

EVIDENCE-BASED CRITERIA ORIGINAL EFFECTIVE DATE: 12/06/22
SECTION: MEDICINE LAST REVIEW DATE: 12/03/24
CURRENT EFFECTIVE DATE: 12/03/24
LAST CRITERIA REVISION DATE: 12/03/24

NEXT ANNUAL REVIEW DATE: 4TH QTR 2025 ARCHIVE DATE:

ALLERGY TESTING AND TREATMENT

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 guidelines.

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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EVIDENCE-BASED CRITERIA ORIGINAL EFFECTIVE DATE:
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12/06/22

12/03/24

NEXT ANNUAL REVIEW DATE: 4TH QTR 2025 ARCHIVE DATE:

ALLERGY TESTING AND TREATMENT

Description:

Allergy or hypersensitivity disorders may be manifested by localized or systemic reactions. Reactions may be acute, subacute or chronic, immediate or delayed, and caused by numerous allergens, including venomous stinging insects (insects from the Hymenoptera family), foods, drugs, fur, inhalant allergens present in the environment (e.g., cockroaches, dust mites, grasses, mold spores, animal dander, trees and weeds). The offending allergen can be diagnosed/identified by history, physical exam and various types of allergy testing.

Treatment is provided by immunotherapy, medication or avoidance. The goal of immunotherapy is to reduce symptoms by administering regular injections of the offending allergen. Therapy begins with low doses once or twice a week. The dose gradually increases as immunity develops. After the maintenance dose is achieved, the interval between injections may range between 2 – 6 weeks. Immunotherapy can continue for several years.

Allergy Tests:

Antigen Leukocyte Antibody Test (ALCAT):

The Antigen Leukocyte Antibody Test (ALCAT) is intended to diagnose intolerance to foods and other environmental agents for which an individual may have intolerance. It is not intended to diagnose food allergy. It is a blood test that assesses the response of leukocytes and platelets to a panel of foods and/or other environmental agents, by measuring the change in size and number of cells following exposure to a specific agent.

Bronchial Challenge Test:

Use of histamine or methacholine to diagnose hyper-responsive airways. Volatile chemicals are used when symptoms are encountered in an occupational setting.

Challenge/Provocative Test:

Extract of the suspected allergen is applied directly to the conjunctiva or nasal mucosa. Degree of response is subjectively determined. Also known as Conjunctival or Nasal Challenge Test.

Cytotoxicity Test:

Extract of the suspected food allergen is added to specially collected white blood cells. If the cells react, an allergic response is said to have occurred. Also known as Bryan's Test, Leukocytotoxicity Test, Cytotoxic Leukocyte Test.



EVIDENCE-BASED CRITERIA ORIGINAL EFFECTIVE DATE: 12/06/22
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NEXT ANNUAL REVIEW DATE: 4TH QTR 2025 ARCHIVE DATE:

ALLERGY TESTING AND TREATMENT

Direct Skin Test:

Extract of the suspected allergen is injected intracutaneously or applied percutaneously to a superficial scratch, prick or puncture on the skin of the arm or back. Can show immediate hypersensitivity. Number of tests required may vary. Rarely are more than 20 intracutaneous or 40 percutaneous tests needed.

Double Blind Food Challenge Test:

Individual is blinded and eats the food to which sensitivity is suspected (disguised within other food or beverage products or in a capsule form). This test is commonly done in the home setting. In some instances of extreme suspected hypersensitivity, it may be performed in the office setting.

E-95 Basic Food Panel:

Enzyme-linked immunosorbent assay technique (ELISA) to measure serum IgG4 and IGE antibodies for food allergy testing. IgG4 is a subclass of IgG. Serum is added to a 96-well plate containing different food antigens and then evaluated for classic antigen/antibody interactions. Accurate testing requires the individual to eat a wide range of foods within 3 weeks of assessment for IgG exposure to be present. The test provides a report of whether the levels of antibody to the various foods suggest that each one is "safe" to eat, best to eat in moderation, or to avoid entirely.

A-95 Extended Food Panel:

The A-95 panel is an extended food allergy test panel and consists of 95 additional foods to the E95 test (combined IgG4 and IgE levels are measured). IgG4 is a subclass of IgG.

IgE Concentration Test (Total Serum):

Detects total quantitative IgE antibodies in the serum.

