BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

EVIDENCE-BASED CRITERIA	**ORIGINAL EFFECTIVE DATE: 07/18/23**
SECTION: ADMINISTRATIVE PROCEDURE	**LAST REVIEW DATE: 07/16/24**
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COVERAGE ELIGIBILITY OF SERVICES ASSOCIATED WITH A CLINICAL TRIAL FOR NON-GRANDFATHERED PLANS

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:

Blue Cross Blue Shield Arizona (BCBSAZ) provides coverage for services described as eligible in the benefit plan booklets and which meet all requirements specified therein.

Benefits are available for covered services directly associated with an eligible clinical trial meeting all of the requirements specified by applicable Arizona and federal law.

Benefits are limited to those services that BCBSAZ normally covers when a member undergoes usual and customary (standard, non-investigational) medical treatment. These services may include laboratory and radiology services, physician services and medical diagnostic and/or surgical procedures.

See Appendix for additional information.

Definitions:

Clinical Trials/Studies:
Research studies that test whether new medical technologies are safe and effective for use in humans. Each study answers scientific questions in an effort to find new or improved ways to prevent, diagnose or treat medical diseases and conditions. Clinical trials may also be performed to determine if new ways of using known therapies are safe and effective. Clinical trials are conducted in phases.

Phase I:
Initial testing of experimental drugs or treatments to evaluate safety, safe dose range and identify side effects. The experimental drug or treatment is given to a small group of people; usually 20 to 80.

Phase II:
The experimental drug or treatment is given to a group of 100 to 300 people in order to determine if it is effective and to continue its safety evaluation.

Phase III:
This phase compares the experimental drug or treatment, or the new use of a known therapy, to current standard therapy. It also confirms the effectiveness of the drug or treatment, monitors its side effects and collects information to enable the experimental drug or treatment to be used safely. A group of 1000 to 3000 people participate in this phase.

Phase IV:
This phase studies the FDA-approved drug or treatment to delineate additional information including the drug's risks, benefits, and optimal use.

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FDA:
One of the criteria BCBSAZ uses to determine if treatments, procedures, equipment, drugs, devices or supplies are eligible for coverage is that the technology under consideration must have final approval from the appropriate government regulatory bodies. The United States Food and Drug Administration (FDA) is one such regulatory body.

The FDA is responsible for ensuring that drugs and medical devices are safe and effective for use by humans before companies and manufacturers can put them on the market. The FDA has different processes by which it can clear or approve a device or drug for marketing as well as a process allowing non-approved devices to be used in clinical studies to obtain safety and effectiveness data.

FDA 510K Premarket Notification (510K):
A before market submission to demonstrate a device is at least as safe and effective (substantially equivalent) to a similar, legally U.S. marketed device that is not subject to Premarket approval (PMA). Once the technology passes through this process, the FDA considers it cleared for marketing. This clearance is identified in a letter from the FDA stating the technology is substantially equivalent and that it can be marketed.

FDA Premarket Approval (PMA):
A before market review process to evaluate the safety and effectiveness of medical devices that sustain human life, prevent impairment of human health or which present a potential, unreasonable risk of illness or injury. In this process, the manufacturer provides the FDA with clinical data regarding the safety and effectiveness of the device. The data is usually gathered through an Investigational Device Exemption trial. The approval is based on the FDA's determination that the device contains enough valid scientific evidence to assure it is safe and effective for its intended use(s). An approved PMA grants permission to market the device.

FDA Humanitarian Device Exemption (HDE):
Similar to a PMA but exempt from certain requirements. HDEs apply to Humanitarian Use Devices (HUDs) which are medical devices intended to treat rare diseases or conditions; those affecting less than 4000 people per year. In this process, the manufacturer submits data on the safety and probable benefit of the device. FDA HDE approval authorizes marketing of HUDs.

FDA Investigational Device Exemption (IDE):
A process that allows an investigational device to be used in a clinical study so that safety and effectiveness data can be collected to support a PMA or a 510K Premarket Notification submission to the FDA. IDE devices are not FDA approved for marketing.

FDA Drug Review and Approval Process:
A several step process involving animal and human testing, study phases of increasing numbers of humans, application submissions, reviews, facility inspections and final decision by the FDA. If the FDA determines the benefits of the drug outweigh the risks, approval is given and the drug can be marketed.

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Criteria:

This Evidence-Based Criteria is applicable for non-grandfathered group and non-grandfathered individual on and off exchange plans effective or renewed on or after January 1, 2014.

For clinical trial coverage under other types of benefit plans, see BCBSAZ Evidence-Based Criteria # AP107, *"Coverage Eligibility of Services Associated with a Cancer Clinical Trial"*.

