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SPECIAL ARTICLES

Quality measures for care of patients with restless legs syndrome: 2025 update after measure maintenance

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Restless legs syndrome, also called Willis–Ekbom disease, is a neurological disorder marked by a strong, uncontrollable urge to move the legs, often paired with unpleasant or uncomfortable sensations. To address gaps and variations in care in this patient population, the American Academy of Sleep Medicine Quality Measures Task Force performed quality measure maintenance on the quality measures for the care of adult patients with restless legs syndrome (originally developed in 2015). The Quality Measures Task Force conducted a comprehensive review of current medical literature, including updated clinical practice guidelines, systematic literature reviews, existing quality measures for restless legs syndrome, and performance data to identify ongoing gaps and variations in care since the implementation of the original quality measure set and to inform potential revisions.

Keywords: restless legs syndrome, RLS, quality measures

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INTRODUCTION

The quality measures for the care of adult patients with restless legs syndrome were originally published in 2015, by the American Academy of Sleep Medicine (AASM), as part of an initiative to develop measures to address various sleep disorders.[1]

Restless legs syndrome (RLS), also called Willis–Ekbom disease, is a neurological disorder marked by a strong, uncontrollable urge to move the legs, often paired with unpleasant or uncomfortable sensations. RLS not only affects a patient's sleep quality but also can cause anxiety, depression, chronic pain, cognitive difficulties, and reduced quality of life.[2]

The global RLS prevalence in 2019 was estimated to be 7.12% among adults 20–79 years of age.[3] RLS affects approximately 5–10% of Caucasians, particularly in Europe and North America, but is less common in Asian populations. Prevalence is about twice as high in women and increases with age, peaking around 60–70 years.[4] Overall, prevalence during pregnancy is about 21%, and RLS prevalence notably declines to about 4% postpartum.[5] RLS affects roughly 2% of children, with higher prevalence (2–4%) in school-aged children and adolescents.[4]

The RLS quality measures are designed to comprehensively evaluate the processes and outcomes associated with providing high-quality patient care. Processes pertain to the specific actions and protocols followed by health care providers in diagnosing, treating, and managing the condition. In contrast, outcomes refer to the tangible results experienced by the patient because of the medical care provided, such as improvements in symptoms, quality of life, or functional status.

This RLS quality measure set aims to improve the accuracy of RLS diagnosis, decrease RLS symptom severity, and minimize treatment complications. These measures also aim to promote continuous improvement in the quality of care delivered to patients with RLS.

The AASM Quality Measures Task Force (hereafter, Task Force) updated the RLS measure set to ensure that the measures are aligned with current evidence, as defined by clinical practice guideline recommendations, systematic literature reviews, and other studies published in medical literature.

METHODS

Literature review

An updated comprehensive literature search was conducted to identify current publications that addressed RLS in terms of the quality measures within this quality measure set. The literature review included clinical practice guidelines, systematic literature reviews, and individual studies (ie, randomized controlled trials). Searches were limited to articles published between 2018 and 2024, specific to humans, in the English language, and meeting the age criteria within the PubMed database. Publication types such as news articles, letters, editorials, and case reports were excluded. A total of 179 abstracts and 54 full journal publications were retrieved for review.

Performance data

In addition to a review of the medical literature, the Task Force searched for performance data, which may demonstrate performance gaps and/or variations in care. The quality measures have not yet been implemented in any clinical data registries and the quality measures are not included in the MIPS program.

Existing quality measures

As a part of the measure maintenance process, the Task Force also reviewed existing quality measures and determined that there were no existing RLS measures that required measure harmonization. The Centers for Medicare & Medicaid Services define measure harmonization as standardizing quality measure specifications for related measures when they have the following[6]:

- The same measure focus (ie, numerator criteria)
- The same target population (ie, denominator criteria)
- Elements that apply to many measures (eg, age designation for children)

Unintended consequences

There were no known unintended consequences identified as a result of reporting these RLS quality measures.

Review and approval

The updated measures were initially revised and approved for public comment by the AASM Board of Directors. The measures were then posted on the AASM website for a 30-day public comment period and were simultaneously shared with several medical specialty societies for an additional peer review, to ensure that all relevant stakeholders had an opportunity to provide feedback. The Task Force reviewed all stakeholder feedback and made additional revisions, where deemed appropriate. The final revised measures were approved for publication and implementation by the AASM Executive Committee. A driver diagram of the final measures is shown in **Figure 1**.

