The autonomic nervous system (ANS) controls physiologic processes that are not under conscious control. ANS testing consists of a battery of individual tests that are intended to evaluate the integrity and function of the ANS. These tests are intended to be adjuncts to the clinical examination in the diagnosis of ANS disorders.

The evidence base on the diagnostic accuracy of ANS testing, and the impact on health outcomes, is incomplete. There is a lack of a criterion standard for determining autonomic dysfunction, which limits the ability to perform high-quality research on diagnostic accuracy. Also, there are numerous different tests that are used in a variety of different conditions, making it difficult to determine values for overall diagnostic accuracy of a battery of tests. The evidence on reliability of individual tests raises concerns about the reproducibility of testing. Scattered reports of diagnostic accuracy are available for certain individual tests, most commonly in the diabetic population, but this does not provide estimates of accuracy for the entire battery of tests. Reported sensitivities and specificities were high for patients with clinically defined distal symmetric polyneuropathy using a symptom-based score as a reference standard, but these estimates are likely biased by the study designs that use patients with clinically diagnosed disease and a control group of healthy volunteers.

There are also few clinical practice guidelines from specialty societies, and the available recommendations are primarily based on expert opinion. The guidelines give general recommendations for testing as an adjunct to clinical examination for the diagnosis of autonomic disorders.

Despite the deficiencies in the evidence base, these tests provide information that cannot be obtained by other methods. Given the limitations of clinical examination, it is likely that ANS testing adds incremental information on the likelihood of an ANS disorder in patients with signs and symptoms of ANS dysfunction. Improved ability to make a diagnosis will lead to management changes that are likely to improve outcomes in some patients, and in others may end the need for further diagnostic testing. In addition, expert opinion strongly supports the use of ANS testing as a diagnostic aid in situations of suspected ANS disorders.

ANS testing should be performed in the setting of a dedicated ANS testing laboratory. Testing in a dedicated laboratory can be performed under closely controlled conditions, and interpretation of the
results performed by an individual with expertise in ANS testing. Portable, automated testing that is intended for office use has not been validated and has a greater potential to lead to erroneous results.

Therefore, based on the available evidence and clinical input, ANS testing in a dedicated ANS testing laboratory may be considered to be medically necessary in patients with signs and symptoms of autonomic dysfunction when criteria are met. ANS testing using portable, automated devices is considered not medically necessary.

Related Policies

None

Policy

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Autonomic nervous system testing, consisting of a battery of tests in several domains (see Policy Guidelines section) may be considered medically necessary when the following criteria are met:

- Signs and/or symptoms of autonomic dysfunction are present; AND
- A definitive diagnosis cannot be made from clinical examination and routine laboratory testing alone; AND
- Diagnosis of the suspected autonomic disorder will lead to a change in management or will eliminate the need for further testing.

Autonomic nervous system testing is considered not medically necessary in all other situations when criteria are not met, including but not limited to the evaluation of the following conditions:

- chronic fatigue syndrome
- fibromyalgia
- anxiety and other psychological disorders
- sleep apnea
- allergic conditions
- hypertension
- screening of asymptomatic individuals
- monitoring progression of disease or response to treatment.

Autonomic nervous system testing using portable automated devices is considered not medically necessary for all indications (see Policy Guidelines section).

Policy Guidelines

Although there is not a standard battery of tests that are part of ANS testing, a full battery of testing generally consists of individual tests in 3 domains.
• Cardiovagal function (heart rate [HR] variability, HR response to deep breathing and Valsalva)
• Vasomotor adrenergic function (blood pressure [BP] response to standing, Valsalva, and hand grip, tilt table testing)
• Sudomotor function (QSART, QST, TST, silastic sweat test)

At least 1 test in each category is usually performed. More than 1 test from a category will often be included in a battery of tests, but the incremental value of using multiple tests in 1 domain is not known.

