid program have a policy that requires prior authorization for ADHD medications prescribed to children younger than age 18 years?” because the patient was not prevented from obtaining coverage for preferred drugs.
       3. States with Children’s Health Insurance Program (“CHIP”) policies, a subgroup of Medicaid, (e.g., Wyoming) or states with traditional fee-for-service programs that did not
encompass all Medicaid beneficiaries in a state (e.g., Louisiana) also were coded as having a policy and were caution noted in the question, “*Does the policy require prior authorization for ADHD medications prescribed to children younger than age 18 years?*”

- Dosing and quantity limitations: The researchers focused on age limitations for ADHD medications and did not code information in the policies about polypharmacy, dosing limitations, quantity limitations, or requirements that a prescriber verify dosing to receive prior authorization.
- Psychotropic medication policies: When a state had two applicable policies, one for a broader category of psychotropic medications and one tailored to ADHD medications, the researchers only coded the ADHD policy (e.g., Massachusetts, Nevada).

- For the question, “*When was prior authorization first implemented?*”
  - This question was coded by the researchers but its results will not be published. The question captured the date that ADHD medication prior authorization for children younger than age 18 years was first implemented in the state. Sources of information used to code this question included email communications from state officials who confirmed the implementation date; policy memoranda, PDLs, or prior authorization forms that listed the implementation date; or the date included on the earliest version of the prior authorization form or PDL that could be identified by the researchers. The source of the implementation date is identified in the citation field for each state coded. If the researchers lacked enough information to be confident in the coding response for this question, this is also noted in the applicable citation field. The implementation date is different from the effective date in this dataset. The implementation date is the date that prior authorization for children younger than age 18 years was first implemented in that state, while the effective date, explained in section III(b) above, is the date that the most recent policy coded for that state became effective.

- For the question, “*Which ages require prior authorization?*”
  - If the statement “child younger than 18” appeared in the policy, the researchers coded “Child younger than 1” and each of the ages from “1” through “17.”
  - If a policy listed specific age-medication combinations (e.g., if stimulants and non-stimulants had different age requirements for prior authorization), the researchers coded all of the ages that appeared and did not caution note the specific medications tied to those ages.
The user will need to read the policies cited in the legal text for that information.

- Depending on the type of documentation included as a policy (e.g., form, PDL), the ways different policies listed the ages for prior authorization varied:

1. A policy that listed ages where prior authorization is explicitly required or approved was coded with those ages as answer choices.

2. A policy that listed a “minimum age” meant that any patient below that minimum age needed prior authorization. For example, in Mississippi, the minimum age limit for amphetamine salts and dextroamphetamine was age 3 years, which meant that prior authorization for those drugs must be obtained for patients younger than age 3 years; therefore, “Child younger than 1,” “1,” and “2” were among the ages coded. Similarly, for example, in Idaho, atomoxetine is approved for payment for eligible participants “over [6] years old,” which means that prior authorization must be obtained for patients ages 6 years or younger. Therefore, “Child younger than 1,” “1,” “2,” “3,” “4,” “5,” and “6” were among the ages coded.

3. A policy that listed a “maximum age” meant that any patient above that age must receive prior authorization. In Oregon, for example, guanfacine had a minimum age of 6 years and a maximum age of 17 years. Thus, prior authorization was required for this medication for patients aged 0–5 years and 18 years or older. Therefore, the ages coded were “Child younger than 1,” “1,” “2,” “3,” “4,” and “5” because patients age 18 years and older were not captured by this dataset.

4. “Ages outside of FDA parameters” was coded when the policy listed specific FDA indicated age ranges for ADHD drugs, outside of which required prior authorization, or states where prior authorization was required for prescriptions outside of age “limits” or “parameters.” This answer choice was not mutually exclusive and was coded along with any applicable ages, when listed.

- For the question, “Does the policy expressly deny authorization for certain ages?”
  - This question intended to identify policies that set an age limit or age range outside of which a request for coverage of the medication would not be considered, and authorization would be denied automatically. For example, Minnesota Medicaid policy stated, “[A] child must be at
least [3] years old for all ADHD … prescriptions. Prior authorization (PA) overrides will not be available for children younger than age 3.”

- This question was coded “yes” if the policy provided an age or age range for which prior authorization would be denied in those states (e.g., Minnesota, Texas). States coded with a “yes” response were also caution noted with details on the applicable age or age range for that response.

- For the question, “Does the policy specify ADHD medications that require prior authorization?”
  - This question was coded as “yes” only if medication types (stimulants or non-stimulants) were listed in the policy, or specific medications or their applicable trade names were listed in the policy as requiring prior authorization. Policies that only listed “all ADHD medications,” “ADHD agents,” or “ADHD medications” were coded as “no” for this question.

