Proposed New Measures for HEDIS®1 2015: Safe and Judicious Antipsychotic Use in Children and Adolescents

NCQA seeks comments on six proposed measures to assess the safe and judicious use of antipsychotics in children and adolescents for inclusion in the HEDIS 2015 measurement set:

- Measures to Assess Appropriateness/Overuse of Medications in Youth
 - Use of Higher-Than-Recommended Doses of Antipsychotics in Children and Adolescents.
 - Use of Multiple Concurrent Antipsychotics in Children and Adolescents.

Note: For these measures, a lower rate indicates better performance.

- Measures to Assess Management of Youth on Antipsychotics
 - Use of First-Line Psychosocial Care for Children and Adolescents on Antipsychotics.
 - Follow-Up Visit for Children and Adolescents on Antipsychotics.
 - Metabolic Screening for Children and Adolescents Newly on Antipsychotics.
 - Metabolic Monitoring for Children and Adolescents on Antipsychotics.

Note: For these measures, a higher rate indicates better performance.

This measure set represents an important area of health care quality for children. Antipsychotic medications are among the most expensive, high-risk and fastest growing of therapeutic classes for children with mental disorders. For example, the frequency of prescribing antipsychotics increased from 8.6 per 1,000 children in 1996 to 39.4 per 1,000 in 2002.²

Although evidence supports the use of antipsychotics in youth for certain narrowly defined conditions, the majority of children on antipsychotics do not have one of these conditions.³ Antipsychotics have serious, common side effects, including weight gain, hyperprolactinemia and metabolic disturbance.⁴ Concerns over the rising use and the safety risks these medications pose to developing children led to the creation of these measures.

The measures are supported by guidelines from national organizations that include the American Academy of Child and Adolescent Psychiatry, the American Psychiatric Association, and the Centers for Education and Research on Mental Health Therapeutics at the Agency for Healthcare Research and Quality. All six measures are specified for administrative data collection.

The set is composed of measures that assess specific aspects of the safe and judicious use of antipsychotics in children. The two appropriateness/overuse measures address the safety concern of children and adolescents who are on higher-than-recommended doses or more than one medication concurrently. The next measure encourages use of psychosocial intervention as a first-line treatment for children who do not have a primary indication for antipsychotics. Two measures assess receipt of services for children and adolescents who initiate antipsychotic treatment: a follow-up visit with a prescriber and a metabolic screening to establish baseline functioning before medication side effects begin. Finally, for children/adolescents with ongoing antipsychotic use, the metabolic monitoring measure addresses the need for continued monitoring for medication side effects.

¹ HEDIS® is a registered trademark of the National Committee for Quality Assurance (NCQA).

² Cooper, W.O., P.G. Arbogast, H. Ding, G.B. Hickson, D.C. Fuchs, and W.A. Ray. 2006. Trends in prescribing of antipsychotic medications for US children. *Ambulatory Pediatrics*. 6(2):79–83.

³ Penfold, R.B., C. Stewart, E.M. Hunkeler, J.M. Madden, J.R. Cummings, A.A. Owen-Smith, R.C. Rosson, C.Y. Lu, F.L. Lynch, B.E. Waitzfelder, K.A. Coleman, B.K. Ahmedani, A.L. Beck, J.E. Zeber, and G.E. Simon. 2013. Use of Antipsychotic Medications in Pediatric Populations: What do the Data Say? *Current psychiatry reports*. 15(12):1–10.

⁴ Correll, C.U., C.J. Kratochvil, J.S. March. 2011. Developments in pediatric psychopharmacology: Focus on stimulants, antidepressants, and antipsychotics. *Journal of Clinical Psychiatry*. 72:655–70.

NCQA field tested these measures using 2008 Medicaid Analytic eXtract data files for 11 states; 2005 data from MEDNET states; and 2010 Medicaid claims data from about 20 managed care plans in one state. In the health plan data, all measures had sufficient denominator size for health plan reporting. For the measures assessing appropriateness/overuse of medications, denominator sizes ranged from 782–1,125. For the measures assessing management of youth on antipsychotics, denominator sizes ranged from 502–834.

Performance rates varied across health plans, states, and age groups. For the two appropriateness/overuse measures (lower rates indicate better performance), the mean performance among health plans was 5.7 percent for *Use of Higher-Than-Recommended Doses of Antipsychotics in Children and Adolescents* and 4.4 percent for *Use of Multiple Concurrent Antipsychotics in Children and Adolescents*.

For the management measures (higher rates indicate better performance), mean performance among health plans was 10.3 percent for *Metabolic Screening for Children and Adolescents Newly on Antipsychotics*; 30.9 percent for *Metabolic Monitoring for Children and Adolescents on Antipsychotics*; 44.7 percent for *Use of First-Line Psychosocial Care for Children and Adolescents on Antipsychotics*; and 80.6 percent for *Follow-Up Visit for Children and Adolescents on Antipsychotics*.

The measures were also tested for reliability and validity using the beta-binomial method, correlations across measures, and expert feedback across multiple advisory panels. Overall, results showed the measures were valid, reliable and feasible to implement in administrative data. Based on these results, our stakeholder panels concluded the measures are valid and reliable means to assessing quality improvement and accountability at the health plan level.

Specific Questions for Public Comment

In addition to the questions of importance, relevance and feasibility, NCQA seeks input on the following questions:

- · Which measures are of highest priority for health plan reporting?
- Performance rates for the two appropriateness/overuse measures (lower rates indicate better performance) were below 10 percent for the health plans in the state we studied. Is there enough of a quality gap to justify a measure, keeping in mind that these measures represent potential harmful practices?
- Are there concerns regarding the ability to keep the *Use of Higher-Than-Recommended Doses* measure current?

Supporting documents for the proposed measures include the draft measure specifications and measure rationale work-ups.

NCQA acknowledges the contributions of the NCQA Behavioral Health Measurement Advisory Panel and the NCQA Technical Measurement Advisory Panel.

NCQA thanks its partners and advisory panels in the AHRQ-CMS CHIPRA National Collaborative for Innovation in Quality Measurement, under which these measures were developed and funded.

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Use of Higher-Than-Recommended Doses of Antipsychotics in Children and Adolescents

SUMMARY OF CHANGES TO HEDIS 2015

First-year measure.

Description

The percentage of children and adolescents 0–17 years of age who were on antipsychotic medication and who received two or more antipsychotic medication prescriptions with higher-than-recommended doses.

Note: A lower rate indicates better performance.

Eligible Population

Product lines Commercial, Medicaid (report each product line separately).

Ages 0–17 years by December 31 of the measurement year. Report four age stratifications

and a total rate:

• 0–5 years.

• 6-11 years.

• 12-17 years.

Total.

The total is the sum of the age stratifications.

Continuous enrollment

90 days or more.

Allowable gap None.

Anchor date December 31 of the measurement year.

Benefit Medical and pharmacy.

Event/diagnosis At least two antipsychotic medication dispensing events (Table XXX-A) on different

dates of service during the measurement year.

Administrative Specification

Denominator The eligible population.

Numerator Received two or more prescriptions for an antipsychotic medication in the

measurement year with higher than recommended doses.

Higher-than-recommended dose is a dispensed antipsychotic that meets "average

daily dose" criteria in Table XXX-A.

Note: For medications in Table XXX-A, identify different drugs using the Drug ID field

located in the NDC list on NCQA's Web site (www.ncqa.org).

Table XXX-A. Antipsychotic Medication Dose Maximums

Antipsychotic	Average Daily Dose Criteria for <13 years	Average Daily Dose Criteria for 13–17 years
Aripiprazole	>15 mg/day	>30 mg/day
Asenapine maleate	>20 mg/day	>20 mg/day
Chlorpromazine hcl	>500 mg/day	>800 mg/day
Clozapine	>300 mg/day	>600 mg/day
Fluphenazine hcl	>10 mg/day	>10 mg/day
Haloperidol	>6 mg/day	>10.5 mg/day
lloperidone	>24 mg/day	>24 mg/day
Loxapine	>100 mg/day	>100 mg/day
Lurisadone	>80 mg/day	>80 mg/day
Olanzapine	>12.5 mg/day	>20 mg/day
Paliperidone	>15 mg/day	>15 mg/day
Perphenazine	>6 mg/day	>64 mg/day
Pimozide	>10 mg/day	>10 mg/day
Quetiapine fumarate	>300 mg/day	>600 mg/day
Risperidone	>3 mg/day	>6 mg/day
Thioridazine hcl	>120 mg/day	>210 mg/day
Thiothixene	>20 mg/day	>20 mg/day
Ziprasidone hcl	>160 mg/day	>160 mg/day

Data Elements for Reporting

Organizations that submit HEDIS data to NCQA must provide the following data elements.

Table XXX-1/2: Data Elements for Use of Higher than Recommended Doses of Antipsychotics in Children and Adolescents

	Administrative
Measurement year	✓
Data collection methodology (Administrative)	✓
Eligible population	For each age stratification and total
Numerator events by administrative data	For each age stratification and total
Reported rate	For each age stratification and total
Lower 95% confidence interval	For each age stratification and total
Upper 95% confidence interval	For each age stratification and total

Use of Higher-Than-Recommended Doses of Antipsychotics in Children and Adolescents Measure Work-up

Measure Description

The percentage of children and adolescents 0–17 years of age who were on antipsychotic medication and who received two or more antipsychotic medication prescriptions with higher-than-recommended doses.

Note: A lower rate indicates better performance.

Topic Overview

Importance and Prevalence

Antipsychotic prescribing for children has increased rapidly in recent decades, driven by new prescriptions and by longer duration of use (Patten et al., 2012). The frequency of prescribing antipsychotics among youth increased almost fivefold from 1996–2002, from 8.6 per 1,000 children to 39.4 per 1,000 (Cooper et al., 2006). Atypical antipsychotics doubled their share of all psychotropic medication prescriptions among privately insured youth between 1997 and 2000, from 2.4 percent of all psychotropic prescriptions to 5.1 percent (Martin & Leslie, 2003). A national study of Medicaid-enrolled children found that prescribing of atypical antipsychotics increased 62 percent from 2002–2007 (Matone et al., 2012).

Health importance

Although some evidence supports the efficacy of antipsychotics in youth for certain narrowly defined conditions, less is known about the safety and effectiveness of antipsychotic prescribing patterns in community use (e.g., combinations of medications, off-label prescribing, dosing outside of recommended ranges). Children and adolescents prescribed antipsychotics are more at risk for serious health concerns, including weight gain, extrapyramidal side effects, hyperprolactinemia and some metabolic effects (Correll et al., 2011).

In general, the field lacks high-quality research on outcomes and side effects associated with the use of higher-than-recommended doses of antipsychotics. Worrisome adverse effects of atypical antipsychotics have been documented even at low doses, including excessive weight gain, resulting in obesity, large increases in prolactin and higher risk of extrapyramidal side effects, including tardive dyskinesia. Girls treated with certain antipsychotics may also be at increased risk for gynecological problems (Talib et al., 2013) and osteoporosis (Cohen et al., 2012).

Studies of atypical antipsychotics in youth have demonstrated equal or worsening response when higher doses are compared with lower doses (Seida et al., 2012; Haas et al., 2009; Schooler et al, 2005). Research has demonstrated that the pharmacokinetics of antipsychotics may vary by developmental stage (Correll et al., 2011). This finding suggests that higher-than-recommended dosing of antipsychotics may pose differing risks for children and adolescents, compared with adults.

Financial importance and cost-effectiveness

Atypical antipsychotics have the greatest mean prescription cost (\$132) of any psychotropic medication (Martin and Leslie, 2003) and are the most costly drug class within the Medicaid program (Crystal et al., 2009).

A review of 55 studies found no evidence that higher doses of antipsychotics were associated with better response (Davis and Chen, 2004); therefore, using higher-than-recommended doses of antipsychotics poses an increase in the cost of treatment without evidence that it is more effective for the patient. Additionally, there

are substantial long-term costs of treating the health impact associated with antipsychotic medications, including treatment of obesity, diabetes and dyslipidemias. There is some evidence that these health conditions, such as new onset diabetes, do not resolve after discontinuation of the antipsychotic (Lean and Pajonk, 2003). Although this is an understudied area, it is reasonable to assume that unresolved health impact of antipsychotics would be associated with long-term increases in health costs established for obesity and diabetes due to other causes.