REVISED QUALITY MEASURES

Overall revisions

The Task Force reviewed the RLS quality measure set and focused on maintaining consistency throughout. The initial 2015 RLS quality measure set included a denominator that captured patients 18 years of age or older with a diagnosis of RLS. The most recent American Academy of Sleep Medicine clinical practice guideline for the treatment of RLS and periodic limb movement disorder discusses RLS in adults and children.[7] Therefore, the Task Force determined it essential to revise the RLS measures to apply to all patients diagnosed with RLS, irrespective of age, because there is no evidence supporting the inclusion of a minimum age requirement. The Task Force removed the "adult" requirement from the denominator population within the measure set and also removed it from the publication title.

For consistency with the updated "Treatment of restless legs syndrome and periodic limb movement disorder: an American Academy of Sleep Medicine clinical practice guideline,"[7] the following revisions were made: the definition of evidence-based treatment plan was clarified to state "for the purposes of this measure, an evidence-based treatment plan includes but is not limited to gabapentin enacarbil, gabapentin, pregabalin, IV ferric carboxymaltose, IV low molecular weight iron dextran, IV ferumoxytol, ferrous sulfate, dipyridamole, extended-release oxycodone, or bilateral high-frequency peroneal nerve stimulation. The recommendation for children is to enhance iron stores through the use of ferrous sulfate."

Additionally, the following notation was added to measures that highlight validated instruments as one way to determine a decrease in symptom severity: "the patient's medical record documentation should include an interpretation of any validated scoring instrument." The Task Force considered this an important addition to ensure alignment with other AASM sleep-specific quality measures, which reference validated instruments. Finally, in measures where clinically significant RLS is referenced, the following definition was created: "For the purposes of this measure, clinically significant RLS is defined as occurring more than twice per week and associated with at least moderate distress."

Process measure #1 – use of accepted RLS diagnostic criteria

2015 Measure description

Proportion of RLS patients that were diagnosed according to accepted diagnostic criteria at the time of their initial evaluation.

2025 Revised measure description

Proportion of patients with RLS who were diagnosed according to accepted diagnostic criteria at the time of their initial evaluation.

Exceptions

There are no exceptions for this measure.

Supporting evidence and rationale for revisions

RLS is one of the most prevalent sleep disorders and has a substantial impact on various aspects of daily functioning. Despite its prevalence, it remains underdiagnosed.[4]

The *International Classification of Sleep Disorders*, third edition, text revision (ICSD-3-TR) was used as the RLS diagnostic reference (see **Table 1**).[8] The Task Force slightly revised the numerator language to align with the ICSD-3-TR updates. No other substantive changes were made to the measure language.

Outcome measure – decrease RLS symptom severity

2015 Measure description

Proportion of RLS patients that showed a decrease in symptom severity within 12 months of being prescribed a new medication for RLS.

2025 Revised measure description

Proportion of patients diagnosed with RLS who showed a decrease in symptom severity within 12 months of receiving a new or changed RLS evidence-based treatment plan.

Figure 1—Revised restless legs syndrome (RLS) quality measures driver diagram.