There is little evidence on the comparative accuracy of different ANS tests, but the following tests are generally considered to have uncertain value in ANS testing:

• Pupillography
• Pupil edge light cycle
• Gastric emptying tests
• Cold pressor test
• QDIRT test
• Plasma catecholamine levels
• Skin vasomotor testing
• The ANSAR® test

Autonomic nervous system should be performed in a dedicated autonomic nervous system testing laboratory. Testing in a dedicated laboratory should be performed under closely controlled conditions, and interpretation of the results should be performed by an individual with expertise in autonomic nervous system testing. Testing using automated devices with interpretation of the results performed by computer software has not been validated and thus has the potential to lead to erroneous results.¹

**Background**

The ANS has a primary role in controlling physiologic processes that are not generally under conscious control. These include heart rate, respirations, gastrointestinal motility, thermal regulation, bladder control, and sexual function.² It is a complex neural regulatory network that consist of 2 complementary systems that work together to maintain homeostasis. The sympathetic nervous system is responsible for arousal, and sympathetic stimulation leads to increased pulse, increased BP, increased sweating, decreased gastrointestinal [GI] motility and an increase on other glandular exocrine secretions. This is typically understood as the “fight or flight” response. Activation of the parasympathetic nervous system will mostly have the opposite effects. BP and pulse will decrease, GI motility increases, and there will be a decrease in sweating and other glandular secretions.

**ANS Disorders**

ANS disorders, also called dysautonomias, are heterogeneous in etiology, clinical symptoms, and severity. ANS disorders can be limited and focal, such as patients with isolated neurocardiogenic
symptoms of autonomic disorders can be varied, based on the etiology and location of dysfunction. Cardiovascular manifestations are often prominent. involvement of the cardiovascular system causes abnormalities in heart rate control and vascular dynamics.\footnote{\textit{Orthostatic} hypotension and other manifestations of BP lability can occur, causing weakness, dizziness, and syncope. Resting tachycardia and an inability to appropriately increase heart rate in response to exertion leads to exercise intolerance. There is an approximately 2- to 3-fold higher incidence of major cardiac events in patients with diabetic autonomic neuropathy (myocardial infarction, heart failure, resuscitation from ventricular arrhythmia, angina, or the need for revascularization).\footnote{There is also an increase in cardiac sudden death and overall mortality for these patients.}} Many other organ systems can be affected by autonomic neuropathy. Involvement of the bladder can lead to incomplete emptying, resulting in urinary retention and possible overflow incontinence. GI involvement is commonly manifested as gastroparesis, which is defined as slowed gastric emptying, and can cause nausea, vomiting, and a decreased tolerance for solid food and large meals. Constipation may also occur if the lower GI tract is involved. Impairment of sexual function in males can manifest as erectile dysfunction and ejaculatory failure. Dysfunction of thermal regulation and sweating can lead to anhidrosis and heat intolerance. Paradoxically, excessive sweating can also occur as a compensatory mechanism in unaffected regions.\footnote{A classification of the different types of autonomic dysfunction, adapted from Freeman et al\cite{Freeman2007} and Macdougall et al,\cite{Macdougall2010} can be made as follows:}

- Diabetic autonomic neuropathy
- Amyloid neuropathy
- Immune-mediated neuropathy
  - Rheumatoid arthritis
  - Systemic lupus erythematosus
  - Sjögren syndrome
- Paraneoplastic neuropathy
- Inflammatory neuropathy
  - Guillain-Barré syndrome
  - Chronic inflammatory demyelinating polyneuropathy
  - Crohn disease
  - Ulcerative colitis
- Hereditary autonomic neuropathies
- Autonomic neuropathy secondary to infectious disease
  - HIV disease
  - Lyme disease
A variety of other chronic diseases may involve an imbalance of the ANS, without outright dysfunction of the nerves themselves. Approximately 40% of individuals with essential hypertension will show evidence of excess sympathetic activity. Sympathetic over activity is also a prominent feature of generalized anxiety, panic disorder, and some types of depression, as well as certain cardiac disorders such as chronic heart failure. These types of ANS imbalances are not usually classified as ANS disorders.

Much of the treatment of autonomic disorders is nonpharmacologic and supportive. However there are specific actions that can be taken to improve symptoms in patients with specific deficits. For patients with orthostatic hypotension, this involves adequate intake of fluids and salt, moving to an upright position slowly and deliberately, use of lower extremity compression stockings, and keeping the head of the bed elevated 4 to 6 inches. In severe cases, treatment with medications that promote salt retention, such as fludrocortisone, is often prescribed. Patients with symptoms of hyperhidrosis may benefit from cooling devices and potent antiperspirants such as drysol, and patients with decreased tearing and dry mucous membranes can use over the counter artificial tears or other artificial moisturizers.

**ANS Testing**

ANS testing consists of a battery of individual tests. Any 1 test may be performed individually, or the entire battery of tests may be ordered. Individual components of testing may include:

- **Cardiovagal function testing**
  - **Heart rate variability.** Beat-to-beat variability in the heart rate can be measured at rest, or in response to provocative measures, such as deep breathing or the Valsalva maneuver. Reduced, or absent, heart rate variability (HRV) is a sign of autonomic dysfunction.
  - **Baroreflex sensitivity.** Baroreflex sensitivity is measured by examining the change in pulse and HRV in response to changes in BP. A medication such as phenylephrine is given to induce a raise in blood pressure, and baroreflex sensitivity is calculated as the slope of the relationship between HRV and BP.

- **Sudomotor function (sweat testing).** Sweat testing evaluates the structure and function of nerves that regulate the sweat glands.
  - **QSART test.** The Quantitative Sudomotor Axon Reflex Test (QSART) is an example of a semiquantitative test of sudomotor function that is commercially available. The test is performed by placing a color sensitive paper on the skin, which changes color on contact with sweat. Measurement of the amount of color change is a semiquantitative measure of sudomotor function.
Silastic Sweat test. In this test, a silastic material is placed on the skin, and the sweat droplets form indentations on the silastic surface, allowing quantitation of the degree of sweating present. The Neuropad® test is an example of a commercially available silastic sweat test.

Thermoregulatory Sweat test. A more complex approach in some centers is the use of a thermoregulatory laboratory. This is a closed chamber in which an individual sits for a defined period of time under tightly controlled temperature and humidity. An indicator dye is brushed on the skin, which changes color when in contact with sweat. Digital pictures are taken and projected onto anatomic diagrams. Computer processing derives values for total area of anhidrosis, and the percent of anhidrotic areas.

Sympathetic skin response. These tests use an electric current to stimulate sympathetic nerves. The tests measure the change in electrical resistance, which is altered in the presence of sweat. In general these tests are considered to be sensitive, but have high variability and the potential for false-positive results.

- A variant of sympathetic skin response testing is electrochemical sweat conductance measured by iontophoresis (eg, Sudoscan®). In this test, a low level current is used to attract chloride ions from sweat glands. The chloride ions interact with stainless-steel plate electrodes to measure electrochemical resistance.

Salivation test. The protocol for this test involves the subject chewing on a preweighed gauze for 5 minutes. At the end of 5 minutes, the gauze is removed and reweighed to determine the total weight of saliva present.

Tilt table testing. Tilt table testing is intended to evaluate for orthostatic intolerance. The patient lies on the table and is strapped in with a foot rest. The table is then inclined to the upright position, with monitoring of the pulse and BP. Symptoms of lightheadedness or syncope in conjunction with changes in pulse or BP constitute a positive test. A provocative medication, such as isoproterenol can be given to increase the sensitivity of the test.

Composite Autonomic Severity Score

This is a composite score ranging from 0 to 10 that is intended to estimate severity of autonomic dysfunction. Scores are based on self-reported symptoms measured by a standardized symptom survey. Scores of 3 or less are considered mild, scores of 3 to 7 are considered moderate, and scores greater than 7 are considered severe.

Regulatory Status

Numerous ANS testing devices have been approved since 1976. A hydraulic, pneumatic, or photoelectric plethysmograph is a noninvasive device to estimate blood flow to a region of the body using hydraulic, pneumatic, or photoelectric measurement techniques. The ANX 3.0® system (Ansar Group) measures both branches of the ANS (sympathetic and parasympathetic) independently and simultaneously in real time. The ANX 3.0 performs respiratory-based digital testing of the ANS and heart rate variability measurements. FDA approval for the ANX 3.0 was received in 2004. The most
recent (2013) FDA 510(k) approvals of ANS measurement devices are the Bodytronic® 200 (Bauerfeind AG) and the Dopplex Ability® (Huntleigh Healthcare). FDA product code: JOM.