Supporting Evidence for Avoiding High Doses of Antipsychotics

A review of 55 studies found no evidence that higher doses of antipsychotics were associated with better response (Davis and Chen, 2004). More recent systematic reviews of risperidone (Li, Xia, Wang, 2009) and quetiapine (Sparshatt, Jones, Taylor, 2008) doses for schizophrenia found that high doses were not associated with better outcomes, but were associated with more adverse effects.

There is no research on *long-term* effects of higher-than-recommended dosing of antipsychotics on children's health. However, given the increased side effect burden of certain antipsychotic medications for youth discussed above, prescribing of higher-than-recommended doses of antipsychotics has serious implications for future physical health concerns including obesity and diabetes.

Practice Guidelines

No published guidelines or practice parameters endorse higher-than-recommended dosing of antipsychotics as routine clinical practice for mental health treatment of youth. Most guidelines that address dosing of antipsychotics endorse the use of the lowest effective dose.

The American Academy of Child and Adolescent Psychiatry (AACAP) Practice Parameters for the Use of Atypical Antipsychotic Medications in Children and Adolescents recommend that "dosing of AAAs [atypical antipsychotic agents] should follow the 'start low and go slow' approach and seek to find the lowest effective dose." The AACAP Practice Parameter for the Assessment and Treatment of Children and Adolescents with Schizophrenia calls for "adequate dosages" of antipsychotic medications and states that "instituting large dosages during the early part of treatment generally does not hasten recovery ... the medication dosage should be periodically reassessed to ensure that the lowest effective dose is being used."

The Texas Psychotropic Medication Utilization Parameters for Foster Children notes, "psychotropic medication dose exceeds usual recommended doses" as a situation that "suggests the need for additional review of a patient's clinical status" and specifies recommended doses.

Gaps in care

A study of 16 state Medicaid programs found that the percentage of enrollees under 19 years of age on an antipsychotic varied greatly according to eligibility category, ranging from 0.6 percent for state Children's Health Insurance Program (CHIP) enrollees to 13.4 percent for those eligible under Aged, Blind and Disabled provisions; the rate for foster care youth was 12.4 percent.

Among those on an antipsychotic, the proportion of youth on higher-than-recommended doses of antipsychotic medications in 2007 in each reporting state ranged from 1.3 percent—17.9 percent, with an average across states of 8.9 percent (Medicaid Medical Directors Learning Network and Rutgers Center for Education and Research on Mental Health Therapeutics, 2010). This variation in prescribing suggests there is significant room for improvement in some states.

As part of the measure's field-testing, we assessed use of higher-thanrecommended doses of medications in Medicaid children using the Medicaid Analytic eXtract data files. Based on data from 2008 for 11 states, the average percentage of children prescribed at least two higher-than-recommended doses of an antipsychotic medication among the general population of children was 7.9 percent, with a range of 5.1 percent–10.6 percent.

In an examination of 2010 Medicaid health plan data from one state, we found that the average percentage of children prescribed at least two higher-than-recommended doses of an antipsychotic medication among the general population of children in health plans was 5.7 percent, with a range of 3.0 percent–10.9 percent. Eligible population size for health plans ranged from 177 children to 3,541 children.

When field testing was conducted, the measure was specified for children and adolescents 0–20 years of age. Following guidance from two measurement advisory panels, the measure is now specified for children and adolescents 0–17 years of age. This change in specification would be expected to have a small impact on the performance rates reported here.

Health care disparities ...based on race/ ethnicity Overall, there is evidence to suggest that there may be racial disparities in antipsychotic medication practices for adults with schizophrenia, although these may not generalize to all ages or diagnoses (Busch et al., 2009; Kuno et al., 2002; Rost et al., 2011). Studies of antipsychotic dosing in adults with schizophrenia have yielded mixed results, with some finding African Americans more likely to receive higher doses (dos Reis et al., 2002; Walkup et al., 2000) and some showing no effect of race/ethnicity on dose (Busch et al. 2009; Leslie and Rosenheck, 2001). We found no published studies examining potential ethnic/racial disparities in higher-than-recommended dosing of antipsychotics in children and adolescents.

As part of the measure's field-testing, we assessed differences in use of higher-than-recommended doses of medications in Medicaid children of different races and ethnicities. Our results indicate that Black, non-Hispanic children had worse (i.e., higher) rates of higher-than-recommended doses of antipsychotics (8.5 percent), compared with White, non-Hispanic (7.9 percent) and Hispanic (7.2 percent) children. The patterns were similar in our analysis of Medicaid children with any time in the foster care system.

...for children in rural areas In field-testing, we assessed prevalence of children on higher-than-recommended doses of antipsychotics by county-level urbanicity. For the general population of children, rates of higher-than-recommended doses of antipsychotic medications were higher (i.e., worse) in metropolitan areas (8.4 percent).

In the foster care population, rates were worse in rural areas (12.9 percent). These findings are broadly consistent with research showing higher use of psychotropic medication among rural youth.

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Recommendations on Dosage for Children on Antipsychotics

Guideline (Date)	Population	Recommendation or Statement	Type/Grade
AACAP-AAA (2011) Practice parameter for the use of atypical antipsychotic medications (AAA) in children and adolescents. ¹	5-18 years	"Dosing of AAAs should follow the 'start low and go slow' approach and seek to find the lowest effective dose, recognizing that dosing may differ based on the targeted symptoms and patient diagnosis(lacking other evidence) the upper limit of dosage of an AAA should not exceed the maximum recommended dose prescribed for adults" (Recommendation 4)	Clinical Guideline
AACAP-SZ (2001) Practice parameter for the assessment and treatment of children and adolescents with schizophrenia. ²	≤18 years	"The use of antipsychotic agents requireslong-term monitoring to reassess dosage needs, dependent on the stage of illness. Higher doses may be required during the acute phases, with smaller dosages during the residual phases." (Recommendations—Psychopharmacology)	Minimal Standard
		"Instituting large dosages during the early part of treatment generally does not hasten recovery; it more often results in unnecessarily excessive doses and side effects". (Under Literature review – Procedures for Use of Medication – Acute Phase)	Not rated
		"The medication dosage should be periodically reassessed to ensure that the lowest effective dose is being used" (Under Literature Review – Procedures for Use of Medication – Recovery/Residual Phase)	Not rated
TMAY (2012) Center for Education and Research on Mental Health Therapeutics—Treatment of maladaptive aggression in youth. ³	≤18 years	"Use recommended titration schedules and deliver an adequate medication trial before changing or adding medication For guidance on specific medications, including titration schedules and maximum doses, and potential drug interactions see TMAY Prescribers Toolkit" (Recommendation 15)	Evidence: A Recommendation: Very Strong
TRAAY (2003) Center for the Advancement of Children's Mental Health: Treatment recommendations for the use of antipsychotics for aggressive youth. ⁴	≤18 years	Physicians should use a conservative dosing strategy ("start low, go slow")	Not specified*
TX (2010)	Children (no age specified)	Higher-than-recommended doses of antipsychotic medications warrants clinical review.	Not specified*
Texas Department of Family and Protective Services—Psychotropic medication utilization parameters for foster children. ⁵		Psychotropic Medication Utilization Parameters for Foster Children "Psychotropic medication dose exceeds usual recommended doses" is a situation that "suggests the need for additional review of a patient's clinical status," and specifies recommended doses.	Not specified*

^{*}TRAAY (2003) and TX (2010) did not specify the use of a rating system.

Grading System Key

Guideline Developer	Definition			
AACAP	Minimal Standard/Clinical Standard: Rigorous/ substantial empirical evidence (meta-analyses, systematic reviews, RCTs) and/or overwhelming clinical consensus; expected to apply more than 95 percent of the time			
	Clinical guidelines: Strong empirical evidence (non-randomized controlled trials, cohort or case-control studies), and/or strong clinical consensus; expect to apply in most cases (75% of the time)			
	Options: Acceptable but not required; there may be insufficient evidence to support higher recommendation (uncontrolled trials, case/series reports).			
	Not endorsed: ineffective or contraindicated.			
AACAP endorsed best-practice principles	Best practice principles that underlie medication prescribing, to promote the appropriate and safe use of psychotropic medications			
TMAY Ratings	Oxford Centre for Evidence-Based Medicine grade of evidence (A–D) ⁶			
	Strength of Recommendation: Very strong (≥90% agreement)			
	Strength of Recommendation: Very strong (70-89% agreement)			
	Strength of Recommendation: Very strong (50-69% agreement)			
	Strength of Recommendation: Very strong (<50% agreement)			

References for Recommendations

American Academy of Child and Adolescent Psychiatry. Practice Parameter for the Use of Atypical Antipsychotic Medications in Children and Adolescents. http://www.aacap.org/App Themes/AACAP/docs/practice parameters/Atypical Antipsychotic Medications Web.pdf (July 12, 2012)

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Use of Multiple Concurrent Antipsychotics in Children and Adolescents

SUMMARY OF CHANGES TO HEDIS 2015

• First-year measure.

Description

Ages

The percentage of children and adolescents 0–17 years of age who were on two or more concurrent antipsychotic medications.

Note: A lower rate indicates better performance.

Eligible Population

Product lines Commercial, Medicaid (report each product line separately).

17 years and younger as of December 31 of the measurement year. Report four age

stratifications and a total rate:

0–5 years.

• 6-11 years.

• 12-17 years.

Total.

The total is the sum of the age stratifications.

Continuous enrollment

The measurement year.

Allowable gap No more than one gap in continuous enrollment of up to 45 days during the

measurement year. To determine continuous enrollment for a Medicaid beneficiary for whom enrollment is verified monthly, the member may not have more than a

1-month gap in coverage (i.e., a member whose coverage lapses for 2 months [60]

days] is not considered continuously enrolled).

Anchor date December 31 of the measurement year.

Benefit Medical and pharmacy.

Event/diagnosis Members with 90 days of continuous antipsychotic medication treatment during the

measurement year. Use the steps below to determine the eligible population.

Step 1 Identify members in the specified age range who were dispensed an antipsychotic

medication (Table XXX-A) during the measurement year.

Step 2 Calculate continuous enrollment.

Step 3 For each member, identify all antipsychotic medication dispensing events

(prescriptions) during the measurement year.

Step 4 Identify continuous drug events. Continuous drug events are identified separately by drug using the Drug ID field located in the NDC list.

For each drug, sort dispensing events chronologically by dispense date. Start with the first prescription and calculate the number of days between the first prescription's dispense date and the second prescription's dispense date. If the number of days is less than or equal to the first prescription's days supply, plus 31 days, include the prescription in the continuous drug event.

Continue assessing each subsequent prescription for inclusion in the continuous drug event. For example, identify the third prescription and calculate the number of days between the second prescription's dispense date and the third prescription's dispense date. If the number of days is less than or equal to the second prescription's days supply plus 31 days, include it in the continuous drug event.

Continue this process for all dispensing events for each drug.

The continuous drug event ends on December 31 of the measurement year, or, when the number of days between two concurrent prescription dispense dates is greater than the first prescription's days supply plus 31 days, whichever comes first.

If there is more than one prescription for the same medication dispensed on the same day, use the longest days supply in the calculation.

Note: A member might have multiple continuous drug events per drug during the measurement year. Continue to assess for continuous drug events until all dispensing events during the measurement year are exhausted.

- **Step 5** For each continuous drug event, identify the start date and end date as follows:
 - Identify the dispense date for the first dispensing event in the continuous drug event. This
 is the start date.
 - Identify the dispense date and days supply for the last dispensing event in the continuous drug event.
 - Determine the end date for the continuous drug event using the dispense date and the days supply from the last dispensing event.
 - For example, a November 1 prescription with 30 days supply has an end date of November 30.

If the days supply for the last dispensing event extends beyond the end of the measurement year, the end date is December 31.

- **Step 6** For each antipsychotic medication prescription that did not qualify for inclusion in a continuous drug event, identify the start date and end date as follows:
 - The start date is the dispense date. Determine the end date using the dispense date and days supply.
 - For example, a November 1 prescription with 30 days supply has an end date of November 30.

If the days supply for the dispensing event extends beyond the end of the measurement year, the end date is December 31.

Step 7 For each member, identify antipsychotic medication treatment days as follows:

For each continuous drug event (identified in step 5) and for prescriptions that did
not qualify for inclusion in a continuous drug event (identified in step 6), all calendar
days, beginning with and including the start date, through and including the end
date, are considered antipsychotic medication treatment days.