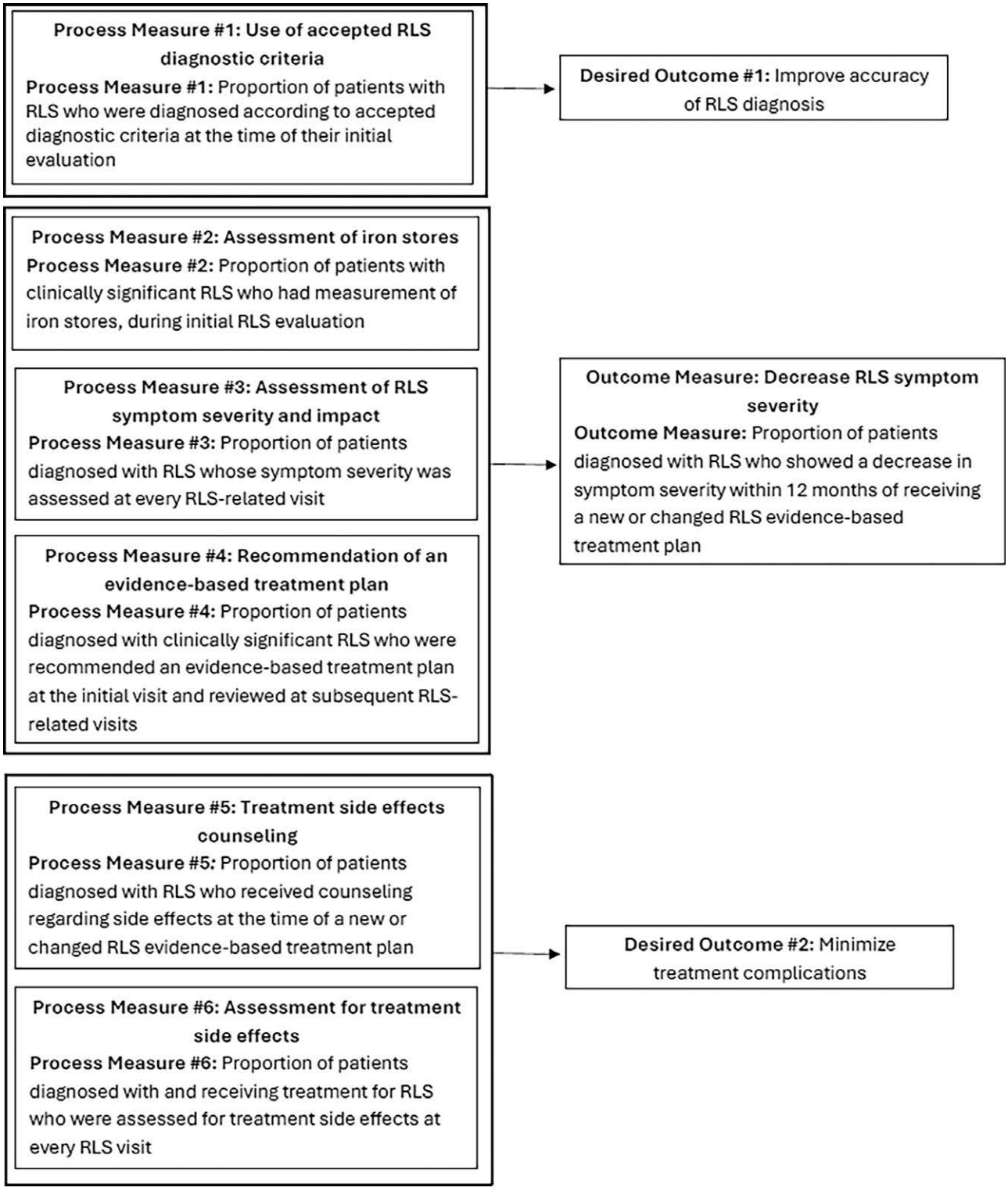

Table 1—ICSD-3-TR diagnostic criteria for restless legs syndrome.

Restless legs syndrome (RLS)
ICD-10-CM Code: G25.81
Alternate names Willis–Ekbom disease
Diagnostic criteria Criteria A–C must be met A. Reported urge to move the legs, usually accompanied by or thought to be caused by uncomfortable and unpleasant sensations in the legs. These symptoms must: 1. Begin or worsen during periods of rest or inactivity such as lying down or sitting; 2. Be partially or totally relieved by movement, such as walking or stretching, at least as long as the activity continues; and 3. Occur exclusively or predominantly in the evening or night rather than during the day. B. The above features are not solely accounted for by a condition that mimics RLS (eg, leg cramps, positional discomfort, myalgia, venous stasis, leg edema, arthritis, habitual foot tapping). C. The symptoms of RLS cause concern, distress, sleep disturbance, or impairment in mental, physical, social, occupational, educational, behavioral, or other important areas of functioning.

Copyright American Academy of Sleep Medicine, used with permission. ICSD-3-TR = *International Classification of Sleep Disorders*, third edition, text revision.

