



# Louisiana

## Actigraphy

**Policy #** 00330

Original Effective Date: 07/27/2012

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*Note: Diagnosis and Management of Obstructive Sleep Apnea Syndrome is addressed separately in medical policy 00328.*

*Note: Surgical Treatment of Snoring and Obstructive Sleep Apnea Syndrome is addressed separately in medical policy 00329.*

### **Services Are Considered Investigational**

*Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.*

Based on review of available data, the Company considers actigraphy when used as the sole technique to record and analyze body movement, including but not limited to its use to evaluate sleep disorders to be **investigational**.<sup>\*</sup> This does not include the use of actigraphy as a component of portable sleep monitoring.

### **Background/Overview**

Actigraphy refers to the assessment of activity patterns by devices typically placed on the wrist or ankle that record body movement, which is interpreted by computer algorithms as periods of sleep (absence of activity) and wake (activity). Actigraphic devices are typically placed on the nondominant wrist with a wristband and are worn continuously for at least 24 hours. Activity is usually recorded for a period of 3 days to 2 weeks but can be collected continuously over extended time periods with regular downloading of data onto a computer. The activity monitors may also be placed on the ankle for the assessment of restless legs syndrome, or on the trunk to record movement in infants.

The algorithms for detection of movement are variable among devices and may include "time above threshold," the "zero crossing method" (the number of times per epoch that activity level crosses zero), or "digital integration" method, resulting in different sensitivities. Sensitivity settings (eg, low, medium, high, automatic) can also be adjusted during data analysis. The digital integration method reflects both acceleration and amplitude of movement; this form of data analysis may be most commonly used today.

Data on patient bed times (lights out) and rise times (lights on) are usually entered into the computer record from daily patient sleep logs or by patient-activated event markers. Proprietary software is then used to calculate periods of sleep based on the absence of detectable movement, along with movement-related level of activity and periods of wake. In addition to providing graphic depiction of the activity pattern, device-specific software may analyze and report a variety of sleep parameters including sleep onset, sleep offset, sleep latency, total sleep duration, and wake after sleep onset. Actigraphy might also be used to measure the level of physical activity.

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Actigraphy has been used for more than 2 decades as an outcome measure in sleep disorders research. For clinical applications, actigraphy is being evaluated as a measure of sleep/wake cycles in sleep disorders including insomnia and circadian rhythm sleep disorders. In addition, actigraphy is being investigated as a measure of sleep/wake disturbances associated with numerous other diseases and disorders.

## **FDA or Other Governmental Regulatory Approval**

U.S. Food and Drug Administration (FDA)

Numerous actigraphy devices have received U.S. FDA approval through the 510(k) process. Some actigraphy devices are designed and marketed to measure sleep/wake states while others are designed and marketed to measure levels of physical activity.

FDA product code: OLV.

Centers for Medicare and Medicaid Services (CMS)

There is no national coverage determination.

## **Rationale/Source**

Assessment of a diagnostic technology typically focuses on 3 categories of evidence: (1) its technical reliability (test-retest reliability or interrater reliability); (2) clinical validity (sensitivity, specificity, and positive and negative predictive value) in relevant populations of patients; and (3) clinical utility (demonstration that the diagnostic information can be used to improve patient outcomes).

## **CONTEXT**

This evidence review was initially informed by the 2002 practice parameters issued by the American Academy of Sleep Medicine (AASM). Because all the specific clinical indications for actigraphy were classified as guidelines or options, the AASM practice parameters recommended that all indications for actigraphy would be considered investigational. In a review article that served as the basis for the 2002 practice parameters, AASM pointed out the challenges in evaluating the diagnostic accuracy of actigraphy:

- Different actigraphy devices use different algorithms for the evaluation of data. There were “no published articles comparing the different algorithms,” making comparison between studies difficult.
- Polysomnography (PSG) is considered the “gold standard” for the evaluation of sleep/wake cycles. However, correlation data may be misleading. For example, a high correlation on total sleep time would mean that individuals who slept longer by PSG criteria also slept longer by actigraphy criteria; however, this would not exclude the possibility that actigraphy data overestimated total sleep time. Different methods of analysis have also been used, such as accuracy for identification of true sleep and true wake epochs. The diagnostic performance will also vary according to how much time the patient is asleep. For example, malfunctioning records will falsely identify the patient as asleep. Finally, comparisons between PSG and actigraphy have to be time-locked; if the 2 technologies “gradually drift apart, over time different segments of sleep or wake may be compared with each other....”

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- Published studies of actigraphy “must contain complete reporting of sensitivity, specificity, scoring algorithm, and filters, as well as reliability, validity, ruggedness, and artifact rejection for the device and computer program used.”

The 2005 update to the AASM practice parameters continued to list actigraphy as an option, and suggested areas such as restless legs syndrome and characterized circadian rhythm patterns for further evaluation. No controlled studies had been conducted to compare the results of actigraphy with other methods to determine if actigraphy would provide incremental information that would result in improved health outcomes.

In 2007, AASM updated its practice parameters on the use of actigraphy in the assessment of sleep and sleep disorders. Whereas the 2005 practice parameters focused on the comparison of actigraphy with polysomnographically recorded sleep, the 2007 update included 108 additional studies comparing actigraphy with a number of standard clinical assessment tools that included sleep logs, subjective questionnaires, caregiver reports, and circadian phase markers. Actigraphy was recommended as a “standard” only as a method to estimate total sleep time in patients with obstructive sleep apnea syndrome when PSG is not available. Other indications changed from “option” to “guideline” but failed to reach a recommendation of “standard” due primarily to the absence of high-quality trials. Few studies reviewed provided technical details related to the administration and scoring of actigraphy. In addition, most studies lacked descriptions of blinding, and there was “an inadequate description of whether visual inspection of data is performed, how missing data is handled, and other important decisions made in the analysis of actigraphy data.” AASM indicated the need for additional research in the following areas:

- Comparison of “results from different actigraphy devices and the variety of algorithms used”
- “Standards for setting start and stop times”
- “Reliability and validity ... compared with reference standards”
- Clarification of “the relative and unique contributions of actigraphy, polysomnography and sleep logs in the diagnosis of sleep disorders and measurement of treatment effects.”

In AASM’s 2007 practice parameter on evaluation and treatment of circadian rhythm sleep disorders (CRSDs), the use of actigraphy was considered as either an option or guideline, depending on the suspected disorder. Specifically, use of actigraphy was recommended as an option for diagnosis of irregular sleep-wake disorder and free-running disorder, and as a guideline for diagnosis of advanced sleep phase disorder, delayed sleep phase disorder, and shift work disorder. The evidence reviewed indicated good agreement between actigraphy and results of other diagnostic tools, including PSG, sleep logs, and markers of circadian phase. It should be noted, however, that there was a relative lack of evidence for any procedure in the diagnosis or evaluation of treatment of CRSDs; eg, use of sleep logs received a guideline recommendation, based primarily on consensus and inclusion in the second edition of the International Classification of Sleep Disorders (ICSD-2). Insufficient evidence was found to recommend the use of circadian phase markers for any CRSDs other than free-running disorder; further, PSG is not routinely indicated for the diagnosis of CRSDs.

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### **ACTIGRAPHY**

Actigraphy is frequently used as an intermediate outcome in research studies. However, literature review updates have not identified any studies that have evaluated whether the use of actigraphy would result in improved health outcomes (clinical utility) for patients with sleep disorders. A number of studies have assessed sensitivity and specificity in either healthy or clinical populations (clinical validity). The following is a summary of key studies to date.

