

EVIDENCE-BASED CRITERIA SECTION: MEDICINE

ORIGINAL EFFECTIVE DATE:
LAST REVIEW DATE:
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08/01/23 08/06/24 08/06/24 08/01/23

**NEXT ANNUAL REVIEW DATE: 3RD QTR 2025** 

# **AUTONOMIC NERVOUS SYSTEM TESTING**

Non-Discrimination Statement and Multi-Language Interpreter Services information are located at the end of this document.

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Evidence-Based Criteria must be read in its entirety to determine coverage eligibility, if any.

This Evidence-Based Criteria provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these quidelines.

The section identified as "<u>Description</u>" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "<u>Criteria</u>" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Evidence-Based Criteria are subject to change as new information becomes available.

For purposes of this Evidence-Based Criteria, the terms "experimental" and "investigational" are considered to be interchangeable.

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# **AUTONOMIC NERVOUS SYSTEM TESTING**

### **Description:**

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

It is likely that these tests provide information beyond that obtainable from the clinical exam alone, given the limitations of the physical exam for assessing physiologic processes.

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

Although there is no standard battery of tests for autonomic nervous system (ANS) testing, a full battery generally consists of individual tests in 3 categories.

- Cardiovagal function (heart rate variability, heart rate response to deep breathing, and Valsalva maneuver)
- Vasomotor adrenergic function (blood pressure response to standing, Valsalva maneuver, hand grip, and tilt table testing)
- Sudomotor function (Quantitative Sudomotor Axon Reflex Test, quantitative sensory test, Thermoregulatory Sweat Test, silastic sweat imprint, sympathetic skin response, and electrochemical sweat conductance).

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 a category is unknown. 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:

- The ANSAR® test
- Cold pressor test
- Gastric emptying tests
- Plasma catecholamine levels
- Pupil edge light cycle
- Pupillography
- Quantitative direct and indirect testing of sudomotor function test
- Skin vasomotor testing

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A Composite Autonomic Severity Score, which ranges from 0 to 10, can be utilized and is intended to estimate the 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.

U.S. Food and Drug Administration (FDA)-approved autonomic nervous system testing devices include, but are not limited to:

- ANX 3.0®
- Bodytronic® 200
- Finapres® Nova Noninvasive Hemodynamic Monitor
- Hrv Acquire
- Sudoscan®
- ZYTO Hand Cradle

#### Criteria:

- Autonomic nervous system testing, consisting of a battery of tests in several domains, is considered *medically necessary* with documentation of **ALL** of the following:
  - 1. Signs and/or symptoms of autonomic dysfunction are present
  - 2. A definitive diagnosis cannot be made from clinical examination and routine laboratory testing alone
  - 3. 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 for all other indications not previously listed or if above criteria not met is considered experimental or investigational when any ONE or more of the following criteria are met:
  - 1. Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or
  - 2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes; or
  - 3. Insufficient evidence to support improvement of the net health outcome; or
  - 4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, or
  - 5. Insufficient evidence to support improvement outside the investigational setting

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These indications include, but are not limited to:

- Allergic conditions
- Anxiety
- Chronic fatigue syndrome
- Fibromyalgia
- Hypertension
- Monitoring progression of disease or response to treatment
- Other psychologic disorders
- Sleep apnea
- Screening of asymptomatic individuals
- Autonomic nervous system testing using portable automated devices is considered experimental or investigational when any ONE or more of the following criteria are met:
  - 1. Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or
  - 2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes: or
  - 3. Insufficient evidence to support improvement of the net health outcome; or
  - 4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, or
  - 5. Insufficient evidence to support improvement outside the investigational setting

#### **Resources:**

Literature reviewed 08/06/24. We do not include marketing materials, poster boards and non-published literature in our review

Resources prior to 08/01/23 may be requested from the BCBSAZ Medical Policy and Technology Research Department.

- American Association of Neuromuscular & Electrodiagnostic. Proper Performance of Autonomic Function Testing: Position Statement. 2021. Accessed April 25, 2024. https://www.aanem.org/Advocacy/Position-Statements/Proper-Performance-of-Autonomic-Function-Testing
- American Association of Neuromuscular & Electrodiagnostic. Recommended Policy for Electrodiagnostic Medicine. 2023. Accessed April 25, 2024. https://www.aanem.org/Advocacy/Position-Statements/Recommended-Policy-for-Electrodiagnostic-Medicine
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- 12. Garcia-Ulloa AC, Almeda-Valdes P, Cuatecontzi-Xochitiotzi TE, et al. Detection of sudomotor alterations evaluated by Sudoscan in patients with recently diagnosed type 2 diabetes. *BMJ Open Diabetes Res Care*. Dec 2022;10(6)doi:10.1136/bmjdrc-2022-003005

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### Coding:

CPT: 95921, 95922, 95923, 95924

<u>History</u>: <u>Date</u>: <u>Activity</u>:

Medical Policy Panel08/06/24Review with revisionsMedical Policy Panel08/01/23Approved guideline

# **Policy Revisions:**

08/06/24 Updated ANS Testing types to align with alphabetical order in Description section;

U.S. Food and Drug Administration (FDA)-approved autonomic nervous system testing devices to align with alphabetical order in Description section; Investigational/experimental indications for autonomic nervous system testing to align with alphabetical order in Criteria section;

Resources section

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### **Non-Discrimination Statement:**

Blue Cross Blue Shield of Arizona (BCBSAZ) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. BCBSAZ provides appropriate free aids and services, such as qualified interpreters and written information in other formats, to people with disabilities to communicate effectively with us. BCBSAZ also provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, call (602) 864-4884 for Spanish and (877) 475-4799 for all other languages and other aids and services.

