Regulatory and Economic Aspects of Sleep Apnea

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## Conflict of Interest Disclosures

<table>
<thead>
<tr>
<th>Type of Potential Conflict</th>
<th>Details of Potential Conflict</th>
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<tbody>
<tr>
<td>Consultant</td>
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<tr>
<td>Speakers’ Bureaus</td>
<td>Jazz (Xyrem)</td>
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<tr>
<td>Other</td>
<td>Affiliated with SleepMed Inc</td>
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Interest Disclosures

Marc Raphaelson, MD

- American Academy of Neurology: RUC Representative
- AAN: Medical Econ & Management Committee Member
- Founding Member: Maryland Sleep Consortium
- Founding Member: Virginia Academy of Sleep Medicine
- Former Member: AASM Health Policy Committee
Sleep Apnea: Medical Economics & Reimbursement

- Sleep Medicine: Growth
- OSA Diagnosis:
  - PSG, Home Sleep Testing
- OSA Therapy:
  - PAP
  - Surgery
  - Oral appliance
- Concerns for 2010 forward
## Sleep Apnea Need vs Therapy Rates: 300 Million People

<table>
<thead>
<tr>
<th>Description</th>
<th>Millions</th>
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<tbody>
<tr>
<td>Est snoring pts (15%)</td>
<td>45.000</td>
</tr>
<tr>
<td>Est OSA pt (3%)</td>
<td>9.000</td>
</tr>
<tr>
<td>PSGs 2007 est Frost&amp;Su llivan</td>
<td>2.500</td>
</tr>
<tr>
<td>CPAP: $1B in 2007</td>
<td>1.000</td>
</tr>
<tr>
<td>Dental apps est sales</td>
<td>?</td>
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</table>
What’s the difference: OSA vs Snoring?

- Definition: AHI vs RDI
- Symptoms?
- Testing technology: nasal pressure vs thermistor
- Testing date: AHI varies from night to night
- Ten pounds?
- Five years?
Medicare Claims Data

- Large national database
- Available to public
- Policies supported by extensive research
- Most patients over 65yo
  - Data from all-payers databases are similar.
- Private insurers often link payment & policies to Medicare.
Insurer Coverage Policies

- CMS national policy (Medicare National Coverage Determinations Manual)
- Local Carrier Decisions (LCDs) by region
  - New division of Medicare Administrative Contractors and Regional DME MACs
- Recovery Audit Contractors are paid a percentage of fraud they find.
- Private Insurers: Check policy by product.
Medicare

- List of carriers by locality:

- Physician fee schedule look-up
  - Look up HCPC/CPT code by state or national
  - Web search: Carrier State physician payment look-up
Rapid growth Medicare PSGs: Indexed

Growth CMS Service 1998-2006

- PSG 2 codes
- UPPP
- EEG 2 codes
- Chest Xray 2views
Sleep Testing

- Home sleep tests, sleep studies or PSGs
- Attended or unattended
- Recording 6 hours or more
Sleep Testing - CPT Codes

- **95805** Multiple sleep latency testing (MSLT), recording, analysis and interpretation of physiological measurements of sleep during multiple nap opportunities

- **95806** Sleep study, simultaneous recording of ventilation, respiratory effort, ECG or heart rate, and oxygen saturation, unattended by a technologist

- **95807** Sleep study, simultaneous recording of ventilation, respiratory effort, ECG or heart rate, and oxygen saturation, attended by a technologist

- **95808** Polysomnography; sleep staging with 1-3 additional parameters of sleep, attended by a technologist

- **95810** Polysomnography; sleep staging with 4 or more additional parameters of sleep, attended by a technologist

- **95811** Polysomnography; sleep staging with 4 or more additional parameters of sleep, with initiation of continuous positive airway pressure therapy or bilevel ventilation, attended by a technologist
Sleep Testing – G Codes – HCPCS

- **G0398 Home sleep test/type II Porta**. Home sleep study test (HST) with type II portable monitor, unattended; minimum of 7 channels: EEG, EOG, EMG, ECG/heart rate, airflow, respiratory effort and oxygen saturation.

- **G0399 Home sleep test/type III Porta**. Home sleep test (HST) with type III portable monitor, unattended; minimum of 4 channels: 2 respiratory movement/airflow, 1 ECG/heart rate and 1 oxygen saturation.

