

Quality Measures for the Care of Patients with Insomnia

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The American Academy of Sleep Medicine (AASM) commissioned five Workgroups to develop quality measures to optimize management and care for patients with common sleep disorders including insomnia. Following the AASM process for quality measure development, this document describes measurement methods for two desirable outcomes of therapy, improving sleep quality or satisfaction, and improving daytime function, and for four processes important to achieving these goals. To achieve the outcome of improving sleep quality or satisfaction, pre- and post-treatment assessment of sleep quality or satisfaction and providing an evidence-based treatment are recommended. To realize the outcome of improving daytime functioning, pre- and post-treatment assessment of

daytime functioning, provision of an evidence-based treatment, and assessment of treatment-related side effects are recommended. All insomnia measures described in this report were developed by the Insomnia Quality Measures Workgroup and approved by the AASM Quality Measures Task Force and the AASM Board of Directors. The AASM recommends the use of these measures as part of quality improvement programs that will enhance the ability to improve care for patients with insomnia.

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Insomnia is the most prevalent sleep disorder, and it has significant consequences for health and function. Efficacious treatments exist. However, the approach to management of insomnia is not standardized, particularly outside of sleep medicine centers. The aim of this paper is to describe the development of quality measures that can be applied to the management of insomnia patients across a wide range of ages and care settings.

Insomnia is characterized by difficulties initiating, sustaining, or obtaining qualitatively satisfying sleep despite adequate sleep opportunities and circumstances, resulting in impaired daytime functioning.^{1,2} Insomnia can occur across the majority of the human lifespan, from childhood years to old age. Over 33% of adults experience insomnia at least intermittently, whereas 10% to 22% suffer chronic sleep difficulties.^{3–8} While prevalence data are more sparse for younger age groups, insomnia symptoms may be seen in as many as 20% to 40% children and teenagers, with slightly higher rates among girls and those with symptoms of mood disturbance.^{9,10} While its significance is often minimized,^{11,12} persistent insomnia is associated with daytime fatigue, decreased mood, impairment in social/vocational functioning or poor school performance, and reduced quality of life.^{1,2,13–15} Insomnia also increases the risks for serious medical disorders, traffic and work-site accidents, alcohol/drug abuse, and major psychiatric illnesses.^{4,16–22} When insomnia is comorbid with a psychiatric illness such as major depression, it complicates disease management and often remains as a residual symptom that enhances risk for both suicide and relapse.^{23–26} Even in younger age groups such as children

and teenagers, insomnia shows strong associations with comorbid conditions such as psychiatric disorders and chronic pain syndromes.^{27,28} Moreover, insomnia contributes to increased health care utilization and costs among the adult population. Indeed, one report published at the end of the past millennium estimated that insomnia sufferers spent well over \$285 million for prescription sleeping pills in 1995 alone, whereas the total annual direct costs of insomnia to the U.S. economy in that year were projected to exceed \$90 billion.²⁹ More than 90% of these direct costs are attributable to work absences and reduced productivity.³⁰ In view of these considerations, ascertaining and implementing the most effective management strategies for the many children and adults who suffer chronic insomnia should be a priority for our health care system.

Effective management of insomnia disorder, like any other chronic condition, benefits from proper clinical assessment practices and the subsequent provision of evidence-based intervention. Evaluation of an insomnia patient requires a comprehensive assessment of the primary sleep complaint, pre-sleep activities, nature of the sleep environment, usual sleep/wake schedule, presence of other nocturnal symptoms (e.g., respiratory, motor behaviors) and nature of the patient's daytime activities and functioning.³¹ Ideally, the assessment process should be thorough enough to affirm the insomnia diagnosis, provide an understanding of how it developed and is sustained, and identify pertinent comorbidities that may require attention during its management. Whenever possible, instruments such as sleep history questionnaires, symptom checklists, self-administered measures of perceived sleep quality/insomnia

symptoms, psychological screening tests, and a prospective sleep diary should be employed to aid in the evaluation and assure a comprehensive insomnia assessment.^{31,32} In younger age groups as well as some geriatric and special-needs populations, parent or caretaker report on diaries and psychometrically validated instruments are useful. At a minimum, a sleep diary/log and a symptom checklist should be completed by the patient and/or caretaker when working with such patients.

Subsequent insomnia management should consider the available evidence-based insomnia therapies as first-line interventions.³³ A variety of psychological and behavioral treatments have established efficacy for insomnia management, including monotherapies such as stimulus control and relaxation therapy as well the multicomponent cognitive behavioral therapy for insomnia (CBT-I), which comprises cognitive therapy, stimulus control and sleep restriction, with/without relaxation therapy.^{31,34} Education about healthy sleep practices, focused on optimizing general lifestyle practices and the sleep environment, may supplement other behavioral therapies but is generally insufficient therapy if used in isolation. When an initial psychological or behavioral monotherapy is not effective, the best current consensus suggests implementing an alternate monotherapy or the multicomponent CBT-I approach.

Among adult age groups, various pharmacological agents can also be used as evidence-based treatments for insomnia. Consensus guidelines³¹ advocate the short-term use of these agents, supplemented with one or more of the evidence-based psychological/behavioral therapies whenever possible. Nonetheless there are limited data showing the continued effectiveness of selected agents for treatment periods as long as one year even when used without any supplemental psychological/behavioral intervention.^{35,36} However, concerns about medication side effects, safety, dependence, and interactions argue against extended use.³¹ Therefore, it is particularly important to monitor safety and effectiveness with use of pharmacologic insomnia therapy.

Despite the availability of consensus guidelines for the evaluation and management of chronic insomnia, incorporation of these guidelines into routine medical practice appears uneven.¹¹ Comprehensive assessment of insomnia is most likely to occur in specialty sleep medicine centers, such as those accredited by the AASM. However, those insomnia patients who present for evaluation and treatment most often do so in primary care venues, where delivery of evidence based care may be encumbered by time and training constraints.^{11,37} Whereas the psychological and behavioral insomnia therapies with proven efficacy are strongly recommended by practice guidelines³⁸ and expert recommendations in the US and elsewhere,^{39,40} access to such therapies and well-trained providers is often limited.^{41–44} Although there have been notable efforts^{45,46} to disseminate these therapies through development of broadly available online interventions, such treatments have yet to find their way into mainstream healthcare. Thus, many patients who would benefit by these therapies never receive them.

In contrast, evidence-based pharmacotherapies are more broadly available, at least for adults with insomnia, since both specialty and primary care providers have equal and ready access to these. Even so, data on national prescription practices shows that clinicians often do not follow pharmacologic treatment guidelines.⁴⁷

In 2013, the AASM Board of Directors (BOD) called for the development of quality measures to serve as guidelines for evaluating quality care for patients with sleep disorders, including insomnia. As the above discussion suggests, there are many gaps in current insomnia assessment and management practices across our healthcare system. Accordingly the BOD commissioned a Workgroup comprised of individuals with expertise in insomnia assessment and treatment, along with assigned AASM support staff and a BOD liaison. Specifically, the Workgroup was asked to develop at least one and no more than 3 outcome measures, and at least three and not more than 10 process measures. Between June 2013 and August 2014 the Workgroup held a series of conference calls and attended two face-to-face meetings in order to develop and refine a set of quality measures to guide insomnia patient care. These final measures were reviewed and approved by the AASM BOD.

METHODS

Literature Search

Two complementary literature searches were performed to assemble evidence in support of these quality measures. As described in the parent paper,⁴⁸ a comprehensive search was first conducted to identify publications, which addressed sleep disorders, inclusive of insomnia, in terms of quality care or measures. A total of 418 articles were retrieved for review using this search, but upon review none directly reflected quality measures pertinent to insomnia care. However, terms and concepts retrieved from this search helped inform the second search, which was conducted to identify clinical practice guidelines, measures, systematic reviews, meta-analyses, and consensus recommendations published by the AASM or other organizations or groups in PubMed, pertaining to insomnia (and all associated MeSH terms). Both searches were limited to articles published between 2002–2013, pertaining to humans, and in the English language. Publication types such as news, letters, editorials, and case reports were excluded.

All titles and abstracts were reviewed by the Workgroup members. Full articles of publications thought to be relevant were obtained and reviewed in full to identify and provide support for the drafted quality measures.

Workgroup members used this evidence base to grade the strength of association between the proposed process and the desired outcome, as shown in **Table 1** and described in detail in the parent paper.⁴⁸

The most pertinent available literature comprised a number of AASM practice parameter and clinical practice guideline papers that provided recommendations largely based on expert consensus rather than an empirical database. The notable exception was the evidence base demonstrating efficacy of psychological/behavioral insomnia therapies for a range of age groups, as well as the many studies documenting the efficacy and safety of pharmacological agents for insomnia management among adults. As a result, the outcome and process quality measures developed for insomnia are largely based on expert consensus. Nonetheless, these measures map on well to current published practice guidelines designed to optimize the quality of insomnia patient care.

