The Centers for Medicare & Medicaid Services (CMS) is seeking comments from stakeholders on a proposed concept to measure clinical quality related to antipsychotic use in the inpatient hospital setting.

This document summarizes the draft measure and includes the following: (1) background, (2) measure rationale and intent, and (3) a summary of the measure specifications with questions for public comment. It also includes information on the potential future direction of the measure’s development.

**Background**

CMS hired Mathematica Policy Research and the National Committee for Quality Assurance (the measure developers) to explore the development of several process and structural measures for hospital-based care. These measures are designed to primarily use data from electronic health records or other electronic data sources.

The measure developers have performed initial research to understand the issues related to the use of antipsychotics. They are now seeking feedback on approaches to measuring certain processes that improve care for patients who receive antipsychotics in a general inpatient setting.

**Measure rationale**

The use of antipsychotics in the U.S. has nearly doubled in recent years, from 28 million annual prescriptions in 2001 to 54 million in 2011. Much of this use goes beyond the Food and Drug Administration’s (FDA’s) approved treatment for schizophrenia (1.1 percent of adults) and bipolar and related disorders (2.6 percent of adults) (Leonhauser 2012). The off-label use of these medications is most pronounced in nursing and long-term care facilities, where overuse has been identified and addressed by several CMS programs focusing on the elderly and patients with dementia. In a recent report, experts suggest that the use of antipsychotics to treat disruptive or aggressive behavior in hospitals might be contributing to the continued use of these medications after discharge (Government Accountability Office 2015).

In its recent “Beers Criteria Update” (2015a), the American Geriatric Society (AGS) strongly recommends avoiding these medications in older adults, including patients experiencing delirium or behavioral problems related to dementia, unless nonpharmacologic options have failed and the patients are a threat to themselves or others. AGS further reports that antipsychotics are associated with an increased risk of stroke and mortality in patients with dementia (AGS 2015a). First- and second-generation (“atypical”) antipsychotics have FDA black-box warnings (FDA 2005, 2008) notifying clinicians and patients about an increased risk of death associated with the off-label use of these drugs to treat behavioral problems in older people with dementia.

**Measure intent**

Concerns about antipsychotic use and patient well-being have led to research on a measure that could support guideline- and evidence-based care, specifically in hospitals. Such a measure could reduce inappropriate use of antipsychotics in inpatient hospital settings and the unnecessary continuation of antipsychotics after discharge, resulting in improved patient outcomes (reduced morbidity and mortality).
Feedback on the measure concept to date suggests that antipsychotic use is an important issue to monitor in the inpatient setting and that there is wide variation in the use of these medications based on setting. However, the decision to prescribe antipsychotics for inpatients is complex. A metric aimed at curtailing use of antipsychotics could promote a shift toward even less safe alternatives.

**Summary of measure specifications and questions for public comment**

We propose the following measure concept to promote appropriate use of antipsychotics in the inpatient setting.

<table>
<thead>
<tr>
<th>Measure component</th>
<th>Description of draft measure component</th>
<th>Feedback on measure component to date</th>
<th>Input sought</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proposed measure title</td>
<td>Use of Antipsychotics in Older Adults in the Inpatient Hospital Setting</td>
<td>Feedback to date has suggested that benzodiazepines may be substituted for antipsychotics to control the behavior of patients experiencing delirium or behavioral or psychological symptoms of dementia.</td>
<td>Are there any unintended consequences of this measure?</td>
</tr>
<tr>
<td>Rationale</td>
<td>This measure examines the potentially inappropriate use of antipsychotic medications, similar to the approach used in nursing homes (CMS 2015). Measuring the use of antipsychotics among older adult patients could help reduce inappropriate use.</td>
<td>Feedback to date suggests that patients of any age may experience delirium in the inpatient setting, but the potential for adverse effects is strongest in the elderly population. Feedback to date suggests that inpatient psychiatric hospitalizations should not be included in this measure. This measure in not intended for use in the inpatient psychiatric setting.</td>
<td>We welcome feedback on the age range for this measure and whether it should be expanded to include all adults.</td>
</tr>
<tr>
<td>Denominator</td>
<td>Inpatient hospitalizations for patients ages 65 and older.</td>
<td></td>
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</tr>
<tr>
<td>Denominator exclusions</td>
<td>Patients with a diagnosis of schizophrenia, Tourette’s syndrome, bipolar disorder, or Huntington’s disease at the time of admission.</td>
<td>These diagnoses are FDA-approved indications for the use of antipsychotics. This list of exclusions is harmonized with a quality related measure currently being used in the long term care setting.</td>
<td>Are there other patients who should be removed from the denominator?</td>
</tr>
<tr>
<td>Numerator</td>
<td>Patients who received an order for an antipsychotic medication during the inpatient encounter.</td>
<td></td>
<td>Are there antipsychotic medications that should not be included in the measure?</td>
</tr>
<tr>
<td>Measure component</td>
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<tr>
<td>Numerator exclusions</td>
<td>Patients with documented indication that they are threatening harm to self or others.</td>
<td>Guidelines acknowledge that antipsychotics may be considered when a patient is threatening harm to self or others (AGS 2015a). Patients who are physically aggressive or combative may impede providers' ability to treat the underlying medical condition. The measure specification (included in the materials for public comment) lists some examples of documented behaviors that are considered numerator exclusions.</td>
<td>We welcome feedback on the language in the measure specification and are seeking recommendations on how to capture behaviors that demonstrate a threat to self or others.</td>
</tr>
</tbody>
</table>

We seek feedback on whether the proposed measure will:

- **Shed light on the magnitude of antipsychotics prescribed and administered in the inpatient setting**
- **Promote improvement in prescribing practices in the hospital**
- **Address a quality gap that justifies changing hospital practices and procedures around antipsychotic use**
- **Provide information that indicates appropriate, patient-centered care**

Your answers to the questions in the chart and in the bullets above will help inform measure development and ensure that the final measure is useful to the field.
References