- **G0400 Home sleep test/type IV Porta**. Home sleep test (HST) with type IV portable monitor, unattended; minimum of 3 channels.
Sleep Testing – G Codes – HCPCS

- Use G codes for HOME testing, 95806 for other unattended
- 2010 Payment: VA: about $100; MD about $200
- 2011: Expect two new codes similar to G codes
- CMS requirements are the same as for PSG:
  - Physician credentials
  - Technologist credential
  - Facility accreditation
- State licensing likely to be the same for techs providing unattended studies as for attended studies
Hospital Facility Fee Payment by Ambulatory Payment Classification (APC)

- Groups procedures/services by clinical and cost similarities; approx 7500 CPT codes grouped into about 450 APC codes.
- Covers hospital costs of non-physician labor, equipment and supplies (technical component).
- Physicians bill interpretation separately.
MD Supervision of PSG

“General supervision means the procedure is furnished under the physician’s overall direction and control, but the physician’s presence is not required during the performance…the training of the nonphysician who performs the diagnostic procedure and the maintenance of the necessary equipment and supplies are the continuing responsibility of the physician.”

Remember this when negotiating medical director or interpretive duties.
Sleep Testing: Attended

“Attended facility-based polysomnogram means a comprehensive diagnostic sleep test including at least electroencephalography, electro-oculography, electromyography, heart rate or electrocardiography, airflow, breathing effort, and arterial oxygen saturation furnished in a sleep laboratory facility in which a technologist supervises the recording during sleep time and has the ability to intervene if needed.” Medicare PFS Oct 2008

Increasing requirement for practice-based and IDTF labs to be AASM-accredited with registered technologists.
CMS and Screening Tests

“We are not providing coverage of preliminary screening tests for beneficiaries in the absence of any signs or symptoms of OSA. Coverage of purely screening tests (not diagnostic tests) are established pursuant to specific legislation (e.g. screening mammography, screening for glaucoma, etc.)”
CMS: Who can interpret HST and PSG?

**HST interp MD (From CMS regs):**
- ABSM diplomate
- ABMS diplomate in sleep medicine
- Active staff member of a sleep center/lab accredited by AASM or The Joint Commission

**PSG interp MD (From Trailblazer regs):**
- "A physician or doctoral level professional with satisfactory training in sleep medicine and significant experience in interpretation of standard polysomnograms must interpret these recordings.”
CMS: Place of Service, diagnostic test interpretation (dec09)

“A. Interpretation Performed In Physician’s Home

- The POS would be either office (POS 11) if it meets the definition of office or “other” (99).
- …the determinant of payment is the locality where the service is performed. CMS requires that the ZIP Code of the interpreting physician’s location be placed on the claim form.”
“B. Interpretation Performed in a Hotel Room

- If the hotel room is neither the office of the physician nor the temporary lodging of the patient then the appropriate POS is “other” (POS 99).

[Section C not here included]

“D. Interpretation Provided Outside of the United States

- Generally, Medicare will not pay for health care or supplies that are performed outside the United States…”
Sleep Treatment Dispensing

- CPAP and Oral Appliances are Durable Medical Equipment (DME).
- Dentists rarely have DME contracts with insurers.
- Physician obstacles to DME dispensing: Federal and State self-referral regulations.
- CMS may require separate entity to get DMERC number, not a medical practice.
- Other insurers may require CMS DMERC number for payment.
For MD to dispense DME to patients, services would include, but not be limited to:

- Personally fit the item for the beneficiary;
- Provide necessary info/instructions concerning use;
- Advise the beneficiary that he or she may either rent or purchase inexpensive or routinely purchased DME;
- Explain the purchase option for capped rental DME;
- Explain all warranties;
- (Usually) deliver the DME to the beneficiary at home; and
- Explain to the beneficiary at the time of delivery how to contact the physician in his or her capacity as a DME supplier by telephone.
CMS CPAP Approval 14mar2008

- “Coverage of CPAP is initially limited to a 12 week period for beneficiaries diagnosed with OSA as subsequently described.
- “CPAP is subsequently covered for those beneficiaries diagnosed with OSA whose OSA improved as a result of CPAP during this 12 week period.”
CMS CPAP Approval 14mar2008

- CPAP for adults is covered when diagnosed using a clinical evaluation and a positive:
  - PSG performed in a sleep laboratory; or
  - unattended home sleep monitoring device of Type II; Type III; or Type IV, measuring at least three channels [Watch-PAT100]; or other Type IV device in a defined clinical trial.
CMS CPAP Approval 14mar2008

- Positive test for OSA:
  - AHI or RDI greater than or equal to 15 events per hour, or
  - AHI or RDI 5-14 per hour with documented symptoms of excessive daytime sleepiness, impaired cognition, mood disorders or insomnia, or documented hypertension, ischemic heart disease, or history of stroke.

- The AHI is equal to the average number of episodes of apnea and hypopnea per hour. The RDI is equal to the average number of respiratory disturbances per hour.

- [“RDI” is NOT (Apneas+Hypopneas+RERAs)/hour]
CMS BiPAP

“A RAD (Respiratory Assist Device) without backup rate (E0470) [Bilevel PAP] is covered for those patients with OSA who meet criteria A-C above, in addition to criterion D:

- A single level (E0601) positive airway pressure device has been tried and proven ineffective, based on a therapeutic trial conducted in either a facility or in a home setting.”

