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L33609

Contractor Name
First Coast Service Options, Inc.

Contractor Number
09101 - Florida
09201 – Puerto Rico/Virgin Islands
09102 – Florida
09202 – Puerto Rico
09302 – Virgin Islands

Contractor Type
MAC – Part A and B

LCD Title
Autonomic Function Tests

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Unless otherwise specified, italicized text represents quotation from one or more of the following CMS sources:

CMS Manual System, Pub. 100-02, Medicare Benefit Policy, Chapter 15, Section 80.

Primary Geographic Jurisdiction
The autonomic nervous system (ANS) is a regulatory branch of both the central and peripheral nervous system, which controls and regulates the autonomic functions within the body through sympathetic and parasympathetic nerves. These functions include regulation of blood pressure, heart rate, airway size and airflow to the lungs, digestive tract functions, sweat production, bladder control, and sexual function. The ANS acts through a balance of its own two components, the sympathetic and parasympathetic nervous systems. Autonomic failure consists of impaired or absent function of autonomic responses, which may be sympathetic or parasympathetic or both and can involve specific organ systems or can be generalized. There are other autonomic disorders that consist of excessive function of autonomic responses. The concept of an imbalance between opposing autonomic systems is applicable to some disorders, such as some cardiac arrhythmias, but not in all autonomic disorders. Autonomic disorders may be congenital or acquired – primary or secondary. If it becomes unbalanced, a person may experience a variety of symptoms that are sometimes vague and can affect many bodily functions. To the specialist, the presentation of autonomic dysfunction can be specific and diagnosed with simple clinical tests. Autonomic testing, properly performed and interpreted, is helpful toward achieving diagnostic specificity. Autonomic failure is associated with increased morbidity and mortality. Orthostatic hypotension is associated with an increased risk of falls and impairment in activities of daily living.

ANS testing can be grouped into the following general categories:

1. **Cardiovagal innervation (CPT code 95921)** – a test that provides a standardized quantitative evaluation of vagal innervation to parasympathetic function of the heart. Responses are based on the interpretation of changes in continuous heart recordings in response to standardized maneuvers and include heart rate response to deep breathing, Valsalva ratio, and 30:15 ratio heart rate responses to standing.

2. **Vasomotor adrenergic innervation (CPT code 95922)** – evaluates adrenergic innervation of the circulation and of the heart in autonomic failure. The following tests are included: beat-to-beat blood pressure and R-R interval response to Valsalva maneuver, sustained hand grip, and blood pressure and heart rate responses to tilt-up or active standing.

3. **Sudomotor (CPT code 95923)** – function testing is used to evaluate and document neuropathic disturbances that may be associated with pain. The quantitative sudomotor axon reflex test (QSART), thermoregulatory sweat test (TST), sympathetic skin responses, and silastic sweat imprints are tests of sympathetic cholinergic sudomotor function.
Autonomic Function Tests AB

The QSART measures axon reflex-mediated sudomotor responses quantitatively and evaluates post-ganglionic sudomotor function. Recording is usually carried out from the forearm and three lower extremity skin sites to assess the distribution of post-ganglionic deficits.

The TST evaluates the distribution of sweating by a change in color of an indicator powder. This test has a high sensitivity, and its specificity for delineating the site of lesion is greatly enhanced when used in conjunction with QSART.

Sweat imprints are formed by the secretion of active sweat glands into a plastic (silastic) imprint. The test can determine sweat gland density, a histogram of sweat droplet size and sweat volume per area.

4. Combined cardiovagal and vasomotor adrenergic innervation testing (CPT code 95924) of the autonomic nervous system is specifically of parasympathetic function and vasomotor adrenergic function using at least a 5-minute tilt with a passive tilt table.

Indications:

Appropriate application and interpretation of ANS testing requires a detailed knowledge of the testing criterion and a match between the tests of suspected clinical/functional impairment with the autonomic activity being tested. Most autonomic disorders are diagnosed clinically, with laboratory and formal diagnostic testing when ordered and performed appropriately playing both a primary diagnostic and an adjunctive or confirmatory role. Testing may also be appropriate to monitor disease progression when there is a change in clinical status or to evaluate a patient’s response to specific treatment for an autonomic disorder.