Note: Continuous drug events allow for gaps in treatment; gap days that were determined to be within the allowable period (step 4) are considered antipsychotic medication treatment days.

Step 8 Identify members with 90 or more consecutive antipsychotic medication treatment days.

Note: This can include members who had a continuous drug event of 90 or more days, or members who had 90 consecutive treatment days across different antipsychotic medications.

Administrative Specification

Denominator

The eligible population.

Numerator

Members on two or more concurrent antipsychotic medications during the measurement year. Use the steps below to determine the numerator.

- **Step 1** For each member, identify all continuous drug events, start dates and end dates (identified in step 5 of the event/diagnosis criteria used to identify the eligible population [denominator]).
- **Step 2** For each member, identify all antipsychotic medication prescriptions that did not qualify for inclusion in a continuous drug event, start dates and end dates (identified in step 6 of the event/diagnosis criteria used to identify the eligible population [denominator]).
- **Step 3** For each continuous drug event and for prescriptions that did not qualify for inclusion in a continuous drug event, identify medication treatment days (identified in step 7 of the event/diagnosis criteria used to identify the eligible population [denominator]).
- Step 4 Identify concurrent antipsychotic medication treatment events. For each member, identify the first medication treatment day during the measurement year where the member was being treated with multiple (i.e., at least two) antipsychotic medications; this is the concurrent antipsychotic medication treatment event start date.

Beginning with (and including) the start date, identify the number of consecutive days where the member remains on multiple antipsychotic medications. If the number of days ≥90 days, the member is numerator compliant.

If the number of consecutive days on multiple antipsychotic medications is <90 days, identify the stop date and identify the next medication treatment day during the measurement year where the member was being treated with multiple antipsychotic medications. If the number of days between the stop date and the next start date is ≤15 days, include the days in the concurrent antipsychotic medication treatment event.

Continue this process until the number of concurrent antipsychotic medication treatment days is ≥90 days (the member is numerator compliant), or until there is a break in concurrent antipsychotic medication treatment that exceeds 15 days, or on December 31 of the measurement year.

Members with a concurrent antipsychotic medication treatment event ≥90 days are numerator compliant.

Note: A member might have multiple concurrent antipsychotic medication treatment events during the measurement year. If there is a break in concurrent antipsychotic medication treatment that exceeds 15 days, continue to assess for concurrent antipsychotic medication treatment events until all treatment days during the measurement year are exhausted.

Table XXX-A. Antipsychotic Medications

First-Generation Antipsychotic Medications	Second-Generation Antipsychotic Medications
Chlorpromazine hcl	Aripiprazole
Fluphenazine hcl	Clozapine
Fluphenazine decanoate	lloperidone
Fluphenazine enanthate	Olanzapine
Haloperidol	Olanzapine pamoate
Haloperidol decanoate	Paliperidone
Haloperidol lactate	Paliperidone palmitate
Loxapine hcl	Quetiapine fumarate
Loxapine succinate	Risperidone
Molindone hcl	Risperidone microspheres
Perphenazine	Ziprasidone hcl
Pimozide	Ziprasidone mesylate
Promazine hcl	
Thioridazine hcl	
Thiothixene	
Thiothixene hcl	
Trifluoperazine hcl	
Triflupromazine hcl	

Data Elements for Reporting

Organizations that submit HEDIS data to NCQA must provide the following data elements.

Table XXX-1/2: Data Elements for Use of Multiple Concurrent Antipsychotics in Children and Adolescents

	Administrative
Measurement year	✓
Data collection methodology (Administrative)	✓
Eligible population	For each age stratification and total
Numerator events by administrative data	For each age stratification and total
Reported rate	For each age stratification and total
Lower 95% confidence interval	For each age stratification and total
Upper 95% confidence interval	For each age stratification and total

Use of Multiple Concurrent Antipsychotics in Children and Adolescents Measure Work-up

Measure Description

The percentage of children and adolescents 0–17 years of age who were on two or more concurrent antipsychotic medications.

Note: A lower rate indicates better performance.

Topic Overview

Importance and Prevalence

Use in children and adolescents

Antipsychotic prescribing for children has increased rapidly in recent decades, driven by new prescriptions and by longer duration of use (Patten et al., 2012). The frequency of prescribing antipsychotics among youth increased almost fivefold from 1996–2002, from 8.6 per 1,000 children to 39.4 per 1,000 (Cooper et al., 2006). Although some evidence supports the efficacy of antipsychotics in youth for certain narrowly defined conditions, less is known about the safety and effectiveness of antipsychotic prescribing patterns in community use (e.g., combinations of medications, off-label prescribing, dosing outside of recommended ranges).

Health importance

Both the efficacy and side effects of antipsychotic medications vary by age. Children and adolescents prescribed antipsychotics are more at risk for serious health concerns, including weight gain, extrapyramidal side effects, hyperprolactinemia and some metabolic effects (Correll et al., 2011). Girls treated with certain antipsychotics may also be at increased risk for gynecological problems (Talib et al., 2013) and osteoporosis (Cohen et al., 2012).

Risks of multiple concurrent antipsychotics in comparison to monotherapy have not been systematically investigated; existing evidence appears largely in case reports, and includes increased risk of serious drug interactions, delirium, serious behavioral changes, cardiac arrhythmias and death (Safer et al., 2003). Research demonstrating that the pharmacokinetics of antipsychotics may vary by developmental stage (Correll et al., 2011) also suggests that use of multiple concurrent antipsychotics may pose differing risks for children and for adolescents. In general, the field lacks high-quality studies of side effects associated with the use of multiple concurrent medications in adults (Van Bennekom et al., 2013).

Financial importance and cost effectiveness

The financial impact of multiple concurrent antipsychotic use in children has not been examined; however, antipsychotics are a costly form of drug therapy. Atypical antipsychotics have the greatest mean prescription cost (\$132) of any psychotropic medication (Martin & Leslie, 2003) and are the most costly drug class within the Medicaid program (Crystal et al., 2009). Additionally, there are substantial long-term costs of treating side effects associated with antipsychotic medications, including treatment of obesity, diabetes and dyslipidemias. There is some evidence that these health conditions, such as new onset diabetes, do not always resolve after discontinuation of the antipsychotic (Lean and Pajonk, 2003). Although this is an understudied area, it is reasonable to assume that unresolved side effects from antipsychotics would be associated with the long-term increases in health care costs that have been established for obesity and diabetes.

Supporting Evidence for Avoiding Multiple Concurrent Antipsychotic Use in Children

Although there is no research on the long-term effects of multiple concurrent antipsychotics on children's health, the increased side effect burden of certain antipsychotic medications for youth, such as weight gain and metabolic disturbances, has implications for future physical health, including concerns such as obesity and diabetes. In addition to these side effect risks, there is little empirical evidence to support the use of multiple concurrent antipsychotics to achieve better clinical outcomes in the mental health treatment of youth.

Guidelines for prescribing in children

The American Academy of Child & Adolescent Psychiatry (AACAP) developed a series of practice parameters that address use of psychotropic medications, the broader class of medications under which antipsychotics fall. None of the 10 AACAP practice parameters recommend concurrent use of multiple antipsychotic medications. For example, the AACAP Practice Parameters for the Use of Atypical Antipsychotic Medications in Children and Adolescents states, "the use of multiple AAAs [atypical antipsychotics] has not been studied rigorously and generally should be avoided" (AACAP, 2012).

Additional practice guidelines also caution against the use of multiple concurrent antipsychotics in children. The Center for Education and Research on Mental Health Therapeutics guideline *Treatment of maladaptive aggression in youth* recommends that "the use of two simultaneous psychotropic medications should be avoided" (Scotto Rosato et al., 2012).

The Texas Psychotropic Medication Utilization Parameters for Foster Children (2013) includes "two or more concomitant antipsychotic medications" as a situation that "suggests the need for additional review of a patient's clinical status."

Gaps in care

A recent systematic review found that among youth prescribed any antipsychotic, about 1 in 10 (9.6 percent, SD 7.2 percent) received multiple concurrent antipsychotics (Toteja et al., 2013). Studies of multiple concurrent antipsychotics among youth prescribed any antipsychotic have found that prevalence among adolescents is twice that of younger children, and that the rate among adolescents has increased two-fold from the 1990s to the 2000s (Toteja et al., 2013). One study of a large state Medicaid fee-for-service program found that about 7 percent of children 6–17 years of age on any antipsychotic were prescribed two or more antipsychotics for longer than 60 days (Constantine et al., 2010).

As part of the measure's field-testing, we assessed use of multiple concurrent use of antipsychotic medications in Medicaid children, using the Medicaid Analytic eXtract (MAX) data files. Analysis of administrative claims data from 11 states demonstrated that the average percentage of children with use of multiple concurrent antipsychotics among the general population of children was 6.0 percent, with a range of 2.8 percent—9.4 percent (a lower percentage is better). For children in foster care, the average rate was 6.7 percent, with a range of 1.9 percent to 10.6 percent.

In additional field-testing in Medicaid health plan data from one state, the average percentage of children with use of multiple concurrent antipsychotics was 4.4 percent, with a range of 1.8 percent to 7.0 percent.

When field-testing was conducted, the measure was specified for children and adolescents 0–20 years of age. Following guidance from two measurement advisory panels, the measure is now specified for children and adolescents 0–17 years of age. This change in specification would be expected to have a small impact on the performance rates reported here.

Health care disparities ...based on race/ethnicity

More than a decade of research suggests that minority youth may have higher unmet needs for mental health care and receive lower-quality care, compared with White American youth (Alegria et al., 2010). Although there is evidence to suggest that there may be racial disparities in antipsychotic medication practices for adults with schizophrenia, these may not generalize to all ages or diagnoses (Busch et al., 2009; Kuno et al., 2002; Rost et al., 2011).

A study of children placed into foster care in New York found that Black children were more likely to be prescribed second-generation antipsychotics than children identified as Latino or another race (White and Asian) (Linares et al., 2013). There is limited research on potential racial/ethnic disparities in the use of multiple concurrent antipsychotics. In a large, cross-sectional study of 637,924 Medicaid-enrolled children in one state, dosReis et al. (2011) found that Black youths were more likely than White youths to be prescribed two or more overlapping antipsychotics, suggesting that certain populations of youth may be at higher risk for this quality concern.

As part of the measure's field-testing, an analysis of administrative claims data from the 2008 MAX data found that use of multiple concurrent antipsychotic medications was higher among Black, non-Hispanic children and children in foster care. Rates of multiple concurrent antipsychotic medication use ranged from 6.1 percent in Hispanics to 7.5 percent in Black, non-Hispanics and 9.1 percent in "other" among the general population of children. Rates ranged from 6.4 percent in Hispanics to 8.1 percent in Black, non-Hispanics and 8.6 percent in "other" among children in foster care.

...based on rurality/urbanicity

Analysis of administrative claims data from the 2008 MAX data found that for the general population of children, higher rates of multiple concurrent antipsychotic use were seen in metropolitan areas (6.8 percent) than rural areas (5.7 percent). However, within the foster care population, higher rates were seen in rural areas (9.5 percent), compared with metropolitan areas (6.6 percent).

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Recommendations for Avoiding Multiple and Concurrent Antipsychotic Use in Children and Adolescents

Guideline (Date)	Population	Recommendation or Statement	Type/Grade
AACAP-AAA (2011) Practice parameter for the use of atypical antipsychotic medications in children and adolescents ¹	5-18 years	"The simultaneous use of multiple concurrent AAAs has not been studied rigorously and generally should be avoided." (Recommendation 8)	Not Endorsed
AACAP-PsyMed (2009) Practice parameter on the use of psychotropic medication in children and adolescents ²	≤18 years	In'	Best practice principle
TMAY (2012) Center for Education and Research on Mental Health Therapeutics—Treatment of maladaptive aggression in youth ³	≤18 years	Use of two simultaneous psychotropic medications should be avoided (Recommendation 18)	Evidence: C Recommendation: Very Strong
TX (2010) Texas Department of Family and Protective Services Psychotropic medication utilization parameters for foster children ⁴	Children (age un- specified)	Prescribing multiple antipsychotics is a situation that warrants clinical review.	Not specified*

^{*}TX (2010) did not specify the use of a rating system.