#### **Adults**

##### ***Actigraphy vs PSG***

Paquet et al (2007) compared actigraphy assessment of sleep and wake with PSG under varying conditions of sleep disturbance (night time sleep, daytime sleep, daytime sleep with caffeine) in 23 healthy subjects. Data were analyzed from a study that evaluated the effects of caffeine on daytime recovery sleep. The experimental protocol involved 2 visits to the sleep laboratory, each including 1 night of nocturnal sleep, 1 night of sleep deprivation, and the next day of recovery sleep (once with placebo and once with caffeine 200 mg). The Actiwatch and PSG equipment were synchronized before recording, and assessment of sleep and wake for each 1-minute interval were compared for sensitivity, specificity, and accuracy of actigraphy with manually staged sleep from PSG recordings. Sensitivity was defined as the proportion of all epochs scored as sleep by PSG that were also scored as sleep by actigraphy. Specificity was the proportion of all epochs scored as wake by PSG that were also scored as wake by actigraphy. Accuracy was the proportion of all epochs correctly identified by actigraphy. Four sensitivity settings/scoring algorithms were compared. In general, as the threshold to detect movement was raised, sensitivity to detect sleep increased, but the specificity to detect wake decreased. With the medium threshold algorithm, the sensitivity to detect sleep was 95% to 96%. However, specificity or the ability to detect wake, was 54% for night time sleep, 45% for daytime recovery sleep, and 37% for daytime recovery sleep with caffeine. A main finding of the study was that the more disturbed the sleep, the less actigraphy was able to differentiate between true sleep and quiet wakefulness, with an accuracy of 72% for the most disrupted sleep condition. Through experimental manipulation of the level of sleep disturbance, this study provided information on the limitations of this technology for clinical populations with sleep disruption.

Marino et al (2013) assessed the clinical validity of wrist actigraphy to measure nighttime sleep using the Cole-Kripke algorithm in 54 young and older adults, either healthy or with insomnia, and in 23 night-workers during daytime sleep. Epoch-by-epoch comparison with PSG showed sensitivity (ability to detect sleep, 97%) and accuracy (86%) during the usual sleep/lights-out period to be high, but specificity (ability to detect wake, 33%) was low. As the amount of wake after sleep onset increased, the more actigraphy underestimated this parameter. Several other studies assessed clinical validity in patients with primary or secondary sleep disorders. A 2006 study assessed the sensitivity and specificity of actigraphy compared with PSG in older adults treated for chronic primary insomnia. Visual scoring of PSG data was blinded, and actigraphy records were scored by proprietary software. The study found that actigraphy agreed with PSG scoring of sleep for 95% of the 30-second epochs (sensitivity), but agreed with PSG scoring of wake only 36% of the time (specificity). The study concluded that "the clinical utility of actigraphy is still suboptimal in older adults treated for chronic primary insomnia." Kaplan et al (2012) compared outcomes from actigraphy, PSG, and sleep diary in 27 patients with bipolar disorder, who were between mood episodes, and in 27

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age- and sex-matched controls. Blinded evaluation found no significant difference in sleep parameters between patients with bipolar disorder and controls. Sleep parameter estimates from actigraphy and PSG were highly correlated. Taibi et al (2013) found a sensitivity of 96.1% and specificity of 36.4% in a study of 16 older adults with insomnia who underwent 8 nights of concurrent actigraphy and PSG. Sleep efficiency (actual sleep as a percentage of total recording time) was overestimated by actigraphy (84.4%) compared with PSG (66.9%), and the accuracy of actigraphy declined as sleep efficiency declined. Actigraphy and PSG measures of total sleep time were highly correlated, but correlations were marginal for sleep onset latency and wake after sleep onset. Sensitivity and specificity were not assessed. Louter et al (2014) reported on a study of actigraphy, compared with video-PSG, as a diagnostic aid for rapid eye movement (REM) sleep behavior disorder (RBD) in 45 consecutive patients with Parkinson disease. The study population included patients referred for a variety of reasons, including insomnia, restless legs syndrome, and sleep apnea. Following video-PSG, 23 patients were diagnosed with RBD. There was no significant difference between groups for the presence of other sleep disorders. Using a cutoff of 95 wake bouts per night, actigraphy had a sensitivity of 26.1% and specificity of 95.5%, with a positive predictive value of 85.7%.

In a 2010 study, actigraphy with a SOMNOWatch in 28 patients with sleep-disordered breathing showed a sensitivity of 90%, a specificity of 95%, and overall accuracy of 86% in comparison with PSG. Pearson correlations were high for total sleep time (0.89), sleep period time (0.91), and sleep latency (0.89), and moderate for sleep efficiency (0.71) and sustained sleep efficiency (0.65).

