

Final Comments and Responses

Autonomic Function Testing

Comment #s 1 through 4 address the considerable input to the LCDs received in one package. This contractor acknowledges that an extensive number of letters from various stakeholders were received in a single mailing in support of *CPT*® code 95943. WPS also acknowledges that we received numerous documents from outside our contractual area addressed to CMD's that are not employees of WPS. These documents referenced LCD numbers that do not belong to any WPS LCD's.

Comment #1: The proposed draft LCD states that *CPT*® code 95943 is not medically reasonable and necessary since it is not proven that these tests are at least as beneficial as existing and available medically appropriate testing alternatives. This code was approved by the AMA to enable a broader application of benefits to patients to improve outcomes and help to reduce costs. The AMA recognizes the benefit of documenting autonomic dysfunction or sub-clinical autonomic neuropathy. It enables earlier intervention (prior to symptomatic autonomic neuropathy) to reduce the well-known morbidity and mortality risks associated with autonomic neuropathy. This is recognized not only for diabetes, but for many chronic diseases, especially those for which adrenergic or cholinergic medications are prescribed, including hypertension, depression, COPD and asthma, sleep apnea and other sleep disorders, chronic pain, orthostatic dysfunction and syncope, GI disturbance, urogenital dysfunction, hypothyroidism, and cardiovascular diseases. Longer-term patients are already demonstrating Advanced Autonomic Dysfunction (AAD) or Diabetic Autonomic Neuropathy (DAN), and Cardiovascular Autonomic Neuropathy (CAN, as defined by very low, resting parasympathetic activity). All of these diagnoses significantly benefit from parasympathetic and sympathetic (P&S) monitoring.

Contractor response: The policy clarifies the clinical validity and clinical utility of CPT Code 95943. If a physician finds that this non-standardized component information of Autonomic Function Testing (AFT) is useful in a patient assessment and clinical decision making given certain patient risks/signs/symptoms, this would be included in the physician's basic evaluation and management service and not separately covered. In addition, testing patients prior to the development of symptomatic autonomic neuropathy would be screening, and there is no such screening Medicare benefit with the absence of disease. When there is the presence of disease, for example, diabetes, screening for distal symmetric polyneuropathy (DPN) and cardiovascular autonomic neuropathy (CAN) are usually done with simple clinical tests that are considered an integral part of the evaluation and management service. In these instances, special Autonomic Function Tests are rarely needed, and there is insufficient evidence that they affect management or outcomes.

Comment #2: *CPT*® code 95943 affects more technologies than ANSAR ANX 3.0 and technologies related to ANSAR. The purpose of this code is to eliminate the need for a tilt table when doing Autonomic Function Testing. Omitting this *CPT*® code would affect patients for whom tilt-testing is either unrevealing or not yet indicated

Contractor response: As stated in contractor response to comment number one, if a physician finds that this non-standardized component information of Autonomic Function Testing is useful in a patient assessment and clinical decision making given certain patient risks/signs/symptoms, this would be included in the physician's basic evaluation and management service and not separately covered. Also, *CPT*® code 95943 was not developed and intended to be specific to any brand/manufacturer.

Comment #3: CAN, whether demonstrated by a diabetic or non-diabetic patient carries significant risk, a 50 percent increase in morbidity or mortality. A significant effect of many cardiovascular medications is to minimize the risks of CAN. CAN is demonstrated to be equivalent to traditional and nontraditional risk factors, as well as modifiable and non-modifiable risk factors. CAN risk is stratified by measures of relative sympathetic or parasympathetic activity (e.g., sympathovagal balance). CAN risk is treatable if the patient's P&S activity is properly documented. P&S Monitors most specifically and reliably documents very low parasympathetic activity in the presence of relatively high sympathetic activity. It is this combination of measures that helps to guide therapy and cardiology referrals, improving outcomes.

Contractor response: The clinical validity and clinical utility of these special testing technologies have not been established. The American Diabetes Association (2010) recommendations on neuropathy screening and treatment state: Screening for signs and symptoms of cardiovascular autonomic neuropathy should be instituted at diagnosis of type two diabetes and five years after the diagnosis of type one diabetes. Special testing is rarely needed and may not affect management or outcomes.

Comment #4: Regarding dizziness and lightheadedness, often a tilt-test is unrevealing, especially for vasovagal and neurogenic syncope, or orthostatic dysfunction with vagal complications. In effect, the tilt table becomes a sympathetic challenge, negating the abnormal parasympathetic response we need to document, resulting in a negative tilt-test. Yet the patients remain symptomatic. Furthermore, there is a significant number of patients who are both dizzy and hypertensive. These patients are difficult because they complain that their anti-hypertensive causes more dizziness and often their therapy for the dizziness causes higher blood pressure. In many of these patients, an underlying P or S dysfunction is documented, providing guidance as to the primary dysfunction, which when treated relieves both the dizziness and hypertension. P&S Monitoring without the need for tilt more reliably documents and differentiates these patients for improved management and outcomes, reduced hospitalizations from complications due to falling, and ultimately reduced cost.

Contractor response: As stated in contractor response to comment number one, if a physician finds that this non-standardized component information of Autonomic Function Testing is useful in a patient assessment and clinical decision making given certain patient risks/signs/symptoms, this would be included in the physician's basic evaluation and management service and not separately covered.

