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 CANCER CLINICAL TRIAL

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. With the exception of cancer clinical trials, no benefits are paid for treatments, procedures, equipment, drugs, devices or supplies associated with a clinical trial.

See Appendix for additional information.

Cancer Clinical Trials:

In compliance with Arizona Revised Statutes §20-826.01, §20-1057.07 and §20-2328, benefits are available for **covered member costs** directly associated with an eligible cancer clinical trial **within the state of Arizona**. The clinical trial must meet all of the requirements of Arizona law.

Covered member costs are those charges for 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.

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.

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

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.

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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.

Criteria:

This Evidence-Based Criteria is not 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 for non-grandfathered group and non-grandfathered individual on and off exchange plans effective or renewed on or after January 1, 2014, see BCBSAZ Evidence-Based Criteria # AP108, *"Coverage Eligibility of Services Associated With a Clinical Trial for Non-Grandfathered Plans".*

Cancer Clinical Trials:

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

  1. Cancer clinical trial is being conducted within the state of Arizona
  2. Individual **or** provider has notified BCBSAZ that the individual is enrolled in a cancer clinical trial determined to meet the requirements of Arizona law **and** that the services to be rendered are directly associated with the trial [1]
  3. Participation in any phase of the cancer clinical trial is voluntary
  4. Any out-of-network provider(s), has agreed, via Letter of Agreement (LOA) to accept BCBSAZ reimbursement as payment in full

  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. Non-health services that might be required for a person to receive treatment or intervention, such as travel/transportation and/or lodging expenses

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3. Costs of managing the research of the trial, e.g., data collection and analysis
4. Treatment or services provided outside of Arizona
5. Costs and services customarily paid for by the research sponsors, government, biotechnical, pharmaceutical or medical device industry sources, or which are free of charge for any trial enrollee
6. Items and services for which coverage is not available under the member's specific benefit plan due to exclusion or limitation, other than those services directly related to the focus of the trial
7. 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

Other Clinical Trials:

- Except as indicated in cancer clinical trials 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 04/27/21 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

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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. 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

8. 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

9. 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

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History:	**Date**:	**Activity**:
Medical Policy Panel	07/16/24	Review no revisions
Legal Division	07/03/24	Review 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]
[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

CANCER CLINICAL TRIAL REQUIREMENTS AS SET FORTH BY ARIZONA LAW

These requirements apply to cancer clinical trial benefits in the following health plans:

- All fully insured, grandfathered individual plans
- All fully insured, grandfathered small group plans
- All fully insured, grandfathered large group plans
- Any self-funded (ASC), grandfathered group plans that elect this benefit

For all non-grandfathered group and individual plans, please refer to the document "Clinical Trial Requirements As Set Forth by the Affordable Care Act."

A. To be eligible for benefits for covered services directly related to an eligible cancer clinical trial, the trial must first meet ***all*** requirements as set forth by Arizona law (e.g., A.R.S. §§ 20-826.01 and 20-1057.07), as determined by your provider(s). These requirements are as follows:

   BCBSAZ is not obligated to pay any costs, other than covered patient costs, that are directly associated with a cancer clinical trial offered in Arizona in which the insured participates voluntarily. A cancer clinical trial is a course of treatment in which all of the following apply:

   - The treatment is part of a scientific study of a new therapy or intervention that is being conducted at an institution in this state, that is for the treatment, palliation or prevention of cancer in humans and in which the scientific study includes all of the following:
     - Specific goals.
     - A rationale and background for the study.
     - Criteria for patient selection.
     - Specific directions for administering the therapy and monitoring patients.
     - A definition of quantitative measures for determining treatment response.
     - Methods for documenting and treating adverse reactions.
   - The treatment is being provided as part of a study being conducted in a phase I, phase II, phase III or phase IV cancer clinical trial.