If you believe that BCBSAZ has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability or sex, you can file a grievance with: BCBSAZ's Civil Rights Coordinator, Attn: Civil Rights Coordinator, Blue Cross Blue Shield of Arizona, P.O. Box 13466, Phoenix, AZ 85002-3466, (602) 864-2288, TTY/TDD (602) 864-4823, <a href="mailto:cro@azblue.com">cro@azblue.com</a>. You can file a grievance in person or by mail or email. If you need help filing a grievance BCBSAZ's Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at <a href="https://ocrportal.hhs.gov/ocr/portal/lobby.jsf">https://ocrportal.hhs.gov/ocr/portal/lobby.jsf</a>, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1–800–368–1019, 800–537–7697 (TDD). Complaint forms are available at <a href="http://www.hhs.gov/ocr/office/file/index.html">http://www.hhs.gov/ocr/office/file/index.html</a>

### Multi-Language Interpreter Services:

Spanish: Si usted, o alguien a quien usted está ayudando, tiene preguntas acerca de Blue Cross Blue Shield of Arizona, tiene derecho a obtener ayuda e información en su idioma sin costo alguno. Para hablar con un intérprete, llame al 602-864-4884.

Navajo: Díí kwe'é atah nílínigíí Blue Cross Blue Shield of Arizona haada yit'éego bína'ídíłkidgo éí doodago Háida bíjá anilyeedígíí t'áadoo le'é yína'ídíłkidgo beehaz'áanii hólo díí t'áá hazaadk'ehjí háká a'doowołgo bee haz'ą doo bąąh ílínígóó. Ata' halne'ígíí kojí bich'í hodíilnih 877-475-4799.

Chinese: 如果您, 或是您正在協助的對象, 有關於插入項目的名稱 Blue Cross Blue Shield of Arizona 方面的問題, 您有權利免費以您的母語得到幫助和訊息。洽詢一位翻譯員, 請撥電話 在此插入數字 877-475-4799。

Vietnamese: Nếu quý vị, hay người mà quý vị đang giúp đỡ, có câu hỏi về Blue Cross Blue Shield of Arizona quý vị sẽ có quyền được giúp và có thêm thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thông dịch viên, xin gọi 877-475-4799.

#### Arabic:

إن كان لديك أو لدى شخص تساعده أسئلة بخصوص Blue Cross Blue Shield of Arizona، فلديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون اية تكلفة المتحدث مع مترجم اتصل ب .877-479-877

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### Multi-Language Interpreter Services:

Tagalog: Kung ikaw, o ang iyong tinutulangan, ay may mga katanungan tungkol sa Blue Cross Blue Shield of Arizona, may karapatan ka na makakuha ng tulong at impormasyon sa iyong wika ng walang gastos. Upang makausap ang isang tagasalin, tumawag sa 877-475-4799.

Korean: 만약 귀하 또는 귀하가 돕고 있는 어떤 사람이 Blue Cross Blue Shield of Arizona 에 관해서 질문이 있다면 귀하는 그러한 도움과 정보를 귀하의 언어로 비용 부담없이 얻을 수 있는 권리가 있습니다. 그렇게 통역사와 얘기하기 위해서는 877-475-4799 로 전화하십시오.

French: Si vous, ou quelqu'un que vous êtes en train d'aider, a des questions à propos de Blue Cross Blue Shield of Arizona, vous avez le droit d'obtenir de l'aide et l'information dans votre langue à aucun coût. Pour parler à un interprète, appelez 877-475-4799.

German: Falls Sie oder jemand, dem Sie helfen, Fragen zum Blue Cross Blue Shield of Arizona haben, haben Sie das Recht, kostenlose Hilfe und Informationen in Ihrer Sprache zu erhalten. Um mit einem Dolmetscher zu sprechen, rufen Sie bitte die Nummer 877-475-4799 an.

Russian: Если у вас или лица, которому вы помогаете, имеются вопросы по поводу Blue Cross Blue Shield of Arizona, то вы имеете право на бесплатное получение помощи и информации на вашем языке. Для разговора с переводчиком позвоните по телефону 877-475-4799.

Japanese: ご本人様、またはお客様の身の回りの方でも、Blue Cross Blue Shield of Arizona についてご質問が ございましたら、ご希望の言語でサポートを受けたり、情報を入手したりすることができます。料金はか かりません。通訳とお話される場合、877-475-4799 までお電話ください。

#### Farsi:

اگر شما، یا کسی که شما به او کمک میکنید ، سوال در مورد Blue Cross Blue Shield of Arizona ، داشته باشید حق این را دارید که کمک و اطلاعات به زبان خود را به طور رایگان دریافت نمایید 479-475-877 اتمان حاصل نمایند

#### Assyrian:

1, نسمه، برسم فلايوفاز وسودوس بمهر، نبطلومه، مصفل عومة عدم Blue Cross Blue Shield of Arizona؛ نسمه ربطلومه ومعلمه ومعطبهم، ويلامه والمعادية ومعادية و

Serbo-Croatian: Ukoliko Vi ili neko kome Vi pomažete ima pitanje o Blue Cross Blue Shield of Arizona, imate pravo da besplatno dobijete pomoć i informacije na Vašem jeziku. Da biste razgovarali sa prevodiocem, nazovite 877-475-4799.

Thai: หากคณ หรอคนทคณกาลงชวยเหลอมคาถามเกยวกบ Blue Cross Blue Shield of Arizona คณมสทธทจะใดรบความชวยเหลอและขอมลในภาษา ของคณไดโดยไมมคาใชจาย พดคยกบลาม โทร 877-475-4799

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