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EVIDENCE-BASED CRITERIA	**ORIGINAL EFFECTIVE DATE: 07/29/26**
SECTION: LABORATORY	**LAST REVIEW DATE: 07/29/26**
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EVALUATION OF CEREBROSPINAL FLUID, URINE, AND PLASMA TESTS FOR ALZHEIMER DISEASE

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 "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.

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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Description:

Biochemical changes associated with the pathophysiology of Alzheimer disease (AD) are being evaluated to aid in the diagnosis of the disease. This includes the potential use of biomarkers, such as amyloid beta peptide 1-42 and total or phosphorylated tau protein, in cerebrospinal fluid (CSF), urine, and plasma. Additionally, the potential correlation between CSF and plasma biomarkers as well as positron emission tomography (PET) amyloid scans has been proposed as useful in selecting appropriate individuals for the initiation or discontinuation of amyloid beta plaque targeted therapy.

Alzheimer Disease

Alzheimer Disease (AD) is a fatal neurodegenerative disease that causes progressive loss in memory, language, and thinking, with the eventual loss of ability to perform social and functional activities in daily life. Survival after a diagnosis of dementia due to AD generally ranges between 4 and 8 years; however, life expectancy can be influenced by other factors, such as comorbid medical conditions. It is estimated that 6.2 million Americans aged 65 and older are currently living with AD dementia, and the number is projected to reach over 12 million by 2050.

Biomarkers

Several potential biomarkers of AD are associated with AD pathophysiology (eg, amyloid beta plaques, neurofibrillary tangles). Altered cerebrospinal fluid (CSF) levels of specific proteins have been found in individuals with AD. These include tau protein, phosphorylated at AD-specific epitopes such as phosphorylated threonine 181 or total tau protein, an amyloid beta peptide such as 1-42 (Aβ42), and the synaptic protein, neurogranin. Other potential CSF, urine, and blood peptide markers have been explored. One study demonstrated that decreased gamma-aminobutyric acid (GABA) levels within CSF or plasma are implicated in AD pathophysiology. Tau protein is a microtubule-associated molecule found in neurofibrillary tangles that are typical of AD. Tau protein is thought to be related to degenerating and dying neurons and high levels of tau protein in the CSF have been associated with AD. Amyloid beta-42 is a subtype of amyloid beta peptide produced from the metabolism of the amyloid precursor protein. Amyloid beta-42 is the key peptide deposited in amyloid plaques characteristic of AD. Low levels of amyloid beta-42 in the CSF have been associated with AD, perhaps because amyloid beta-42 is deposited in amyloid plaques instead of remaining in the fluid. Investigators have suggested the tau/amyloid beta-42 ratio may be a more accurate diagnostic marker than either alone. Neurogranin is a dendritic protein and CSF measurement may serve as a biomarker for dendritic instability and synaptic degeneration. Elevated CSF neurogranin may predict prodromal AD in MCI and has been confirmed in AD dementia and prodromal AD in several studies.

A variety of kits are commercially available to measure amyloid beta-42 and tau proteins. Between-laboratory variability in CSF biomarker measurement is large. Neural thread protein is associated with neurofibrillary tangles of AD. Both CSF and urine levels of this protein have been investigated as a potential marker of AD. Urine and CSF tests for neural thread protein may be referred to as the AD7C test.

More recently, research has focused on blood, more specifically plasma, as a new matrix for AD biomarkers that have already been validated in the CSF. As blood is more accessible than CSF, blood sampling would be preferable to CSF when taking samples to measure AD biomarkers, both for clinical

diagnosis or screening. However, developing blood AD biomarkers has proven complex. While the CSF is continuous with the brain extracellular fluid, with a free exchange of molecules from the brain to the CSF, only a fraction of brain proteins enter the bloodstream. Examples of blood biomarkers that are currently under examination for use in AD include amyloid beta, tau protein, and neurofilament light. Results from initial studies show that these blood biomarkers may potentially assist in early and more precise diagnosis, prognosis, or monitoring of disease progression and treatment in AD.

Amyloid PET using an FDA-approved tracer are used as qualitative assessments of beta-amyloid (Aβ) plaque density with positive scans being indicative of amyloid plaque pathology. Furthermore, the FDA has authorized amyloid CSF Ratio tests to be routinely used in clinical practice to confirm amyloid pathology as it has proven to be just as effective as amyloid PET in characterizing the biological underpinnings of amyloid etiology with RCTs demonstrating the utility of these tests in identifying individuals who would benefit from anti-amyloid therapy. Amyloid-targeted therapies refer to recombinant monoclonal antibodies directed against amyloid beta. These agents are highly effective in reducing amyloid plaque burden on positron emission tomography (PET) imaging and are therefore believed to be disease modifying. However, their use is limited to those individuals proven to be amyloid positive (by amyloid PET scan or the presence of AD biomarkers in the cerebrospinal fluid [CSF]), as was required in the clinical trials that evaluated these drugs, as their efficacy on clinical outcomes is modest, slowing progression by approximately 25 to 30 percent in carefully selected individuals, and are associated with risk for significant adverse effects.