Grading System Key

Guideline Developer	Definition
AACAP	Minimal Standard/ Clinical Standard: Rigorous/ substantial empirical evidence (meta-analyses, systematic reviews, RCTs) and/or overwhelming clinical consensus; expected to apply more than 95 percent of the time
	Clinical guidelines: Strong empirical evidence (non-randomized controlled trials, cohort or case-control studies), and/or strong clinical consensus; expect to apply in most cases (75% of the time)
	Options: Acceptable but not required; there may be insufficient evidence to support higher recommendation (uncontrolled trials, case/series reports).
	Not endorsed: Ineffective or contraindicated.
AACAP endorsed best-practice principles	Best-practice principles that underlie medication prescribing, to promote the appropriate and safe use of psychotropic medications
TMAY Ratings	Oxford Centre for Evidence-Based Medicine grade of evidence (A-D) ⁵
	Strength of Recommendation: Very strong (≥90% agreement)
	Strength of Recommendation: Very strong (70-89% agreement)
	Strength of Recommendation: Very strong (50-69% agreement)
	Strength of Recommendation: Very strong (<50% agreement)

References for Recommendations

- American Academy of Child and Adolescent Psychiatry. Practice Parameter for the Use of Atypical Antipsychotic Medications in Children and Adolescents.
 - http://www.aacap.org/App_Themes/AACAP/docs/practice_parameters/Atypical_Antipsychotic_Medications_Web.p_df (July 12, 2012)
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Use of First-Line Psychosocial Care for Children and Adolescents on Antipsychotics

SUMMARY OF CHANGES TO HEDIS 2015

• First-year measure.

Description

The percentage of children and adolescents 0–17 years of age who had a new prescription for an antipsychotic medication and had documentation of psychosocial care as first-line treatment.

Definitions

Intake Period The 12-month window starting March 1 of the year prior to the measurement year and

ending February 28 of the measurement year.

Negative Medication History

A period of 120 days (4 months) prior to the IPSD when the member had no antipsychotic

medications dispensed for either new or refill prescriptions.

IPSD Index Prescription Start Date. The earliest prescription dispensing date for an

antipsychotic medication where the date is in the Intake Period and there is a Negative

Medication History.

New Episode The member must have a 120-day (4-month) Negative Medication History on or before

the IPSD.

Eligible Population

Product lines Commercial, Medicaid (report each product line separately).

Ages 0 years as of March 1 of the year prior to the measurement year to 17 years as of February 28 of the measurement year. Report four age stratifications and a total rate:

• 0–5 years.

6–11 years.

• 12-17 years.

• Total.

The total is the sum of the age stratifications.

Continuous enrollment

120 days (4 months) prior to 30 days following the IPSD of a new antipsychotic

prescription.

Allowable gap None.

Anchor date None.

Benefit Medical, mental health, pharmacy.

Event

Follow the steps below to identify the eligible population.

- **Step 1** Identify all members in the specified age range who were dispensed an antipsychotic medication (Table XXX-A) during the 12-month Intake Period.
- **Step 2** Test for Negative Medication History. For each member identified in step 1, test each antipsychotic prescription for a Negative Medication History. The IPSD is the dispensing date of the earliest antipsychotic prescription in the Intake Period with a Negative Medication History.
- Step 3 Calculate continuous enrollment. Members must be continuously enrolled for 120 days (4 months) prior to the IPSD through 30 days after the IPSD.

Step 4 Required exclusions

Exclude members who had an inpatient encounter or two outpatient encounters with a diagnosis for which antipsychotic medications are clinically appropriate. Any of the following during the measurement year meet criteria:

- At least one acute inpatient encounter with any diagnosis of schizophrenia, bipolar disorder or other psychotic disorder. Any of the following code combinations meets criteria:
 - BH Stand Alone Acute Inpatient Value Set with Schizophrenia Value Set.
 - BH Stand Alone Acute Inpatient Value Set with Bipolar Disorder Value Set.
 - BH Stand Alone Acute Inpatient Value Set with Other Psychotic Disorders Value Set.
 - BH Acute Inpatient Value Set with BH Acute Inpatient POS Value Set and Schizophrenia Value Set.
 - BH Acute Inpatient Value Set with BH Acute Inpatient POS Value Set and Bipolar Disorder Value Set.
 - BH Acute Inpatient Value Set with BH Acute Inpatient POS Value Set and Other Psychotic Disorders Value Set.
- At least two visits in an outpatient, intensive outpatient or partial hospitalization setting, on different dates of service, with any diagnosis of schizophrenia, bipolar disorder or other psychotic disorder. Any of the following code combinations meet criteria:
 - BH Stand Alone Outpatient/PH/IOP Value Set with Schizophrenia Value Set.
 - BH Outpatient/PH/IOP Value Set with BH Outpatient/PH/IOP POS Value Set and Schizophrenia Value Set.
 - BH Stand Alone Outpatient/PH/IOP Value Set with Bipolar Disorder Value Set.
 - BH Outpatient/PH/IOP Value Set with BH Outpatient/PH/IOP POS Value Set and Bipolar Disorder Value Set.
 - BH Stand Alone Outpatient/PH/IOP Value Set with Other Psychotic Disorders Value Set.
 - BH Outpatient/PH/IOP Value Set with BH Outpatient/PH/IOP POS Value Set and Other Psychotic Disorders Value Set.

Administrative Specification

Denominator

The eligible population.

Numerator

Documentation of psychosocial care (<u>Psychosocial Care Value Set</u>) in the 121-day period from 90 days prior to the IPSD through 30 days after the IPSD.

Table XXX-A. Antipsychotic Medications

First-Generation Antipsychotic Medications	Second-Generation Antipsychotic Medications
Chlorpromazine hcl	Aripiprazole
Fluphenazine hcl	Clozapine
Fluphenazine decanoate	lloperidone
Fluphenazine enanthate	Olanzapine
Haloperidol	Olanzapine pamoate
Haloperidol decanoate	Paliperidone
Haloperidol lactate	Paliperidone palmitate
Loxapine hcl	Quetiapine fumarate
Loxapine succinate	Risperidone
Molindone hcl	Risperidone microspheres
Perphenazine	Ziprasidone hcl
Pimozide	Ziprasidone mesylate
Promazine hcl	
Thioridazine hcl	
Thiothixene	
Thiothixene hcl	Combinations
Trifluoperazine hcl	Olanzapine-fluoxetine hcl (Symbyax)
Triflupromazine hcl	Perphenazine-amitriptyline hcl (Etrafon, Triavil [various])

Data Elements for Reporting

Organizations that submit HEDIS data to NCQA must provide the following data elements.

Table XXX-1/2: Data Elements Access to Psychosocial Care for Children and Adolescents on Antipsychotics

	Administrative
Measurement year	✓
Data collection methodology (Administrative)	✓
Eligible population	✓
Numerator events by administrative data	✓
Reported Rate	✓
Lower 95% confidence interval	✓
Upper 95% confidence interval	✓

Use of First-Line Psychosocial Care for Children and Adolescents on Antipsychotics Measure Work-Up

Measure Description

The percentage of children and adolescents 0–17 years of age who had a new prescription for an antipsychotic medication and had documentation of psychosocial care as first-line treatment.

Topic Overview

Importance and Prevalence

Prevalence of use in children and adolescents

Antipsychotic prescribing for children and adolescents has increased rapidly in recent decades, driven by new prescriptions and by longer duration of use (Patten et al., 2012). The frequency of prescribing antipsychotics among children and youth increased almost fivefold from 1996–2002, from 8.6 per 1,000 children to 39.4 per 1,000 (Cooper et al., 2006).

Although antipsychotic medications may serve as effective treatment for a narrowly defined set of psychiatric disorders in children, they are often being prescribed for nonpsychotic conditions such as attention-deficit disorder and disruptive behaviors (McKinney and Renk, 2011; Cooper et al., 2004; Olfson et al., 2006), conditions for which psychosocial interventions are considered first-line treatment (Kutcher et al., 2004; Pappadopulos et al., 2003; Scotto Rosato et al., 2012). Thus, clinicians may be underutilizing safer first-line psychosocial interventions and using antipsychotics for nonprimary indications in children and adolescents.

Health importance

Use of antipsychotics in children can increase a child's risk for developing serious health issues, such as metabolic and physical health complications (Crystal et al., 2009), which are of particular concern, given the potential for adversely affecting development. Antipsychotic medications are associated with a number of potential adverse impacts, including weight gain (Correll et al., 2009) and diabetes (Andrade et al. 2011; Bobo et al., 2013), which can have serious implications for future health outcomes. For example, metabolic problems in childhood and adolescence are associated with poor cardiometabolic outcomes in adulthood (Srinivasan et al. 2002).

Obesity and dyslipidemias in childhood carry increased long-term health risk into adulthood, including heart disease, cancer and shortened life span (Daniels, 2006). Other serious risks associated with antipsychotic medications in children include extrapyramidal side effects, sedation and somnolence, liver toxicity and cardiac arrhythmias (Correll, 2008).

Children without primary indication for an antipsychotic, who are not given the benefit of a trial of psychosocial treatment first, may unnecessarily incur the risks associated with antipsychotic medications. Mental health conditions in youth are associated with a number of potential adverse effects, including increased risk for substance use (Substance Abuse and Mental Health Services Administration, 2007).

To the extent that psychosocial interventions are associated with better outcomes (Jensen et al., 2001; Eyberg et al., 2008; Schimmelmann et al., 2013), underuse of these therapies may lead to poorer mental and physical health outcomes.

Financial importance and cost effectiveness

There have been no studies comparing the short-term cost-effectiveness of antipsychotic treatment with psychosocial interventions, but psychosocial treatment is not known or proposed to have any ongoing costs after termination, while antipsychotics have the potential to cause lasting health impacts and associated treatment costs.

Children without a primary indication for an antipsychotic who are not given the benefit of a trial of psychosocial treatment may unnecessarily incur the costs/harms associated with antipsychotics, one of the most costly medication classes (Crystal et al., 2009), and substantial long-term costs of treating the health impacts associated with antipsychotic medications, including treatment of obesity, diabetes and dyslipidemias.

There is some evidence that these health conditions, such as new onset diabetes, may not resolve after discontinuation of the antipsychotic (Lean and Pajonk, 2003). Although this is an understudied area, it is reasonable to assume that unresolved health impacts of antipsychotics would be associated with long-term increases in health costs established for obesity and diabetes.

Supporting Evidence for Psychosocial Care for Children on Antipsychotic Medication

Use of antipsychotics in the absence of a primary indication Many children and adolescents receiving antipsychotic medications do not have a primary indication for their use. Studies have found that antipsychotics are increasingly being prescribed for children who have conditions such as attention-deficit hyperactivity disorder (ADHD) and disruptive behavior disorders (Cooper et al., 2004; Olfson et al., 2006), which are not primary indications for the use of antipsychotics. Use of antipsychotics in children and adolescents has been examined for a broad array of other nonprimary indications including depression, anxiety disorders, eating disorders, obsessive compulsive disorder, post-traumatic stress disorder and even insomnia. However, for these nonprimary indications, psychosocial interventions are recommended treatment options, while antipsychotics are not.

Although aggression and disruptive behavior disorders do not have a Food and Drug Administration (FDA)-approved indication for use of antipsychotics outside of autism, there is a small but growing body of evidence that antipsychotics can be effective, and current treatment guidelines endorse a trial of antipsychotics as a second-line treatment, after first-line psychosocial treatments, such as parent and child skills training, have been tried (Scotto Rosato et al., 2012).

Psychosocial care as a first-line treatment

In the absence of an FDA indication for an antipsychotic, guidelines recommend psychosocial treatments *prior* to initiating an antipsychotic (American Academy of Child and Adolescent Psychiatry, 2011; Pappadopulos et al., 2003; Scotto Rosato et al., 2012). Psychosocial interventions are first-line treatment for very young children (Gleason et al., 2001), youth with aggression (Pappadopulos et al., 2003; Scotto Rosato et al., 2012) and disruptive behavior disorders (Steiner and Remsing, 2007), among other conditions. Increasing access to indicated psychosocial treatments prior to initiating an antipsychotic in the absence of a primary indication may improve the safety of treatment by decreasing the use of antipsychotics.

Psychosocial care is a broad term that encompasses many types of psychological services, such as behavioral interventions, psychological therapies, and skills training, among others. Research demonstrates that psychosocial interventions are associated with positive outcomes for children and youth diagnosed with conditions such as ADHD, disruptive behavior and early-onset schizophrenia (Ollendick et al., 2006; Pelham and Fabiano, 2008; Weisz et al., 2005; Kutcher et al., 2004). Practice guidelines for many pediatric behavioral health conditions commonly treated with antipsychotics recommend psychosocial interventions as part of a comprehensive treatment plan.