- [Forced expiration test is adequate.]
Auto-PAP

- No separate code for auto-CPAP or auto-BiPAP.
- Auto devices can be set to fixed pressures and have efficacy as well as adherence monitor.
- Patients do not pay more for auto-PAP than PAP.
- Autos add ~$100 to DME provider cost.
- Should every patient be prescribed auto-PAP?
  - Limited published data
- Will we need separate codes for
  - HCPCS: Auto-CPAP and Auto-BiPAP
  - CPT: interpretation of AutoPAP data without office visit
Medicare and CPAP

- Practical approach to scoring/reporting:
  - Score apneas, hypopneas, and RERAs separately.
  - Report RDI and AHI.
- Document symptoms at baseline.
- Notify pts: after 12 weeks must document:
  - Symptomatic improvement
  - Adherence; how to get the info – MD, DME or self-check
- Document CPAP intolerance/ need for expiratory relief.
Trends in Sleep Apnea Surgery: HCUPnet

- Database: HCUPNET info
- Federal-State-Industry partnership sponsored by the Agency for Healthcare Research and Quality
- Search for admissions with principal dx OSA.
- About $18,162 per OSA discharge in 2005
Sleep Apnea Surgery

- New 2008 codes for base of tongue surgery.
- Oral-Maxillary surgery (Kent Moore, MD, DDS):
  - “telegnathic” = “jaw at a distance,” not
  - “orthognathic” = “straight jaw”
  - similar techniques, different purpose.
- Many surgeons are opting out of Medicare.
Oral Appliance HCPCS Codes = DME

- E0485: Oral device/appliance used to reduce upper airway collapsibility, adjustable or non-adjustable, prefabricated, includes fitting and adjustment.
- E0486: Oral device/appliance used to reduce upper airway collapsibility, adjustable or non-adjustable, custom fabricated, includes fitting and adjustment.
- 90% patient coverage in some markets.
Oral Appliance development requirement:

- Class II Special Controls Guidance Document: Intraoral Devices for Snoring and/or Obstructive Sleep Apnea; Guidance for Industry and FDA. Issued on: November 12, 2002
  - “the agency will not request clinical studies for new devices unless there is a specific justification for asking for such information to support a substantially equivalent determination.”
Oral Appliance: CMS Coverage Reqs

1. Face-to-face clinical evaluation by MD
2. Medicare covered sleep test;
3. Intolerance/contraindication for PAP
4. The device is provided by a licensed dentist.

Custom device may be covered for anatomical abnormality that cannot be accommodated by a prefabricated appliance.
“Oral maxillofacial prostheses used in the treatment of Obstructive Sleep Apnea (OSA) will be covered when specifically fashioned to the needs and measurements of individual patients and used to treat essential sleep apnea (780.53) and obstructive sleep apnea (780.57).”
Oral Appliance: United Healthcare 2009

- Proven for treatment of mild or moderate obstructive sleep apnea (OSA) as documented by laboratory-based polysomnography (PSG).

- Tongue-retaining devices and surgically inserted palatal implants are unproven for the treatment of obstructive sleep apnea due to inadequate clinical evidence of safety and/or efficacy in published, peer-reviewed medical literature.
# CMS 2009 Avg National Fees (adj locality GPCI)

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
<th>CMS Facility Prof Payment 2009</th>
<th>Conversion factor</th>
</tr>
</thead>
<tbody>
<tr>
<td>0088T</td>
<td>Radiofrequency tongue base volume reduction</td>
<td>N/A</td>
<td>$36.07</td>
</tr>
<tr>
<td>42145</td>
<td>Repair palate, pharynx/uvula</td>
<td>$643</td>
<td></td>
</tr>
<tr>
<td>42825</td>
<td>Removal of tonsils</td>
<td>$242</td>
<td></td>
</tr>
<tr>
<td>95806</td>
<td>Sleep study, unattended</td>
<td>$209</td>
<td></td>
</tr>
<tr>
<td>95810</td>
<td>Polysomnography, 4 or more</td>
<td>$768</td>
<td></td>
</tr>
<tr>
<td>95811</td>
<td>Polysomnography with CPAP</td>
<td>$845</td>
<td></td>
</tr>
<tr>
<td>94762</td>
<td>Overnight oximetry</td>
<td>$30</td>
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CMS and OSA: Summary

- Final decisions are made locally.
- Doctor can’t dispense CPAP (self referral fraud and abuse).
- Independent Diagnostic Testing Facilities (IDTF)
  - Sleep lab not part of physician practice.
  - Extensive rules: facility, tech qualifications, space sharing
- Home sleep studies are adequate; treat based on AHI, not RDI.
- Specialists must interpret. (Check LCD!)
- CPAP is harmless; CPAP titration not needed.
- DME company can do testing only in facility.
- Recovery Audit Contractors are growing in scope.
- PSG is on OIG agenda for 2010.
American Board Medical Specialties