IgE In Vitro Test (Specific):

Detects allergen-specific IgE antibodies in the serum. Includes the following:

- Enzyme-linked Immunosorbent Assay (ELISA)
- Fluorescent Allergosorbent Test (FAST)
- Multiple Radioallergosorbent Test (MAST)
- Radioallergosorbent Test (RAST)

IgG In Vitro Test (Specific):

Detects allergen-specific IgG antibodies in the serum.

Mediator Release Test:

Measures the aggregate release of inflammatory mediators in the blood after exposure to specific foods and food additives to help design individual-specific oligoantigenic diet. The Lifestyle Eating and Performance Programs (LEAP®) use the Mediator Release test as part of their evaluation of migraine headaches and irritable bowel syndrome (IBS).



EVIDENCE-BASED CRITERIA ORIGINAL EFFECTIVE DATE: 12/06/22
SECTION: MEDICINE LAST REVIEW DATE: 12/03/24
CURRENT EFFECTIVE DATE: 12/03/24
LAST CRITERIA REVISION DATE: 12/03/24

NEXT ANNUAL REVIEW DATE: 4TH QTR 2025 ARCHIVE DATE:

ALLERGY TESTING AND TREATMENT

Patch Test:

Extract of the suspected allergen is applied to the skin of the back and covered with a dressing for 48 hours. Area is then examined for a delayed reaction. Used to determine the offending allergen that is causing contact dermatitis (not mediated through IgE). Also known as Application Test.

Photo Patch Test:

Extract of the suspected allergen is applied to a patch of skin for 48 hours. If no reaction occurs, the area is exposed to a dose of ultraviolet light sufficient to produce inflammatory redness of the skin. If the test is positive, a more severe reaction develops at the patch site than on surrounding skin.

Provocative and Neutralization Test:

Also known as Food and Chemical Allergy Test/Therapy. Used to diagnose (provoke) <u>and</u> treat (neutralize) food and food additive allergens.

Diagnose: Diluted extracts of the suspected food allergen are administered intradermally,

subcutaneously or sublingually to "provoke" the allergy symptoms to appear.

Treatment: Immediately after symptoms appear, weaker or stronger dilutions are administered until

the "provoked" symptoms subside. The dose at which the symptoms subside is

considered the "neutralizing dose" that will be used in future treatment of the food allergy.

Rebuck Skin Window Test:

Extract of the suspected allergen is applied directly to skin that has been abraded. Lab cover slips are placed over the area for 24 hours and then analyzed for a reaction.

Sage ELISA Test:

The SAGE Systems' Food Allergy Test uses an Enzyme Linked Immunosorbant Assay (ELISA) to measure the presence of both IgG and immune complexes against a wide variety of food, food additive and dye antigens in serum in an attempt to identify food allergies or food related chronic illnesses.

Allergy Treatment - Immunotherapy:

Intravenous Nutrient Therapy and Intravenous Vitamin Therapy:

Nutrient and vitamin solutions administered intravenously.

Repository Emulsion Therapy:

Certain materials are placed inside the body to improve allergies.

Rhinophototherapy:

Intranasal application of ultraviolet and visible light to the nasal cavities investigated for allergic rhinitis as an immunosuppressive to inhibit hypersensibility reactions.



EVIDENCE-BASED CRITERIA ORIGINAL EFFECTIVE DATE: 12/06/22
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LAST CRITERIA REVISION DATE: 12/03/24

NEXT ANNUAL REVIEW DATE: 4TH QTR 2025 ARCHIVE DATE:

ALLERGY TESTING AND TREATMENT

Subcutaneous Immunotherapy:

Offending allergen is administered through the skin.

Urine Auto-injection:

Also known as Autogenous Urine Immunization. Substance from an individual's own urine is injected into the skin.

Criteria:

Antigen Leukocyte Antibody Test (ALCAT):

- ALCAT test 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
 - 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.

Bronchial Challenge Test:

- Bronchial Challenge Test to diagnose/identify hyper-responsive airways is considered medically necessary.
- ➤ Bronchial Challenge Test is considered *not medically necessary* if dust, ragweed, or other common allergens are the <u>suspected</u> cause. (Direct skin test can be used.)

IgE Concentration Test (Total Serum):

> IgE Concentration Test is considered *medically necessary*.