The labels for FDA-approved, amyloid beta targeting therapies, LEQEMBI® (lecanemab) and Kisunla™ (donanemab) state that the presence of amyloid beta pathology should be confirmed prior to initiating treatment. In the pivotal randomized controlled trial for lecanemab (Clarity AD), the protocol states that the eligibility criteria related to amyloid beta pathology required "confirmed amyloid pathology indicated by either 1) positive amyloid load confirmed by amyloid PET assessment, or 2) CSF assessment of t-tau / Aβ[1-42]." In the pivotal randomized controlled trial for donanemab (TRAILBLAZER-ALZ 2), eligibility was based on flortaucipir F18 and florbetapir F18 PET assessment only. Per the protocol, p-tau 181 was removed as a screening and eligibility criterion in February 2021. In May, 2025 the U.S. Food and Drug Administration published the results of a clinical cohort study that evaluated the performance of the Lumipulse G p-tau217/ß-Amyloid 1-42 Plasma Ratio as an aid in the assessment of individuals presenting with cognitive impairment, AD, and other causes of cognitive decline to determine who would test positive or negative for amyloid plaques. The results demonstrated that the test was consistent with both, amyloid PET scans and CSF ratio tests, deeming the test clinically equivalent in its ability to confirm amyloid pathology when used under research conditions using bio-banked samples, which is consistent with the labels of lecanemab and donanemab. Furthermore, donanemab specifically demonstrated a reduction in plasma p-tau217.

No specific non-imaging tests are included in FDA labels for confirmation testing prior to amyloid beta targeting therapies. Clinical input suggests that any test should include, at a minimum, measurement of amyloid beta and/or tau protein and display performance characteristics that are comparable to amyloid PET and/or FDA cleared/approved CSF biomarker tests that are used for confirmation of amyloid pathology (i.e., Lumipulse *G* Amyloid Ratio 1-42/1-40). There is biological plausibility for the use of plasma-based testing, and clinical utility of such hinges on confirming amyloid pathology and clinical equivalence to the tests used in the trials for the amyloid beta targeting therapies. The FDA 510(k)

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submission for the Lumipulse G® pTau217/β-Amyloid 1-42 Plasma Ratio (K242706) demonstrated concordance with both amyloid PET scans and CSF ratio tests under research biobank conditions. Whether this performance is attainable under routine clinical laboratory conditions has not been prospectively demonstrated. The product is subject to an active FDA Class 2 recall (Z-1301-2026, initiated December 2025) for falsely elevated ratio results. Clinical equivalence under the usual conditions of medical practice has not been established.

Clinical laboratories may develop and validate tests in-house and market them as a laboratory service; laboratory-developed tests must meet the general regulatory standards of the Clinical Laboratory Improvement Amendments (CLIA). Laboratories that offer laboratory-developed tests (LDTs) must be certified by CLIA for high-complexity testing. To date, the FDA has chosen not to require any regulatory review of these tests. Several AD biomarker tests are available as LDTs.

Several AD biomarker tests are available as LDTs. Several plasma based tests have received Breakthrough Device Designation from the FDA, including Roche and Eli Lilly's Elecsys p-Tau217 plasma assay, and Beckman Coulter Diagnostics p-Tau217/β-Amyloid 1-42 plasma ratio.

The FDA has cleared CSF and plasma based AD biomarker tests for marketing via the De Novo and 510(k) pathways with product code QSE.

FDA cleared biomarker tests for Alzheimer Disease include, but not limited to:

- Lumipulse G Amyloid Ratio (1-42/1-40)
- Lumipulse G p-tau217/β-Amyloid 1-42 Plasma Ratio
- Elecsys B-Amyloid (1-42) CSF II
- Elecsys Phospho-Tau (181P) CSF
- Elecsys Phospho-Tau (181P) Plasma
- Elecsys ß-Amyloid (1-42) CSF II
- Elecsys Total-Tau CSF

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Criteria:

- Cerebrospinal fluid testing as an adjunct to clinical diagnosis in individuals with mild cognitive impairment 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:*

  - Amyloid beta peptides
  - Tau protein
  - Neural thread proteins

- Cerebrospinal fluid testing as an adjunct to clinical diagnosis in individuals with mild dementia due to Alzheimer disease 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:*

  - Amyloid beta peptides
  - Tau protein
  - Neural thread proteins

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- Plasma testing as an adjunct to clinical diagnosis in individuals with mild cognitive impairment 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:*

  - Amyloid beta peptides
  - Tau protein
  - Neural thread proteins

- Plasma testing as an adjunct to clinical diagnosis in individuals with mild dementia due to Alzheimer disease 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:*