- The following usual and customary (standard, non-investigational) services associated with an eligible clinical trial are ***eligible for coverage*** with documentation of **ALL** of the following:

  1. Individual **or** provider has notified BCBSAZ that the individual is enrolled in a clinical trial determined to meet the requirements of Arizona and federal law if the clinical trial is to occur in Arizona, or Federal Law if the clinical trial is to occur outside of Arizona **and** that the services to be rendered are directly associated with the trial [1]
  2. Participation in any phase of the clinical trial is voluntary

  These services include:

  - Laboratory and radiology services
  - Physician services for consultations, medical assessments and follow-up visits
  - Medical diagnostic and/or surgical procedures

[1] Lack of notification will result in administration of benefits in accordance with the other terms of the benefit plan which may cause a denial of benefits.

- The following services that may be required for an individual to receive treatment or intervention are a ***benefit plan exclusion*** and ***not eligible for coverage***:

  1. Any investigational medication or device
  2. Any item, device or service that is the subject of the clinical study or which is provided solely to meet the need for data collection and analysis
  3. Costs and services customarily paid for by government, biotechnical, pharmaceutical or medical device industry sources
  4. Costs of managing the research of the trial
  5. Non-health services that might be required for an individual to receive treatment or intervention, such as travel and transportation and lodging expenses
  6. Services otherwise not covered under this plan

COVERAGE ELIGIBILITY OF SERVICES ASSOCIATED WITH A CLINICAL TRIAL FOR NON-GRANDFATHERED PLANS

- Except as indicated above, treatments, procedures, equipment, devices, drugs, supplies and facility and provider services associated with a clinical trial are considered ***experimental or investigational***. This includes devices with and without 510K, PMA, HDE and IDE status and drugs with and without FDA approval. This applies even if the procedure and services are otherwise considered medically necessary. This ***experimental or investigational*** status is based upon the association with the clinical trial. Therefore, it is considered ***experimental or investigational*** based upon:

  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, 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 07/16/24. We do not include marketing materials, poster boards and non-published literature in our review

Resources prior to 04/07/21 may be requested from the BCBSAZ Medical Policy and Technology Research Department.

1. Blue Cross Blue Shield of Arizona Benefit Plan Booklet.

2. Arizona Revised Statutes §20-826.01. Hospital or medical service corporations; clinical trials; cancer definitions. Accessed July 5, 2024. https://www.azleg.gov/viewdocument/?docName=https://www.azleg.gov/ars/20/00826-01.htm

3. Arizona Revised Statutes §20-1057-07. Health care services organizations; clinical trials; cancer, definitions. Accessed July 5, 2024. https://www.azleg.gov/viewdocument/?docName=https://www.azleg.gov/ars/20/01057-07.htm

4. Arizona Revised Statutes §20-2328. Accountable health plans; clinical trials; cancer; definitions. Accessed. July 5, 2024. https://www.azleg.gov/viewdocument/?docName=https://www.azleg.gov/ars/20/02328.htm

5. Humanitarian Device Exemption (HDE) Overview. U.S. Food and Drug Administration. October 3, 2022. Accessed July 5, 2024. https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/humanitarian-device-exemption

6. Investigational Device Exemption (IDE). U.S. Food and Drug Administration. October 3, 2022. Accessed July 5, 2024. https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/investigational-device-exemption-ide

7. Patient Protection and Affordable Care Act. Sec. 2709 [42 U.S.C. 300gg–8]. Coverage for Individuals Participating in Approved Clinical Trials. Accessed July 5, 2024. https://www.hhs.gov/sites/default/files/ppacacon.pdf

8. Premarket Approval (PMA) Overview. U.S. Food and Drug Administration. May 16, 2019. Accessed July 5, 2024. https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/premarket-approval-pma

9. Premarket Notification 510(k) Overview. U.S. Food and Drug Administration. October 3, 2022. Accessed July 5, 2024. https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/premarket-notification-510k

10. The Drug Development Process. U.S. Food and Drug Administration. January 4, 2018. Accessed July 5, 2024. https://www.fda.gov/patients/learn-about-drug-and-device-approvals/drug-development-process

Coding:

CPT:	Various
HCPCS:	Various, G0276, G0293, G0294, G9057, S9988, S9990, S9991, S9992, S9994, S9996
Modifier(s):	Q0, Q1

History:	Date:	Activity:
Medical Policy Panel	07/16/24	Review with no revisions
Legal Division	07/03/24	Review with no revisions
Medical Policy Panel	07/18/23	Approved guideline
Legal Division	07/10/23	Review with no revisions
Pediatric Subspecialty Advisory Sub-Committee	05/18/23	Review with no revisions

Policy Revisions:

07/16/24 Updated: Resources section

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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: 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.

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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 877-475-4799
[تماس حاصل نمایید.

Assyrian:

[illegible] Blue Cross Blue Shield of Arizona [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

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APPENDIX
CLINICAL TRIAL REQUIREMENTS
AS SET FORTH IN THE AFFORDABLE CARE ACT

These requirements apply to clinical trial benefits in **all non-grandfathered** benefit plan books.