Exceptions

- **Medical reasons:** Patients whose symptoms are refractory to, or who did not tolerate, at least 2 medications for RLS; pregnant women
- **Patient reasons:** Patients who are not adherent with treatment; patients who do not return for follow-up
- **System reasons:** None

Supporting evidence and rationale for revisions

This measure was originally developed to evaluate the reduction in symptom severity within a 12-month period following the initiation of a newly prescribed medication. During the measure maintenance discussions, the Task Force emphasized the distinction between merely prescribing a medication and ensuring that the patient is placed on a comprehensive, evidence-based treatment plan. This distinction reflects the recommendations outlined in the updated clinical practice guidelines for RLS, emphasizing personalized care based on the latest clinical guidelines. Furthermore, given that treatment regimens may evolve in response to changes to the patients' condition or other medications, it is essential that clinicians consistently reassess symptom severity each time a new treatment plan is introduced, or an existing one is modified. This approach supports continuous quality improvement in patient management and ongoing symptom monitoring.

Additionally, to more clearly reflect the measures' intent, the Task Force removed the previously included medical exception for patients whose symptoms are reported as mild or who had an International Restless Legs Scale score < 15. After an extensive discussion, the Task Force concluded that the presence of mild symptoms should not exempt patients from ongoing assessment if an evidence-based treatment plan is initiated or changed. Regardless of initial symptom severity, it remains essential to evaluate whether the patient is experiencing ongoing control and/or reduction in symptoms over time. This ensures that all individuals, including those with less severe presentations, receive appropriate follow-up and that the effectiveness of the treatment plan can be accurately monitored and adjusted, as needed.

The Task Force also discussed the inappropriate use of polysomnography to assess the severity of RLS. Although polysomnography can be valuable in diagnosing other sleep disorders, it is not designed to accurately measure RLS symptoms' frequency, intensity, or impact. No modifications were made to the measure specifications in response to this highlighted issue.

Process measure #2 – assessment of iron stores

2015 Measure description

Proportion of RLS patients that had measurements of iron stores, including at least serum ferritin, performed during initial RLS evaluation.

2025 Revised measure description

Proportion of patients with clinically significant RLS who had measurement of iron stores, during initial RLS evaluation.

Exceptions

- **Medical reasons:** Patient has documented measurement of iron stores at least once within the past year; patient has documented disorder of iron overload (eg, hemochromatosis)
- **Patient reasons:** Patient and/or caregiver declines testing/blood draw
- **System reasons:** Payer does not cover iron stores testing

Supporting evidence and rationale for revisions

The measure intends to promote the assessment of iron status in patients presenting with clinically significant RLS during their initial evaluation. This process measure supports evidence-based practice by ensuring patients receive a thorough diagnostic workup and providing clinicians with essential information to guide treatment decisions. Peripheral iron storage should be

evaluated at the time of the initial diagnosis of RLS and later during long-term treatment whenever there is a change in symptom control, particularly if the frequency or severity of symptoms is characterized by an increase or an overall clinical deterioration, or if the response to previously effective therapy is diminished.[9] To clarify this measure, the Task Force created the following definition for iron store evaluation: "For the purposes of this measure, iron store evaluation includes but is not limited to serum ferritin and iron with total iron binding capacity (transferrin saturation percentage). Testing should ideally be administered in the morning, avoiding all iron-containing supplements and foods at least 24 hours prior to blood draw. Ferritin is an acute phase reactant." Moreover, although this measure is focused on the initial RLS evaluation, the frequency of checking iron testing must be determined using clinical judgment in the context of clinical changes. To address this matter, the Task Force added the following notation: "Following initial iron testing clinicians should regularly assess iron studies and whenever clinically indicated. Examples include but are not limited to blood loss, worsening of RLS symptoms, pregnancy, iron supplementation, and conditions requiring iron monitoring."

The Task Force revised the patient reason exception to now state that if a caregiver declines testing or blood draw on behalf of the patient, such as in cases involving minors, individuals with cognitive impairment, or those unable to make medical decisions independently, the patient will be considered an exception. The Task Force recognizes that caregiver involvement is often essential in a patient's decision-making process, and this addition ensures that the measure remains patient-centered while acknowledging real-world clinical scenarios where patients rely on others to make health care decisions on their behalf.