- Exam new fall 2007, given again Nov 2009, for MDs certified in internal medicine, family practice, neurology, pediatrics, psychiatry, otolaryngology.
- First exam: under 1400 diplomates; pass rate 73%.
- Window of opportunity for MDs.
- Expect spike in board-certified sleep MDs.
Sleep Tech Issues 2010

- PSG tech duties impinge on RRT scope of practice.
  - State law: Who can administer CPAP or O2?
  - Sleep labs are vulnerable to prosecution!!!
  - (By the way, RPsgT cannot admin medicine.)
- Credentials for IDTF may be strict.
- Establishing the independent health profession
  - National standard education
    - AASM approved 80-hour training
    - A-Step 80-hr curriculum
    - CAAHEP curriculum
  - National standard demonstration of competency: RPsgT
- aastweb.org
USA and OSA

- Army, 11sep07:
  - “The soldier can be deployed if nasal CPAP is required and can be supported in the area of deployment.”

- Navy:
  - Fitness for duty: Fit for full duty unless local MD feels sailors can’t be deployed to that station.

- Retirement with OSA; Medical Care transferred to VAMC
  - 40% disability for OSA; 50% if treated with CPAP.
  - Benefit about $1,000 per month.
  - Snoring soldiers and sailors nearing retirement get PSG.
Concerns for 2010 forward:

- **E&M services:**
  - Per-hour CMS payment $5-$22/hour net.
  - Consult codes “not recognized” by CMS & others.
  - ↑ FU visit payment increases surgical global fees.
  - Adherence monitoring is routine part of FU visit.
- EHR
  - CMS incentive payments begin 2011.
  - CMS penalties begin 2015.
Concerns for 2010 forward:

- **Testing**
  - Codes to be proposed: split-night PSG, pediatric PSG and split; PSG with extended EEG montage
  - HST models; making it work financially:
    - Equipment in MD office
    - Remote delivery and analysis

- **Therapy**
  - Cost-effective ways to demonstrate adherence
  - Adherence data delivery: ? Web-based
  - Use of auto-PAP
  - Oral appliance integration
Concerns for 2010 forward

- Added burdens on MD:
  - Discuss DME coverage and policies: Patients see the doctor as responsible for DME provider performance.
  - Preauthorization for therapy.
  - Document PAP adherence and clinical improvement.
  - Technologist/facility licensing policies and laws.
Activities of Interest: 2010

- OIG 2010 Work Plan targets PSG:
  - “We will examine the appropriateness of Medicare payments for sleep studies. Sleep studies are reimbursable for patients with symptoms consistent with sleep apnea, narcolepsy, impotence, or parasomnia . . . Medicare payments for polysomnography increased from $62 million in 2001 to $215 million in 2005. We will also examine the factors contributing to the rise in Medicare payments for sleep studies and assess provider compliance with Federal program requirements.”
Activities of Interest: 2010

- All diagnostic sleep procedures are due for review by RUC in 2010, with any revisions to take effect Jan 1, 2011.

- Current value for PSG (95810) is based on older survey data including:
  - Physician time: 95 minutes
  - Technologist time: 630 minutes
  - Equipment cost per bed: $88,000
  - Disposable costs per study: $55
GET IN THE GAME!

- AASM Health Policy Committee needs your support at AMA & its committees.
- Support the AASM Political Action Committee (PAC).
- State medical societies are needed to:
  - Meet with CMS Local carriers and provide payers.
  - Establish and protect sleep technology as an independent health profession.
References

- OIG Workplan Fiscal year 2010

- HCUPNET info:
  - http://hcupnet.ahrq.gov/

- CMS Place of Service (POS) and Date of Service (DOS) Instructions for the Interpretation (Professional Component) and Technical Component of Diagnostic Tests
References cont

- Medicare 2010 Hospital Outpatient Prospective Payment System
  - http://www.cms.hhs.gov/HospitalOutpatientPPS/

- Medicare 2010 Physician Fee Schedule corrections, Jan 2010
  - http://www.cms.hhs.gov/PhysicianFeeSched/PFSRVF/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=1&sortOrder=ascending&itemID=CMS1230197&intNumPerPage=10

- Medicare coverage database for NCDs and LCDs

- United Healthcare Tech reviews/policy
  - https://www.unitedhealthcareonline.com/b2c/CmaAction.do?channelId=016228193392b010VgnVCM100000c520720a
References cont

- Medicare Portable monitoring decision 2008:

- Medicare Portable monitoring technology assessment: