GENETIC AND AUTOANTIBODY TESTING FOR INHERITED PERIPHERAL NEUROPATHY

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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Description:

Peripheral Neuropathy (PN) is a neurological disorder that affects sensory, motor and/or autonomic nerves. Neurological symptoms include numbness, weakness, decreased reflexes, tingling and pain affecting the arms and/or legs. Electrophysiological studies used to help diagnose PN include electromyography and nerve conduction studies (NCS). There is no standard course of treatment.
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Description: (cont.)

Acquired Peripheral Neuropathies:
Acquired peripheral neuropathies may be caused by trauma to a nerve, tumors, toxins, nutritional deficiencies, alcoholism, autoimmune disorders, vascular disorders and metabolic disorders. Diabetes is a leading metabolic cause of peripheral neuropathy. When a diagnosis cannot be made based on assessment and electrophysiological studies, autoantibody testing may be used to determine if the neuropathy is the result of an autoimmune response. Autoimmune disorders include celiac disease, Guillain-Barré syndrome, lupus, rheumatoid arthritis, sarcoidosis and Sjögren's syndrome.

Inherited Peripheral Neuropathies:
Inherited peripheral neuropathies are a heterogeneous group of diseases that may be inherited in an autosomal dominant, autosomal recessive, or X-linked dominant manner. These diseases can generally be diagnosed based on clinical presentation, nerve conduction studies, and family history. Genetic testing has been used to diagnose specific inherited peripheral neuropathies.

Definitions:

Genetic Testing:
Analysis of DNA, RNA, chromosomes, proteins and certain metabolites in order to detect alterations related to an inherited disorder.

Gene:
A hereditary unit consisting of segments of DNA that occupies a specific location on chromosomes. Genes undergo mutation when their DNA sequence changes.

Genetic Counseling:
Instruction that provides interpretation of genetic tests and information about courses of action that are available for the care of an individual with a genetic disorder or for future family planning.

Affected Individual:
An individual displaying signs or symptoms characteristic of a suspected or specific disorder.

Unaffected Individual:
An individual who displays no signs or symptoms characteristic of a suspected or specific disorder.

Screening:
Genetic screening is the testing of an individual with no symptoms for a specific inherited disorder to determine if the individual carries an abnormal gene. Screening can be used to predict risk or potential risk for the individual or their offspring.
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Criteria:

- Testing and/or counseling of an unaffected individual, regardless of risk factors is considered screening and not eligible for coverage.

- Testing and/or counseling of an affected individual to confirm a disease when confirmation of the diagnosis would not impact the care and/or management is considered not medically necessary and not eligible for coverage.

Genetic Testing for Inherited Peripheral Motor or Sensory Neuropathy:

- Genetic testing and/or counseling of an affected individual for an inherited peripheral motor or sensory neuropathy is considered medically necessary with documentation of ALL of the following:
  
  1. The individual demonstrates signs or symptoms of a genetically linked inherited peripheral motor or sensory neuropathy but a definitive diagnosis cannot be made without genetic testing
  2. The test results will directly impact the treatment decisions and clinical outcome
  3. The test is a proven method to identify an inherited peripheral motor or sensory neuropathy

- Genetic testing and/or counseling of an affected individual for an inherited peripheral motor or sensory neuropathy for all other indications not previously listed or if above criteria not met is considered experimental or investigational based upon:

  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
  4. Insufficient evidence to support improvement outside the investigational setting.
GENETIC AND AUTOANTIBODY TESTING FOR INHERITED PERIPHERAL NEUROPATHY (cont.)

Criteria: (cont.)

Autoantibody Testing for Autoimmune Peripheral Neuropathy:

➢ Autoantibody testing to diagnose suspected autoimmune peripheral neuropathy in an affected individual is considered medically necessary for the following antibodies:

1. Anti-Asialo-GM1
2. Anti-GD1a, AntiGD1b
3. Anti-GM1
4. Anti-GQ1b
5. Anti-Hu
6. Anti-MAG
7. Anti-SGPG
8. Anti-Sulfatide
9. IgM antibodies bound to GALOP antigen

➢ Autoantibody testing to diagnose suspected autoimmune peripheral neuropathy of an affected individual for all other indications not previously listed or if above criteria not met is considered experimental or investigational based upon:

1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
2. Insufficient evidence to support improvement of the net health outcome, and
3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
4. Insufficient evidence to support improvement outside the investigational setting.
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Resources:

Literature reviewed 02/20/18. 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.


GENETIC AND AUTOANTIBODY TESTING FOR INHERITED PERIPHERAL NEUROPATHY (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 níilnígíí Blue Cross Blue Shield of Arizona haada yil’t’éego bíná’dííldíkídgo éí doodago Háida bįį
aniyeeedíígí t’aadoó le’é yina’dííldíkídgo beeňa’áą́nii hóóló díí t’aá hazaad’ehí háhá a’doowołgo bee hə̀z’ą́ doo bąąh
ilíngóó. Ata’hálne’íígíí koj’ bíchį’hódíilihí 877-475-4799.

Chinese: 如果您，或是您正在资助的對象，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 thợ dịch viên,
xin gọi 877-475-4799.

Arabic: إن كان لديك أو لدى شخص تساعدته أسئلة بخصائص
الضرورة بلغتك من دون أي تكلفة. للتحدث مع متخصص اتصل ب 877-475-4799.
GENETIC AND AUTOANTIBODY TESTING FOR INHERITED PERIPHERAL NEUROPATHY (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 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 Arizona에 관해서 질문이 있다면 귀하의 도움과 정보를 귀하의 언어로 비용 부담없이 얻을 수 있는 권리가 있습니다. 그렇게 동역사와 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、またはお客様の身内の方でも、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 آن کمک می‌کنید، سوال دارید که مربوط به Blue Cross Blue Shield of Arizona باشد نه‌ایکن تاریکی بگیرید. اطلاعات به زبان خود را به طور رایگان دریافت کنید. 877-475-4799.

Assyrian: Blue Cross Blue Shield of Arizona ئەگەر شما، یا کسی کە شما بیەکەیە دەکەئەوە، سەوە یەکە ڕۆڵەرەوە بە کەسەکەیە. 877-475-4799.

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: หากคุณหรือคนที่คุณช่วยเหลือมีคำถามเกี่ยวกับ Blue Cross Blue Shield of Arizona คุณสามารถได้รับความช่วยเหลือและข้อมูลภาษาของคุณได้โดยไม่ต้องเสียค่าใช้จ่าย โทร 877-475-4799.