Treatment recommendations that endorse the use of psychosocial treatment *prior* to antipsychotics are based on established metabolic impacts of antipsychotics and other health risks, and evidence of efficacy of psychosocial treatments. This approach preserves access to antipsychotic medications when needed, while ensuring that children have had access to effective and safer alternatives first.

Guidelines for treatment

Three treatment guidelines address the use of psychosocial care and antipsychotics, one in general (American Academy of Child and Adolescent Psychiatry Practice Parameters for the Use of Atypical Antipsychotic Medications in Children and Adolescents [AACAP-AAA]), and two for use in managing aggression (TRAAY, TMAY). The American Psychiatric Association, as part of the Choosing Wisely campaign, released recommendations regarding antipsychotic use. All four recommend use of psychosocial treatments prior to use of antipsychotic medications for nonprimary indications. Recommendations were rated as a minimal standard of care by two guidelines, while the other two guidelines did not rate individual recommendations. (See the Guidelines Table for more information.)

Guidelines for individual conditions that recommend use of antipsychotics in the absence of a primary indication address the use of psychosocial interventions prior to use of an antipsychotic. Treatment guidelines for management of aggression (Scotto Rosato et al., 2012; Pappadopulos et al., 2003) and disruptive behavior disorders all endorse psychosocial interventions as first-line treatment. Antipsychotics are a recommended second-line treatment option only after psychosocial interventions have been tried, and symptoms are severe and persistent.

The AACAP practice parameters for Oppositional Defiant Disorder recommend psychosocial treatments, such as parent-management training and cognitive problem-solving skills training, as a standard of care, and endorse use of antipsychotics with a lower level of recommendation only after psychosocial interventions have been tried. The AACAP sponsored Preschool Psychopharmacology Working Group published treatment algorithms for a number of conditions, including disruptive behavior disorders, ADHD, major depression, anxiety disorders (GAD, SAD, SM, SP), PTSD, OCD, PDD) and sleep disorders, primarily focusing on preschool children 0–5 years of age, but also rated recommendations for children and adolescents 6–18 years. Psychosocial treatments were first-line for all conditions. Only the disruptive behavior disorders had a nonprimary indication for use of an antipsychotic, but only after psychosocial interventions (e.g., parent management training, parent-child interaction therapy) are provided for 10–20 weeks. For very young children, the guideline recommends psychosocial interventions prior to any psychotropic medication.

Gaps in care

Even as the use of psychopharmacological interventions has increased, the proportion of children and adolescents receiving outpatient psychotherapy declined from 2.95 percent in 1998 to 2.72 percent in 2007 (Olfson et al., 2010). One study of Medicaid-enrolled children and youth starting an antipsychotic medication found that almost one-third did not receive concurrent psychosocial therapy (Harris et al., 2012). This study also found that youth 12–17 years who are prescribed antipsychotics are less like to receive concurrent psychotherapy than children 6–11. A study of privately insured children 2–5 years found that only 40 percent prescribed an antipsychotic also had one or more therapy visits in the measurement year (Olfson et al., 2010).

As part of the measure's field-testing, using the Medicaid Analytic eXtract (MAX) data files, we assessed the percentage of children age 0-20 years covered by Medicaid on antipsychotic medications that had documented psychosocial care. Analysis of administrative claims data from 11 states demonstrated that the average percentage of children prescribed antipsychotic medication who had documented psychosocial care among the general population of children was 48.2 percent, with a range of 35.8 percent—64.1 percent. For children in foster care, the average rate was 56.3 percent, with a range of 38.8 percent—68.9 percent.

Additional field-testing using data from one state's Medicaid plans found the average percentage of children prescribed antipsychotic medication who had documented psychosocial care to be 44.7 percent, with a range of 26.4 percent–67.7 percent.

Health care disparities

Research using the Medical Expenditure Panel Survey shows that Black and Latino youth 5–21 years were significantly less likely to access outpatient mental health care (LeCook et al., 2013). This finding is consistent with more than a decade of research suggesting that minority youth may have higher unmet needs for mental health care and receive lower-quality care than White American youth (Alegria et al., 2010).

Data also suggest that youth in the child welfare system, particularly those 10 and younger, may have significant unmet mental health needs (Burns et al., 2004). Analysis of Medicaid data shows that youth in foster care are more likely to be prescribed antipsychotics than those not in foster care (Zito et al., 2008). Taken together, these trends suggest that access to psychosocial interventions for minority and foster care youth prescribed antipsychotics may be of particular importance.

Research demonstrates that children without health insurance have higher rates of unmet needs for mental health care compared with those with public insurance, suggesting that Medicaid and the Children's Health Insurance Program may play an important role in promoting access to care (Kataoka et al., 2001). Further, the rate of increase in the use of antipsychotics is higher for children and adolescents with public insurance than commercial insurance, suggesting this measure may help improve the quality of mental health care for children with public insurance. It is unclear what factors are associated with lack of access to psychotherapy in this population.

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Recommendations Supporting Use of Psychosocial Interventions for Children and Adolescents

Guideline (Date)	Population	Recommendation or Statement	Type/Grade
AACAP-AAA (2011) Practice parameter for the use of atypical antipsychotic	5-18 years	"Prior to the initiation of and during treatment with an AAA, the general guidelines that pertain to the prescription of psychotropic medications should be followed including education and psychotherapeutic interventions for the treatment and monitoring of improvement" (Recommendation1)	Clinical Standard
medications in children and adolescents.1		"In the absence of specific FDA indications or substantial evidence for effectiveness, physicians should consider other medication or psychosocial treatments before initiating antipsychotic treatment." (under Recommendation 2)	Clinical Standard
AACAP-BP (2007) Practice parameter for the assessment and treatment of children and adolescents with bipolar disorder. ²	≤18 years	"Psychotherapeutic interventions are an important component of a comprehensive treatment plan for early-onset bipolar disorder".(Recommendation 10)	Minimal Standard
AACAP-ODD (2007) Practice parameter for the assessment and treatment of	≤18 years	"The clinician should develop an individualized treatment plan based on the specific clinical situationThe two types of evidence-based treatments for youth with ODD are individual approaches in the form of problem solving skills and family interventions in the form of parent management training" (Recommendation 7)	Minimal Standard
children and adolescents with oppositional defiant disorder. ³		"The clinician should consider parent intervention based on one of the empirically tested interventions" (Recommendation 8)	Minimal Standard
		"Medications may be helpful as adjuncts to treatment packages, for symptomatic treatment and to treat comorbid conditions" (Recommendation 9) Supporting notes recommend that if medications are initiated, it should be after psychosocial interventions are in place, and that medications should not be the only treatment. "Several open and double-blind placebo controlled studies show that typical and atypical antipsychotics are helpful in treating aggression after appropriate psychosocial interventions have been applied in the context of mental retardation and PDD" (under Recommendation 9)	Clinical Guideline
AACAP-SZ (2001) Practice parameter for the	≤18 years	"Adequate treatment requires the combination of psychopharmacological agents plus psychosocial interventions" (Recommendations – Treatment)	Minimal Standard
assessment and treatment of children and adolescents with schizophrenia.4		 "The following psychosocial interventions are recommended: 1. Psychoeducational therapy for the patient, including ongoing education about the illness, treatment options, social skills training, relapse prevention, basic life skills training, and problem-solving skills and strategies, 2. Psychoeducational therapy for the family to increase their understanding of the illness, treatment options, and prognosis and for developing strategies to cope with the patients symptoms." (Recommendations—Psychosocial Interventions) 	Minimal Standard
		"Specialized educational programs and/or vocational training programs may be indicated for some children or adolescents to address the cognitive and functional deficits with the illness" (Recommendations—Psychosocial Interventions.	Clinical Guidelines

Guideline (Date)	Population	Recommendation or Statement	Type/Grade
PPWG (2007) The AACAP-sponsored Preschool Psycho- pharmacology Working Group—Psychopharma-	<6 years	"Universal guidelines are provided to encourage careful and planful clinical practice: Avoid medications when therapy is likely to produce good results Generally, an adequate trial of psychotherapy precedes consideration of medication, and psychotherapy continues if medications are used"	(See diagnostic specific ratings)
cological treatment for very young children: Contexts and		ADHD: Parent Management Training or other behavioral intervention x 8 weeks minimum, is first line for preschoolers	A (preschool)
guidelines. ⁵		Disruptive behavioral disorders: Psychotherapy (e.g., Parent management training, parent child interaction therapy) x 10-20 weeks	A (preschool)
		MDD: Psychotherapy is first line (e.g., dyadic psychotherapy, target emotional regulation) x 3-6 months	C (preschool) A (6-18yrs)
		BP: Psychotherapy is first line (e.g., dyadic psychotherapy, target emotional regulation) x 8-12 sessions	C (preschool) A (6-18yrs)
		Anxiety (GAD, SAD, SM, SP): CBT is first line, x 12 weeks	C (preschool) A (6-18yrs)
		PTSD: Psychotherapy is first line (Child Parent Psychotherapy x 6 months minimum; or CBT x 12 weeks minimum, or if unavailable then Play therapy x months	A (Preschool CPP, CBT) B (Preschool; Play therapy) A (6-18yrs, CBT)
		OCD: CBT with parent involvement, behavioral therapy x 12 weeks minimum	C (Preschool) A (6-18 yrs)
		PPD: Behavioral, developmental, psychoeducational intervention is first line	A (Preschool and 0-18 yrs)
		Sleep: Parent education and sleep hygiene	C (Preschool) A (6-18yrs)
TMAY (2012) Center for Education and Research on Mental Health Therapeutics—Treatment of maladaptive aggression in youth.6	ealth ent of	"Provide or assist the family in obtaining evidence-based parent and child skills training during all phases of care" (Recommendation 10)	Grade of evidence= A Strength of recommendation = Very Strong
		"Engage the child and family in taking an active role in implementing psychosocial strategies and help them to maintain consistency" (Recommendation 11)	Grade of evidence= B Strength of recommendation= Very Strong
		"Recommendations 10 and 11 pertain to psychosocial interventions, which should be the first line of treatment because of its lower risk, preceding the use of medication to address aggression except in emergency circumstances" (Under Treatment Recommendations – unrated explanatory comment)	Not specified

Guideline (Date)	Population	Recommendation or Statement	Type/Grade
TRAAY (2003) Center for the Advancement of Children's Mental Health:	≤18 years	Psychosocial and educational interventions should continue after medication treatment begins.	Not specified*
Treatment recommendations for the use of antipsychotics for aggressive youth. ⁷			

^{*}TRAAY (2003) did not specify the use of a rating system.

Grading System Key

Guideline Developer	Definition			
AACAP	Minimal Standard/Clinical Standard: Rigorous/ substantial empirical evidence (meta-analyses, systematic reviews, RCTs) and/or overwhelming clinical consensus; expected to apply more than 95 percent of the time			
	Clinical guidelines: Strong empirical evidence (non-randomized controlled trials, cohort or case-control studies), and/or strong clinical consensus; expect to apply in most cases (75% of the time)			
	Options: Acceptable but not required; there may be insufficient evidence to support higher recommendation (uncontrolled trials, case/series reports).			
	Not endorsed: Ineffective or contraindicated.			
AACAP endorsed best- practice principles	Best practice principles that underlie medication prescribing, to promote the appropriate and safe use of psychotropic medications			
PPWG	A: Well controlled RCTs, large meta-analyses, or overwhelming clinical consensus			
	B: Empirical evidence (open trials, case series) or strong clinical consensus			
	C: Single case reports or no published reports, recommendation developed by expert consensus (informal)			
TMAY Ratings	Oxford Centre for Evidence-Based Medicine grade of evidence (A-D) ⁸			
	Strength of Recommendation: Very strong (≥90% agreement)			
	Strength of Recommendation: Very strong (70-89% agreement)			
	Strength of Recommendation: Very strong (50-69% agreement)			
	Strength of Recommendation: Very strong (<50% agreement)			

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Follow-up Visit for Children and Adolescents on Antipsychotics

SUMMARY OF CHANGES TO HEDIS 2015

First-year measure.

Description

The percentage of children and adolescents 0–17 years of age who had a new prescription for an antipsychotic medication and had one or more follow-up visits with a prescriber.