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- The treatment is being provided as part of a study being conducted in accordance with a clinical trial approved by at least one of the following:
    - One of the national institutes of health.
    - A national institute of health cooperative group or center.
    - The United States Food and Drug Administration in the form of an investigational new drug application.
    - The United States Department of Defense.
    - The United States Department of Veterans Affairs.
    - A qualified research entity that meets the criteria established by the national institutes of health for grant eligibility.
    - A panel of qualified recognized experts in clinical research within academic health institutions in this state.
- The proposed treatment or study has been reviewed and approved by an institutional review board of an institution in this state.
- The personnel providing the treatment or conducting the study:
    - Are providing the treatment or conducting the study within their scope of practice, experience and training and are capable of providing the treatment because of their experience, training and volume of patients treated to maintain expertise.
    - Agree to accept reimbursement as payment in full from the insurer at the rates that are established by the insurer and that are not more than the level of reimbursement applicable to other similar services provided by health care providers with the insurer's provider network.
- There is no clearly superior, noninvestigational treatment alternative.
- The available clinical or preclinical data provide a reasonable expectation that the treatment will be at least as efficacious as any noninvestigational alternative.

B. Pursuant to the patient informed consent document, no party is liable for damages associated with the treatment provided during any phase of a cancer clinical trial.

C. Benefits are available as set forth in the subscriber’s benefit booklet. BCBSAZ is not responsible for any portion of the clinical trial that is customarily paid for by government, biotechnical, pharmaceutical or medical device industry sources.

D. Neither A.R.S. §§ 20-826.01 and 20-1057.01 requiring BCBSAZ and other insurers to provide benefits for covered services related to a cancer clinical trial meeting all of the requirements set forth by law creates any private right or cause of action for or on behalf of any patient/subscriber against BCBSAZ. Instead, this law provides solely an administrative remedy to the director of the Arizona Department of Insurance for any violation of this law or any related rule.

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E. Nothing in A.R.S. §§ 20-826.01 and 20-1057.01 prohibits BCBSAZ from imposing deductibles, coinsurance or other cost sharing measures in relation to benefits provided pursuant to these laws.

F. Definitions as set forth in A.R.S. §§ 20-826.01 and 20-1057.01:

- "Cooperative group" means a formal network of facilities that collaborates on research projects and that has an established national institutes of health approved peer review program operating within the group, including the national cancer institute clinical cooperative group and the national cancer institute community clinical oncology program.

- "Institutional review board" means any board, committee or other group that is both:

  - Formally designated by an institution to approve the initiation of and to conduct periodic review of biomedical research involving human subjects and in which the primary purpose of such review is to assure the protection of the rights and welfare of the human subjects and not to review a clinical trial for scientific merit.

  - Approved by the national institutes of health office for protection from research risks.

- "Multiple project assurance contract" means a contract between an institution and the united states department of health and human services that defines the relationship of the institution to the united states department of health and human services and that sets out the responsibilities of the institution and the procedures that will be used by the institution to protect human subjects.

- "Patient" means the insured or the insured's covered dependent.

- "Patient cost" means any fee or expense that is covered under the contract and that is for a service or treatment that would be required if the patient were receiving usual and customary care. **Patient cost does not include the cost**:

  - of any drug or device provided in a phase I cancer clinical trial.
  - of any investigational drug or device.
  - of nonhealth services that might be required for a person to receive treatment or intervention.
  - of managing the research of the clinical trial.
  - that would not be covered under the patient's contract.
  - of treatment or services provided outside this state.

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Disclaimer – Please read carefully: In administering claims for covered services directly associated with an eligible cancer clinical trial, BCBSAZ does not represent or warrant that the cancer clinical trial meets all of the requirements set forth by Arizona Law. BCBSAZ also does not represent or warrant that the treatment, device, drug, service or other item provided through the cancer clinical trial is safe, effective or appropriate for any subscriber. Decisions regarding whether the cancer clinical trial meets the criteria set forth by Arizona law and whether the cancer 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 cancer clinical trial is safe and effective and/or meets the criteria established by Arizona law, 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 Arizona law for covered services related to a cancer clinical trial, please contact the customer service department at the telephone number listed in the front of your benefit booklet.