Finally, the Task Force concluded that process measure #2 (assessment of iron stores) is more appropriately aligned with the outcome measure (decrease RLS symptom severity) rather than the originally desired outcome (improve accuracy of RLS diagnosis). This decision was based on the understanding that although the assessment does not necessarily enhance diagnostic accuracy it is closely related to symptom management. Accordingly, the driver diagram was revised to reflect this adjustment.

Process measure #3 – assessment of RLS symptom severity and impact

2015 Measure description

Proportion of RLS patients whose severity was assessed at every RLS-related visit. The assessment of severity should include a global measure of severity, as well as assessment of at least 1 RLS-associated domain including sleep quality, daytime sleepiness/tiredness, daytime function, or mood. This may be documented with a variety of validated scales or through free text within the medical record (eg, "the patient reports that RLS symptoms are less severe and sleep quality has improved").

2025 Revised measure description

Proportion of patients diagnosed with RLS whose symptom severity was assessed at every RLS-related visit.

Exceptions

There are no exceptions for this measure.

Supporting evidence and rationale for revisions

Assessing RLS symptom severity and impact during the initial evaluation is essential for identifying patients whose symptoms may or may not require treatment and establishing a baseline to evaluate treatment response over time. To define assessment of symptom severity, the Task Force created the following definition: For the purposes of this measure, the assessment of symptom severity should include completion of an International Restless Legs Scale severity scale (or other validated instrument) or an evaluation of RLS symptom severity and the impact on at least ONE of the following domains:

1. Sleep quantity and/or quality
2. Daytime sleepiness or tiredness
3. Daytime function
4. Mood

In response to a comment received during the public comment period regarding the measure intent, this measure underwent a minor but purposeful revision to emphasize the importance of assessing the symptom severity and impact during every clinical visit for patients with RLS. Consistently evaluating the severity and impact of RLS symptoms at each encounter is critical to establishing a reliable baseline, which serves as a reference point for tracking changes over time. Such ongoing assessment enables clinicians to make informed decisions regarding the effectiveness of treatment interventions, allowing them to monitor progress accurately and adjust the management plan to optimize patient outcomes.

No other substantive changes were made to the measure language.

Process measure #4 – recommendation of an evidence-based treatment plan

2015 Measure description

Proportion of RLS patients that were prescribed treatment consistent with available evidence-based guidelines at the time of diagnosis.

2025 Revised measure description

Proportion of patients diagnosed with clinically significant RLS who were recommended an evidence-based treatment plan at the initial visit and reviewed at subsequent RLS-related visit.

Exceptions

There are no exceptions for this measure.

Supporting evidence and rationale for revisions

The Task Force revised the numerator language in this measure to highlight that patients with clinically significant RLS should be recommended an evidence-based treatment plan during their initial visit and subsequent visits. To further clarify that this measure applies to all RLS-related visits, the Task Force removed the following notation: In the case where a physician is confirming a pre-existing diagnosis of RLS (eg, a second

opinion or transfer of care to a new practice), this measure should be collected from the visit when RLS is confirmed.

All exceptions have been removed, because evidence-based treatment plans should be recommended for all patients diagnosed with clinically significant RLS. This measure ensures that an evidence-based treatment plan is recommended at every visit. Failure of the patient to follow through with the identified treatment plan is not a reflection of the intended treatment recommendation.

RLS is a manageable condition that often shows a favorable response to pharmacologic treatment. The Task Force created the following notation to address a critical step in management: The first step in the management of RLS should be assessing for pregnancy and addressing potentially exacerbating factors. Examples include but are not limited to alcohol, caffeine, certain medications, and untreated sleep disorders.

Process measure #5 – treatment side effects counseling

2015 Measure description

Proportion of patients diagnosed with RLS who receive counseling regarding side effects at the time of initiation of a new RLS medication.

2025 Revised measure description

Proportion of patients diagnosed with RLS who received counseling regarding side effects at the time of a new or changed RLS evidence-based treatment plan.

Exceptions

There are no exceptions for this measure.