Definitions

Intake Period The 12-month window starting March 1 of the year prior to the measurement year

and ending February 28 of the measurement year.

New Episode The member must have a 120-day (4-month) Negative Medication History on or

before the IPSD.

Negative Medication History A period of 120 days (4 months) prior to the IPSD when the member had no antipsychotic medications dispensed for either new or refill prescriptions.

IPSD Index Prescription Start Date. The earliest prescription dispensing date for an

antipsychotic medication where the date is in the Intake Period and there is a

Negative Medication History.

Eligible Population

Product lines Commercial, Medicaid (report each product line separately).

Ages 0 years as of March 1 of the year prior to the measurement year to 17 years as of

February 28 of the measurement year. Report four age stratifications and a total

rate:

• 0-5 years.

• 6-11 years.

• 12-17 years.

• Total.

The total is the sum of the age stratifications.

Continuous enrollment

Members must be continuously enrolled in the organization for 120 days (4 months)

prior to the IPSD through 30 days after the IPSD.

Allowable gap None.
Anchor date None.

Benefit Medical and pharmacy.

Event

Follow the steps below to identify the eligible population.

- **Step 1** Identify all children and adolescents in the specified age range who were dispensed an antipsychotic medication (Table XXX-A) during the 12-month Intake Period.
- **Step 2** Test for Negative Medication History. For each member identified in step 1, test each antipsychotic prescription for a Negative Medication History. The IPSD is the dispensing date of the earliest antipsychotic prescription in the Intake Period with a Negative Medication History.
- **Step 3** Calculate continuous enrollment. Members must be continuously enrolled for 120 days (4 months) prior to the IPSD through 30 days after the IPSD.

Step 4 Required exclusions

Exclude members who had an acute inpatient encounter for mental health or chemical dependency during the 30 days after the IPSD. An acute inpatient encounter in combination with any of the following meets criteria:

- A principal mental health diagnosis (Mental Health Diagnosis Value Set).
- A principal diagnosis of chemical dependency (<u>Chemical Dependency Value</u> Set).

Administrative Specification

Denominator

The eligible population.

Numerator

One or more follow-up visits with a practitioner with prescribing authority, within 30 days after the IPSD.

An outpatient, intensive outpatient or partial hospitalization follow-up visit with a practitioner with prescribing authority, within 30 days after the IPSD. Any of the following code combinations billed by a practitioner with prescribing authority meet criteria:

- · ADD Stand Alone Visits Value Set.
- ADD Visits Group 1 Value Set with ADD POS Group 1 Value Set.
- ADD Visits Group 2 Value Set with ADD POS Group 2 Value Set.

Note: Do not count a visit on the IPSD as the follow-up visit.

Table XXX-A. Antipsychotic Medications

First Generation Antipsychotic Medications	Second Generation Antipsychotic Medications
Chlorpromazine hcl	Aripiprazole
Fluphenazine hcl	Clozapine
Fluphenazine decanoate	lloperidone
Fluphenazine enanthate	Olanzapine
Haloperidol	Olanzapine pamoate
Haloperidol decanoate	Paliperidone
Haloperidol lactate	Paliperidone palmitate
Loxapine hcl	Quetiapine fumarate
Loxapine succinate	Risperidone
Molindone hcl	Risperidone microspheres
Perphenazine	Ziprasidone hcl
Pimozide	Ziprasidone mesylate
Promazine hcl	
Thioridazine hcl	
Thiothixene	
Thiothixene hcl	Combinations
Trifluoperazine hcl	Olanzapine-fluoxetine hcl (Symbyax)
Triflupromazine hcl	Perphenazine-amitriptyline hcl (Etrafon, Triavil [various])

Exclusions

None.

Data Elements for Reporting

Organizations that submit HEDIS data to NCQA must provide the following data elements.

Table XXX-1/2: Data Elements for Follow-Up Visit for Children and Adolescents on Antipsychotics

	Administrative
Measurement year	✓
Data collection methodology (Administrative)	✓
Eligible population	✓
Numerator events by administrative data	✓
Reported Rate	
Lower 95% confidence interval	✓
Upper 95% confidence interval	✓

Follow-Up Visit for Children and Adolescents on Antipsychotics Measure Work-Up

Measure Description

The percentage of children and adolescents 0–17 years of age who had a new prescription for an antipsychotic medication and had one or more follow-up visits with a prescriber.

Topic Overview

Importance and Prevalence

Prevalence

Antipsychotic prescribing for children has increased rapidly in recent decades, driven both by new prescriptions and by longer duration of use (Patten et al., 2012). The frequency of prescribing antipsychotics among youth increased almost fivefold from 1996–2002, from 8.6 per 1,000 children to 39.4 per 1,000 (Cooper et al., 2006). Use has increased in children and adolescents, particularly for conditions without a primary clinical indication, such as ADHD and disruptive behavior disorders (Matone et al., 2010).

Health importance

Antipsychotic medications offer the potential for effective treatment of psychiatric disorders in children; however, they can also increase a child's risk for developing serious health concerns such as metabolic and physical health complications. Antipsychotic medications are associated with a number of potentially adverse effects, including weight gain (Correll et al., 2009) and diabetes (Andrade et al., 2011; Bobo et al., 2013), which can have serious implications for future health outcomes.

Metabolic problems in childhood and adolescence are associated with poor cardiometabolic outcomes in adulthood (Srinivasan et al., 2002). The association of atypical antipsychotics with diabetes has been found to be greater among children and adolescents, compared with adults (Hammerman et al., 2008). In addition to metabolic risks, other serious risks associated with antipsychotic medications in children include extrapyramidal side effects, sedation and somnolence, liver toxicity and cardiac arrhythmias (Correll, 2008).

Financial importance and cost effectiveness

Although there is little research available on the fiscal burden associated with adverse effects of antipsychotic use among children and adolescents, one study of Medicaid-enrolled youth on antipsychotics found that health care costs for patients who developed cardio-metabolic side effects were 34 percent higher than for those who did not (Jerrell et al., 2009). Proper monitoring of side effects through follow-up visits presents a possible solution to alleviate these costs.

Supporting Evidence for Follow-Up Visits

Guidelines

Follow-up care for children and adolescents on psychotropic medications, the broader class of medications under which antipsychotics fall, is a minimum standard of care. Follow-up visits provide a mechanism for assessing medication efficacy and side effects, dose adjustments and medication adherence, and support the doctor-family-patient relationship.

The American Academy of Child and Adolescent Psychiatry (AACAP) developed a series of practice parameters that address use of psychotropic medications. The AACAP Practice Parameter on the Use of Psychotropic Medication in Children and Adolescents "best practice principles for using psychotropic medications in children and adolescents" identifies follow-up care as one of the core principles of prescribing. Principle 5 states, "the prescriber develops a plan to monitor the patient, short and long term" based in part on the timing of onset of side effects.

Further support comes from the AACAP Practice Parameter for the Use of Atypical Antipsychotic Medications in Children and Adolescents, where three recommendations endorse follow-up for youth on antipsychotics as a standard of care, focusing on the importance of monitoring BMI, blood glucose and extrapyramidal symptoms.

AACAP Practice Parameters for the Assessment and Treatment of Children and Adolescents with Schizophrenia, and the AACAP Practice Parameters for the Assessment and Treatment of Children and Adolescents with Bipolar Disorder also recommend follow-up as a minimum practice standard.

Frequency of follow-up visit

Follow-up visits are needed to monitor side effects, assess treatment engagement and response and adjust dosages, as necessary. Clinical practice guidelines call for more frequent follow-up for serious mental illnesses, such as schizophrenia, where initially weekly follow-up is recommend, followed by a minimum of monthly visits with a physician in the recovery phase of treatment to "adequately monitor symptom course, side effects, and compliance, while also directing any necessary psychosocial interventions."

Similarly, in very young children, a minimum of monthly assessment of target symptoms is recommended by the AACAP-sponsored Preschool Psychopharmacology Working Group for very young children on risperidone as a second-stage treatment for disruptive behavior disorders.

The Texas Department of Family and Protective Services guidelines for youth in foster care echo other guidelines in underscoring that follow-up frequency should be based on the child's severity of illness and treatment response.

The American Diabetic Association/American Psychiatric Association recommends a minimum monthly follow-up for the first three months after initiating an antipsychotic, then quarterly monitoring for metabolic side effects.

In summary, follow-up visits are recommended at monthly intervals for the first three months, then every three months, for metabolic monitoring. However, depending on the age, diagnosis, phase of illness, treatment engagement and response, more frequent follow-up visits may be needed.

Opportunities for Improvement

Gaps in care

Having a follow-up visit with a prescriber is a minimal standard of care, however, studies suggest that children may not be receiving adequate follow-up care. One national study of privately insured children found that fewer than 30 percent of children with a new prescription for psychotropic medication had a follow-up visit within 30 days (Harpaz-Rotem et al., 2006). To the extent that side effects are not monitored, identified and addressed appropriately, lack of follow-up care places children at risk for poorer health. Recent reviews of clinical trials of antipsychotics in youth note that there is little evidence on the long-term safety of antipsychotic prescribing in children (Hammerman et al., 2008; Jerrell et al., 2009)

As part of the measure's field-testing, using the Medicaid Analytic eXtract data files, we assessed the rates of children in Medicaid who were prescribed antipsychotics and received a follow-up visit with a prescriber. Based on data from 2008 for 9 states, the percentage of children receiving a follow-up visit within 30 days of a new antipsychotic medication prescription among the general population was 72.8 percent, with a range of 60.2 percent–81.3 percent. For children in foster care, the rate of receiving a follow-up visit was 75.2 percent, ranging from 59.2 percent–87.6 percent.

In an examination of Medicaid health plan claims data from one state, we found that the average percentage of children receiving a follow-up visit with a prescriber within 30 days of a new antipsychotic medication prescription among the general population of children in health plans was 80.6 percent, with a range of 70.4 percent—98.7 percent. Eligible population size for health plans ranged from 66 children to 1,719 children.

When field-testing was conducted, the measure was specified for children and adolescents 0–20 years of age. Following guidance from two measurement advisory panels, it is now specified for children and adolescents 0–17 years of age. This change in specification would be expected to have a small impact on the performance rates reported here.

Health care disparities

More than a decade of research suggests that minority youth receive lower quality mental health care, compared with White American youth (Alegria and Pumariega, 2010). Research suggests that minority children are more likely to be prescribed antipsychotic medication, compared with White children (Adams et al., 2009). Analysis of Medicaid data shows that youth in foster care are more likely to be prescribed antipsychotic medications than those not in foster care (Zito et al., 2008).

In a study of 13 state Medicaid programs, 12.4 percent of children in foster care were prescribed antipsychotics, compared with 1.4 percent of children not in foster care (Medicaid Medical Directors, 2010). In addition, children and adolescents with public insurance are more likely to be prescribed an antipsychotic than those with private insurance (Crystal et al., 2009). Taken together, these trends suggest that access to follow-up care for minority, low socioeconomic status and foster care youth prescribed antipsychotics may be of particular importance.

As part of the measure's field-testing, we assessed differences in rate of receiving a follow-up visit with a prescriber within 30 days of a new antipsychotic medication prescription in Medicaid children of different races and ethnicities. Our results indicate that Black, non-Hispanic children had worse (i.e., lower) rates of receiving a follow-up visit with a prescriber (65.5 percent), compared with Hispanic children (70.5 percent) and White, non-Hispanic children (75.6).