- The questions asking “Are stimulants included?” and “Are non-stimulants included?” were coded “yes” when the policy stated that “stimulant” or “non-stimulant” medications required prior authorization, or when the following medications or applicable trade names were listed as requiring prior authorization:
  - Examples of stimulant medications coded:
    1. Methylphenidate derivatives (short-acting/immediate release and long-acting/extended release)
    2. Amphetamine derivatives (short-acting/immediate release and long-acting/extended release)
    3. Modafinil (when used to treat ADHD)
    4. Armodafinil (when used to treat ADHD)
  - Examples of non-stimulant medications (sometimes also referred to as stimulant-like medications) coded:
    1. Atomoxetine
    2. Clonidine (including extended release)
    3. Guanfacine (including extended release)
  - For more information about stimulant and non-stimulant medication classifications, see http://adhdmedicationguide.com/adhd_med_guide_lr.pdf.
  - Some policies listed medications merely as “other,” undefined agents used to treat ADHD. These other agents were not coded, as the researchers chose to focus on stimulants and non-stimulants.

- For the question, “Does the policy list criteria for approval?”
  - The researchers coded this question as “no” if the policy listed criteria, but the only criteria listed were outside of the dataset’s scope. For example, the researchers coded “no” if the only criteria in the policy pertained to dosing and quantity limitations, which were
determined to be criteria outside the project’s scope. Therefore, this question and the question, “What criteria are listed to receive approval?” did not capture all criteria listed in the policy but rather all criteria that were within the project’s scope. Additional criteria considered outside the project’s scope are described below.

- For the question, “What criteria are listed to receive approval?”
  - This question captured approval criteria listed in the policy for children younger than age 18 years. The criteria coded included both criteria that were mandatory for the prescriber to demonstrate and criteria that only needed to be considered by the prescriber. The latter type of criteria sometimes appeared in the form of a question on the prior authorization form (e.g., for Virginia, “[H]as the provider consulted with a Psychiatrist, Neurologist, or a Developmental/Behavioral Pediatrician before prescribing the requested medication?” was coded as “Prescriber consultation with a medical provider”). The criteria captured by this question include all applicable criteria, within the researchers’ scope defined here, that the researchers found for children younger than age 18 years. If some criteria only applied to certain ages, the researchers did not capture the specific age-criteria relationship, and the user will need to refer to the policy to see whether the criteria applied to a particular age.
  - “ADHD diagnosis” was coded when the policy prompted the prescriber to list ADHD as a diagnosis or its applicable diagnosis code to receive prior authorization.
  - “Psychological evaluation” was coded when a patient psychological or behavioral evaluation or consultation was listed in the prior authorization criteria.
  - “Prescriber consultation with a medical provider” was coded when a prescriber was asked to consult with a specialist (e.g., psychiatrist, pediatrician) or obtain approval from one or more other medical professionals as part of the prior authorization process.
  - The responses “consideration of non-medication alternatives” or “consideration of medication alternatives” were coded when the prescriber was asked to show that these alternatives were considered or attempted but did not need to show that the alternatives failed. Contraindications or allergies to a medication alternative were not considered “consideration” of that alternative and were not coded in this dataset.
  - The responses “failure of medication alternatives” or “failure of non-medication alternatives” were only coded when the prescriber was asked to demonstrate that an attempted medication or non-medication
alternative did not succeed. States that listed “trial and failure” of a particular drug were coded as “failure of medication alternatives.”

- Many state children and family services agencies have consent-related policies for medicating children in foster care. Researchers did not specifically code approval requirements or criteria that were for foster children.

- The researchers did not code criteria that were not specifically attributable to ADHD medications but could be applicable to all psychotropic medications. As such, the following criteria were excluded from the project scope:
  1. Risk of harm to self or others
  2. Hospitalization for psychiatric conditions

- The researchers also did not code the following criteria:
  1. Clinical rationale, review, or reasons
  2. Yearly evaluation or primary care evaluation
  3. Patient history (including school performance, family history, lab results)
  4. Treatment plan or patient-monitoring plan
  5. Prescriber involvement

- Criteria that were highly specific to one ADHD drug were not coded:
  1. For example, in Minnesota and Wyoming, the need to show some benefit from immediate release forms of medications was not coded; however, if the policy clearly included a trial of immediate release medications, this was coded as “consideration of medication alternatives.”

V. Quality Control:

Quality control consisted of the supervisor exporting the data into a Microsoft Excel document each day the researchers completed coding to examine the data for any missing entries, citations, and caution notes and to calculate divergence rates. Of the records, 100% were redundantly coded throughout the duration of the project (27 of 27). After coding the first 10 jurisdictions, the rate of divergence was 14.4% on October 19, 2015. The supervisor assigned the next 10 jurisdictions for redundant coding and the rate of divergence rose to 19.6% on November 6, 2015. The supervisor and researchers identified issues with the coding scheme and made modifications to the questions and answers to address this divergence rate. The supervisor assigned the final set of jurisdictions for redundant coding and the rate of divergence was 21.4% on December 3, 2015. This divergence rate was, in part, attributable to the researchers leaving the most difficult policies to code until the end of the coding process. The team discussed all divergences throughout the process and recoded as necessary.
A naïve coder coded 20% of the total records (5 of 27). The rate of divergence was 15% on December 1, 2015. The supervisor conducted a coding review of the naïve coding and assigned recoding as necessary.

Prior to publication, the supervisor downloaded all coding data into Microsoft Excel to do a final review of coding answers, citations, and caution notes. All unnecessary caution notes were deleted, and all necessary caution notes were edited.