Table 1—Strength of association between process measure and desired outcome.

Strength	Characteristic
Level 1: Strong Evidence	<ul style="list-style-type: none"> • AASM Practice Parameter paper recommendations—STANDARD level of recommendation • Recommendation statements from other clinical guidelines developed using an evidence-based approach and without serious biases—Strong(est) level of recommendation
Level 2: Moderate Evidence	<ul style="list-style-type: none"> • AASM Practice Parameter paper recommendations—GUIDELINE level of recommendation • AASM Best Practice Guide or Clinical Guideline recommendations—STANDARD or GUIDELINE level of recommendation • Recommendation statements from other clinical guidelines developed using an evidence-based approach and without serious biases—Moderately strong level of recommendation
Level 3: Supporting Evidence	<ul style="list-style-type: none"> • AASM Practice Parameter paper recommendations—OPTION level of recommendation • AASM Best Practice Guide or Clinical Guideline recommendations—OPTION or CONSENSUS level of recommendation • Recommendation statements from other clinical guidelines developed using an evidence-based approach and without serious biases—Lower levels of recommendation • Conclusions from other systematic reviews and meta-analyses • Randomized controlled trials with at least moderate effect size* and no serious bias/quality issues
Level 4: Workgroup Consensus	<ul style="list-style-type: none"> • Randomized controlled trials with low effect size** • Observational studies • Expert consensus of the Workgroup

*To calculate effect size (Cohen's *d*): <http://www.uccs.edu/~lbecker/>, moderate effect size = Cohen's $d \geq 0.5$.

**To calculate effect size (Cohen's *d*): <http://www.uccs.edu/~lbecker/>, low effect size = Cohen's $d < 0.5$.

In formulating the insomnia measures, considerable effort was devoted to making them applicable to the full age range over which insomnia might be diagnosed. Our literature search, as well as consultation with pediatric sleep medicine specialists, suggested that insomnia disorder is a condition that can appear as early as midway through the first decade of life. Accordingly, current diagnostic manuals^{1,2} provide diagnostic criteria that apply to the youngest ages groups with insomnia while remaining also applicable to adults. The measures developed allow for their use with patients of all ages who meet the diagnostic criteria for insomnia disorder.

Measure Selection

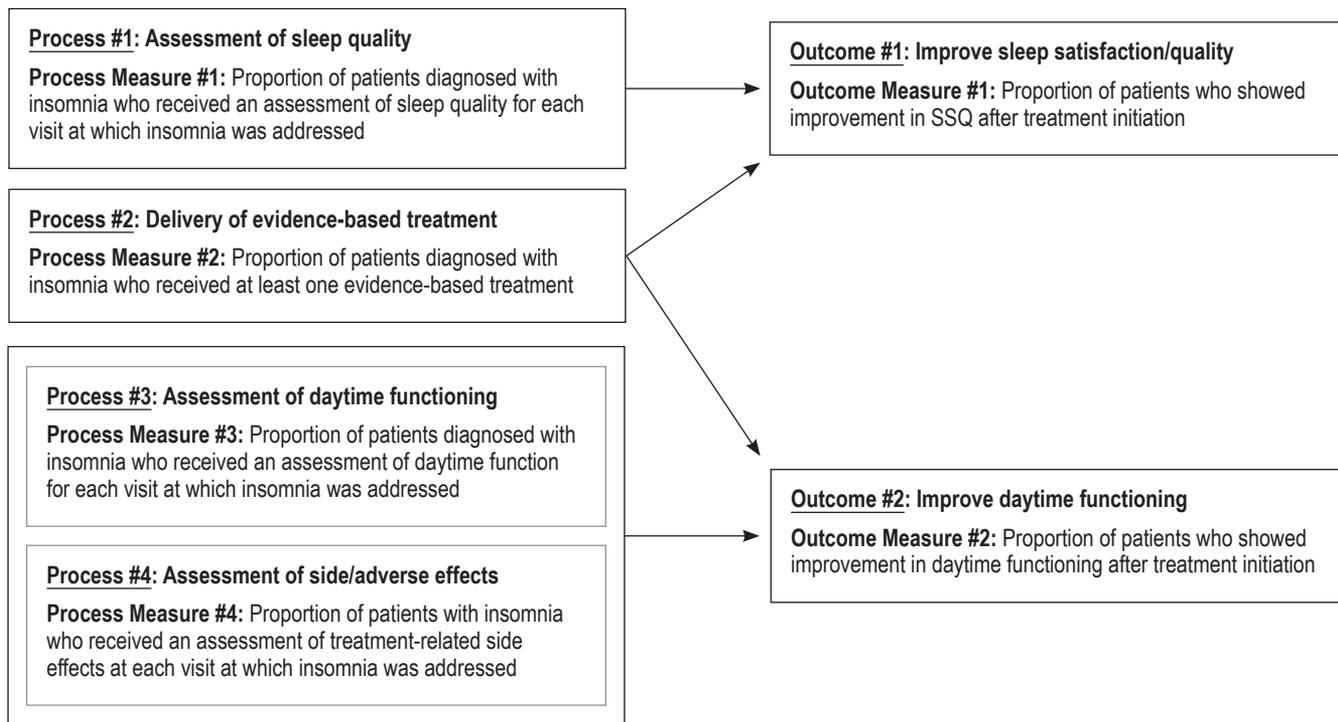
Initial identification of candidate outcome measures was guided by the collective expertise and clinical experiences of the Workgroup members as well as by the published practice parameters and clinical guidelines identified in our literature search. At first we identified four candidate quality outcomes that we considered pertinent to quality insomnia care: (1) provide accurate insomnia diagnosis; (2) improve sleep satisfaction or quality; (3) improve daytime functioning; and (4) minimize treatment-related adverse effects. Collectively, this initial set of outcomes was chosen to ensure that insomnia patients first receive a comprehensive assessment of their condition and then receive an evidence-based intervention which optimizes sleep and wake functioning while doing the least harm. However, we quickly realized it would be difficult to measure how an accurate insomnia diagnosis was rendered in clinical practice, and that “reducing adverse effects” overlaps with “improving daytime functioning” since most adverse effects of therapies tend to affect daytime function. Thus, we chose to develop measurements for only two outcomes: (a) improve subjective sleep satisfaction or quality (SSQ), and (b) improve daytime functioning.

We next identified candidate processes that would most likely result in improved sleep satisfaction/quality and daytime functioning. Since demonstrating improvement in these outcomes

necessitates tracking them over time, assessing SSQ and daytime functioning to demonstrate improvement in these outcomes was considered an important process of care. Hence, assessment of sleep quality and assessment of daytime functioning were delineated as required processes for improving sleep quality and daytime functioning respectively. We also thought that chances for achieving these two outcomes would be enhanced by ensuring that each patient has access to an evidence-based treatment. Accordingly we included the provision of an evidence-based insomnia therapy as a process pertinent to both the sleep quality and daytime functioning outcomes. Finally we decided that assessment of treatment-related side effects would also be important as a process to optimize patients daytime functioning during treatment. The relationship between selected outcomes and processes is depicted in the driver diagram (**Figure 1**).

A final key decision focused on whether the quality measures should apply to children and adolescent cases as well as adults. Since current sleep disorder nosologies (ICSD-3; DSM-5) include a single insomnia disorder diagnosis for children, adolescent, and adult cases, there was significant impetus for us to develop measures that are relevant for the entire age range of those who could be assigned this diagnosis. However, in our efforts to do so we recognized the need for diagnostic specificity, age cutoffs, and minor modifications to assessment approaches. The behavioral insomnias of childhood differ from insomnia disorder in older children, teenagers, and adults both in terms of clinical features, contribution of environmental cues and reinforcers, and type of evidence-based therapies they require. A recommended cutoff of seven years of age was selected for use of the insomnia measures described herein because: (1) the efficacy of the psychological/behavioral therapies proven effective for adult cases are also regarded as effective for children at least of this age and older,^{2,49–51} and (2) children at this age in comparison to younger children have more robust capacity to report on their own symptoms and independently implement components of the psychological/behavioral therapies.

Figure 1—Insomnia quality measures driver diagram.



Nonetheless, we also recognized the need to allow for flexibility in the insomnia measures to account for some important differences between adult and younger cases. First, the measures should recognize that the pharmacological interventions considered evidence-based and appropriate for adults do not have an evidence basis in younger individuals. Second, the measures also should allow for including reports from parents/caretakers as well as patients themselves when assessing sleep quality and daytime functioning in child cases. Finally, the measures should also recognize that distinctive sets of self-report instruments have been validated for adults and younger age groups so a range of such instruments should be included as allowable tools for use. Given these relatively straightforward considerations, we developed the measures for use with the wide age range of individuals who could be assigned an insomnia disorder. The technical specifications associated with each of these quality measures can be found in the **Appendix**. These specifications outline how to calculate an individual provider’s performance in meeting these measures using a combination of diagnostic and CPT codes and chart review.