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Recommendations for Follow-Up Visits for Children and Adolescents on Antipsychotic Medications

Organization (Date)	Recommendation	Type/Grade
AACAP (2009) Practice Parameter on the Use of Psychotropic Medication in Children and Adolescents ¹	Principle 5, "The prescriber develops a plan to monitor the patient, short and long term," states that "the frequency of visits is determined by the need for dose titration, by the timing of onset of side effects, and to maintain the doctor-family-patient relationship."	Not specified— "Best practice principles"
AACAP-AAA (2011) Practice parameter for the use of atypical antipsychotic medications in children and adolescents ²	Three recommendations rated as a "Clinical Standard" call for follow-up care for all youth on atypical antipsychotics agents (AAA): Recommendation 14. "Measurements of movement disorders utilizing structured measures, such as the Abnormal Involuntary Movement Scale, should be done at baseline and at regular intervals during the treatment and during tapering of the AAA."	Clinical Standard
	Recommendation 10. "The acute and long-term safety of these medications [atypical antipsychotics] has not been fully evaluated and therefore careful and frequent monitoring of side effects should be performed." Under this recommendation the American Diabetes Association/ American Psychiatric Association monitoring recommendations are endorsed.	Clinical guideline
AACAP-SZ (2001) Practice Parameter for the Assessment and Treatment of Children and Adolescents with Schizophrenia ³	Psychopharmacological recommendations rated as Minimum Standards (MS): "Antipsychotic agents are recommended for the treatment of the psychotic symptoms associated with schizophrenia"(MS) "The use of antipsychotic agents require: (MS) 1. Documentation of any required baseline and follow-up laboratory monitoring, dependent upon agent being used. 2. Documentation of treatment response. 3. Documentation of suspected side-effects (e.g. extrapyramidal side effects, weight gain,) 4. Long-term monitoring to reassess dosage needs, dependent upon the stage of illness. "	Minimum Standard
	Under Literature Review (statements are not rated; literature review supports recommendations): "During the acute psychotic phase, either frequent outpatient visits or hospitalization is needed Once the patient is stabilized, the monitoring should first occur at least weekly with the frequency then decreasing as clinically indicated." Under Literature Review: Treatment - Recovery/Residual Phase: "Physician contact, however, should be maintained (at least monthly) to adequately monitor symptom course, side effects, and compliance, while also directing any necessary psychosocial interventions."	Not specified—included in summary of Literature
AACAP-BP (2007) Practice Parameter for the Assessment and Treatment of Children and Adolescents with Bipolar Disorder ⁴	"Recommendation 8: Psychopharmacological interventions require baseline and follow-up symptom, side-effect (including patient's weight) and laboratory monitoring as indicatedThe atypical antipsychotics as a class are associated with significant weight gain and other metabolic problems (e.g. type 2 diabetes, hyperlipidemia). Thus the American Diabetes Association's recommendations for managing weight gain for patients taking antipsychotics should be followedThe body mass index should be followed monthly for three months and then quarterly."	Minimal Standard

Organization (Date)	Recommendation	Type/Grade
Preschool Psychopharmacology Working Group— Psychopharmacological treatment for very young children: Contexts	Disruptive Behavior Disorder (DBD) Algorithm: "Stage 2: (If) DBD is causing severe persistent impairment and symptoms (then) risperidone x 6 weeks. (If risperidone leads to improvement) Continue risperidone for 6 month trial with regular monitoring of symptoms and adverse effects" Explanatory comment (unrated): "Before initiating medication, structured measures should be used to identify baseline symptomatology and these should be <u>administered at least monthly during treatment.</u> "	 Children and Adolescents: A (RCTs, large meta-analyses, or overwhelming clinical consensus) Preschool children: C (single case reports or no reports, recommendation developed by PWG based on clinical and research experiences)
TX Department of Family and Protective Services (2010) Psychotropic medication utilization parameters for foster children ⁶	General Principles section includes the statement, "The frequency of clinician follow-up with the patient should be appropriate for the severity of the child's condition and adequate to monitor response to treatment including: symptoms, behavior, function, and potential medication side effects."	Not specified*

^{*}TX (2010) did not specify the use of a rating system.

Grading System Key

Guideline Developer	Definition
AACAP	Minimal Standard/ Clinical Standard: rigorous/ substantial empirical evidence (meta-analyses, systematic reviews, RCTs) and/or overwhelming clinical consensus; expected to apply more than 95 percent of the time
	Clinical guidelines: strong empirical evidence (non-randomized controlled trials, cohort or case-control studies), and/or strong clinical consensus; expect to apply in most cases (75% of the time)
	Options: acceptable but not required; there may be insufficient evidence to support higher recommendation (uncontrolled trials, case/series reports)
	Not endorsed: ineffective or contraindicated.
AACAP endorsed best practice principle	Best practice principles that underlie medication prescribing, to promote the appropriate and safe use of psychotropic medications
Preschool Psycho- pharmacology Working Group	A: Well controlled RCTs, large meta-analyses, or overwhelming clinical consensus
	B: Empirical evidence (open trials, case series) or strong clinical consensus
	C: Single case reports or no published reports, recommendation developed by expert consensus (informal)

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Metabolic Screening for Children and Adolescents Newly on Antipsychotics

SUMMARY OF CHANGES TO HEDIS 2015

• First-year measure.

Description

The percentage of children and adolescents 0-17 years of age who had a new prescription for an antipsychotic medication and had baseline metabolic screening.

Definitions

IPSD Index Prescription Start Date. The earliest prescription dispensing date for an

antipsychotic medication where the date is in the Intake Period and there is a

Negative Medication History.

Intake Period The 12-month window starting March 1 of the year prior to the measurement year

and ending February 28 of the measurement year.

Negative Medication

History

A period of 120 days (4 months) prior to the IPSD when the member had no

antipsychotic medications dispensed for either new or refill prescriptions.

Eligible Population

Product lines Commercial, Medicaid (report each product line separately).

Ages 0 years as of March 1 of the year prior to the measurement year to 17 years as of

February 28 of the measurement year. Report four age stratifications and a total rate:

• 0-5 years.

• 6-11 years.

12–17 years.

Total.

The total is the sum of the age stratifications.

Continuous enrollment

Members must be continuously enrolled in the organization for 120 days (4 months)

prior to the IPSD through 30 days after the IPSD.

Allowable gap None.

Anchor date December 31 of the measurement year.

Benefit Medical and pharmacy.

Event/ diagnosis

Follow the steps below to identify the eligible population.

- **Step 1** Identify all children and adolescents in the specified age range who were dispensed an antipsychotic medication (Table XXX-A) during the 12-month Intake Period.
- **Step 2** Test for Negative Medication History. For each member identified in step 1, test each antipsychotic prescription for a Negative Medication History.
- **Step 3** Determine the IPSD. The IPSD is the dispensing date of the earliest antipsychotic prescription in the Intake Period with a Negative Medication History.
- **Step 4** Calculate continuous enrollment. Members must be continuously enrolled for 120 days (4 months) prior to the IPSD through 30 days after the IPSD.

Administrative Specification

Denominator

The eligible population.

Numerator

Both of the following within 90 days prior to 15 days after the IPSD.

- At least one test for blood glucose (<u>Glucose Tests Value Set</u>) or HbA1c (<u>HbA1c Tests Value Set</u>).
- At least one test for LDL-C (<u>LDL-C Tests Value Set</u>) or cholesterol (<u>Cholesterol Tests Other Than LDL Value Set</u>).

Table XXX-A. Antipsychotic Medications

First-Generation Antipsychotic Medications	Second-Generation Antipsychotic Medications
Chlorpromazine hcl	Aripiprazole
Fluphenazine hcl	Clozapine
Fluphenazine decanoate	lloperidone
Fluphenazine enanthate	Olanzapine
Haloperidol	Olanzapine pamoate
Haloperidol decanoate	Paliperidone
Haloperidol lactate	Paliperidone palmitate
Loxapine hcl	Quetiapine fumarate
Loxapine succinate	Risperidone
Molindone hcl	Risperidone microspheres
Perphenazine	Ziprasidone hcl
Pimozide	Ziprasidone mesylate
Promazine hcl	
Thioridazine hcl	
Thiothixene	
Thiothixene hcl	Combinations
Trifluoperazine hcl	Olanzapine-fluoxetine hcl (symbyax)
Triflupromazine hcl	Perphenazine-amitriptyline hcl (etrafon, triavil [various])

Data Elements for Reporting

Organizations that submit HEDIS data to NCQA must provide the following data elements.

Table XXX-1/2: Data Elements for Metabolic Screening for Children and Adolescents Newly on Antipsychotics

	Administrative
Measurement year	✓
Data collection methodology (Administrative)	✓
Eligible population	✓
Numerator events by administrative data	✓
Reported rate	✓
Lower 95% confidence interval	✓
Upper 95% confidence interval	✓

Metabolic Screening and Monitoring for Children and Adolescents on Antipsychotics Measure Work-Up

Measure Description

This work-up supports two measures related to assessment of metabolic side effects of children and adolescents on antipsychotics.

- Metabolic Screening for Children and Adolescents Newly on Antipsychotics.
 The percentage of children and adolescents 0–17 years of age who had a new prescription for an antipsychotic medication and had baseline metabolic screening.
- Metabolic Monitoring for Children and Adolescents on Antipsychotics.
 The percentage of children and adolescents 0–17 years of age who had two or more antipsychotic prescriptions and had metabolic testing.

Topic Overview

Importance and Prevalence

Prevalence in children and adolescents

Antipsychotic prescribing for children has increased rapidly in recent decades, driven by new prescriptions and by longer duration of use (Patten et al., 2012). The frequency of prescribing antipsychotics among youth increased almost fivefold from 1996–2002, from 8.6 per 1,000 children to 39.4 per 1,000 (Cooper et al., 2006).

Use has increased in children and adolescents, particularly for conditions without a primary clinical indication, such as ADHD and disruptive behavior disorders (Matone et al, 2010).

Health importance

Antipsychotic medications offer the potential for effective treatment of psychiatric disorders in children; however, they can also increase a child's risk for developing serious health concerns, including metabolic health complications. Antipsychotic medications are associated with a number of potentially adverse impacts, including weight gain (Correll et al., 2009) and diabetes (Andrade et al. 2011; Bobo et al., 2013).

Diabetes is one of the most common chronic illnesses among children and adolescents, affecting an estimated 215,000 people younger than 20 in 2011. Diabetes is associated with serious cardiovascular, neurological and renal complications, including heart disease, stroke, blindness, kidney failure and nervous system damage (Centers for Disease Control and Prevention, 2011). At the current incidence rate, it is estimated that the rate of type 2 diabetes will increase by 49 percent in the next 40 years (Imperatore et al., 2012).

A multi-year study of youth enrolled in three health maintenance organizations found that exposure to atypical antipsychotics was associated with a fourfold risk of diabetes in the following year, compared with children not prescribed a psychotropic medication, the broader class of medications under which antipsychotics fall (Andrade et al., 2011). Another study of youth enrolled in a state Medicaid plan found that those starting an antipsychotic had three times the risk of developing diabetes, compared with youth starting other psychotropic medications (Bobo, 2013). The association of atypical antipsychotics with diabetes has been found to be greater among children and adolescents than among adults (Hammerman et al., 2008).

Research suggests that metabolic problems in childhood and adolescence are associated with poor cardiometabolic outcomes in adulthood (Srinivasan et al., 2002). The long-term consequences of pediatric obesity and other metabolic disturbances include higher risk of heart disease in adulthood (Baker et al., 2007). Due to the potential negative health consequences associated with children developing cardiometabolic side effects from an antipsychotic medication, it is important to both establish a baseline and continuously monitor metabolic indices to ensure appropriate management of side-effects.

Financial importance and cost effectiveness

Diabetes is one of the most expensive chronic conditions in children (Imperatore et al., 2012). Although there is little research available on the fiscal burden associated with adverse effects of antipsychotic use among children and adolescents, one study of Medicaid-enrolled youth on antipsychotics found that health care costs for patients who developed cardiometabolic side effects were 34 percent higher than those who did not (Jerrell, 2009). Proper screening and monitoring can contribute to early detection and management of cardiometabolic side effects and thus reduce long-term costs.

Supporting Evidence for Metabolic Screening and Monitoring

Several guidelines address metabolic screening for children prescribed antipsychotics, with consensus that baseline and ongoing metabolic monitoring is a standard of care for this population. The specificity of recommendations for ongoing metabolic monitoring varies; some guidelines recommend "appropriate" monitoring and others offer varying levels of detail about specific tests and follow-up intervals. The American Academy of Child & Adolescent Psychiatry (AACAP) practice parameters endorse APA/ADA recommendations for laboratory monitoring, including a fasting glucose and fasting lipid profile at baseline, 3 and 12 months. CAMESA calls for more frequent monitoring in youth, at baseline, 3, 6 and 12 months, and additional monitoring of fasting insulin. (See the Guideline Table for details.)

Gaps in care

Despite the risk of adverse side effects, there is reason to believe that children and adolescents do not receive appropriate laboratory monitoring. For example, a study of Medicaid-enrolled children in three states found that only 31 percent of youth starting an atypical antipsychotic received a glucose test and only 14 percent received a lipid test—far lower than rates reported for adults (Morrato et al., 2010). The association of atypical antipsychotics with diabetes has been found to be greater among children and adolescents than adults (Hammerman et al., 2008).