Comment #5: Assuming that the proposed draft is in response to concerns about the abuse of autonomic billing codes, certain stakeholders share the concern that over-utilization of autonomic billing codes may be occurring with the use of several devices on the market that claim to perform complete autonomic assessment in 10-15 minutes. However, such devices have not been scientifically validated and may provide misleading or erroneous results, particularly when they do not include beat-to-beat blood pressure monitoring and at least five minutes of tilt table testing. A related concern is that such devices are being marketed for use by physicians who do not have training in autonomic testing. By contrast, the CPT® codes for autonomic testing (95921, 95922, 95923) were designed for careful, detailed autonomic nervous system testing under controlled conditions. Such studies typically take about two hours to perform.

Contractor response: Thank you for your comments. Your concern is acknowledged regarding the inappropriate marketing for use by physicians who do not have appropriate training in autonomic testing.

Comment # 6 : Diabetics need to have their ANS (Autonomic Nervous System) tested, Medical Associations list ANS testing as part of their clinical guidelines.

Contractor response: We concur with the American Diabetes Association (ADA) that autonomic disorder special testing is rarely needed and may not affect management or outcomes. AFT could have clinical utility when used as a diagnostic tool to evaluate symptoms indicative of vasomotor instability, such as hypotension, orthostatic tachycardia, and hyperhidrosis after more common causes have been excluded by other testing. After reviewing the literature, it is this contractor's determination that there is a paucity of evidence documenting how special autonomic tests change management or impact treatment in clinical disorders associated with autonomic nervous systems dysfunction. The contractor also agrees with the ADA (2010) recommendations on neuropathy screening and treatment which state: All patients should be screened for distal symmetric polyneuropathy (DPN) at diagnosis and at least annually thereafter using simple clinical tests.

Comment #7: P&S Monitoring provides additional insight into patients with difficult to control BP and pulmonary hypertension. With P&S monitoring, patients are treated on a more individualized basis to stabilize them, which enables a more aggressive approach to the remaining hypertension. Many patients present with sleep apnea, which is associated with a state of marked sympathetic excess leading to many of the comorbidities associated with this condition. Even in highly-compliant patients, CPAP does not always sufficiently reduce sympathetic levels to where they are not contributing to mortality and morbidity risk. P&S monitoring, and its ability to reliably differentiate parasympathetic from sympathetic activity, provides the additional information needed to truly assess the individual patient's responses to CPAP and disease, and properly reduce their risk, improving outcomes and reducing hospitalization.

Contractor response: There is insufficient evidence that parasympathetic and sympathetic monitoring affect management or outcomes. The clinical validity and clinical utility of testing technologies used for P&S monitoring has not been established.

Comment #8: Patients with orthostatic dizziness may have autonomic dysfunction, and the diagnosis cannot be made on the basis of symptoms alone but requires objective autonomic testing to yield a valid diagnosis. Once a diagnosis is established, an appropriate course of treatment can be determined. The results of autonomic testing are essential to establishing whether medication is indicated, which type, and at what dose. Successful treatment of orthostatic hypotension can substantially improve the patient's quality of life and reduce impairment in activities of daily living.

Contractor response: Please see comment responses to numbers one and two.

Comment #9: The code 95924 is not mentioned in the upper "coverage guidance" part of the document and only shows up at the end of the document. Since the providers doing autonomic testing may not be fully familiar with that combined testing code I suggest discussion of 95924 be moved up into the "Coverage Guidance" section.

Contractor response: WPS appreciates your comment but after reviewing the LCD, we determined the coverage of CPT Code 95924 is best explained under Utilization Guidelines.

Comment #10: Reimbursement is lowered by one third, and then excessive documentation is requested to demonstrate the necessity for the testing. The ANSAR ANS testing of the individual P&S responses helps us to detect and confirm diagnosis of autonomic imbalance associated with cardiovascular risks. We ask you to please keep this diagnostic tool in our "tool belt" to best serve our patients.

Contractor response: This is a coverage decision; the contractor is not addressing pricing at this time. CPT® code 95943 and related technologies are not medically reasonable and necessary since the clinical validity and clinical utility of these technologies have not been established, and it is not proven how these tests affect management or outcomes. Providers have available other medically appropriate testing

alternatives. The contractor considers reasonable to request, when necessary, information on the equipment used to perform ANS studies to ensure all studies performed meet the requirements of the procedure. Also, it considers that it's not excessive to require that the medical record documentation maintained by the performing provider must clearly support the medical necessity for ANS testing, as well as, the test reports and interpretation. Supportive documentation showing medically reasonable and necessary indications as outlined in this LCD are expected to be documented in the medical record and be available upon request. This documentation includes, but is not limited to, relevant medical history, physical examination, results of pertinent diagnostic tests or procedures. All of this is considered standard medical record documentation.

Comment #11: Regarding the sentence; "Testing performed by physicians who do not have evidence of training." I think that that training should be defined and how much training do they need. I think that what specifically should be required should be listed.

Contractor response: Thank you for your comment, our final LCD will have more specific provider educational requirements outlined.

Comment #12: Regarding the sentence; "Not endorsed by the United States." Do we ever consider the European Union?

Contractor response: Although we do read articles from outside the United States, only those "endorsed" in the United States are considered relevant for policy decision making.

Comment #13: Regarding the sentence; "Providers who perform these tests on an unusually high proportion of patients will be likely reviewed." Why is that? Some people would – if they needed to, refer to specialists, who in turn would see more patients.

Contractor response: Based on the data collected, we have determined that some non-specialty providers have had a high utilization of Autonomic Function Testing claims.