QUALITY MEASURES

Outcome Measure 1 – Improve Sleep Satisfaction or Quality (SSQ)

Description

Proportion of patients who showed improvement in SSQ after treatment initiation, as measured by at least one of the assessment methods listed on the accompanying Process Measure #1.

Dissatisfaction with sleep quantity or sleep quality is a defining feature of insomnia and included in its definition in current diagnostic manuals.^{1,2} Measuring improvement requires that SSQ be assessed as outlined in Process Measure 1 both before treatment initiation and again sometime after treatment is initiated. Typically the initial assessment after treatment initiation occurs one to three months after treatment is started, and may be repeated at each subsequent visit while the patient is on treatment.

Exceptions and Exception Justifications

Medical Reasons: None.

Patient Reasons: Patients who decline treatment; patients who do not return and do not complete assessment at a follow-up visit after the insomnia treatment is initiated; patients who are unable to engage in treatment; and patients < 7 years of age should be excluded. At least one follow-up visit with a patient engaged in treatment is needed to assess improvement.

Sleep quality/satisfaction improvements resulting from treatment require assessment of these constructs **both before and sometime after treatment is introduced**. Patients who are unwilling or unable to engage in treatment cannot be considered in the assessment of this outcome since they never receive an evidence-based treatment. Those who do not return for assessment after treatment is introduced provide no measures of pre-to-post intervention change/improvement and therefore cannot be considered in the denominator of this outcome.

System Reasons: None.

Supporting Evidence and Rationale

There is a CONSENSUS level of recommendation in the existing Clinical Practice Guidelines for adults and the

Workgroup Consensus for children that improvement of the insomnia patient's SSQ should be a primary goal of treatment.³¹

Opportunities for Improvement/Gaps

Assessment of SSQ before and after treatment is necessary to ascertain treatment efficacy and to determine when an alternate treatment approach may be needed.³¹ Formal assessment and documentation of SSQ improvements may be quite variable across clinical settings, especially in settings other than sleep specialty clinics.

Issues Addressed During Development

Dissatisfaction with one's sleep and poor quality sleep are core features of insomnia. Improvement of SSQ is a fairly global and generic target for insomnia treatment outcome. The Workgroup considered more specific quantitative sleep-focused outcome measures such as changes in sleep efficiency, total sleep time, or total time awake during the night. However in recognition of the varied settings in which insomnia patients receive care, the varied practitioners who may provide such care, and the availability of measurement tools available, the Workgroup considered that measuring improvement in SSQ is practical and highly relevant to the management of insomnia patients.

Process Measure 1 – Assessment of Sleep Satisfaction/Quality

Description

Proportion of patients diagnosed with insomnia who received an assessment of sleep quality for each visit at which insomnia is addressed.

This measure is designed to capture the proportion of patients who receive an assessment of SSQ during a visit when insomnia is addressed. When assessing SSQ in children, a parent/caretaker report as well as the child's report should both be collected (all further references to patient in this document should be assumed to include parent/caretaker for pediatric populations). The assessment can include one or more of the following methods. At a minimum, the clinician should solicit

- Patient self-reported SSQ documented in patient's medical record. Such global assessments should be compared to prior global assessments if any were performed.
- Patient reported subjective sleep latency or wake time during the middle or end of the night documented in the patient's medical record.
- Patient completed prospective sleep diary that includes daily measures of sleep onset latency, wake time after sleep onset, total sleep time and rating of overall sleep quality; or a raster (graphical) diary may be used, wherein the patient shades those time blocks during the day and night when sleep occurs. The actual sleep diary completed by the patient can be included in the patient's medical record but a global summary of the diary results should be documented in the patient's medical record.
- Use of a validated questionnaire that assesses sleep quality or insomnia severity (e.g., Insomnia Severity Index,⁵² Pittsburgh Sleep Quality Index,^{53,55} Children's

Sleep Habits Questionnaire,⁵² Sleep Self-Report.⁵³ A global summary or interpretation of the questionnaire results provided by the clinician should be documented in the patient's medical record.

To document improvements in SSQ, as required for Outcome Measure 1, it is necessary to complete one or more of these assessments before and after the initiation of insomnia therapy.

Exceptions and Exception Justifications

Medical Reasons: None.

Patient Reasons: Patients who decline treatment; patients who do not return and do not complete assessment at a follow-up visit after the insomnia treatment is initiated; patients who are unable to engage in treatment; and patients < 7 years of age should be excluded.

Sleep quality/satisfaction improvements resulting from treatment require assessment of these constructs **both before and sometime after treatment is introduced**. Patients who decline treatment cannot be considered in the assessment of this outcome since they never receive intervention. Those who do not return for assessment after treatment is introduced provide no measures of pre-to-post intervention change/improvement and therefore cannot be considered in the denominator of this outcome.

System Reasons: None.

Supporting Evidence and Rationale

Assessment instruments that may aid in the baseline evaluation and treatment outcomes of patients with chronic insomnia include measures of SSQ (CONSENSUS level of recommendation in the existing Clinical Practice Guidelines^{31,32} – LEVEL 3). Various assessment procedures including sleep diaries, psychometric instruments such as the Insomnia Severity Index⁵⁴ and Pittsburgh Sleep Quality Index,^{55,56} as well as clinician-rated Clinical Global Improvement⁵⁷ have proven effective for detecting pre-to-post treatment changes with both psychological and behavioral insomnia therapies and pharmacotherapies for insomnia in well controlled randomized clinical trials (CONSENSUS level of recommendation in the existing Clinical Practice Guidelines^{31,32} – LEVEL 3). For children, measures can include parent/caretaker and child self-report,²⁸ the Children's Sleep Habits Questionnaire (CSHQ),⁵³ Sleep Self-Report, Children's Sleep Disturbance Scale⁵⁸; and the Sleep Habits Survey.⁵⁹ When used, sleep diary data should be collected prior to and during the course of active treatment and in the case of relapse at later follow-up time points (CONSENSUS³¹ – LEVEL 3).

Relationship to Desired Outcome

The assessments described above directly measure patient-reported SSQ and, when used both before and after treatment initiation, can determine if there are improvements in sleep satisfaction or quality following treatment provision.

Opportunities for Improvement/Gaps

Clinical settings where insomnia patients seek care vary in regard to the type of expertise present and their knowledge of and access to validated measures of SSQ improvement. In some

healthcare settings (e.g., primary care) outcome assessment is expected to rely primarily on interview assessments or a somewhat more formal *Clinical Global Improvement (CGI)*⁵⁷ rating as is conducted in treatment outcomes studies. Such measures are perhaps the most subject to bias and may not provide the same information provided by validated measures of patient-reported outcomes. Making reliable and valid patient reported outcome measures widely available should remain a priority.

Issues Addressed During Development

There were wide-ranging opinions about the specification of measures for assessment of SSQ expressed by Workgroup members, the wider Task Force membership, and also the stakeholders who provided feedback. On the one hand, there was cogent argument for prescribing measurement of SSQ using validated instruments like the Insomnia Severity Index,⁵⁴ Pittsburgh Sleep Quality Index,⁵⁵ or the Consensus Sleep Diary.⁶⁰ Such prescription would provide a level of standardization of SSQ sleep assessment across settings and ensure that practitioners who work with insomnia patients attend to this assessment in a systematic manner. However, there was equally tenable opinion that the assessment of SSQ should remain flexible and offer the practitioner a wide range of options. Rationale for this position comes from the consideration that treatment settings and practitioners who manage insomnia patients vary widely. Some settings place significant time constraints on the assessment process and practitioners therein are not familiar with the validated assessment tools at this time. Also, whereas validated questionnaires have been used widely in insomnia treatment outcome research, there is a lack of research to demonstrate use of these specific sorts of instruments directly enhances the quality of care. In fact, the insomnia literature is generally devoid of studies designed to relate specific assessment methods to desired treatment outcomes. In the end, the Workgroup and larger Task Force decided that offering flexibility and range of assessment options would better meet the needs of the range of practitioners currently involved in insomnia patient care. Thus, a flexible set of outcome assessments was delineated so as to encourage broad acceptance of SSQ assessment.

Process Measure 2 – Delivery of Evidence-Based Treatment

Description

Proportion of patients diagnosed with insomnia who received at least one evidence-based treatment.

To assure optimal outcomes in insomnia care, it is essential that patients receive evidence-based therapies. This measure is designed to determine the proportion of patients with insomnia who are offered an evidence-based insomnia treatment.

Evidence-based psychological/behavioral treatments for adults and children include stimulus control, sleep restriction, relaxation, and cognitive-behavioral insomnia therapy (CBT-I).^{61,62} For adults, evidence-based pharmacotherapies are also available. These include benzodiazepine receptor agonist (BzRA) hypnotics (e.g., zolpidem, eszopiclone, zaleplon, temazepam, flurazepam, estazolam), doxepin, ramelteon, and suvorexant. Other agents with some evidence for efficacy, but without a specific

FDA indication for insomnia also might be considered. These include BzRAs not specifically indicated for insomnia treatment (e.g., clonazepam, lorazepam); sedating antidepressants, used alone or in combination with BzRA or ramelteon; and, for patients with specific comorbidities, other agents such as gabapentin, tiagabine, quetiapine, or olanzapine.³¹

Exceptions and Exception Justifications

Medical Reasons: None.

