

Pulmonology Addendum: Polysomnography

1. MCG Criteria Used

Clinical Criteria: MCG Care Guidelines, 30th Edition

- Polysomnography (PSG), Sleep Center (MCG ORG: A-0145 AC, 30th Edition)

Applicable CPT / HCPCS Codes:

CPT / HCPCS Code	Description
95782, 95783	Polysomnography; younger than 6 years, with sleep staging and additional parameters, attended; or with initiation of positive airway pressure therapy
95807	Sleep study, simultaneous recording of ventilation, respiratory effort, ECG or heart rate, and oxygen saturation, attended
95808	Polysomnography; any age, sleep staging with 1 to 3 additional parameters of sleep, attended
95810	Polysomnography; age 6 or older, sleep staging with 4 or more additional parameters of sleep, attended
95811	Polysomnography; age 6 or older, sleep staging with initiation of continuous positive airway pressure therapy or bilevel ventilation, attended

2. Statement of Rationale

Akido Labs uses the criteria in MCG Care Guidelines (30th Edition) to supplement the general Medicare criteria regarding sleep-center polysomnography for the diagnosis of sleep-disordered breathing and other sleep disorders, where Medicare coverage criteria are not fully established or require additional clinical specificity. MCG criteria are used to ensure consistency in reviewing the conditions to be met for coverage of attended polysomnography and to determine when such testing is medically necessary.

Sleep-disordered breathing, including obstructive sleep apnea and obesity hypoventilation syndrome, is highly prevalent in the Medicare Advantage population and is associated with cardiovascular disease, stroke, and excess mortality when untreated. Attended sleep-center polysomnography is the diagnostic standard for complex presentations, while home sleep apnea testing is appropriate for uncomplicated adult obstructive sleep apnea. Absent consistent, evidence-based criteria, there is material risk of both inappropriate denial of medically necessary attended studies and inappropriate approval of in-laboratory testing where a home study would suffice.

Potential Clinical Harms:

Sleep-center polysomnography: Inappropriate denial of attended polysomnography for suspected obstructive sleep apnea with complicating features, obesity hypoventilation syndrome, central sleep apnea or sleep-related hypoventilation, suspected narcolepsy, or other complex sleep disorders could delay diagnosis and treatment of conditions that contribute to hypertension, arrhythmia, heart failure, stroke, and motor-vehicle and occupational injury. For central sleep

apnea, hypoventilation syndromes, and pediatric obstructive sleep apnea in particular, attended in-laboratory testing is required because home testing is insufficient, so denial leaves these patients without an adequate diagnostic pathway.

Clinical Benefits:

Sleep-center polysomnography: MCG criteria provide validated, indication-specific thresholds drawn from numerous specialty society guidelines and published evidence, demonstrating at least moderate certainty of at least moderate net benefit for obesity hypoventilation syndrome and supporting attended polysomnography for the complex presentations where home testing is inadequate. By reserving attended polysomnography for suspected obstructive sleep apnea with complicating features, obesity hypoventilation syndrome, central sleep apnea and hypoventilation, narcolepsy, parasomnias, periodic limb movement disorder, and pediatric obstructive sleep apnea, the criteria directly counter the harm of delayed diagnosis of cardiovascularly significant and otherwise serious sleep disorders identified above, while recognizing home sleep study as the appropriate alternative for uncomplicated adult obstructive sleep apnea.

Reduction of unwarranted variation and overutilization: MCG criteria explicitly direct uncomplicated adult obstructive sleep apnea to home sleep apnea testing, reserving the more resource-intensive attended study for indications that require it, reducing unnecessary in-laboratory testing. The clinical benefits of using MCG Care Guidelines are highly likely to outweigh any clinical harms, including delayed or decreased access to services. The criteria are unlikely to lead to inappropriate denials because they incorporate indications drawn directly from current sleep medicine specialty society guidelines and high-quality evidence. Use of these criteria ensures patients receive the most clinically appropriate testing, and decreases inappropriate denials by applying a consistent, objective, evidence-based set of review criteria across the Medicare Advantage population.

3. Explanation of Supplementation

Basis for Use:

Original Medicare clinical criteria are not fully established and require supplementation to ensure consistent medical necessity determinations for sleep-center polysomnography. While Medicare statutes establish the general 'reasonable and necessary' standard and CMS maintains coverage policy for certain sleep testing applications, the available determinations do not specify the full set of clinical thresholds (e.g., the complicating features that require attended rather than home testing, and the specific presentations of central sleep apnea, hypoventilation, narcolepsy, and pediatric obstructive sleep apnea) required to distinguish indicated from nonindicated attended polysomnography. Where a national or local coverage determination applies, MCG criteria are used to supplement and do not replace, modify, or supersede it.

