## SLEEP APNEA SYNDROME PREAMBLE

Driver sleepiness<sup>A</sup> is a major cause of motor vehicle crashes. Most crashes due to drowsy driving likely occur in healthy but sleep deprived individuals, but drivers with sleep apnea are at increased risk for motor vehicle accidents.

OSA (and possibly central sleep apnea) can cause impairment in daytime performance. It is associated with increased risk of motor vehicle crashes, with estimates ranging from 2% to 7% in those with sleep apnea compared to those without.<sup>B, C</sup> The condition is common (2-8% in older literature, with more recent estimates suggesting that 25% of adult men in the US are affected), and the frequency of occurrence increases with age, BMI (body mass index) and comorbid conditions such as diabetes.

People with sleep apnea may have delayed reaction times and inattentiveness in addition to frank sleepiness. Some are unaware of their sleepiness and cognitive impairment. It is important to recognize that excessive daytime sleepiness and crash risk may not correlate with the severity of the sleep apnea. A recent study demonstrated that increased risk of motor vehicle crashes is present in those with mild OSA as well as those with severe disease. The diagnosis of OSA is made through polysomnography (PSG), and/or Home Sleep Studies (HSAT).

Treatment of sleep apnea generally improves daytime sleepiness. Use of continuous or bi-level positive airway pressure (CPAP or BPAP) is a highly effective treatment with studies suggesting that daytime symptoms improve within two weeks of positive airway pressure (PAP) treatment.<sup>E, F</sup> It is the only treatment modality demonstrated to reduce crash risk.<sup>G</sup>

Other treatment options for sleep apnea potentially may include weight loss through lifestyle modifications and/or bariatric surgery for severe obesity, use of oral mandibular advancement devices, positional therapy (if non-supine AHI equal to or less than 15), upper airway (hypoglossal nerve) stimulation therapy, upper airway surgery and craniofacial surgery, Hand craniofacial surgery. Hypoglossal nerve stimulators have been approved by the FDA for treatment of sleep apnea. Assessment of treatment efficacy (AHI equal to or less than 15) with sleep testing is recommended.

It is difficult for clinicians to assess sleepiness (and possible impairment while driving) in a patient with sleep apnea. Sleepiness cannot be measured easily by objective testing. Maintenance of Wakefulness Tests (MWT)<sup>J</sup> and Multiple Sleep Latency Tests (MSLT)<sup>J</sup> are the objective measures of daytime sleepiness. They are not routinely used to assess daytime sleepiness in drivers, however, may be used at the clinician's discretion when subjective measures suggest excessive sleepiness despite treatment. The clinician uses subjective reports as well as objective data from CPAP downloads to assess adherence to treatment and level of daytime sleepiness.

The Epworth Sleepiness Scale (ESS) is a widely used measure of subjective daytime sleepiness. It is a validated sleep questionnaire containing eight items that ask for self-reported disclosure of expectation of "dozing" in a variety of situations. Dozing probability ratings are none (0), slight (1), moderate (2), or high (3) in eight hypothetical situations. A score of 0 to 10 is normal, 11-12 is mild, 13-15 is moderate, and 16 or greater is severe daytime sleepiness.<sup>K</sup>

The diagnosis of sleep apnea should only be made by a physician or nurse practitioner or physician's assistant with specialized training in Sleep Medicine. Those with sleep apnea are frequently followed by a sleep specialist, neurologist, or a pulmonologist. In some cases, a dentist with specialized education and certification, may collaborate with the sleep specialist to provide oral appliance therapy.

Patients on PAP therapy should have data downloaded from their device to measure adherence with therapy. Medicare guidelines<sup>L</sup> are the standard for adherence to treatment and require an average of 4 hours PAP use per night 70% of the time.

The clinician must educate patients that driving safety is ultimately the individual's responsibility. Insufficient sleep time, medications, shift work and illness may affect one's ability to drive safely despite consistent use of PAP therapy.