Patient Reasons: Patients who decline treatment; patients who do not return and do not complete assessment at a follow-up visit after the insomnia treatment is initiated; patients who are unable to engage in treatment; and patients < 7 years of age should be excluded.

Generally clinicians should offer all patients either an evidence-based behavioral or pharmacological insomnia therapy. Individuals who decline such intervention cannot be included in the denominator statement since they never accept and receive such intervention.

System Reasons: None.

Supporting Evidence and Rationale

Among psychological/behavioral treatments, stimulus control therapy, cognitive behavioral treatment for insomnia, and relaxation training are effective therapies (STANDARD level of recommendation in the existing Clinical Practice Guidelines³⁸ – LEVEL 1). Sleep restriction therapy, multicomponent behavioral therapy, biofeedback, and paradoxical intention are also effective therapies (adult GUIDELINE³⁸ – LEVEL 2; pediatric – Workgroup CONSENSUS – LEVEL 4). Effective medication treatments in adults include short-acting benzodiazepine receptor agonists (BzRAs), ramelteon, doxepin, or suvorexant (CONSENSUS level of recommendation in the existing Clinical Practice Guidelines³¹ – LEVEL 3). Other medication treatments may also be effective, including BzRA not specifically indicated for insomnia treatment (e.g., clonazepam, lorazepam); other sedating antidepressants; combinations of BzRAs, ramelteon and/or sedating antidepressants; and (for patients with specific comorbidities) other agents such as gabapentin, tiagabine, quetiapine, or olanzapine (CONSENSUS level of recommendation in the existing Clinical Practice Guidelines³¹ – LEVEL 3). However, it should be noted that, of these pharmacologic treatments, only the following are FDA-approved for the treatment of insomnia: zolpidem, zaleplon, eszopiclone, temazepam, triazolam, ramelteon, doxepin (3, 6 mg), and suvorexant. Meta-analyses of efficacy for insomnia have been conducted for BzRA hypnotics as well as some antidepressants (see reviews^{63,64}).

Relationship to Desired Outcome

Evidence-based treatments provide the greatest likelihood for achieving the desired outcomes of improved sleep quality and daytime function. Although other treatments are available and may be appropriate for specific individuals, their efficacy and safety are less predictable.

Opportunities for Improvement/Gaps

Use of evidence-based treatments should improve the consistency and quality of insomnia care. It may also lead to better

recognition of treatment-resistant subgroups and the need for alternative treatment approaches. Evidence-based psychological or behavioral therapies are more difficult to access in some settings and continued efforts to disseminate these treatments more widely are warranted. Also, among some providers there is reticence to prescribe the evidence-based BzRA hypnotics despite their FDA indication for insomnia.⁴⁷

Issues Addressed During Development

In developing this measure both Workgroup members as well as the stakeholders who provided us comments noted that insomnia is highly comorbid with other disorders including other sleep disorders. Admittedly, optimal outcomes of insomnia patients with comorbidities often require treatments that target both insomnia and sleep-disruptive comorbidities. For example outcomes with insomnia patients who have comorbid sleep disordered breathing (SDB) are optimized when both the insomnia and SDB are effectively treated.^{65,66} For such cases, there may be an argument for specifying evidence-based therapies for both disorders in the context of the current insomnia measures. However, inasmuch as another Workgroup is establishing outcome measures for patients with SDB, those could be used in conjunction with the current measures to provide optimal management for patients with these comorbidities. Moreover, it seemed that delineating the array of therapies needed to manage all relevant comorbidities would make the insomnia specific measures overly cumbersome and far too difficult to implement. Given such considerations, the Workgroup chose to confine our focus to insomnia specific therapies.

Outcome Measure 2 – Improve Daytime Functioning

Description

Proportion of patients who showed improvement in at least one domain of daytime functioning after treatment initiation as measured by at least one of the assessment methods listed on the accompanying Process Measure #3.

A primary goal of all insomnia treatments is improving daytime functioning.³¹ Daytime dysfunction or impairment associated with sleep complaints is a defining feature in current diagnostic criteria for insomnia disorder.^{1,2} Common forms of daytime impairment reported by insomnia sufferers include fatigue and subjective sleepiness; impairment of attention, concentration or memory; mood disturbances or irritability; decrements in academic and/or vocational/occupational functioning; impaired social or familial functioning; reduced motivation, or initiative; somatic complaints including tension, headache or stomach upset in response to sleep loss; and distress/anxiety about nighttime sleep difficulties.^{1,2,67} The number and nature of daytime symptoms vary across insomnia sufferers, but by definition all patients presenting with an insomnia syndrome present at least one of these sorts of daytime complaints. Adequate insomnia treatment, therefore, requires improvement in insomnia patients' daytime complaint(s) as well as their reported sleep disturbances. Measuring improvement requires that daytime function be assessed as outlined in Process Measure 3 both before treatment initiation and again sometime after treatment is initiated.

Exceptions and Exception Justifications

Medical Reasons: None.

Patient Reasons: Patients who decline treatment; patients who do not return and do not complete assessment at a follow-up visit after the insomnia treatment is initiated; patients who are unable to engage in treatment; and patients < 7 years of age should be excluded. The rationale for these exceptions is the same as that provided for Outcome Measure 1.

Improvements in daytime functioning resulting from treatment require assessment of these constructs **both before and sometime after treatment is introduced**. Patients who decline treatment cannot be considered in the assessment of this outcome since they never receive treatment. Those who do not return for assessment after treatment is introduced provide no measures of pre-to-post intervention change/improvement and therefore cannot be considered in the denominator of this outcome.

System Reasons: None.

Supporting Evidence and Rationale

Improvement in daytime functioning is a primary goal of all insomnia treatments as supported by CONSENSUS level of recommendation in the existing Clinical Practice Guidelines.³¹ Domains of daytime functioning that have shown treatment-related improvements include: affect (mood, anxiety); cognition (attention, memory, concentration); educational/academic or vocational/occupational functioning; social, familial, or interpersonal functioning; fatigue; daytime sleepiness; motivation and energy; and somatic complaints (tension, headache, stomach upset); and general distress about ongoing sleep difficulties.^{32,64} The number and types of daytime impairments reported can vary across insomnia patients; many patients do not report impairment in all domains. However, the patient's particular presenting daytime complaints serve as targets for insomnia therapy. Thus, tracking these daytime symptoms before and after the initiation of insomnia therapy is recommended to ascertain treatment efficacy. There is a general lack of treatment outcomes studies in pediatric insomnia patients, but there is evidence that adequate sleep in children is associated with improvement in the same domains in which adults' impairment improves.⁶⁸⁻⁷⁰ There is also consensus among pediatric sleep specialists that improved sleep quality, sleep quantity, and insomnia symptoms improve daytime function and quality of life.

Opportunities for Improvement/Gaps

Daytime function is related to insomnia patients' sleep complaints, decision to seek treatment, and satisfaction with treatment. Assessment of treatment often focuses mainly or solely on changes in the patient's sleep pattern without attention to changes in daytime functioning.⁷¹ Insomnia treatments can have positive and negative effects on daytime function, so failure to assess daytime functioning may result in an inadequate appreciation of treatment effects. Patients with comorbidities may have daytime symptoms associated with another disorder. Therefore, clinicians treating insomnia must recognize that the daytime symptoms may result from sleep disturbance or comorbid disorders.

Issues Addressed During Development

The Workgroup deliberated about the specificity of this outcome measure, reflecting similar concerns to those noted previously in regard to Outcome Measure 1, Sleep Quality or Satisfaction. Rational for choosing flexible measures over specific instruments in determining improvement in daytime function were similar to those outlined with respect to Outcome Measure 1.

Process Measure 3 – Assessment of Daytime Functioning

Description

Proportion of patients diagnosed with insomnia who received an assessment of daytime functioning for each visit at which insomnia is addressed.

This process measure is designed to capture the proportion of visits for insomnia in which an assessment of daytime functioning is performed. Assessment of daytime functioning is essential to the initial assessment of patients' insomnia complaints as well as to the assessment of treatment effects. Methods for assessing daytime function allow for some flexibility and clinician choice given the nature of the practice setting and clinician's training background. Acceptable assessment can include one of the following:

- A medical record documentation of patient-reported and, when indicated, parent/caregiver-reported level of daytime functioning in at least one of the following domains: fatigue/daytime sleepiness, energy/motivation, family/social/educational/occupational functioning, mood, or cognitive function.
- Clinician ratings of global daytime functioning in at least one domain and documented in patient's medical record.
- Administration of a validated questionnaire that assesses domains of daytime functioning. The actual questionnaire completed by the patient can be included in the patient's medical record, but a global summary or interpretation of the questionnaire results provided by the clinician should be documented in the patient's medical record.