IgE In Vitro Test (Specific):

- ➤ IgE In Vitro Test (e.g., inhalant allergens) is considered *medically necessary*.
- ➢ IgE as a component of a food panel (which can include the subclass IgG4), to diagnose/identify an offending food allergen is considered experimental or investigational when any ONE or more of the following criteria are met:



EVIDENCE-BASED CRITERIA ORIGINAL EFFECTIVE DATE: 12/06/22
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CURRENT EFFECTIVE DATE: 12/03/24
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NEXT ANNUAL REVIEW DATE: 4TH QTR 2025 ARCHIVE DATE:

ALLERGY TESTING AND TREATMENT

- 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
- Insufficient evidence to support improvement outside the investigational setting.

These tests include, but are not limited to:

- E95 Basic Food Panel (test includes IgE and IgG4)
- A95 Basic Food Panel (test includes IgE and IgG4)

IgG In Vitro Test (Specific):

- IgG In Vitro Test to diagnose/identify the offending IgG antibody titer of a stinging insect (a member of the Hymenoptera family) when performed on an individual who has been on stinging insect immunotherapy for an extended period of time is considered *medically necessary*.
- ➤ IgG as a specific In Vitro Test and/or IgG as a component of a food panel (which is the subclass IgG4), to diagnose/identify an offending food allergen 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.

These tests include, but are not limited to:

- E95 Basic Food Panel (test includes IgE and IgG4)
- A95 Extended Food Panel (test includes IgE and IgG4)
- Immuno 1 BloodprintTM
- Allergy Smarts Food Intolerance Test
- FoodScan IgG ELISA Food Intolerance Test
- IgG In Vitro Test for all other indications not previously listed is considered experimental or investigational when any ONE or more of the following criteria are met:



EVIDENCE-BASED CRITERIA ORIGINAL EFFECTIVE DATE: 12/06/22
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NEXT ANNUAL REVIEW DATE: 4TH QTR 2025 ARCHIVE DATE:

ALLERGY TESTING AND TREATMENT

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- 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
- 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.

These tests include, but are not limited to:

Stachybotrys chartarum (black mold) exposure

Other Allergy Tests:

- The following allergy tests to diagnose/identify an offending allergen are considered medically necessary:
 - 1. Direct Skin Test
 - 2. Double Blind Food Challenge Test
 - 3. Patch Test
 - 4. Photo Patch Test
- The following allergy tests to diagnose/identify an offending allergen are 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
 - Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives; or
 - Insufficient evidence to support improvement outside the investigational setting.

These tests include, but are not limited to:

- Challenge/Provocative Test (Conjunctival Challenge Test, Nasal Challenge Test)
- Cytotoxicity Test (Bryan's Test, Leukocytotoxicity Test, Cytotoxic Leukocyte Test)
- Mediator Release Test for oligoantigenic food sensitivity (includes testing/treatment for irritable bowel syndrome and/or migraine headaches as part of the LEAP® program)
- Provocative and Neutralization Test (includes treatment of the offending food allergen)
- Rebuck Skin Window Test



EVIDENCE-BASED CRITERIA ORIGINAL EFFECTIVE DATE: 12/06/22
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LAST CRITERIA REVISION DATE: 12/03/24

NEXT ANNUAL REVIEW DATE: 4TH QTR 2025 ARCHIVE DATE:

ALLERGY TESTING AND TREATMENT

Sage ELISA Test, for delayed food allergy/sensitivity

Allergy Treatment - Immunotherapy:

- Subcutaneous immunotherapy is considered *medically necessary* when administered by a professional for inhalant or insect venom allergens with demonstrated hypersensitivity and inability to be managed by avoidance or medication with the limit of 150 units maximum allowed for any rolling twelve (12) month period.
- The following treatments/immunotherapy are 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.

These treatments/immunotherapy include, but are not limited to:

- Intravenous Nutrient Therapy and Intravenous Vitamin Therapy
- Repository Emulsion Therapy
- Urine Auto-injection
- Rhinophototherapy 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 12/03/24. We do not include marketing materials, poster boards and non-published literature in our review.



EVIDENCE-BASED CRITERIA ORIGINAL EFFECTIVE DATE: 12/06/22
SECTION: MEDICINE LAST REVIEW DATE: 12/03/24
CURRENT EFFECTIVE DATE: 12/03/24
LAST CRITERIA REVISION DATE: 12/03/24

NEXT ANNUAL REVIEW DATE: 4TH QTR 2025 ARCHIVE DATE:

ALLERGY TESTING AND TREATMENT

Resources prior to 12/03/24 may be requested from the BCBSAZ Medical Policy and Technology Research Department.

