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 Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Medical Coverage Guideline 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 guidelines.

The section identified as “Description” 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 “Criteria” 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.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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AUTONOMIC NERVOUS SYSTEM TESTING (cont.)

Description:

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.

Given the limitations of clinical examination, it is likely that ANS testing adds incremental information on the likelihood of an ANS disorder in individuals 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 individuals, and in others may end the need for further diagnostic testing.

ANS testing should be performed in a dedicated ANS 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 ANS testing. Testing using portable 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.

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 and at least one test in each category is usually performed:

- Cardiovagal function (heart rate [HR] variability, HR response to deep breathing and Valsalva).
- Sudomotor function (quantitative sudomotor axon reflex test [QSART], QST, thermoregulatory sweat test [TST], silastic sweat test, sympathetic skin response, electrochemical sweat conductance).
- Vasomotor adrenergic function (blood pressure [BP] response to standing, Valsalva and hand grip, tilt table testing).

More than one test from a category will often be included in a battery of tests, but the incremental value of using multiple tests in one domain is not known.
AUTONOMIC NERVOUS SYSTEM TESTING (cont.)

**Description:** (cont.)

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:

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

A Composite Autonomic Severity Score ranging from 0 to 10 can be utilized 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.

FDA-approved ANS testing devices, include, but are not limited to:

- ANX3.0®
- Bodytronic® 200
- Dopplex Ability®
- Neuropad®
- Sudoscan®
- ZYTO Hand Cradle
AUTONOMIC NERVOUS SYSTEM TESTING (cont.)

Criteria:

For tilt table testing for the evaluation of syncope, see BCBSAZ Medical Coverage Guideline #O291, “Tilt Table Testing for the Evaluation of Syncope”.

- Autonomic nervous system testing, consisting of a battery of tests in several domains in a dedicated ANS testing laboratory 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 in a dedicated ANS testing laboratory for all other indications not previously listed or if above criteria not met is considered experimental or investigational based upon:
  1. Lack of final approval from the Food and Drug Administration, and
  2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  3. Insufficient evidence to support improvement of the net health outcome, and
  4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
  5. Insufficient evidence to support improvement outside the investigational setting.

These indications include, but are not limited to:

- Allergic conditions
- Anxiety and other psychologic disorders
- Chronic fatigue syndrome
- Fibromyalgia
- Hypertension
- Monitoring progression of disease or response to treatment
- Screening of asymptomatic individuals
- Sleep apnea
AUTONOMIC NERVOUS SYSTEM TESTING (cont.)

Criteria: (cont.)

- Autonomic nervous system testing using portable automated devices is considered *experimental or investigational* based upon:

  1. Lack of final approval from the Food and Drug Administration, and
  2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  3. Insufficient evidence to support improvement of the net health outcome, and
  4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
  5. Insufficient evidence to support improvement outside the investigational setting.

Resources:

Literature reviewed 07/19/18. We do not include marketing materials, poster boards and non-published literature in our review.

The BCBS Association Medical Policy Reference Manual (MPRM) policy is included in our guideline review. References cited in the MPRM policy are not duplicated on this guideline.

AUTONOMIC NERVOUS SYSTEM TESTING (cont.)

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, crc@azblue.com. 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 https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, 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 http://www.hhs.gov/ocr/office/file/index.html

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 nílígíí Blue Cross Blue Shield of Arizona haada yit’éego bina’ildíkídgo éí doodago Háida bíjá aníïyeeélígíí t’aadoo le’é yina’ildíkídgo bee hazá’áánii hóóló díí t’áá hazaad’k’ehíí háká a’doooolgwó bee haz’a doó bágh ilínígóó. Atá’hálne’ilgyíí kojí bích’éjí hodíílnííí 877-475-4799.

Chinese: 如果您，或您正在幫助的對象，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 thể thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thợ dịch viễn, xin gọi 877-475-4799.

Arabic:
إن كان لديك أو أدى شخص تساعدك أسلحة بخصوص مرضية، تناوب الحق في الحصول على المساعدة والموارد، Blue Cross Blue Shield of Arizona في مراقبة بكم عن كنون لتلكرة للتحدث مع مترجم التصلب 877-475-4799.
AUTONOMIC NERVOUS SYSTEM TESTING (cont.)

Multi-Language Interpreter Services: (cont.)

Tagalog: Kung ikaw, o ang iyong tinutulungan, ay may mga katanungan tungkol sa Blue Cross Blue Shield of Arizona, may karapatang na makakuha ng tulong at impormasyon sa iyong wiya ng walang gastos. Upang mabasahin ang isang tigas, tumawag sa 877-475-4799.

Korean: 만약 귀하 또는 귀하가 돕고 있는 어떤 사람이 Blue Cross Blue Shield of Arizona에 관해서 질문이 있다면 귀하는 그러한 도움과 정보를 귀하의 언어로 비용 부담없이 얻을 수 있는 권리가 있습니다. 그렇게 편의적으로 얘기하기 위해서는 877-475-4799로 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: آگر شما، یا کسی که شما با او کمک می‌کنید، سوال‌های مربوط به اطلاعات بی‌خود را به دو语‌ران گرفت نمایید 997475-4799.

Assyrian: Blue Cross Blue Shield of Arizona ئی‌ئەگە کە چەم یاردنەوەیە، یەکە لە سەرەتەیەکیە بە کەمکیەکەیە بە گەورەکەیەکیەیە. 877-475-4799

Serbo-Croatian: Ukoiko 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 prevodioceom, nazovite 877-475-4799.

Thai: หากคุณ หรือผู้ที่คุณช่วยเหลือมีคำถามเกี่ยวกับ Blue Cross Blue Shield of Arizona คุณมีสิทธิ์จะได้รับความช่วยเหลือและข้อมูลในภาษา ของคุณได้โดยไม่ค่าใช้จ่าย โทร 877-475-4799.