Supporting evidence and rationale for revisions

Side effects such as drowsiness, dizziness, augmentation, nausea, somnolence, fatigue, headache, and nasopharyngitis are frequently experienced by patients receiving pharmacological treatment for RLS,[10–12] and counseling patients about potential treatment-specific side adverse effects is needed. To align with the measure's true intent, the Task Force updated the measure name from "counseling about medication side effects" to "treatment side effects counseling." The revisions to this process measure aim to minimize treatment complications.

Because treatment plans may change, clinicians should counsel patients whenever a treatment plan is newly initiated or changed. Patients who have been prescribed an evidence-based treatment plan should receive comprehensive counseling regarding prescribed medications, including potential side effects, expected outcomes, and adherence strategies to ensure optimal efficacy and safety throughout the course of treatment.[10] The Task Force also included a note in this measure to indicate that counseling is dependent on the recommended evidence-based treatment plan.

No other substantive changes were made to the measure language.

Process measure #6 – assessment for treatment side effects

2015 Measure description – assessment for impulse control disorders

Proportion of RLS patients treated with a dopamine agonist or levodopa that were assessed for impulse control disorders at every RLS visit. Assessment of impulse control disorders may be performed either by history or a validated scale.

2015 Measure description – assessment for augmentation

Proportion of RLS patients treated with a dopamine agonist or levodopa that were assessed for augmentation at every RLS visit.

2025 Revised measure description

Proportion of patients diagnosed with and receiving treatment for RLS who were assessed for treatment side effects at every RLS visit.

Exceptions

There are no exceptions for this measure.

Supporting evidence and rationale for revisions

The Task Force conducted a comprehensive review of process measures 6 and 7 to ensure alignment with the updated RLS clinical practice guidelines. Following this review, the Task Force concluded that it would be appropriate to consolidate the 2 measures.

Originally, the separate measures evaluated patients for impulse control disorders and augmentation at each clinical encounter following treatment with either dopamine agonist or levodopa. However, because both conditions are potential side effects to these therapies, the Task Force determined that monitoring them under a unified measure would enhance clarity and clinical utility.

The 2 measures have been combined into a single process measure, and the references to dopamine agonists and levodopa have been removed from the measure description and numerator and replaced with the more general term "treatment" to emphasize that clinicians should assess for side effects regardless of the treatment provided. This revised approach is intended to align closely with current clinical standards and improve consistency in patient care monitoring.

The Task Force deliberated whether exceptions were necessary for this measure, and after a lengthy discussion about the measure's intent it was decided that none were needed. Because the measure requires that patients be assessed for side effects at every RLS visit, if a patient refuses and/or declines treatment or fails to attend an RLS appointment or the payer does not cover the treatment the patient would not be included in the measure's population.

Finally, the following note was added to clarify the numerator requirements further: Assessment for treatment side effects is dependent on the received evidence-based treatment plan.

- Although dopaminergic agents are no longer recommended as first-line, common or potentially severe side effects include but are not limited to augmentation and impulse control disorders.

IMPLEMENTATION STRATEGIES

This revised set of quality measures can be incorporated into a clinical data registry. Reporting these measures through a registry would provide valuable data that can be used for validation of quality measures, the assessment of scientific acceptability, the establishment of benchmarking standards, the promotion of quality improvement initiatives, and the advancement of clinical research.

FUTURE DIRECTIONS

The Task Force strongly supports further future development of the following outcome measures: (1) improving the accuracy of RLS diagnosis and (2) minimizing treatment-related complications. Standardization and tracking of these quality measures are critical to advancing RLS quality of care and aligning clinical practice with patient-centered outcomes.

ABBREVIATIONS

AASM, American Academy of Sleep Medicine
RLS, restless legs syndrome

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SUBMISSION & CORRESPONDENCE INFORMATION

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DISCLOSURE STATEMENT

Dr. Revana is currently the principal investigator of a phase 2 clinical trial at Harmony Biosciences, LCC, and a consultant at Trend, LLC. Dr. Donald holds stock in the following entities: Becton, Dickinson and Company, Medtronic, Pfizer, and Zimmer Biomet Holdings, Inc. Dr. Junna is Secretary of the Minnesota Sleep Society Board of Directors. Ms. Crawford and Ms. Gray are employed by the AASM. The other authors report no conflicts of interest.