Studies have also assessed different modes of data collection and analysis, including varying the sensitivity settings for existing algorithms and developing new scoring algorithms. A 2011 publication compared 3 collection modes (proportional integration, time above threshold, zero crossings) with PSG in 889 older community-dwelling men who participated in the Outcomes of Sleep Disorders in Men (MrOS) study. The proportional integration mode was found to correspond best to PSG, with moderate interclass correlation coefficients ranging from 0.32 to 0.57. Actigraphy in this mode overestimated total sleep time by an average of 13.2 minutes, with an absolute difference (positive or negative direction) of 52.9 minutes. There was a systematic bias for overestimating total sleep time, which increased with decreasing sleep duration.

A 2014 systematic review of leg actigraphy to quantify periodic limb movements of sleep found significant heterogeneity for the sensitivity and specificity of different devices. Factors contributing to the heterogeneity were variability in devices tested, placement of the devices (eg, foot, ankle), thresholds to define clinically significant periodic limb movements of sleep (eg, 5, 10, or 15 per hour), and algorithms used to calculate the periodic limb movements. The inability to combine actigraphy data from both legs also presents a limitation for clinical use at this time.

### ***Actigraphy vs Sleep Diaries***

Levenson et al (2013) evaluated the utility of sleep diaries and actigraphy in differentiating older adults with insomnia (n=79) from good sleeper controls (n=40). Sensitivity and specificity were determined for sleep onset latency, wake after sleep onset, sleep efficiency, and total sleep time; patients with insomnia completed PSG studies, but controls did not. Using receiver operating characteristic curve analysis, sleep

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diary measurements produced areas under the curve in the high range (0.84-0.97), whereas actigraphy performed less well at discriminating between older adults with insomnia and controls (area under the curve range, 0.58-0.61).

### Children and Adolescents

#### **Actigraphy vs PSG**

In 2016, Meltzer et al compared actigraphy with concurrently worn comprehensive ambulatory home PSG among 148 children ages 5 to 12 born prematurely. Subjects were participating in a larger study on the long-term effect of caffeine therapy for apnea of prematurity on sleep. After controlling for sleep disorders, compared with PSG, actigraphy underestimated total sleep time (mean difference [MD], -30.1 minutes; 95% confidence interval [CI], -35.3 to -25.0 minutes;  $p=0.02$ ) and overestimated sleep onset latency (MD=2.16 minutes; 95% CI, -1.7 to 6.0 minutes;  $p=0.02$ ). The sensitivity and specificity of actigraphy were 88% and 84%, respectively; accuracy was 46%.

In 2010, O'Driscoll et al compared actigraphy with PSG in 130 children referred for assessment of sleep-disordered breathing. The Arousal Index and Apnea-Hypopnea Index (AHI) scores from PSG were compared with the number of wake bouts per hour and actigraphy Fragmentation Index. Using a PSG-determined AHI of greater than 1 event per hour, the measure of wake bouts per hour had a sensitivity and specificity of 14.9% and 98.8%, respectively, and the Fragmentation Index had a sensitivity and specificity of 12.8% and 97.6%, respectively. Using a PSG-determined Arousal Index greater than 10 events per hour as the reference standard, the actigraphy measure of wake bouts per hour had a sensitivity and specificity of 78.1% and 52.6%, and the Fragmentation Index had a sensitivity and specificity of 82.2% and 50.9%, both respectively. Based on receiver operating characteristic curves, the ability of actigraphy measures to classify correctly a child as having an AHI of greater than 1 event per hour was considered poor.

A 2007 study examined the validity of actigraphy for determining sleep and wake in children with sleep-disordered breathing using data analyzed over 4 separate activity threshold settings (low, medium, high, automatic). The low and auto activity thresholds were found to determine sleep adequately (relative to PSG) but to underestimate wake significantly, with a sensitivity of 97% and specificity of 39%. The medium- and high-activity thresholds significantly underestimated sleep time (sensitivity, 94% and 90%) but did not differ significantly from the total PSG estimates of wake time (specificity, 59% and 69%), respectively. Overall agreement rates between actigraphy and PSG (for both sleep and wake) ranged from 85% to 89%. Belanger et al (2013) assessed the sensitivity and specificity of different scoring algorithms in healthy preschoolers. An algorithm designed specifically for children showed the highest accuracy (95.6%) in epoch-by-epoch comparison with PSG.