  - Amyloid beta peptides
  - Tau protein
  - Neural thread proteins

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- Cerebrospinal fluid testing of amyloid beta peptides and tau protein using tests that confirm amyloid pathology as part of an evaluation for the initiation of amyloid beta targeting therapy in individuals with mild cognitive impairment or mild dementia due to Alzheimer disease is considered ***medically necessary*** with documentation of the following:

    1. FDA approved or cleared tests that have proven to confirm amyloid pathology (through establishing clinical equivalency to amyloid PET imaging) for selecting amyloid beta targeting therapy with **ANY** of the following tests:

        - Aβ42:Aβ40 ratio (Lumipulse G Amyloid Ratio 1-42/1-40)
        - Aβ42:phosphorylated-tau181 (p-tau181) (Elecsys B-Amyloid 1-42 CSF II, Elecsys Phospho-Tau 181P) CSF)
        - Aβ42:total-tau (Elecsys ß-Amyloid 1-42 CSF II, Elecsys Total-Tau CSF)

- Plasma testing of amyloid beta peptides and tau protein using tests that confirm amyloid pathology as part of an evaluation for the initiation of amyloid beta targeting therapy in individuals with mild cognitive impairment or mild dementia due to Alzheimer disease 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

- Cerebrospinal fluid testing of neural thread proteins as part of an evaluation for the initiation of amyloid beta targeting therapy in individuals with mild cognitive impairment or mild dementia due to Alzheimer disease 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
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- Plasma testing of neural thread proteins as part of an evaluation for the initiation of amyloid beta targeting therapy in individuals with mild cognitive impairment or mild dementia due to Alzheimer disease 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

- Cerebrospinal fluid testing as part of an evaluation for the continuation of amyloid beta targeting therapy in individuals with mild cognitive impairment or mild dementia due to Alzheimer disease 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:*

  - Amyloid beta peptides
  - Tau protein
  - Neural thread proteins

- Measurement of urine analytes as an adjunct to clinical diagnosis in individuals with mild cognitive impairment or mild dementia due to Alzheimer disease 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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Resources:

Literature reviewed 07/29/26. We do not include marketing materials, poster boards and non-published literature in our review.

Resources prior to 07/29/26 may be requested from the BCBSAZ Medical Policy and Technology Research Department.

1. 2021 Alzheimer's disease facts and figures. Alzheimers Dement. Mar 2021; 17(3): 327-406. PMID 33756057

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EVIDENCE-BASED CRITERIA
SECTION: LABORATORY

NEXT ANNUAL REVIEW DATE: 3RD QTR 2027

ORIGINAL EFFECTIVE DATE: 07/29/26
LAST REVIEW DATE: 07/29/26
CURRENT EFFECTIVE DATE: 07/29/26
LAST CRITERIA REVISION DATE: 07/29/26
ARCHIVE DATE:

EVALUATION OF CEREBROSPINAL FLUID, URINE, AND PLASMA TESTS FOR ALZHEIMER DISEASE

Coding:

CPT: 0358U, 0361U, 0412U, 0443U, 0445U, 0459U, 0547U, 81099, 82233, 82234, 83520, 83884, 84393, 84394, 86849

History:	Date:	Activity:
Medical Policy Panel	07/29/26	Approved guideline
Clinical Pharmacist	06/23/26	Review with revisions
Medical Director (Dr. Raja)	05/13/26	Review with revisions

Policy Revisions:

EVIDENCE-BASED CRITERIA	**ORIGINAL EFFECTIVE DATE: 07/29/26**
SECTION: LABORATORY	**LAST REVIEW DATE: 07/29/26**
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EVALUATION OF CEREBROSPINAL FLUID, URINE, AND PLASMA TESTS FOR ALZHEIMER DISEASE

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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 hóló díí t'áá hazaadk'ehjí háká a'doowołgo bee haz'ą doo bąąh íłínígóó. Ata' halne'ígíí kojį' bich'į' 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. للتحدث مع مترجم اتصل ب 877-475-4799.

An Independent Licensee of the Blue Cross Blue Shield Association

EVALUATION OF CEREBROSPINAL FLUID, URINE, AND PLASMA TESTS FOR ALZHEIMER DISEASE

<u>Multi-Language Interpreter Services</u>:

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 877-475-4799
.[تماس حاصل نمایید

Assyrian:
[illegible] Blue Cross Blue Shield of Arizona [illegible]
[illegible] 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: หากคณ หรอคนทคณกาลงชวยเหลอมคาถามเกยวกบ Blue Cross Blue Shield of Arizona คณมสทธทจะไดรบความชวยเหลอและขอมลในภาษา ของคณไดโดยไมมคาใชจาย พดคยกบลาม โทร 877-475-4799