**Rationale**

Assessment of a diagnostic technology typically focuses on 3 categories of evidence: (1) technical performance (test-retest reliability or interrater reliability); (2) diagnostic accuracy (sensitivity, specificity, and positive and negative predictive value) in relevant populations of patients; and (3) demonstration that the diagnostic information can be used to improve patient outcomes. In addition, subsequent use of a technology outside of the investigational setting may also be evaluated. These categories of evidence, although not always evaluated in sequence, can be considered similar to the 4 phases of therapeutic studies.

**Technical Performance**

Autonomic nervous system (ANS) testing is essentially the only laboratory method available to evaluate dysfunction of the ANS. Because of the lack of a true criterion standard of autonomic dysfunction, the validity of results of ANS testing cannot be determined.

Some evidence was identified about the reliability of ANS testing, particularly for heart rate variability (HRV). A number of studies have reported that the test-retest reliability of ANS is high over short periods of time, but reliability over longer time periods is less certain. A systematic review of published studies on the reliability of HRV was published in 2005. The author identified 8 studies (183 individuals) that reported on the reliability of short-term recordings (ie, excluding studies that used 24-hour monitoring). Four studies included healthy patients, 3 included patients with cardiac disease, and 1 included both healthy and cardiac patients. Studies used different measures of HRV, and the authors performed a qualitative synthesis of the results. For 3 of the 5 studies that included healthy individuals, the reliability was high, with coefficients of variation (CV) ranging from 6% to 15%. However, in 2 studies the CV was much higher, 20% in one and 45% in the other. For patients with cardiac disease, the reliability was lower, with CVs being higher and reaching 100% in 1 study.

Less evidence was available for other specific tests. For sudomotor testing, 2 small studies of reliability were identified. Berger et al evaluated the reliability of the Quantitative Sudomotor Axon Reflex Test (QSART) measure in 20 healthy individuals. They reported intraclass correlation coefficients (ICCs) at 3 different body sites ranging from 0.49 to 0.75 indicating moderate reliability, and standard error of measurements ranging from 0.273 to 0.978 indicating large standard errors. Peltier et al evaluated both QSART and the Quantitative Sensory Test (QST) measures in 23 patients with impaired glucose regulation and neuropathy. The ICCs were high for both measures, ranging from 0.52 to 0.80. The QST measure was more reliable (ICC range, 0.75-0.80) than the QSART (ICC=0.52) indicating suboptimal reliability.

Some studies have evaluated the reproducibility of tilt testing, usually by repeating the study in patients with an initial positive test. An example of this type of study was published by Kochiadakis et al in 1998. This study evaluated 35 patients with syncope and a positive tilt table test with a repeat tilt table test. The study also included a comparison group of 15 healthy volunteers who underwent 2 tilt table tests. In conjunction with tilt table testing the study also recorded HRV. A total of 21 of the 35 patients
(60%) had a second positive test, while none of the healthy controls had any positive test. HRV results showed that high parasympathetic predicted a second positive test.

**Section Summary**

The main evidence on the technical performance of ANS testing is on the reliability of some individual tests, mostly test-retest reproducibility. The available evidence is incomplete, and there is a lack of high-quality studies reporting on reliability. The research that is available is variable, but in most cases does not show high reproducibility. Therefore, there is a concern that these tests are not reliable, although further research is needed to evaluate this with more certainty.

**Diagnostic Accuracy**

There are a number of challenges in evaluating the diagnostic accuracy of ANS testing:

- There is a lack of a true criterion standard for determining autonomic dysfunction. Comparisons to imperfect criterion standards, such as clinical examination or nerve conduction studies, may lead to biased estimates of accuracy.
- Most of the ANS is inaccessible to testing, and the available tests are measures of end-organ response rather than direct measures of ANS function.
- There are numerous individual tests of ANS function, and a combination of these is typically used in ANS testing. Diagnostic accuracy could be reported for each individual test or for the package of testing performed.
- Different types of equipment may be used for testing, and the accuracy of different systems may vary.