## FUNCTIONAL ABILITY PROFILE Sleep Apnea Syndrome<sup>1</sup>

Profile Levels	Degree of Impairment/ Potential for At Risk Driving	Condition Definition / Example	Interval for Review and Other Actions
1.	No diagnosed condition	No diagnosis of sleep apnea	N/A
2.	Condition fully recovered	Recovered after treatment such as independent weight loss, bariatric surgery, or ENT surgery that has been confirmed with a Polysomnography or Home Sleep Apnea Test (HSAT) demonstrating an AHI <sup>2</sup> less than 5 events/hour.	N/A
3.	Active impairment  (Profile levels are intended to describe potential for at risk driving; they are NOT consistent with clinical definitions for mild, moderate or severe.)	See footnote regarding PAP therapy. <sup>3</sup> This diagnosis should be made only after a sleep study. Neurology, pulmonary or sleep medicine specialists are often the clinicians to provide follow-up.	
	a. Mild risk	No report of accident or near miss of concern; and  AHI <sup>2</sup> 5-15 on diagnostic PSG or HSAT and not sleepy, ESS (Epworth Sleepiness Scale) <sup>4</sup> 12 or less and not on treatment; or,  Treatments such as upper airway stimulation therapy, surgery, positional therapy, or oral appliance <sup>5</sup> . Polysomnogram or HSAT demonstrates an AHI <sup>2</sup> on treatment of equal to or less than 15. ESS <sup>4</sup> score 12 or less; or,  PAP download demonstrates adherence to treatment. <sup>3,6,7</sup> AHI <sup>2</sup> equal	3 years

	to or less than 15 on download. ESS <sup>4</sup> 12 or less.	
b. Moderate risk	No report of accidents or near miss of concern; and  PAP download demonstrates adherence to treatment. <sup>3, 6, 7</sup> AHI <sup>2</sup> may be greater than 15 on download (could include central sleep apnea). ESS <sup>4</sup> 13-15.	1 year
c. Severe risk	History of falling asleep while driving or near miss, or strong suspicion of sleep apnea with concern for unsafe driving; and/or  Non-responsive <sup>7</sup> or non-adherent <sup>8</sup> to therapy.	No driving

<sup>&</sup>lt;sup>1</sup> For further discussion regarding SLEEP APNEA SYNDROME, please refer to Preamble at the beginning of this section.

<sup>&</sup>lt;sup>2</sup> AHI: apnea/hypopnea index: number of obstructive events per hour of sleep.

<sup>&</sup>lt;sup>3</sup> Treatment with positive airway pressure therapy. PAP devices include but are not limited to, CPAP (continuous positive airway pressure), BiPAP (bi-level positive airway pressure), and ASV (adaptive servo-ventilation).

<sup>&</sup>lt;sup>4</sup> The Epworth Sleepiness Scale is a widely used measure of subjective daytime sleepiness. A score of 10 or less out of 24 is considered normal. A score greater than 10 suggests a degree of excessive sleepiness.<sup>K</sup> For those with an oral appliance, positional therapy, upper airway stimulation therapy or surgery, repeat PSG or HSAT must be done with treatment in place.

<sup>&</sup>lt;sup>6</sup> Adherence to or compliance with PAP treatment derived from Medicare guidelines: use of PAP an average of four or more hours per night at least 70% of the time.

<sup>&</sup>lt;sup>7</sup> Other or new treatments may be considered on an individual basis if effective in treating AHI and excessive somnolence, when recommended by the clinician and upon review of the Medical Advisory Board. Assessment by a sleep specialist may be required.

<sup>&</sup>lt;sup>8</sup> For drivers who have not been compliant with PAP therapy but are willing to seek effective treatment, the clinician may write a letter to request that driving be allowed during workup if there are no specific concerns for unsafe driving. Normally, this should be done before completing the Driver Medical Evaluation form. The letter must contain a recent ESS score, the request to allow driving, the plan for treatment and the estimated time frame. Clinician may call BMV Medical Section with any questions or concerns, at 207-624-9000, Ext. 52124.