Insana et al (2010) compared ankle actigraphy recording with PSG in 22 healthy infants (age range, 13-15 months). Actigraphy underestimated total sleep time by 72 minutes and overestimated wake after sleep onset by 14 minutes. In 55% of the infants, total sleep time was underestimated by 60 minutes or more. Sensitivity was calculated for total sleep time (92%), stages 1 and 2 combined (91%), slow wave sleep (96%), and REM sleep (89%). Specificity for identifying wake was 59%, and accuracy was 90%. Overall, actigraphy identified sleep relatively well but was unable to discriminate wake from sleep. A 2011 study

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compared wrist actigraphy with PSG in 149 healthy school-aged children. Although the sleep period time did not differ significantly, actigraphy underestimated total sleep time by 32 minutes (correlation coefficient, 0.47) and overestimated wake after sleep onset by 26 minutes (correlation coefficient, 0.09). The authors concluded that actigraphy was relatively inaccurate for determine sleep quality in this population.

### ***Actigraphy vs Sleep Diaries***

Werner et al (2008) assessed the agreement between actigraphy and parent diary or questionnaire for sleep patterns in 50 children, ages 4 to 7 years, recruited from kindergarten schools in Switzerland. Sixty-eight (10%) of 660 invited families participated. Each child was home-monitored with an actigraph for 6 to 8 consecutive nights, and parents were asked to complete a detailed sleep diary (15-minute intervals) during the monitoring days to indicate bedtime, estimated sleep start, wake periods during the night, and estimated sleep end. Parents' assessment of habitual wake time, get up time, bedtime, time of lights off, sleep latency, and nap duration were obtained through a questionnaire. The satisfactory agreement, defined a priori as differences smaller than 30 minutes, was achieved between actigraphy and diary for sleep start, sleep end, and assumed sleep. Actual sleep time and nocturnal wake time differed by an average of 72 minutes and 55 minutes, respectively. The satisfactory agreement was not reached between actigraphy and the questionnaire for any of the parameters. Authors concluded that the diary was a cost-effective and valid source of information about children's sleep-schedule time, while actigraphy might provide additional information about nocturnal wake time or might be used if parents are unable to report in detail. Compliance and accuracy in the diaries were likely affected by the motivation of the parents, who self-selected into this study.

Discrepancies between actigraphy and sleep diary measures of sleep in adolescents were reported by Short et al in 2012. A total of 290 adolescents (age range, 13-18 years) completed 8 days of sleep diaries and actigraphy. Actigraphy estimates of total sleep time (median, 6 hours 57 minutes) were significantly lower than total sleep time recorded in adolescent's sleep diaries (median, 8 hours 17 minutes) or parent reports (median, 8 hours 51 minutes). Wake after sleep onset averaged 7 minutes in sleep diaries and 74 minutes by actigraphy. Actigraphy estimated wake after sleep onset of up to 3 hours per night in the absence of any waking from sleep diaries, suggesting an overestimation of wake in this population. The discrepancy between actigraphy and sleep diary estimates of sleep was greater for boys than for girls, consistent with PSG studies that have shown increased nocturnal motor behavior in boys.

### ***Actigraphy vs Behavioral Observations***

A validation study of actigraphy for determining sleep and wake was conducted in 10 preterm infants using videotaped behavioral observations. This 2009 study was conducted for a 24-hour period each week while the infants were in the nursery, resulting in a total of 38 studies. Wakefulness was scored as quiet wake with eyes open and "bright," active wake with eyes open and gross body movements, or crying. Sleep included quiet sleep with regular breathing and eyes closed, active sleep with irregular breathing and REMs, and indeterminate sleep, during which characteristics of both active and quiet sleep were observed. Behavioral sleep-wake scoring was carried out blinded to the knowledge of the actigraphy data. The actigraph, which was synchronized to the video recording, was placed in a custom-designed sleeve bandage and positioned on the infant's leg midway between the knee and ankle. The agreement rate

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between actigraphy determination of sleep and wake and behavioral scoring ranged from 66% for the high-sensitivity setting at the youngest gestational age (30-33 weeks) to 89% at the low-sensitivity setting for infants of 37 to 40 weeks of gestational age. For the youngest infants, the sensitivity and specificity at the low threshold were 88% and 34%, respectively. For infants at 37 to 40 weeks of gestational age, the sensitivity and specificity were 97% and 32%, respectively. Similar results (97% sensitivity, 24% specificity) were obtained in a 2008 study with an epoch-by-epoch comparison of actigraphy and videosomnography in 22 autistic, 11 developmentally delayed, and 25 normally developing preschool children.