Exceptions and Exception Justifications

Medical Reasons: None.

Patient Reasons: Patients who decline treatment; patients who do not return and do not complete assessment at a follow-up visit after the insomnia treatment is initiated; patients who are unable to engage in treatment; and patients < 7 years of age should be excluded.

Improvements in daytime functioning resulting from insomnia treatment require assessment of these constructs **both before and sometime after treatment is introduced**. Patients who decline treatment cannot be considered in the assessment of this outcome since they never receive evidence-based treatment. Those who do not return for assessment after treatment is introduced provide no measures of pre-to-post intervention change/improvement and therefore cannot be considered in the denominator of this outcome.

System Reasons: None.

Supporting Evidence and Rationale

Daytime impairments are an important factor in patients' motivation to seek and receive treatments for insomnia. The assessment of the severity and nature of daytime impairments is essential to adequately monitor and quantify the benefits of insomnia treatments on daytime functioning. This represents CONSENSUS level of recommendation in the existing Clinical Practice Guidelines^{31,32,72} – LEVEL 3. The assessment of daytime function should occur initially and during any follow-up visits when insomnia treatment effects are evaluated (CONSENSUS level of recommendation in the existing Clinical Practice Guidelines³¹ – LEVEL 3). Follow-up assessment guidelines in children and adolescents have not been established and the most prudent approach at this time is to follow recommendations for adults.

In addition to interview-based assessments of daytime functioning, repeated administration of validated questionnaires and survey instruments that target functioning in one or more of the above-mentioned domains may be useful in assessing outcome and guiding ongoing treatment efforts (CONSENSUS level of recommendation in the existing Clinical Practice Guidelines³¹ – LEVEL 3). The number and range of potential instruments that may be considered for this purpose are large. Some examples of such instruments to consider include: the Epworth Sleepiness Scale⁷³ for assessing daytime sleepiness; the Fatigue Severity Scale⁷⁴ or Multidimensional Fatigue Inventory⁷⁵ for assessing daytime fatigue; the Beck Depression Scale,⁷⁶ PHQ-9,⁷⁷ CES-D Scale,⁷⁸ or Profile of Mood States⁷⁹ for assessing daytime mood/depression; the State-Trait Anxiety Inventory,⁸⁰ GAD-7,⁸¹ the Sheehan Disability Scale,⁸² SF-36 Health Survey,⁸³ and RAND-12⁸⁴ for overall daytime dysfunction and quality of life; and the PROMIS scales for assessing general sleep/wake disturbances,⁷² fatigue, and mood. There are also extensive measures available for younger age groups that provide assessments of: daytime sleepiness⁸⁵; fatigue⁸⁶; attention⁸⁷; anxiety⁸⁸; depression⁸⁹ and more broadband measures of behavior and mood (e.g., Child Behavior Check List and Youth Self Report⁹⁰).

Relationship to Desired Outcome

Assessment of daytime function prior to treatment initiation may inform or target treatment choices. Assessment at follow-up is necessary to demonstrate whether improvements occur.

Opportunities for Improvement/Gaps

Assessing daytime impairment in insomnia may not be as common as assessment of sleep satisfaction or quality, yet daytime impairment is a cardinal feature of insomnia disorder, and daytime improvement is among the primary goals of therapy. It is likely that many adverse effects of treatment may become more apparent if daytime function is assessed at follow up. Daytime functional impairment is a common cause for patients seeking healthcare, and effective improvement may lead to improved quality of life and reduced healthcare resource utilization.

Issues Addressed During Development

As was the case for the selection of procedures for assessment of sleep satisfaction/quality, there were tradeoffs to consider

when choosing between considering assessment using only validated tools versus using more universally available subjective global assessments. Both Workgroup members and stakeholders voiced concerns about prescribing specific assessment procedures for assessing daytime function. In recognition of the varied settings in which insomnia patients receive care, the varied practitioners who may provide such care, and the measurement tools available, the Workgroup considered that assessing even subjective or global aspects of daytime function is practical and highly relevant to the management of insomnia patients. Thus, the Workgroup recommended wide flexibility in assessment methods.

Process Measure 4 – Assessment of Side Effects of Treatments

Description

Proportion of patients diagnosed with insomnia who received an assessment of treatment-related side effects at each visit in which insomnia is addressed.

This measure is designed to track the proportion of patients diagnosed with insomnia who received an assessment of treatment-related side effects once an insomnia treatment is initiated. Treatment-related side effects can occur with both psychological/behavioral and pharmacological therapies for insomnia. When psychological or behavioral treatments are used, patients of all ages should be evaluated for potential side effects including increased daytime sleepiness and decreased vigilance particularly when sleep restriction therapy is employed.⁹¹ When pharmacological treatments are used in adults, patients should be evaluated for potential side effects including: (1) sedation during waking hours, particularly upon awakening; (2) headache; (3) nausea and other GI disturbances; (4) nightmares; (5) complex sleep-related behaviors (e.g., sleep walking, sleep eating, sexual activity during sleep); (6) cognitive effects (e.g., memory loss, confusion, disorientation); (7) psychomotor effects (e.g., dizziness, balance impairment, falls); (8) motor vehicle and other accidents; (9) depression; and (10) tolerance, dependence, rebound, and withdrawal. Side effects should be evaluated and managed since they adversely affect daytime functioning and can detract from the overall benefits of the insomnia therapy employed.

Exceptions and Exception Justifications

Medical Reasons: None.

Patient Reasons: Patients who decline treatment; patients who do not return and do not complete assessment at a follow-up visit after the insomnia treatment is initiated; patients who are unable to engage in treatment; and patients < 7 years of age should be excluded.

Assessments of side effects are not warranted for those who decline treatment or who do not return for assessment after treatment is initiated.

System Reasons: None.

Supporting Evidence and Rationale

Whereas side effects of psychological/behavioral treatments have generally not been reported systematically, one side effect noted with the use of sleep restriction therapy is increased

daytime sleepiness⁹¹ (Workgroup CONSENSUS – LEVEL 4). Fatigue, headaches and other somatic complaints, as well as cognitive complaints resulting from sleep restriction may also be present. The side effects noted for pharmacotherapy have been documented in meta-analyses of side effects with benzodiazepine receptor agonist hypnotics,^{63,92} one clinical guideline,³¹ and numerous published papers (reviewed in^{93–97}) (CONSENSUS level of recommendation in the existing Clinical Practice Guidelines³¹ – LEVEL 3). When combination treatments are used (psychological/behavioral and pharmacological), patients should be evaluated for potential side effects related to each treatment type, as well as their potentially additive or interactive effects such as increased likelihood of sedation with combined sleep restriction-hypnotic treatment (Workgroup CONSENSUS – LEVEL 4).

Relationship to Desired Outcome

This process measure outlines procedures to assess and monitor treatment-related side effects in relation to the desired outcome of improvement of daytime functioning (outcome measure #2). Treatment-related side effects may diminish or negate the intended improvements in daytime functioning, alter the risk-benefit ratio of treatment, and/or lead to poor treatment adherence or discontinuation of treatment.

Opportunities for Improvement/Gaps

Side effects may limit treatment efficacy, adherence, safety, and satisfaction, particularly if the provider is unaware of their occurrence. Systematic assessment of treatment-related side effects may lead to modifications of the treatment plan, which in turn could lead to improved efficacy, adherence, safety, and satisfaction.

Issues Addressed During Development

The Workgroup recognized that assessment of side effects is common when medications are used for treating insomnia, but relatively uncommon when psychological/behavioral insomnia treatments are employed. However it has long been recognized and recently documented that application of sleep restriction therapy can result in enhanced daytime sleepiness and reduced daytime vigilance.⁹¹ For that reason the Workgroup decided it was important to advocate for assessment of treatment side effects for both the psychological/behavioral treatment and medicinal interventions. Hence, this measure was designed to encourage such assessment.

IMPLEMENTATION STRATEGIES

The measures are designed to be used by non-sleep-specialist staff including medical records technicians, billing and coding specialists and others who routinely perform medical records audits. These measures offer a level of flexibility so that they can be used in various settings from primary care to sleep specialty centers. In many practices, the information for evaluating these measures will require abstraction by review of clinical notes. In settings where both electronic health records (EHR) and validated questionnaire assessments of sleep quality or satisfaction and/or daytime functioning are administered, electronic templates might be created to facilitate data

capture from the psychometric instruments used and, thus, facilitate data retrieval for auditing the quality of care. The use of such templates also will facilitate the tracking of the insomnia measures over time. Given the variety of settings in which insomnia patients are managed as well as the range of EHR in use across healthcare settings, development of such templates was regarded as outside the current Workgroup aims. Nonetheless, efforts to develop such templates, at least for the more commonly used EHR, remains a reasonable endeavor for the future.