Autonomic function testing is covered as reasonable and necessary 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, and the ANS testing is directed at establishing a more accurate or definitive diagnosis or contributing to clinically useful and relevant medical decision making for one of the following indications:

1. To diagnose the presence of autonomic neuropathy in a patient with signs or symptoms suggesting a progressive autonomic neuropathy.
2. To evaluate the severity and distribution of a diagnosed progressive autonomic neuropathy.
3. To differentiate the diagnosis between certain complicated variants of syncope from other causes of loss of consciousness.
4. To evaluate inadequate response to beta blockade in vasodepressor syncope.
5. To evaluate distressing symptoms in a patient with a clinical picture suspicious for distal small fiber neuropathy in order to diagnose the condition.
6. To differentiate the cause of postural tachycardia syndrome.
7. To evaluate change in type, distribution, or severity of autonomic deficits in patients with autonomic failure.
8. To evaluate the response to treatment in patients with autonomic failure who demonstrate a change in clinical exam.
9. To diagnose axonal neuropathy or suspected autonomic neuropathy in the symptomatic patient.
10. To evaluate and treat patients with recurrent unexplained syncope to demonstrate autonomic failure, after more common causes have been excluded by other standard testing.

Equipment for Autonomic Nervous System Studies

General professional standards apply for all equipment. Unknown algorithms untested on the Medicare population in systematic trials do not constitute the professional component of diagnostic testing. Equipment with FDA clearance for heart rate variability measurements in response to paced respirations and exercises that tests only heart rate variability does not meet the full range of testing parameters required for the performance of 95921 and 95922 and does not ensure full test requirements, such as blood pressure monitoring, nor do they incorporate proper testing conditions, such as the use of a tilt table. Providers may be asked to supply information on the equipment used to perform autonomic nervous system studies to ensure that all studies performed meet the requirements of the procedure.
Limitations:

Syndromes of autonomic dysfunction for which ANS testing might add valuable clinical information are relatively rare. Generally, only after excluding more common causes of autonomic signs or symptoms (e.g., hypotension, hyperhidrosis, and orthostatic tachycardia) may formal autonomic testing be indicated to exclude or confirm autonomic disorders. The following indications are not considered medically reasonable and necessary and will not be covered:

- To screen patients without signs or symptoms of autonomic dysfunction, including patients with diabetes, hepatic or renal disease;
- Testing for the sole purpose of monitoring disease intensity or treatment efficacy in diabetes, hepatic or renal disease;
- Testing where the results are not used in clinical decision-making and patient management;
- Testing performed by physicians who do not have evidence of training, and expertise to perform and interpret these tests. Testing must be done for an accepted clinical indication by a properly trained examiner and interpreted by qualified individuals within their scope of practice (weekend courses may not demonstrate expertise). Physicians must have knowledge, training, and expertise to perform and interpret these tests, and to assess and train personnel working with them. This training and expertise must have been acquired within the framework of an accredited residency and/or fellowship program or must reflect extensive continued medical education activities. If these skills have been acquired by way of continued medical education, the courses must be comprehensive, and designated for the American Medical Association (AMA) -category I credit by an ACCME (Accreditation Council for Continuing Medical Education) or SMS (State Medical Society) accredited CME provider.

CPT code 95943, for example Ansar (ANX 3.0), is not medically reasonable and necessary since it is not proven that this type of testing is at least as beneficial as existing and available medically appropriate testing alternatives. The clinical validity and clinical utility of these technologies have not been established. The qualifications of the personnel performing the testing are not standardized. 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. When patients have significant symptoms, the primary physician should consider referring to the appropriate specialist or subspecialist for testing.

Type of Bill Code

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>012x</td>
<td>Hospital inpatient (Medicare Part B only)</td>
</tr>
<tr>
<td>013x</td>
<td>Hospital outpatient</td>
</tr>
<tr>
<td>071x</td>
<td>Clinic – rural health</td>
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<tr>
<td>085x</td>
<td>Critical access hospital</td>
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Revenue Codes

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<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>092x</td>
<td>Other Diagnostic Services – General Classification</td>
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</table>

CPT/HCPCS Codes

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>95921</td>
<td>Testing of autonomic nervous system function; cardiovagal innervation (parasympathetic function), including 2 or more of the following: heart rate response to deep breathing with recorded R-R interval, Valsalva ratio, and 30:15 ratio</td>
</tr>
<tr>
<td>95922</td>
<td>Testing of autonomic nervous system function; vasomotor adrenergic innervation (sympathetic adrenergic function), including beat-to-beat blood pressure and R-R interval changes during Valsalva maneuver and at least 5 minutes of passive tilt</td>
</tr>
<tr>
<td>95923</td>
<td>Testing of autonomic nervous system function; sudomotor, including 1 or more of the following: quantitative sudomotor axon reflex test (QSART), silastic sweat imprint, thermoregulatory sweat test, and changes in sympathetic skin potential</td>
</tr>
</tbody>
</table>
ICD-10 Codes that Support Medical Necessity

E10.40 – E10.49  Type 1 diabetes mellitus with neurological complications
E10.610  Type 1 diabetes mellitus with diabetic neuropathic arthropathy
E11.40 – E11.49  Type 2 diabetes mellitus with neurological complications
E11.610  Type 2 diabetes mellitus with diabetic neuropathic arthropathy
E11.65  Type 2 diabetes mellitus with hyperglycemias
E85.0  Non-neuropathic heredofamilial amyloidosis
E85.1  Neuropathic heredofamilial amyloidosis
E85.3  Secondary systemic amyloidosis
E85.8  Other amyloidosis
G23.0  Hallervorden-Spatz disease
G23.1  Progressive supranuclear ophthalmoplegia
G23.2  Striatonigral degeneration
G60.3  Idiopathic progressive neuropathy
G60.8  Other hereditary and idiopathic neuropathies
G60.9  Hereditary and idiopathic neuropathy, unspecified
G90.09  Other idiopathic peripheral autonomic neuropathy
G90.50 – G90.59  Complex regional pain syndrome I (CRPS I)
I95.1  Orthostatic hypotension
R00.0  Tachycardia, unspecified
R55  Syncope and collapse
R61  Generalized hyperhidrosis

Diagnoses that Support Medical Necessity

N/A

ICD-10 Codes that DO NOT Support Medical Necessity

N/A

Diagnoses that DO NOT Support Medical Necessity

N/A
Associated Information

Documentation Requirements

General professional standards with FDA clearance apply for all equipment used in ANS testing. Providers may be asked to supply information on the equipment used to perform ANS studies to ensure all studies performed meet the requirements of the procedure.

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, and after more common causes of autonomic signs or symptoms have been excluded (see limitations section of LCD).

The CMS Manual System, Pub. 100-08, Program Integrity Manual, Chapter 13, Section 5.1 outlines that “reasonable and necessary” services are "ordered and/or furnished by qualified personnel."

A qualified physician for this service/procedure is defined as follows: A) Physician is properly enrolled in Medicare. B) Training and expertise must have been acquired within the framework of an accredited residency and/or fellowship program in the applicable specialty/subspecialty in the United States or must reflect equivalent education, training, and expertise endorsed by an academic institution in the United States and/or by the applicable specialty/subspecialty society in the United States.

If the provider of the ANS studies is other than the ordering/referring physician/nonphysician practitioner, the provider of the service must maintain a copy of the test results and interpretation, along with copies of the ordering/referring physician/nonphysician practitioner’s order for the studies.

Utilization Guidelines

Diagnostic testing may be allowed once to confirm or exclude specific autonomic disease. For patients with diagnosed autonomic disorders, repeat testing is governed by a change in clinical status or response to a therapeutic intervention. If a repeat test is needed, it is not expected to exceed once per year.

Providers who perform these tests on an unusually high proportion of their patients, or at frequencies exceeding once per year may be subject to medical review.

Sources of Information and Basis for Decision

FCSO reference LCD number(s) – L31461


References:


Start Date of Comment Period

N/A

End Date of Comment Period

N/A

Start Date of Notice Period

04/01/2014

Revision Number: Original

This LCD replaces all previous LCD versions (refer to “Sources of Information and Basis for Decision” section of the LCD) and publications on this subject to comply with ICD-10-CM based on Change Request 8112. The effective date of this LCD is based on date of service.