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- 4. Buczylko K, Obarzanowski T, Rosiak K, et al. Prevalence of food allergy and intolerance in children based on MAST CLA and ALCAT tests. *Rocz Akad Med Bialymst*. 1995;40(3):452-6.
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- 9. Jiang RS, Wang JJ. Effect of Red Light Rhinophototherapy on Nasal Patency in Patients with Allergic Rhinitis. *Int J Otolaryngol*. 2018;2018:6270614. doi:10.1155/2018/6270614
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- Kelso JM. Unproven and disproven tests for food allergy. In: TePas E, ed. *UpToDate*. UpToDate;
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EVIDENCE-BASED CRITERIA ORIGINAL EFFECTIVE DATE: 12/06/22
SECTION: MEDICINE LAST REVIEW DATE: 12/03/24
CURRENT EFFECTIVE DATE: 12/03/24
LAST CRITERIA REVISION DATE: 12/03/24

NEXT ANNUAL REVIEW DATE: 4TH QTR 2025 ARCHIVE DATE:

ALLERGY TESTING AND TREATMENT

- 12. Kowal K, DuBuske L. Overview of in vitro allergy tests. In: Feldweg AM, ed. *UpToDate*. UpToDate; 2024. Accessed November 6, 2024. https://www.uptodate.com/contents/overview-of-in-vitro-allergy-tests
- 13. Koycu A, Bas C, Musabak UH, et al. Effects of Combined Visible and Infrared Light Rhinophototherapy in Patients With Allergic Rhinitis. *Am J Rhinol Allergy*. Jan 2023;37(1):65-73. doi:10.1177/19458924221133898
- Krzych-Fałta E, Białek S, Sybilski AJ, Tylewicz A, Samoliński B, Wojas O. Differential diagnostics of food allergy as based on provocation tests and laboratory diagnostic assays. *Postepy Dermatol Alergol*. Dec 2023;40(6):709-715. doi:10.5114/ada.2023.132501
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EVIDENCE-BASED CRITERIA ORIGINAL EFFECTIVE DATE: 12/06/22
SECTION: MEDICINE LAST REVIEW DATE: 12/03/24
CURRENT EFFECTIVE DATE: 12/03/24
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NEXT ANNUAL REVIEW DATE: 4TH QTR 2025 ARCHIVE DATE:

ALLERGY TESTING AND TREATMENT

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Coding:

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86828, 86830, 86831, 86832, 86833, 86834, 86835, 95004, 95024, 95028, 95044, 95052, 95056, 95060, 95065, 95070, 95076, 95079, 95115, 95117, 95120, 95125, 95130, 95131, 95132, 95133, 95134, 95144, 95145, 95146, 95147, 95148, 95149, 95165, 95170, 95180,

95199

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<u>History</u> :	<u>Date</u> :	Activity:
Medical Policy Panel	12/03/24	Review with revisions
Medical Director (Dr. Raja)	11/07/24	Review with revisions
Pediatric Subspecialty Advisory	08/15/24	Review with no revisions
Sub-Committee		
Medical Policy Panel	12/05/23	Review with no revisions
Medical Policy Panel	12/06/22	Approved guideline
Medical Director (Dr. Deering)	11/10/22	Review with revisions
Pediatric Advisory	08/18/22	Review with no revisions
Subcommittee		

Policy Revisions:

12/03/24 Revised: Rhinotherapy to Rhinophototherapy in criteria statement "Rhinotherapy is

considered experimental or investigational when any ONE or more of

the following criteria are met:"

12/03/24 Updated: Resources section



EVIDENCE-BASED CRITERIA ORIGINAL EFFECTIVE DATE: 12/06/22
SECTION: MEDICINE LAST REVIEW DATE: 12/03/24
CURRENT EFFECTIVE DATE: 12/03/24
LAST CRITERIA REVISION DATE: 12/03/24

NEXT ANNUAL REVIEW DATE: 4TH QTR 2025 ARCHIVE DATE:

ALLERGY TESTING AND TREATMENT

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 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 koji' bich'j' 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 اللتحدث مع مترجم اتصل ب .877-475-877



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ALLERGY TESTING AND TREATMENT

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 _[تماس حاصل نمایید.

Assyrian:

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 หรอคนทคณกาลงช่วยเหล่อมคาถามเกี่ยวกบ Blue Cross Blue Shield of Arizona คณมสทธทจะไดรบความช่วยเหลือและขอมลในภาษา ของคณไดโดยไม่มคาใช้จาย พดคยกบลาม โทร 877-475-4799