Scattered reports of diagnostic accuracy for specific tests in specific patient groups were available, but high-quality research on the diagnostic accuracy of testing is lacking. The most rigorous evaluation of diagnostic accuracy identified was in the systematic review by the American Academy of Neurology (AAN), the American Association of Neuromuscular and Electrodiagnostic Medicine (AANEM), and the American Academy of Physical Medicine and Rehabilitation (AAPM&R), which focused on the accuracy of autonomic testing for distal symmetric polyneuropathy. Scattered reports of diagnostic accuracy for specific tests in specific patient groups were available, but high-quality research on the diagnostic accuracy of testing is lacking. The most rigorous evaluation of diagnostic accuracy identified was in the systematic review by the American Academy of Neurology (AAN), the American Association of Neuromuscular and Electrodiagnostic Medicine (AANEM), and the American Academy of Physical Medicine and Rehabilitation (AAPM&R), which focused on the accuracy of autonomic testing for distal symmetric polyneuropathy.8 Table 1 summarizes the results on diagnostic accuracy from this study. While reported sensitivity and specificity are high, the populations in these studies include patients with known disease and healthy volunteers. These populations are not optimal for determining diagnostic accuracy and are known to lead to inflated estimates of both sensitivity and specificity.

**Table 1. Diagnostic Accuracy of Autonomic Nervous System Testing for the Diagnosis of Distal Symmetric Polyneuropathy (Adapted from AAN Practice Parameters 2013)***

<table>
<thead>
<tr>
<th>Study/Year</th>
<th>Disorder Studied</th>
<th>Test(s) Used</th>
<th>Reference Standard</th>
<th>N</th>
<th>Sensitivity, %</th>
<th>Specificity, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stewart (1992)</td>
<td>DSNF</td>
<td>HRV, QST, QSART</td>
<td>Clinical exam EDx studies</td>
<td>169</td>
<td>80</td>
<td>72</td>
</tr>
<tr>
<td>Dyck (1992)</td>
<td>Diabetic polyneuropathy</td>
<td>QAE</td>
<td>EDx studies</td>
<td>737</td>
<td>97</td>
<td>&gt;90</td>
</tr>
</tbody>
</table>
Low (1997) Parkinson, multisystem atrophy QSART Older scale for autonomic neuropathy 575 >90 >90
Tobin (1999) DSFN Clinical sx, QSART, QST EDx studies 495 80 (QSART) 67 (QST) 93
Novak (2001) Painful neuropathy QSART, ART CASS Clinical exam 483 93 (ART) 73 (QSART) 94
Low (1993) Diabetic polyneuropathy CASS Clinical exam EDx studies 428 >90% >90
Schrezenmaier (2007) Adrenergic failure BRSI MSNA 113 86 >90
Vogel (2005) Polyneuropathy, multisystem atrophy PRT, CASS Clinical exam 194 >90 >90
Singer (2004) DSFN, diabetic and idiopathic neuropathy CASS Neurologic exam 49 95 90

ART: autonomic reflex testing; BRSI: baroreflex sensitivity index; CASS: composite autonomic severity score; DSFN: distal small fiber neuropathy; EDx: electrodiagnostic studies (electromyography/nerve conduction velocity); HRV: heart rate variability; MSNA: muscle sympathetic nerve activity; PRT: BP recovery time; QAE: quantitative autonomic evaluation; QSART: quantitative sudomotor axon reflex testing; QST: quantitative sensory testing; sx: symptoms.

Evidence on the sensitivity and specificity of a silastic sweat testing device, the Neuropad® device (Crawford Healthcare, Knutsford Cheshire, UK) was identified. Kamenov et al enrolled 264 inpatients with diabetes. Patients with autonomic neuropathy were identified by the Neuropathy Disability Score, with a cutoff of 5 indicating autonomic neuropathy. An abnormal silastic sweat test had a sensitivity of 76%, a specificity of 56%, and a positive predictive value of 86% and a negative predictive value of 40%. In a similar study, Quattrini et al evaluated 57 diabetic patients with several autonomic tests, including the Neuropad® device. The sensitivity of silastic sweat testing in this study was 85%, the specificity was 45%, the positive predictive value was 69% and the negative predictive value was 71%.

