

**EVIDENCE-BASED CRITERIA
SECTION: MEDICINE**

ORIGINAL EFFECTIVE DATE: 11/01/26
LAST REVIEW DATE: 09/01/26
CURRENT EFFECTIVE DATE: 11/01/26
LAST CRITERIA REVISION DATE:
ARCHIVE DATE:

NEXT ANNUAL REVIEW DATE: 3RD QTR 2027

EXPERIMENTAL-INVESTIGATIONAL SERVICES

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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EXPERIMENTAL-INVESTIGATIONAL SERVICES

Description:

This medical policy addresses healthcare services that are not covered because they are considered experimental or investigational.

AZ Blue in its sole and absolute discretion, decides whether a service or item is experimental or investigational. AZ Blue may classify the service or item as experimental or investigational if any one or more of the following apply:

- Published reports and articles in authoritative (peer-reviewed) medical and scientific literature show that the prevailing opinion among experts is that further studies or clinical trials are necessary to determine maximum tolerated dose, toxicity, safety, appropriate selection, efficacy or efficacy as compared with the standard treatment for the diagnosis;
- The provider rendering the service or item documents that the service or item is experimental or investigational; or
- The service or item cannot be lawfully marketed or used without full (unrestricted) approval of appropriate governmental regulatory bodies and approval for marketing or use has not been given at the time the service or item is submitted for prior authorization or rendered.

Unless otherwise specified in another applicable medical policy utilized by BCBSAZ, the CPT/HCPCS codes addressed in this policy are considered experimental or investigational due to insufficient evidence of efficacy.

Criteria:

- Unless otherwise specified in another applicable medical policy utilized by BCBSAZ, the CPT/HCPCS codes addressed in this policy 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

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Resources:

Literature reviewed 09/01/26. We do not include marketing materials, poster boards and non-published literature in our review.

1. American Medical Association. CPT. 2026. Accessed August 27, 2026. <https://www.ama-assn.org/practice-management/cpt>
2. Blue Cross Blue Shield of Arizona. Benefit Plan Booklet.
3. Centers for Medicare & Medicaid Services. Healthcare Common Procedure Coding System (HCPCS). 2026. Accessed August 27, 2026. <https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system>

Coding:

CPT: 0064U, 0077U, 0105U, 0224U, 0248U, 0295U, 0303U, 0304U, 0312U, 0337U, 0338U, 0344U, 0351U, 0407U, 0472U, 0490U, 0491U, 0492U, 0511U, 0522U, 0535U, 0541U, 31634, 33370, 57465, 64657, 77089, 77090, 77091, 77092, 82777, 83006, 84112, 84431, 86328, 86343, 86769, 87467, 91065, 91112, 92512, 92548, 92549, 92572, 92972, 93050, 93740, 93895, 94015, 94016, 94690, 95919, 96904, 96933, 97026, 97607, 97608

HCPCS: A4563, A4575, A7021, A8005, A9268, A9269, A9292, A9294, A9610, C1601, C1608, C1761, C1824, C9758, C9760, C9764, C9765, C9766, C9767, C9772, C9773, C9774, C9775, C9777, C9779, C9781, C9785, E0221, E0944, G0281, G0282, L8608, L8702, S9002

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<u>History:</u>	<u>Date:</u>	<u>Activity:</u>
Medical Policy Panel	09/01/26	Approved guideline (effective 11/01/26)
Medical Director (Dr. Deering, Dr. Raja)	08/27/26	Development
Legal Division	08/05/26	Development
Medical Director (Dr. Raja)	07/30/26	Development
Medical Director (Dr. Raja, Dr. Sutanto)	07/23/26	Development
Legal Division	07/15/26	Development

Policy Revisions:



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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, 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: Dii kwe'é atah nilinigií Blue Cross Blue Shield of Arizona haada yit'éego bina'idilkidgo éi doodago Háida bíjá anilyeedigií t'áadoo le'é yina'idilkidgo beehaz'áanii hólo dii t'áa hazaadk'ehjí háká a'doowotgo bee haz'á doo baqah ilinígóó. Ata' halne'ígíí kojí' bich'í' hodilnih 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 تساعد أسئلة بخصوص Blue Cross Blue Shield of Arizona، فلديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون أية تكلفة. للتحدث مع مترجم اتصل بـ 877-475-4799.



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