### ***Actigraphy vs Video-Electroencephalography***

A prospective validation study of actigraphy for determining sleep-wake patterns in children with epilepsy was reported in 2014. In this study, 27 children with medically refractory epilepsy wore activity monitors while being evaluated with at least 24-hour video-electroencephalography (vEEG; mean, 70.5 hours) in an inpatient epilepsy monitoring unit. The vEEG and actigraphy data were evaluated by 2 independent and blinded reviewers. Although sensitivity and specificity were not reported, correlation coefficients between the 2 measures were very high ( $r$  range, 0.93-0.99) for night sleep period, night sleep time, duration of night wake time, and percent time of sleep during the day. Consistent with lower specificity to detect awakenings during sleep, the correlation for the number of awakenings after sleep onset was less robust.

### **SUMMARY OF EVIDENCE**

For individuals who have circadian sleep-wake rhythm disorders, central disorders of hypersomnolence, or insomnia who receive actigraphy, the evidence includes prospective and retrospective validation studies. Relevant outcomes are test accuracy and validity. The clinical validity of actigraphy depends on the modality to which it is being compared. Comparisons with sleep diaries have shown reasonable correlations for measures of bedtime, sleep onset, and wake time in adults but not in adolescents. The relative and unique contributions of actigraphy and sleep logs in the diagnosis of sleep disorders and measurement of treatment effects remain to be demonstrated. Comparisons with the more resource-intensive polysomnography or behavioral scoring have indicated that, with the appropriate sensitivity threshold, actigraphy has sufficient sensitivity to detect sleep but has poor specificity distinguishing between wake and sleep. The literature has also revealed that the accuracy of actigraphy for differentiating between wake and sleep decreases as the level of sleep disturbance increases. Overall, progress has been made, especially since 2007 when the American Academy of Sleep Medicine made research recommendations that compared the reliability and validity of different algorithms with the reference standard. Although actigraphy appears to provide reliable measures of sleep onset and wake time in some patient populations, its clinical utility over sleep diaries has not been demonstrated. Moreover, evidence has shown that actigraphy does not provide a reliable measure of sleep efficiency in clinical populations. The evidence is insufficient to determine the effects of the technology on health outcomes.

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# Louisiana

Actigraphy

Policy # 00330  
 Original Effective Date: 07/27/2012  
 Current Effective Date: 07/11/2018

## **Policy History**

Original Effective Date: 07/27/2012  
 Current Effective Date: 07/11/2018

06/28/2012	Medical Policy Committee review
07/27/2012	Medical Policy Implementation Committee approval. New policy.
06/27/2013	Medical Policy Committee review
07/17/2013	Medical Policy Implementation Committee approval. No change to coverage.
07/10/2014	Medical Policy Committee review
07/16/2014	Medical Policy Implementation Committee approval. Investigational statement clarified regarding portable sleep monitoring.
06/25/2015	Medical Policy Committee review
07/15/2015	Medical Policy Implementation Committee approval. No change to coverage.
06/30/2016	Medical Policy Committee review
07/20/2016	Medical Policy Implementation Committee approval. No change to coverage.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
07/06/2017	Medical Policy Committee review
07/19/2017	Medical Policy Implementation Committee approval. No change to coverage.
07/05/2018	Medical Policy Committee review
07/11/2018	Medical Policy Implementation Committee approval. No change to coverage.

Next Scheduled Review Date: 07/2019

## **Coding**

*The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT)<sup>®</sup>†, copyright 2017 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.*

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	95803

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HCPCS	No codes
ICD-10 Diagnosis	All related diagnoses

\*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. FDA and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
  - 1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
  - 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
  - 3. Reference to federal regulations.

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