FUTURE DIRECTIONS

Assuring quality care in the management of insomnia patient represents an important undertaking given insomnia's high prevalence and the significant morbidity and costs associated with it. The proposed outcome and process measures represent a consensually derived minimal data set that might characterize the quality of care for insomnia patients. Obviously many other factors influence the quality of care a given insomnia patient receives, so the outcomes and processes addressed should not be construed as exhaustive.

The Workgroup recognizes the major role that consensus played in developing these measures, since there is little empirical data in the insomnia literature linking processes to desired outcomes. Specifically there is a general lack of studies that answer the question: "What insomnia assessment and treatment processes lead to the best outcomes at the least cost per average patient?" Until such research is conducted, we are left to rely on expert consensus to guide insomnia quality care practices. However, the measures proposed here should be viewed as a starting point that may be augmented over time as research becomes available to specifically link insomnia management processes to outcomes. Discovery of new treatments, advances in technology or treatment delivery and record keeping, and shifts in health care settings where insomnia is managed might influence future versions of quality measures. Hopefully, the current set of measures will both begin our journey to improving insomnia management and spur the process-outcome research we sorely need for their refinement.

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APPENDIX

The following are the technical specifications for the insomnia quality measures, which can be used to calculate an individual provider's performance in meeting these measures. Tracking and periodically reviewing this performance data will help providers identify opportunities for improvement within their own practices.

$$\text{Performance} = \frac{\# \text{ of patients meeting numerator criteria}}{(\# \text{ of patients meeting denominator criteria} - \# \text{ of patients with valid exclusions})}$$

Outcome Measure #1: Improve sleep satisfaction/quality

Measure Description	
Description	Proportion of patients who showed improvement in SSQ after treatment initiation, as measured by at least one of the assessment methods listed on the accompanying Process Measure #1.
Measure Components	
Denominator Statement	All patients diagnosed with insomnia who receive evidence-based insomnia management such as initiation or renewal of insomnia treatments during their visit with the clinician.
Exceptions	<p>Medical Reasons: None.</p> <p>Patient Reasons: Patients who decline treatment; patients who do not return and do not complete assessment at a follow-up visit after the insomnia treatment is initiated; patients who are unable to engage in treatment; and patients < 7 years of age should be excluded.</p> <p>System Reasons: None.</p>
Numerator Statement	<p>Number of patients who showed improvement in sleep satisfaction or quality after treatment initiation by at least one of the assessment methods listed on the accompanying process measure #1.</p> <p>Note: The pre-treatment sleep quality assessment should be conducted within one month maximum prior to treatment initiation and the post-treatment measure should be administered sometime between one (minimum interval) and three months after treatment initiation</p>

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Outcome Measure #1: Improve sleep satisfaction/quality *(continued)*

Technical Specifications: Administrative/Claims Data	
Administrative claims data collection requires users to identify the eligible population (denominator) and numerator using codes recorded on claims or billing forms (electronic or paper). Users report a rate based on all patients in a given practice for whom data are available and who meet the eligible population/denominator criteria.	
Denominator (Eligible Population)	<p>One of the following codes indicating insomnia: 291.82 Alcohol induced sleep disorders (includes alcohol induced insomnia) 292.85 Drug induced sleep disorders (includes drug induced insomnia) 307.41 Transient disorder of initiating or maintaining sleep 307.42 Persistent disorder of initiating or maintaining sleep 307.49 Other (includes "subjective insomnia complaints") 327.00 Organic insomnia, unspecified 327.01 Insomnia due to medical condition classified elsewhere 327.02 Insomnia due to mental disorder 327.09 Other organic insomnia 780.51 Insomnia with sleep apnea, unspecified 780.52 Insomnia, unspecified</p> <p>Accompanied by One of the following patient encounter codes: 90832 Psychotherapy, 30 min 90834 Psychotherapy, 45 min 90837 Psychotherapy, 60 min 99212, 99213, 99214, 99215 (office/other outpatient services – established patient) 90833 Psychotherapy, 30 minutes, when performed with an evaluation and management service 90836 Psychotherapy, 45 minutes, when performed with an evaluation and management service 90838 Psychotherapy, 60 minutes, when performed with an evaluation and management service 90863 Pharmacologic management, when performed with psychotherapy services 96152 Health and behavior intervention</p> <p>Accompanied by All patients diagnosed with insomnia who received insomnia management during the visit. Management may include initiation or renewal of insomnia treatments during the visit with the clinician.</p>
Exceptions	<p>At least one of the following is documented in the patient chart:</p> <ul style="list-style-type: none"> • Patient declines treatment. • Patient does not return and does not complete assessment at a follow-up visit after the insomnia treatment is initiated. • Patient is unable to engage in treatment. • Patient is < 7 years of age.
Numerator	<p>Chart review indicates:</p> <ul style="list-style-type: none"> • Documented improvement in sleep quality or satisfaction as determined by one of the methods listed for Process Measure # 1.

Process Measure #1: Assessment of sleep quality

Measure Description	
Description	Proportion of patients diagnosed with insomnia who received an assessment of sleep quality for each visit at which insomnia is addressed.
Measure Components	
Denominator Statement	All patients diagnosed with insomnia who receive evidence-based insomnia management such as initiation or renewal of insomnia treatments during their visit with the clinician.
Exceptions	<p>Medical Reasons: None.</p> <p>Patient Reasons: Patients who decline treatment; patients who do not return and do not complete assessment at a follow-up visit after the insomnia treatment is initiated; patients who are unable to engage in treatment; and patients < 7 years of age should be excluded.</p> <p>System Reasons: None.</p>
Numerator Statement	<p>Number of patients diagnosed with insomnia who received an appropriately documented assessment of sleep quality for each visit at which insomnia is addressed. The assessment can include any one of the following reported by the patient or a caregiver/parent:</p> <ol style="list-style-type: none"> 1. Patient-reported sleep quality or satisfaction documented in patient's medical record. 2. Patient-reported sleep latency or wake time during the middle or end of the night documented in patient's medical record. 3. Prospective sleep diary that includes daily measures of sleep onset latency, wake time after sleep onset, total sleep time and rating of overall sleep quality. The actual sleep diary completed by the patient can be included in the patient's medical record but a global summary of the diary results should be provided by the clinician and documented in the patient's medical record. 4. Administration of a validated questionnaire that assesses sleep quality or insomnia severity (e.g., ISI, PSQI). The actual questionnaire completed by the patient can be included in the patient's medical record but a global summary or interpretation of the questionnaire results provided by the clinician should be documented in the patient's medical record.

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Process Measure #1: Assessment of sleep quality (*continued*)

Technical Specifications: Administrative/Claims Data	
<p>Administrative claims data collection requires users to identify the eligible population (denominator) and numerator using codes recorded on claims or billing forms (electronic or paper). Users report a rate based on all patients in a given practice for whom data are available and who meet the eligible population/denominator criteria.</p>	
Denominator (Eligible Population)	<p>One of the following codes indicating insomnia: 291.82 Alcohol induced sleep disorders (includes alcohol induced insomnia) 292.85 Drug induced sleep disorders (includes drug induced insomnia) 307.41 Transient disorder of initiating or maintaining sleep 307.42 Persistent disorder of initiating or maintaining sleep 307.49 Other (includes "subjective insomnia complaint") 327.00 Organic insomnia, unspecified 327.01 Insomnia due to medical condition classified elsewhere 327.02 Insomnia due to mental disorder 327.09 Other organic insomnia 780.51 Insomnia with sleep apnea, unspecified 780.52 Insomnia, unspecified</p> <p>Accompanied by One of the following patient encounter codes: 90791 Psychiatric diagnostic evaluation 90792 Psychiatric diagnostic evaluation with medical services (this includes prescribing of medications) 90832 Psychotherapy, 30 min (actual time can be 16–37 min) 90834 Psychotherapy, 45 min (actual time can be 38–52 min) 90837 Psychotherapy, 60 min (actual time can be 53–67 min) 99201, 99202, 99203, 99204, 99205 (office/other outpatient services – new patient) 99212, 99213, 99214, 99215 (office/other outpatient services – established patient) 90833 Psychotherapy, 30 minutes, when performed with an evaluation and management service 90836 Psychotherapy, 45 minutes, when performed with an evaluation and management service 90838 Psychotherapy, 60 minutes, when performed with an evaluation and management service 90863 Pharmacologic management, when performed with psychotherapy services (Note: A new Add On code, +90863, pharmacologic management, including prescription and review of medication, can be added to a primary psychotherapy code—90833, 90836, 90837—but NOT with an E/M code. This Add On code should NEVER be used by a physician, only by a Prescribing Psychologist.)</p> <p>Accompanied by Documentation in the patient record that insomnia management was discussed during the encounter. Management may include initiation or renewal of insomnia treatments during the visit with the clinician.</p>
Exceptions	<p>At least one of the following is documented in the patient chart:</p> <ul style="list-style-type: none"> • Patient declines treatment. • Patient does not return and does not complete assessment at a follow-up visit after the insomnia treatment is initiated. • Patient is unable to engage in treatment. • Patient is < 7 years of age.
Numerator	<p>Chart review indicates:</p> <ul style="list-style-type: none"> • Patient received an assessment of sleep quality including: <ul style="list-style-type: none"> • Minimally acceptable assessment: patient, caretaker/parent-reported sleep quality or satisfaction documented in patient's medical record. • Preferable assessment: report of sleep latency, WASO, and/or EMA documented in patient's medical record. • Optimal assessment: Prospective sleep diary, validated sleep measures (e.g., adult – ISI, PSQI, BISQ; pediatric – CHQ, CSDQ, SHS, SRS). • Sleep quality assessment has occurred at each patient encounter in which insomnia management is discussed. • Caregiver/parent subjective report of their sleep quality.