Applicable Medicare References:

- Social Security Act Section 1862(a)(1): 'Reasonable and necessary' standard
- Medicare Benefit Policy Manual, Chapter 6: Hospital Services Covered Under Part B (CMS IOM Publication 100-02)
- Medicare Benefit Policy Manual, Chapter 14: Medical Devices (CMS IOM Publication 100-02)
- Medicare Benefit Policy Manual, Chapter 15: Covered Medical and Other Health Services (CMS IOM Publication 100-02)
- Medicare Benefit Policy Manual, Chapter 16: General Exclusions from Coverage (CMS IOM Publication 100-02)

- Medicare Program Integrity Manual, Chapter 6, Section 6.5: Medical Review of Inpatient Hospital Claims for Part A Payment (CMS IOM Publication 100-08)
- Code of Federal Regulations: 42 CFR 419.22; 42 CFR 422.101
- National Coverage Determinations: CMS maintains coverage policy applicable to sleep testing for obstructive sleep apnea; applicable NCDs and LCDs are followed first, and MCG criteria are used to supplement and do not replace them. For indications not fully addressed by an NCD or LCD, Original Medicare criteria are not fully established, requiring supplementation.
- Medicare Coverage Database:
<https://www.cms.gov/medicare-coverage-database/search.aspx>

Within the above statutes and regulations, coverage criteria for attended sleep-center polysomnography are not fully established, and the use of MCG Care Guidelines is necessary to provide additional clinical specificity. Specifically, MCG criteria assist in determining:

- Medical necessity and appropriateness of attended sleep-center polysomnography versus home sleep apnea testing for suspected obstructive sleep apnea;
- Medical necessity and appropriateness of attended polysomnography for obesity hypoventilation syndrome, central sleep apnea and hypoventilation, narcolepsy, parasomnias, periodic limb movement disorder, and pediatric obstructive sleep apnea;
- Appropriate diagnostic setting and expected course for sleep testing services.

The use of MCG Care Guidelines ensures consistency in reviewing the conditions to be met for coverage of polysomnography. Use of these criteria to supplement the coverage criteria noted above provides clinical benefits by helping ensure diagnostic testing is not incorrectly denied when medically appropriate for a particular patient, nor incorrectly approved when not reasonable and necessary. The clinical benefits of using these criteria are highly likely to outweigh any clinical harms, including from inappropriate denials, because the criteria are unlikely to lead to inappropriate denials. The added criteria will provide numerous clinical benefits in helping ensure patients receive the appropriate level of care. In addition, use of the criteria may decrease inappropriate denials by creating a consistent set of evidence-based review criteria.

4. Summary of Clinical Evidence

Background

Polysomnography (PSG), Sleep Center (MCG ORG: A-0145 AC)

Sleep-center polysomnography is an attended, in-laboratory diagnostic study indicated for suspected obstructive sleep apnea with complicating features, obesity hypoventilation syndrome, central sleep apnea or sleep-related hypoventilation, pediatric obstructive sleep apnea, insomnia with qualifying features, suspected narcolepsy, parasomnias, periodic limb movement disorder, and restless leg syndrome with qualifying features. For uncomplicated adult obstructive sleep apnea, home sleep study is the appropriate alternative. This MCG care guideline may overlap CMS guidance located in statutes and regulations; for Medicare Advantage beneficiaries, applicable NCDs, LCDs, and other regulations are followed first, and MCG criteria supplement but do not replace them.

Evidence Summary

Polysomnography (PSG), Sleep Center (MCG ORG: A-0145 AC)

The evidence for the clinical indications in this guideline includes 104 published peer-reviewed articles, 15 specialty society or other evidence-based guidelines, and 19 book sections. Key evidence includes:

- For adults with obesity hypoventilation syndrome, evidence demonstrates at least moderate certainty of at least moderate net benefit. A review article identifies overnight oximetry and polysomnography as important diagnostic modalities for obesity hypoventilation syndrome.
- For suspected obstructive sleep apnea, specialty society guidelines support attended polysomnography for complex presentations, while directing uncomplicated adult obstructive sleep apnea to home sleep apnea testing as the appropriate alternative.
- For central sleep apnea, sleep-related hypoventilation, narcolepsy, parasomnias, periodic limb movement disorder, and pediatric obstructive sleep apnea, specialty society guidance supports attended in-laboratory polysomnography because home testing is insufficient for these presentations.

Rationale (from MCG)

Use of this MCG care guideline helps the clinician identify patient-specific complex clinical factors that determine the medical necessity and appropriate setting for sleep testing. The evidence-based clinical criteria assist the clinician in deciding when attended sleep-center polysomnography is appropriate versus a home sleep study, based on the specific suspected sleep disorder and its complicating features. Use of these evidence-based clinical criteria ensures patients receive the most appropriate care for their specific condition, reduces unnecessary risks, promotes recovery, and provides a standard that can reduce disparities in care. Appropriate use of the evidence-based clinical criteria ensures Medicare patients receive full access to Medicare benefits without risk of delay or decreased access. These guidelines supplement but do not replace, modify, or supersede existing Medicare regulations or applicable National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs).

Related CMS Coverage Guidance (as cited in MCG 30th Edition):

- Code of Federal Regulations (CFR): 42 CFR 419.22; 42 CFR 422.101
- CMS IOM Publication 100-02, Medicare Benefit Policy Manual: Chapter 6 (Hospital Services Under Part B); Chapter 14 (Medical Devices); Chapter 15 (Covered Medical and Other Health Services); Chapter 16 (General Exclusions from Coverage)
- CMS IOM Publication 100-08, Medicare Program Integrity Manual, Chapter 6, Section 6.5
- National Coverage Determinations: Applicable CMS coverage policy for sleep testing in obstructive sleep apnea; followed first, with MCG criteria used to supplement
- Medicare Coverage Determinations: Medicare Coverage Database:
<https://www.cms.gov/medicare-coverage-database/search.aspx>

References with Citation Summary -- Polysomnography (PSG), Sleep Center (MCG ORG: A-0145 AC, 30th Edition)

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