CIRCULATING TUMOR DNA AND CIRCULATING TUMOR CELLS FOR CANCER MANAGEMENT

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 Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Medical Coverage Guideline 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.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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CIRCULATING TUMOR DNA AND CIRCULATING TUMOR CELLS FOR CANCER MANAGEMENT (cont.)

Description:

Circulating tumor DNA (ctDNA) or circulating tumor cells (CTCs) in peripheral blood, also referred to as liquid biopsy, have been investigated as a noninvasive alternative to tissue biopsy for therapeutic decision making and clinical prognosis in individuals with cancer.

Laboratories offering liquid biopsy tests, include, *but are not limited to*:

- Biocept Inc.
- Circulogene Theranostics
- Foundation Medicine® (test referred to as FoundationACT™)
- Genomic Health (test referred to as Oncotype SEQ™)
- PacificDX HER2
- Pathway Genomics® (test referred to as CancerIntercept™ Monitor)
- Silicon Biosystems® (test referred to as DEPArray™)

Criteria:

- The use of ctDNA and/or CTCs for all indications is considered *experimental or investigational* based upon:
  
  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
  4. Insufficient evidence to support improvement outside the investigational setting.
CIRCULATING TUMOR DNA AND CIRCULATING TUMOR CELLS FOR CANCER MANAGEMENT (cont.)

Resources:

Literature reviewed 06/14/16. We do not include marketing materials, poster boards and non-published literature in our review.

The BCBS Association Medical Policy Reference Manual (MPRM) policy is included in our guideline review. References cited in the MPRM policy are not duplicated on this guideline.


CIRCULATING TUMOR DNA AND CIRCULATING TUMOR CELLS FOR CANCER MANAGEMENT (cont.)

Resources: (cont.)


CIRCULATING TUMOR DNA AND CIRCULATING TUMOR CELLS FOR CANCER MANAGEMENT (cont.)

Resources: (cont.)


FDA 510K Summary for CellSearch Epithelial Cell Kit/Cell Spotter Analyzer (Veridex, LLC):

- FDA-approved indication: Intended for use in adjunctively monitoring and predicting cancer disease progression and response to therapy.
CIRCULATING TUMOR DNA AND CIRCULATING TUMOR CELLS FOR CANCER MANAGEMENT (cont.)

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 niliniigii Blue Cross Blue Shield of Arizona haada yit’éego bina’ídilkidgo éi doodago Háida biiá anilyeedigii t’aadoo le’e yina’Idilkidgo beeheaz’ánnii holqó dídí t’aad hazaad’éhjí háká a’doooolgo bee haza’q doo baqh illinígóó. Ata’ halne’igii kojí bíchjí’ hodilííní 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

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 thể 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، في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون أي تكلفة للتحدث مع مترجم مختص بـ 877-475-4799.
CIRCULATING TUMOR DNA AND CIRCULATING TUMOR CELLS FOR CANCER MANAGEMENT (cont.)

Multi-Language Interpreter Services: (cont.)

Tagalog: Kung ikaw, o ang iyong tinutulungan, ay may mga katanungan tungkol sa Blue Cross Blue Shield of Arizona, may karapatan ka na makakuha ng tulong at impormasyon sa iyon ng wika ng walang gastos. Upang makausap ang isang tagasalin, tumawag sa 877-475-4799.

Korean: 만약 귀하 또는 귀하의 가족이 Blue Cross Blue Shield of Arizona에 관해서 질문이 있다면 귀하는 그러한 도움과 정보를 귀하의 언어로 비용 부담없이 얻을 수 있는 권리가 있습니다. 그렇게 통역사와 얘기하기 위해서는 877-475-4799로 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 вы или лица, которым вы помогаете, имеете 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々でも、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る、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 مرود اطلاعات به زبان خود را به طور رایگان دریافت نمایید 877-475-4799.

Assyrian: Blue Cross Blue Shield of Arizona ئاین کەکەیە کە ئەوەیە بەرەوەدا، ئەوەیە بەرەوەدا، ئەوەیە بەرەوەدا، ئەوەیە بەرەوەدا، ئەوەیە بەرەوەدا، ئەوەیە بەرەوەدا.

Serbo-Croatian: Ukoiko 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 pravodocem, nazovite 877-475-4799.

Thai: ถ้าคุณมีข้อสงสัยเกี่ยวกับข้อมูลเกี่ยวกับ Blue Cross Blue Shield of Arizona คุณสามารถติดต่อเราได้โดยไม่มีค่าใช้จ่าย ที่เบอร์ 877-475-4799