A 2013 publication by Casselini et al evaluated the accuracy of an electrochemical sweat conductance test, compared with other available tests of sudomotor function. This study evaluated 83 patients with DM (60 with peripheral neuropathy, 20 without peripheral neuropathy) and 210 normal controls with the Sudoscan test. Electrochemical skin conductance of the feet was lowest for patients with DM and neuropathy (56.3±3), intermediate for patients with DM without neuropathy (75.9±5.5) and highest for normal volunteers (84.4±0.9, p<0.001 for group differences). Using clinically defined neuropathy as the gold standard, sensitivity was 78% and specificity was 92%. Results of the test correlated significantly with a number of other measures, including symptom scores, QST, and measures of HRV. The correlations were in the low-to-moderate range with Spearman’s p ranging from 0.24 to 0.47.

Section Summary

It is not possible to determine the diagnostic accuracy of ANS testing. The lack of a criterion standard makes it difficult to perform high-quality research in this area. The available research reports sensitivity in patients with clinically defined disease, and specificity in health volunteers. This type of study design
is known to produce inflated estimates of sensitivity and specificity; therefore, the results of these studies probably do not reflect the diagnostic accuracy of testing in clinical practice.

Impact on Health Outcomes

Use of autonomic testing will improve outcomes if the test has incremental diagnostic accuracy over clinical exam alone, and if establishing the diagnosis leads to changes in management that improves outcomes. There is a lack of direct evidence on the impact of autonomic testing on changes in management or health outcomes. It is likely that these tests provide information beyond that obtainable from the clinical exam alone, given the limitations of physical exam for assessing physiologic processes. Some autonomic disorders have specific treatments, such as medications to retain salt and preserve hydration status. In other cases, the use of autonomic testing may limit the need for further diagnostic testing, when symptoms are possibly autonomic related, but may be due to other pathology as well. In those cases, determining that autonomic dysfunction is the cause of symptoms may end the need for further testing.

Evaluation of Clinical Practice Guidelines

This section will evaluate the existing clinical practice guidelines, with a focus on whether they are evidence-based. The consistency of recommendations will also be considered. In cases where guidelines differ from each other, the ones which are more evidence-based will be favored.

For autonomic testing in general, there are few guidelines that focus on indications for testing. The guidelines that do exist restrict their recommendations to specific diagnoses.

A single evidence-based guideline was identified. This document addressed the use of autonomic testing in the evaluation of patients with distal symmetric polyneuropathy, developed jointly by American Academy of Neurology (AAN), American Association of Neuromuscular and Electrodiagnostic Medicine (AANEM), and American Academy of Physical Medicine and Rehabilitation (AAPM&R). The societies convened a Polyneuropathy Task Force, consisting of 19 physician representatives from the 3 societies. All had expertise in polyneuropathy, in addition, 4 had expertise in evidence-based methodology and practice parameter development. The taskforce developed a set of questions, and subcommittees were formed to address each question.

Each subcommittee performed a systematic review of the literature on their specific question. The subcommittee members determined whether articles were potentially relevant to the evaluation of polyneuropathy. For each included article, 3 physicians reviewed independently for risk of bias, disagreements were resolved by discussion. The strength of recommendations and levels of evidence were taken from existing procedures used by AAN.

Section Summary

There is a lack of evidence-based guidelines on ANS testing. Even in guidelines that involve a systematic review of the literature, such as the joint AAN/AANEM/AAPM&R guidelines previously discussed, the recommendations are largely based on expert consensus.
Summary of Evidence

The evidence base on the diagnostic accuracy of autonomic nervous system (ANS) testing, and the impact on health outcomes, is incomplete. There is a lack of a criterion standard for determining autonomic dysfunction, which limits the ability to perform high-quality research on diagnostic accuracy. Also, there are numerous different tests that are used in a variety of different conditions, making it difficult to determine values for overall diagnostic accuracy of a battery of tests. The evidence on reliability of individual tests raises concerns about the reproducibility of testing. Scattered reports of diagnostic accuracy are available for certain individual tests, most commonly in the diabetic population, but this does not provide estimates of accuracy for the entire battery of tests. Reported sensitivities and specificities were high for patients with clinically defined distal symmetric polyneuropathy using a symptom based score as a reference standard, but these estimates are likely biased by the study designs that use patients with clinically diagnosed disease and a control group of healthy volunteers.