Process Measure #2: Delivery of evidence-based treatment

Measure Description	
Description	Proportion of patients diagnosed with insomnia who received at least one evidence-based treatment.
Measure Components	
Denominator Statement	All patients diagnosed with insomnia who receive insomnia evidence-based management such as initiation or renewal of insomnia treatments during their visit with the clinician.
Exceptions	<p>Medical Reasons: None.</p> <p>Patient Reasons: Patients who decline treatment; patients who do not return and do not complete assessment at a follow-up visit after the insomnia treatment is initiated; patients who are unable to engage in treatment; and patients < 7 years of age should be excluded.</p> <p>System Reasons: None.</p>
Numerator Statement	<p>Number of patients who received at least one appropriately documented evidence-based treatment. Evidence based treatments include:</p> <p>Psychological/behavioral treatments including but not limited to: stimulus control, sleep restriction, relaxation, CBT (adults and children) or any combination of these approaches; Medications (adults only): Benzodiazepine receptor agonist (BzRA) hypnotics (zolpidem, eszopiclone, zaleplon, ramelteon, temazepam, triazolam); doxepin 3, 6 mg; suvorexant; other sedating antidepressants, alone or in combination with BzRA or ramelteon; and (for patients with specific comorbidities) other agents such as gabapentin, tiagabine, quetiapine, or olanzapine.</p>

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Process Measure #2: Delivery of evidence-based treatment (*continued*)

Technical Specifications: Administrative/Claims Data	
<p>Administrative claims data collection requires users to identify the eligible population (denominator) and numerator using codes recorded on claims or billing forms (electronic or paper). Users report a rate based on all patients in a given practice for whom data are available and who meet the eligible population/denominator criteria.</p>	
Denominator (Eligible Population)	<p>One of the following codes indicating insomnia: 291.82 Alcohol induced sleep disorders (includes alcohol induced insomnia) 292.85 Drug induced sleep disorders (includes drug induced insomnia) 307.41 Transient disorder of initiating or maintaining sleep 307.42 Persistent disorder of initiating or maintaining sleep 307.49 Other (includes "subjective insomnia complaints") 327.00 Organic insomnia, unspecified 327.01 Insomnia due to medical condition classified elsewhere 327.02 Insomnia due to mental disorder 327.09 Other organic insomnia 780.51 Insomnia with sleep apnea, unspecified 780.52 Insomnia, unspecified</p> <p>Accompanied by One of the following patient encounter codes: 90791 Psychiatric diagnostic evaluation 90792 Psychiatric diagnostic evaluation with medical services 90832 Psychotherapy, 30 min 90834 Psychotherapy, 45 min 90837 Psychotherapy, 60 min 99201, 99202, 99203, 99204, 99205 (office/other outpatient services – new patient) 99212, 99213, 99214, 99215 (office/other outpatient services – established patient) 90833 Psychotherapy, 30 minutes, when performed with an evaluation and management service 90836 Psychotherapy, 45 minutes, when performed with an evaluation and management service 90838 Psychotherapy, 60 minutes, when performed with an evaluation and management service 90863 Pharmacologic management, when performed with psychotherapy services 96150 Health and behavior assessment 96152 Health and behavior intervention</p> <p>Accompanied by Documentation in the patient record that evidence-based insomnia management was discussed during the encounter. Management may include initiation, continuation, or renewal of insomnia treatments during a visit with the clinician.</p>
Exceptions	<p>At least one of the following is documented in the patient chart:</p> <ul style="list-style-type: none"> • Patient declines treatment. • Patient does not return and does not complete assessment at a follow-up visit after the insomnia treatment is initiated. • Patient is unable to engage in treatment. • Patient is < 7 years of age.
Numerator	<p>Chart review indicates:</p> <ul style="list-style-type: none"> • Patient receives evidenced-based treatment (psychological/behavioral and/or pharmacological) including at least one of the following: <ul style="list-style-type: none"> • Acceptable psychological/behavioral treatments: stimulus control; sleep restriction; relaxation; cognitive behavioral therapy (CBT) or any combination of these approaches • Acceptable medications for adults: Benzodiazepine receptor agonist (BzRA) hypnotics (zolpidem, eszopiclone, zaleplon, ramelteon, temazepam, triazolam); doxepin 3, 6 mg; suvorexant; other sedating antidepressants, alone or in combination with BzRA or ramelteon; and (for patients with specific comorbidities) other agents such as gabapentin, tiagabine, quetiapine, and/or olanzapine

Outcome Measure #2: Improve daytime functioning

Measure Description	
Description	Proportion of patients who showed improvement in at least one domain of daytime functioning after treatment initiation as measured by at least one of the assessment methods listed on the accompanying Process Measure #3.
Measure Components	
Denominator Statement	All patients diagnosed with insomnia who receive insomnia evidence-based management such as initiation or renewal of insomnia treatments during their visit with the clinician.
Exceptions	<p>Medical Reasons: None.</p> <p>Patient Reasons: Patients who decline treatment; patients who do not return and do not complete assessment at a follow-up visit after the insomnia treatment is initiated; patients who are unable to engage in treatment; and patients < 7 years of age should be excluded.</p> <p>System Reasons: None.</p>
Numerator Statement	<p>Number of patients who showed improvement in at least one domain of daytime functioning after treatment initiation by at least one of the assessment methods listed on the accompanying process measure #3.</p> <p>The "return visit" measure should be administered sometime between one (minimum interval) and three months after treatment initiation.</p>

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Outcome Measure #2: Improve daytime functioning (*continued*)

Technical Specifications: Administrative/Claims Data	
Administrative claims data collection requires users to identify the eligible population (denominator) and numerator using codes recorded on claims or billing forms (electronic or paper). Users report a rate based on all patients in a given practice for whom data are available and who meet the eligible population/denominator criteria.	
Denominator (Eligible Population)	<p>One of the following codes indicating insomnia: 291.82 Alcohol induced sleep disorders (includes alcohol induced insomnia) 292.85 Drug induced sleep disorders (includes drug induced insomnia) 307.41 Transient disorder of initiating or maintaining sleep 307.42 Persistent disorder of initiating or maintaining sleep 307.49 Other (includes "subjective insomnia complaint") 327.00 Organic insomnia, unspecified 327.01 Insomnia due to medical condition classified elsewhere 327.02 Insomnia due to mental disorder 327.09 Other organic insomnia 780.51 Insomnia with sleep apnea, unspecified 780.52 Insomnia, unspecified</p> <p>Accompanied by One of the following patient encounter codes: 90832 Psychotherapy, 30 min 90834 Psychotherapy, 45 min 90837 Psychotherapy, 60 min 99212, 99213, 99214, 99215 (office/other outpatient services – established patient) 90833 Psychotherapy, 30 minutes, when performed with an evaluation and management service 90836 Psychotherapy, 45 minutes, when performed with an evaluation and management service 90838 Psychotherapy, 60 minutes, when performed with an evaluation and management service 90863 Pharmacologic management, when performed with psychotherapy services 96152 Health and behavior intervention</p> <p>Accompanied by Documentation that the patient is currently receiving evidence-based treatment for his/her insomnia.</p> <p>Accompanied by Documentation that assessments of daytime functioning have been performed at baseline and at a return visit: • Documented baseline assessment of daytime functioning administered within one month maximum prior to treatment initiation. • Documented assessment at a return visit of daytime functioning administered at least once at minimum between one and three months after treatment initiation.</p>
Exceptions	<p>At least one of the following is documented in the patient chart:</p> <ul style="list-style-type: none"> • Patient declines treatment. • Patient does not return and does not complete assessment at a follow-up visit after the insomnia treatment is initiated. • Patient is unable to engage in treatment. • Patient is < 7 years of age.
Numerator	<p>Chart review indicates: Documented improvement in daytime functioning as determined by one of the methods listed for Process Measure #3.</p>