As part of the measure's field-testing, we assessed the rates of baseline metabolic screening and ongoing monitoring in Medicaid children, using the Medicaid Analytic eXtract data files. Based on data from 2008 for 11 states, the percentage of children receiving metabolic screening within 15 days of a new antipsychotic medication prescription among the general population was 6.0 percent, with a range of 0.4 percent—14.0 percent. For children in foster care, the rate of baseline metabolic screening was 6.3 percent, ranging from 0.0 percent—13.2 percent.

In an examination of claims data from around 20 Medicaid health plans in one state, we found that the average percentage of children receiving baseline metabolic screening within 15 days of a new antipsychotic medication prescription among the general population of children in health plans was 10.3 percent, with a range of 0.2 percent–17.8 percent. Eligible population size for health plans ranged from 66 children to 1,719 children.

For ongoing metabolic monitoring during the measurement year, the data suggests similar gaps in care. Based on data from 2008 for 11 states, the percentage of children with an antipsychotic medication prescription receiving ongoing metabolic monitoring during the measurement year was 18.5 percent, with a range of 4.8

percent to 36.2 percent. For children in foster care, the average rate of ongoing metabolic monitoring was 20.7 percent, ranging from 3.0 percent to 38.1 percent.

In an examination of claims data from around 20 Medicaid health plans in one state, we found that the average percentage of children receiving ongoing metabolic monitoring among the general population of children in health plans was 30.9 percent, with a range of 2.3 percent—40.0 percent. Eligible population size for health plans ranged from 125 children to 2,437 children.

When field-testing was conducted, the measure was specified for children and adolescents 0–20 years of age. Following guidance from two measurement advisory panels, the measure is now specified for children and adolescents 0–17 years of age. This change in specification would be expected to have a small impact on the performance rates reported here.

Health care disparities

There is little research on potential disparities in metabolic monitoring for youth prescribed antipsychotics. One study found that race/ethnicity was not associated with glucose or lipid screening rates (Morrato et al., 2010). Among adults, in general, minority groups are at much greater risk for diabetes than Whites (Centers for Disease Control and Prevention, 2011).

As part of the measure's field-testing, we assessed differences in metabolic screening and monitoring in Medicaid children of different races and ethnicities. Our results indicate that Hispanic children had better (i.e., higher) rates of baseline metabolic screening (10.3 percent), compared with White, non-Hispanic children (5.7 percent) and Black, non-Hispanic children (6.1 percent). We also found that Hispanic children had better (i.e., higher) rates of ongoing metabolic monitoring (24.8 percent), compared with White, non-Hispanic children (19.1 percent) and Black, non-Hispanic children (19.4 percent).

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- Srinivasan, S.R., L. Myers, G.S. Berenson. January 2002. Predictability of childhood adiposity and insulin for developing insulin resistance syndrome (syndrome X) in young adulthood: the Bogalusa Heart Study. *Diabetes.* 51(1):204–9.

Recommendations for Metabolic Screening and Monitoring for Children and Adolescents on Antipsychotic Medication

Organization (Date)	Recommendation	Type/Grade
AACAP-AAA (2011) Practice parameter for the use of atypical antipsychotic medications in children and adolescents. ¹	"The acute and long-term safety of these medications in children and adolescents has not been fully evaluated and therefore careful and frequent monitoring of side effects should be performedIdeally, monitoring of BMI, blood pressure, fasting glucose and fasting lipid profiles should follow, whenever feasible, the recommendations found in the consensus statement put forth by the American Diabetes Association and American Psychiatric Association." Table: Fasting plasma glucose—Baseline, 12 wks, annually; Fasting lipid profile—Baseline, 12 wks (Recommendation 10, and Table 2)	Clinical Guideline
	"Careful attention should be given to the increased risk of developing diabetes with the use of AAA, and blood glucose and other parameters should be assessed at baseline and monitored at regular intervals." (Recommendation 12)	Clinical Standard
	"In those patients with significant weight changes and/or a family history indicating high risk, lipid profiles should be obtained at baseline and monitored at regular intervals." (Recommendation 13)	Clinical Guideline
AACAP-BP (2007) Practice parameter for the assessment and treatment of children and adolescents with bipolar disorder. ³	"Psychopharmacological interventions require baseline and follow-up symptom, side effect, and laboratory monitoring as indicatedThe American Diabetes Association's recommendations for managing weight gain for patients taking antipsychotics should be followed. This includes baseline BMI, waist circumference, blood pressure, fasting glucose, and a fasting lipid panel. The BMI should be followed monthly for 3 months and then quarterly. Blood pressure, fasting glucose and lipids should be followed up after 3 months then yearly." (Recommendation 8)	Minimal Standard
AACAP-SZ (2001) Practice parameter for the assessment and treatment of children and adolescents with schizophrenia. ²	"The use of antipsychotic agents requires documentation any required baseline and follow-up laboratory monitoring"	Minimal Standard
CAMESA (2011) Canadian Alliance for Monitoring Effectiveness and Safety of Antipsychotics in Children—Evidence- based recommendations for monitoring safety of second generation antipsychotics in children and youth. ⁴	The guideline provides antipsychotic medication-specific recommendations for monitoring physical examination maneuvers (height, weight, BMI, waist circumference, blood pressure, and neurological examination for extrapyramidal symptoms), and laboratory tests (glucose, insulin, lipid profile tests, AST, ALT, prolactin, and TSH) for children on AAAs. The GRADE rating system is used to rate each test, for each medication, at each time point examined (baseline, 3, 6, and 12 months). In recognition that clinicians may not have the resources to apply drug specific recommendations, the guideline developers also created a simplified version of the recommendations. Summary recommendation: All children prescribed AAAs should be monitored for metabolic side effects at baseline, 3, 6, and 12 months with the following tests: fasting glucose, fasting insulin, and fasting lipid profile (total cholesterol, LDL, HDL, TG). (Note: Fasting insulin is not recommended for youth on aripiprazole, but is appropriate for all other AAAs.)	Ranges from 1A (strong) to not recommended depending on the specific medication, laboratory test and timeframe. Strongest evidence and recommendations are for baseline tests.
	A baseline fasting glucose is recommended for all children and adolescents on AAAs (strong recommendation/low quality evidence all AAAs except Ziprasidone, weak recommendation/ consensus based).	1C (all AAA except Ziprasidone) 3 (Zip=3)
	A baseline fasting lipid profile is recommended for all children and adolescents on AAAs (strong recommendation with high to low evidence depending upon the AAA, except Ziprasidone, weak recommendation/consensus based).	1A-1C (all AAAs except Ziprasidone) 3 (Zip=3)

Organization (Date)	Recommendation	Type/Grade
	A follow-up fasting glucose and fasting lipid panel (one or more of the tests within the panel) is strongly recommended for all children at one or more time points during the year. (strong recommendation/high-moderate-low evidence for all AAAs, except Ziprasidone, weak recommendation/consensus based).	1A-1C (all AAAs except Ziprasidone) 3 (Zip=3)
PPWG (2007) The AACAP-sponsored Preschool Psychopharmacology Working Group— Psychopharmacological treatment for very young children: Contexts and guidelines. ⁵	"Use of AAA should follow the AACAP practice parameter on AAAs. This practice parameter describes the minimum standards for monitoring vital signs, BMI, fasting blood glucose, extrapyramidal symptoms, lipid profiles, and electrocardiography." (Disruptive Behaviors Algorithm, Stage 2: Pharmacological Intervention).	Not specified
T-MAY (2012) Center for Education and Research on Mental Health Therapeutics—Treatment of maladaptive aggression in youth. ⁶	Practitioners should conduct appropriate, guideline-based laboratory monitoring.	Evidence: A, Recommendation: Very strong
TX (2010) Texas Department of Family and Protective Services—Psychotropic medication utilization parameters for foster children. ⁷	Practitioners should document appropriate monitoring of laboratory findings.	Not specified*

^{*}TX (2010) did not specify the use of a rating system.

Grading System Key

Guideline Developer	Definition
AACAP	Minimal Standard/ Clinical Standard: Rigorous/substantial empirical evidence (meta-analyses, systematic reviews, RCTs) and/or overwhelming clinical consensus; expected to apply more than 95 percent of the time
	Clinical guidelines: Strong empirical evidence (nonrandomized controlled trials, cohort or case-control studies), and/or strong clinical consensus; expect to apply in most cases (75% of the time)
	Options: Acceptable but not required; there may be insufficient evidence to support higher recommendation (uncontrolled trials, case/series reports).
	Not endorsed: Ineffective or contraindicated.
AACAP endorsed best-practice principles	Best-practice principles that underlie medication prescribing, to promote the appropriate and safe use of psychotropic medications
CAMESA	GRADE ^{8,9}
	1A: Strong recommendation, High-quality evidence
	1B: Strong recommendation, Moderate-quality evidence
	1C: Strong recommendation/ Low-quality evidence
	2A: Weak recommendation, High- or moderate-quality evidence
	2B: Weak recommendation, Low-quality evidence
	3: Weak recommendation, No evidence, consensus based
PPWG	A: Well controlled RCTs, large meta-analyses, or overwhelming clinical consensus
	B: Empirical evidence (open trials, case series) or strong clinical consensus
	C: Single case reports or no published reports, recommendation developed by expert consensus (informal)
TMAY Ratings	Oxford Centre for Evidence-Based Medicine grade of evidence (A-D) ¹⁰
	Strength of Recommendation: Very strong (≥90% agreement)
	Strength of Recommendation: Very strong (70-89% agreement)
	Strength of Recommendation: Very strong (50-69% agreement)
	Strength of Recommendation: Very strong (<50% agreement)

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Metabolic Monitoring for Children and Adolescents on Antipsychotics

SUMMARY OF CHANGES TO HEDIS 2015

First-year measure.

Description

The percentage of children and adolescents 0–17 years of age who had two or more antipsychotic prescriptions and had metabolic testing.

Note: A higher rate indicates better performance.

Eligible Population

Product lines Commercial, Medicaid (report each product line separately).

Ages 0 years as of March 1 of the year prior to the measurement year to 17 years as of February 28 of the measurement year. Report four age stratifications and a total rate:

• 0-5 years.

• 6-11 years.

• 12-17 years.

Total.

The total is the sum of the age stratifications.

Continuous enrollment

The measurement year.

Allowable gap None.

Anchor date December 31 of the measurement year.

Benefit Medical and pharmacy.

Event/diagnosis At least two antipsychotic medication dispensing events (Table XXX-A) on different

dates of service during the measurement year.

Administrative Specification

Denominator The eligible population.

Numerator Both of the following during the measurement year.

At least one test for blood glucose (<u>Glucose Tests Value Set</u>) or HbA1c (<u>HbA1c</u> Tests Value Set).

At least one test for LDL-C (<u>LDL-C Tests Value Set</u>) or cholesterol (<u>Cholesterol Tests Other Than LDL Value Set</u>).

Table XXX-A. Antipsychotic Medications

First-Generation Antipsychotic Medications	Second-Generation Antipsychotic Medications
Chlorpromazine hcl	Aripiprazole
Fluphenazine hcl	Clozapine
Fluphenazine decanoate	lloperidone
Fluphenazine enanthate	Olanzapine
Haloperidol	Olanzapine pamoate
Haloperidol decanoate	Paliperidone
Haloperidol lactate	Paliperidone palmitate
Loxapine hcl	Quetiapine fumarate
Loxapine succinate	Risperidone
Molindone hcl	Risperidone microspheres
Perphenazine	Ziprasidone hcl
Pimozide	Ziprasidone mesylate
Promazine hcl	
Thioridazine hcl	
Thiothixene]
Thiothixene hcl	Combinations
Trifluoperazine hcl	Olanzapine-fluoxetine hcl (symbyax)
Triflupromazine hcl	Perphenazine-amitriptyline hcl (etrafon, triavil [various])

Data Elements for Reporting

Organizations that submit HEDIS data to NCQA must provide the following data elements.

Table XXX-1/2: Data Elements for Metabolic Monitoring for Children and Adolescents on Antipsychotics

	Administrative
Measurement year	✓
Data collection methodology (Administrative)	✓
Eligible population	✓
Numerator events by administrative data	✓
Reported rate	✓
Lower 95% confidence interval	✓
Upper 95% confidence interval	✓