For the requirements applicable to cancer clinical trial benefits in most *grandfathered* plans, please refer to the document "Cancer Clinical Trial Requirements as Set Forth by Arizona Law."

Effective for plan years beginning on or after January 1, 2014, the Affordable Care Act (ACA) requires all non-grandfathered health plans to provide coverage for "routine patient costs" when a "qualified individual" is participating in an "approved clinical trial" for the treatment of cancer or other life-threatening disease or condition.

Who is a "qualified individual"? A qualified individual is a member who meets the following conditions:

- Is a participant in a group or individual **non-grandfathered** health plan;
- Is eligible to participate in an approved clinical trial according to the trial protocol with respect to treatment of cancer or other life-threatening disease or condition; and
- Either:
    - The referring health care professional is a participating health care provider and has concluded that the individual's participation in such trial would be appropriate based upon the individual meeting eligibility according to the trial protocol; **OR**
    - The participant provides medical and scientific information establishing that the individual's participation in the trial would be appropriate according to the trial protocol.

A group health plan or a health insurance issuer may not discriminate against a member on the basis of the member's participation in an approved clinical trial.

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For the requirements applicable to cancer clinical trial benefits in most *grandfathered* plans, please refer to the document "Cancer Clinical Trial Requirements as Set Forth by Arizona Law."

What is a "life-threatening condition"? The term "life-threatening condition" means any disease or condition from which the likelihood of death is probable unless the course of the disease or condition is interrupted.

What are "routine patient costs"? Routine patient costs include all items and services consistent with the coverage provided in the member's benefit plan that are typically covered for a qualified individual who is not enrolled in a clinical trial.

Routine patient costs **do not** include:

- The investigational item, device, or service that is being studied
- Items and services that are provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient
- A service that is clearly inconsistent with widely accepted and established standards of care for a particular diagnosis

What are "routine patient costs"?
Group health plans and health insurance issuers are not required to provide benefits for routine patient care services provided outside of the plan network unless out-of-network benefits are otherwise provided under the benefit plan.

If one or more in-network (participating) providers are participating in a clinical trial, the plan may require that a qualified individual participate in the trial through such in-network provider if the provider will accept the member as a participant in the clinical trial.

A qualified individual may participate in an approved clinical trial that is conducted outside the state in which the qualified individual lives.

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What is an "approved clinical trial"? An approved clinical trial is:

- A Phase I, Phase II, Phase III, or Phase IV clinical trial;
- Conducted in relation to the prevention, detection, or treatment of cancer or other life-threatening disease or condition; **and** is described in one of the following subsections:
- Is approved or funded by one or more of the following:
    - The National Institutes of Health
    - The Centers for Disease Control and Prevention
    - The Agency for Health Care Research and Quality
    - The Centers for Medicare & Medicaid Services
    - Cooperative group or center of any of the entities described above or the Department of Defense or the Department of Veterans Affairs
    - A qualified non-governmental research entity identified in the guidelines issued by the National Institutes of Health for center support grants
    - Any of the following if certain conditions are met:
        - The Department of Veterans Affairs
        - The Department of Defense
        - The Department of Energy
    - Is conducted under an investigational new drug application reviewed by the Food and Drug Administration
    - Is a drug trial that is exempt from having such an investigational new drug application
- If the clinical trial is conducted by a federal governmental department, it has been reviewed and approved through a system of peer review that the department Secretary determines
    - To be comparable to the system of peer review of studies and investigations used by the National Institutes of Health; **and**
    - Assures unbiased review of the highest scientific standards by qualified individuals who have no interest in the outcome of the review

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These requirements apply to clinical trial benefits in **all non-grandfathered** benefit plan books.

For the requirements applicable to cancer clinical trial benefits in most *grandfathered* plans, please refer to the document "Cancer Clinical Trial Requirements as Set Forth by Arizona Law."

Disclaimer – Please read carefully:
In administering claims for covered services directly associated with an eligible clinical trial, Blue Cross Blue Shield of Arizona ("BCBSAZ") does not represent or warrant that the clinical trial meets all of the requirements set forth by the Affordable Care Act. BCBSAZ also does not represent or warrant that the treatment, device, drug, service or other item provided through the clinical trial is safe, effective or appropriate for any member. Decisions regarding whether the clinical trial meets the criteria set forth by the Affordable Care Act and whether the clinical trial is safe, effective and appropriate for you, are decisions to be made by you and your provider and/or the trial investigator, using his/her independent medical judgment. If you have any questions concerning whether the clinical trial is safe and effective and/or meets the criteria established by the Affordable Care Act, BCBSAZ encourages you to speak with your treating provider and provide him/her with a copy of this disclaimer for discussion. Should you have any questions concerning available benefits pursuant to the Affordable Care Act for covered services related to a clinical trial, please contact the BCBSAZ Claims and Customer Service Unit at (602) 864-4400 or (800) 232-2345. If you are hearing impaired, please call (602) 864-4823 (TDD) or (800) 232-2345 ext. 4823.