Process Measure #3: Assessment of daytime functioning

Measure Description	
Description	Proportion of patients diagnosed with insomnia who received an assessment of daytime functioning for each visit at which insomnia is addressed.
Measure Components	
Denominator Statement	All patients diagnosed with insomnia who receive evidence-based insomnia management such as initiation or renewal of insomnia treatments during their visit with the clinician.
Exceptions	<p>Medical Reasons: None.</p> <p>Patient Reasons: Patients who decline treatment; patients who do not return and do not complete assessment at a follow-up visit after the insomnia treatment is initiated; patients who are unable to engage in treatment; and patients < 7 years of age should be excluded.</p> <p>System Reasons: None.</p>
Numerator Statement	<p>Number of patients diagnosed with insomnia who received an appropriately documented assessment of daytime functioning for each visit at which insomnia is addressed. The assessment can include one of the following:</p> <ul style="list-style-type: none"> • A medical record documentation of patient-reported level of daytime functioning in at least one of the following domains: fatigue/daytime sleepiness; energy/motivation, family/social/educational/occupational functioning; mood; or cognitive function. • Clinician ratings of global daytime functioning in at least one domain and documented in patient's medical record. • Administration of a validated questionnaire that assesses domains of daytime functioning. The actual questionnaire completed by the patient can be included in the patient's medical record but a global summary or interpretation of the questionnaire results provided by the clinician should be documented in the patient's medical record. <ul style="list-style-type: none"> • Validated self-report measures can adequately assess daytime functioning and capture changes in functioning over time and/or with treatment. • Mood/affective disturbances: Validated measures of mood/affective disturbances such as the PHQ-9, POMS (PMID: PMID 226658), or CESD; child measures: CDI • Anxiety: GAD-7 from the PHQ/PRIME-MD; child measures SCARED • Fatigue: Fatigue Severity Scale, MFI • Sleepiness: Epworth Sleepiness Scale • Somatic complaints: PHQ scale • Overall Functioning and quality of life: Sheehan Disability Scale, SF-36, RAND-12 (PMID: 19051059) • Broadband measures of children's adaptive and problem behaviors : Child Behavior Checklist; Connor's Rating scale 3 • PROMIS scales

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Process Measure #3: Assessment of daytime functioning (continued)

Technical Specifications: Administrative/Claims Data	
Administrative claims data collection requires users to identify the eligible population (denominator) and numerator using codes recorded on claims or billing forms (electronic or paper). Users report a rate based on all patients in a given practice for whom data are available and who meet the eligible population/denominator criteria.	
Denominator (Eligible Population)	<p>One of the following codes indicating insomnia: 291.82 Alcohol induced sleep disorders (includes alcohol induced insomnia) 292.85 Drug induced sleep disorders (includes drug induced insomnia) 307.41 Transient disorder of initiating or maintaining sleep 307.42 Persistent disorder of initiating or maintaining sleep 307.49 Other (includes "subjective insomnia complaints") 327.00 Organic insomnia, unspecified 327.01 Insomnia due to medical condition classified elsewhere 327.02 Insomnia due to mental disorder 327.09 Other organic insomnia 780.51 Insomnia with sleep apnea, unspecified 780.52 Insomnia, unspecified</p> <p>Accompanied by One of the following patient encounter codes: 90791 Psychiatric diagnostic evaluation 90792 Psychiatric diagnostic evaluation with medical services 90832 Psychotherapy, 30 min 90834 Psychotherapy, 45 min 90837 Psychotherapy, 60 min 99201, 99202, 99203, 99204, 99205 (office/other outpatient services – new patient) 99212, 99213, 99214, 99215 (office/other outpatient services – established patient) 90833 Psychotherapy, 30 minutes, when performed with an evaluation and management service 90836 Psychotherapy, 45 minutes, when performed with an evaluation and management service 90838 Psychotherapy, 60 minutes, when performed with an evaluation and management service 90863 Pharmacologic management, when performed with psychotherapy services 96150 Health and behavior assessment 96152 Health and behavior intervention</p> <p>Accompanied by Documentation in the patient record that insomnia management was discussed during the encounter. Management may include initiation or renewal of insomnia treatments during the visit with the clinician.</p>
Exceptions	<p>At least one of the following is documented in the patient chart:</p> <ul style="list-style-type: none"> • Patient declines treatment. • Patient does not return and does not complete assessment at a follow-up visit after the insomnia treatment is initiated. • Patient is unable to engage in treatment. • Patient is < 7 years of age.
Numerator	<p>Chart review indicates:</p> <ul style="list-style-type: none"> • Patient received an assessment of daytime functioning including: <ul style="list-style-type: none"> • Minimal documentation includes: patient-reported assessment of daytime functional status (fatigue/sleepiness; energy/motivation, family/social functioning, educational/occupational performance; and/or emotional status and cognitive functioning) documented in medical record. • Optimal documentation includes: daytime functioning assessment via validated self- and caregiver/parent report measures: <ul style="list-style-type: none"> • Mood/affective disturbances: Validated measures of mood/affective disturbances such as the PHQ-9, POMS or CESD. • Anxiety: GAD-7 from the PHQ/PRIME-MD • Fatigue: Fatigue Severity Scale, MFI • Sleepiness: Epworth Sleepiness Scale • Somatic complaints: PHQ scale • Overall Functioning and quality of life: Sheehan Disability Scale, SF-36, RAND-12 • PROMIS scales

Process Measure #4: Assessment of side effects of treatments

Measure Description	
Description	Proportion of patients diagnosed with insomnia who received an assessment of treatment-related side effects at each visit in which insomnia is addressed.
Measure Components	
Denominator Statement	All patients diagnosed with insomnia who receive insomnia management such as initiation or renewal of insomnia treatments during their visit with the clinician.
Exceptions	<p>Medical Reasons: None.</p> <p>Patient Reasons: Patients who decline treatment; patients who do not return and do not complete assessment at a follow-up visit after the insomnia treatment is initiated; patients who are unable to engage in treatment; and patients < 7 years of age should be excluded.</p> <p>System Reasons: None.</p>
Numerator Statement	<p>Number of patients diagnosed with insomnia who received an appropriately documented assessment of treatment-related side effects at each visit when insomnia is addressed.</p> <p>When psychological/behavioral treatments are used, patients should be evaluated for potential side effects including increased daytime sleepiness.</p> <p>When pharmacological treatments are used, patients should be evaluated for potential side effects including one or more of the following:</p> <ol style="list-style-type: none"> 1) Sedation during waking hours, particularly upon awakening; 2) Headache; 3) Nausea and other GI disturbances; 4) Nightmares; 5) Complex sleep-related behaviors (e.g., sleep walking, sleep eating, sexual activity during sleep); 6) Cognitive effects (e.g., memory loss, confusion, disorientation); 7) Psychomotor effects (e.g., dizziness, balance impairment, falls); 8) Motor vehicle and other accidents; 9) Depression; 10) Tolerance, dependence, rebound, and withdrawal.

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Process Measure #4: Assessment of side effects of treatments (continued)

Technical Specifications: Administrative/Claims Data	
Administrative claims data collection requires users to identify the eligible population (denominator) and numerator using codes recorded on claims or billing forms (electronic or paper). Users report a rate based on all patients in a given practice for whom data are available and who meet the eligible population/denominator criteria.	
Denominator (Eligible Population)	<p>One of the following codes indicating insomnia: 291.82 Alcohol induced sleep disorders (includes alcohol induced insomnia) 292.85 Drug induced sleep disorders (includes drug induced insomnia) 307.41 Transient disorder of initiating or maintaining sleep 307.42 Persistent disorder of initiating or maintaining sleep 307.49 Other (includes "subjective insomnia complaints") 327.00 Organic insomnia, unspecified 327.01 Insomnia due to medical condition classified elsewhere 327.02 Insomnia due to mental disorder 327.09 Other organic insomnia 780.51 Insomnia with sleep apnea, unspecified 780.52 Insomnia, unspecified</p> <p>Accompanied by One of the following patient encounter codes: 90791 Psychiatric diagnostic evaluation 90792 Psychiatric diagnostic evaluation with medical services 90832 Psychotherapy, 30 min 90834 Psychotherapy, 45 min 90837 Psychotherapy, 60 min 99201, 99202, 99203, 99204, 99205 (office/other outpatient services – new patient) 99212, 99213, 99214, 99215 (office/other outpatient services – established patient) 90833 Psychotherapy, 30 minutes, when performed with an evaluation and management service 90836 Psychotherapy, 45 minutes, when performed with an evaluation and management service 90838 Psychotherapy, 60 minutes, when performed with an evaluation and management service 90863 Pharmacologic management, when performed with psychotherapy services 96150 Health and behavior assessment 96152 Health and behavior intervention</p> <p>Accompanied by Documentation in the patient record that insomnia management was discussed during the encounter. Management may include initiation, continuation, or renewal of insomnia treatments during the visit with the clinician.</p>
Exceptions	<p>At least one of the following is documented in the patient chart:</p> <ul style="list-style-type: none"> • Patient declines treatment. • Patient does not return and does not complete assessment at a follow-up visit after the insomnia treatment is initiated. • Patient is unable to engage in treatment. • Patient is < 7 years of age.
Numerator	<p>Chart review indicates:</p> <ul style="list-style-type: none"> • Patient was assessed for side effects related to insomnia treatment(s).