There are also few clinical practice guidelines from specialty societies, and the available recommendations are based primarily on expert opinion. The guidelines give general recommendations for testing as an adjunct to clinical examination for the diagnosis of autonomic disorders.

Despite the deficiencies in the evidence base, these tests provide information that cannot be obtained by other methods. Given the limitations of clinical examination, it is likely that ANS testing adds incremental information on the likelihood of an ANS disorder in patients with signs and symptoms of ANS dysfunction. Improved ability to make a diagnosis will lead to management changes that are likely to improve outcomes in some patients, and in others may end the need for further diagnostic testing. In addition, expert opinion strongly supports the use of ANS testing as a diagnostic aid in situations of suspected ANS disorders.

ANS testing should be performed in the setting of a dedicated ANS testing laboratory. Testing in a dedicated laboratory can be performed under closely controlled conditions, and interpretation of the results performed by an individual with expertise in ANS testing. Portable, automated testing that is intended for office use has not been validated and has a greater potential to lead to erroneous results. Therefore, based on the available evidence and clinical input, ANS testing in a dedicated ANS testing laboratory may be considered to be medically necessary in patients with signs and symptoms of autonomic dysfunction when criteria are met. ANS testing using portable, automated devices is considered not medically necessary.

Supplemental Information

Practice Guidelines and Position Statements

The American Academy of Neurology, American Association of Neuromuscular and Electrodiagnostic Medicine, and the American Academy of Physical Medicine and Rehabilitation issued a 2009 practice parameter, which were reaffirmed in July of 2013 on the evaluation of distal symmetric polyneuropathy. The following conclusion and recommendation was made: “Autonomic testing is probably useful in documenting autonomic nervous system involvement in polyneuropathy (class II and III). The sensitivity and specificity vary with the particular test. The utilization of the combination of
Autonomic reflex screening tests in the CASS probably provides the highest sensitivity and specificity for documenting autonomic dysfunction (class II). Autonomic testing should be considered in the evaluation of patients with polyneuropathy to document autonomic nervous system involvement (level B). Autonomic testing should be considered in the evaluation of patients with suspected autonomic neuropathies (level B) and may be considered in the evaluation of patients with suspected distal SFSN (level C). The combination of autonomic screening tests in the CASS should be considered to achieve the highest diagnostic accuracy (level B).

The American Diabetes Association published standards of care for treatment in diabetes in 2010.\textsuperscript{18} This document contained the following statement about autonomic neuropathy in diabetes:

- Screening for signs and symptoms of cardiovascular autonomic neuropathy should be instituted at diagnosis of type 2 diabetes and 5 years after the diagnosis of type 1 diabetes. Special testing is rarely needed and may not affect management or outcome (Expert opinion).
- Medications for the relief of specific symptoms related to DPN and autonomic neuropathy are recommended, as they improve the quality of life of the patient (Expert opinion)

The European Federation of Neurological Societies issued a 2011 revision of their guideline on orthostatic hypotension.\textsuperscript{19} The guideline made a level C recommendation stating that ANS screening tests with other appropriate investigations, should be considered depending on the possible etiology of the underlying disorder.

**U.S. Preventive Services Task Force Recommendations**

Autonomic nervous system testing is not a preventive service.

**Medicare National Coverage**

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

**References**


Autonomic Nervous System Testing

Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Reason</th>
</tr>
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<tr>
<td>March 2015</td>
<td>New Policy—Add to Medicine section</td>
<td>Policy created with literature review through July 24, 2014; clinical input reviewed. Autonomic nervous system (ANS) testing may be considered medically necessary when criteria are met. ANS testing using portable, automated devices is considered not medically necessary.</td>
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This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 20, 2015 and is effective April 15, 2015.

Signature on file

Deborah M. Smith, MD, MPH