GENE EXPRESSION PROFILING FOR CUTANEOUS MELANOMA

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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GENE EXPRESSION PROFILING FOR CUTANEOUS MELANOMA (cont.)

Description:

Gene expression profile (GEP) tests have been developed that detect the expression of different genes in pigmented lesions or melanoma tumor tissue. Tests include:

DermTech Pigmented Lesion Assay (PLA) has been investigated for individuals with suspicious pigmented lesions to determine which lesions should proceed to biopsy. Pigmented lesion samples are collected with a proprietary adhesive patch and RNA is isolated from the lesion samples. The PLA melanoma associated gene expression (MAGE) test detects the expression of the PRAME and LINC00518 genes. The PLA Score, a single number ranging from 0 to 100, supplements the PLA MAGE. The PLA MAGE and the PLA Score have been investigated to differentiate melanomatous and non-melanomatous lesions.

DecisionDx-Melanoma biomarker based gene expression profile test has been investigated to assist in identifying high risk individuals classified with stage I or II cutaneous melanoma to determine whether to perform sentinel lymph node biopsy.

Myriad myPath Melanoma gene expression profiling test has been investigated for individuals who have melanocytic lesions with indeterminate histopathologic features. The myPath test is meant as an add-on test to standard histopathology to differentiate benign nevi from melanoma and to aid in decisions regarding treatment and surveillance.

Definitions:

Gene Expression:
The translation of the information encoded in a gene into messenger RNA (mRNA) which may or may not then be translated into a protein.

Gene:
A hereditary unit consisting of segments of DNA that occupies a specific location on chromosomes. Genes undergo mutation when their DNA sequence changes.

Genetic Counseling:
Instruction that provides interpretation of genetic tests and information about courses of action that are available for the care of an individual with a genetic disorder or for future family planning.
GENE EXPRESSION PROFILING FOR CUTANEOUS MELANOMA (cont.)

**Definitions**: (cont.)

**Affected Individual**:  
An individual displaying signs or symptoms characteristic of a suspected or specific inherited disorder.

**Unaffected Individual**:  
An individual who displays no signs or symptoms characteristic of a suspected or specific inherited disorder.

**Screening**:  
Genetic screening is the testing of an individual with no symptoms for a specific inherited disorder to determine if the individual carries an abnormal gene. Screening can be used to predict risk or potential risk for the individual or their offspring.

**Criteria**:  

- Genetic testing and/or counseling of an *unaffected* individual, regardless of risk factors is considered *screening* and *not eligible for coverage*.

- Genetic testing and/or counseling of an *affected* individual to confirm a disease when confirmation of the diagnosis would not impact the care and/or management is considered *not medically necessary* and *not eligible for coverage*.

- Gene expression testing in the evaluation of individuals with suspicious pigmented lesions 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.
GENE EXPRESSION PROFILING FOR CUTANEOUS MELANOMA (cont.)

Criteria:

- Gene expression testing in the evaluation of individuals with cutaneous melanoma 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.

- Gene expression testing in the evaluation of individuals with melanocytic lesions with indeterminate histopathologic features 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.

Resources:

Literature reviewed 06/05/18. We do not include marketing materials, poster boards and non-published literature in our review.


GENE EXPRESSION PROFILING FOR CUTANEOUS MELANOMA (cont.)

Resources: (cont.)


GENE EXPRESSION PROFILING FOR CUTANEOUS MELANOMA (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 niłíingedí Blue Cross Blue Shield of Arizona haadá yit’éego bina’idíkkídgo éí doodago Háída bíjá aniíyeeéíígíí t’aadoo le’e yina’idíkkídgo beehaz’áání hólo díí t’áá hazaadk’éhíí háká a’dowolgo bee haz’á doo bąáh ilínígóó. Ata’ halne’iígií kójí bích’jí hodíínih 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: إذا كنت لديك الحق في الحصول على المساعدة والمعلومات، Blue Cross Blue Shield of Arizona للديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون اية تكلفة. للتحدث مع مترجم انصل ب 877-475-4799.
GENE EXPRESSION PROFILING FOR CUTANEOUS MELANOMA (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 iyong wika ng walang gastos. Upang makuasa ang isang tagasalin, tumawag sa 877-475-4799.

Korean: 만약 문제가 되는 사항이 Blue Cross Blue Shield of Arizona 에 관해서 질문이 있다면 문제를 해결하기 위한 방안으로 이용 부담없이 원할 수 있는 권리가 있습니다. 그렇게 합리적으로 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 et sans 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:

آگر شما یا کسی که شما به او کمک می‌کنید، سوال‌های مورد اطلاعات به زبان خود را به طور رایگان دریافت نمایید 877-475-4799.

Assyrian:

Blue Cross Blue Shield of Arizona لید، یکه له ناسی تارم ناکات نئو یو جی. 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 dobiête pomoć i informacije na Vašem jeziku. Da biste razgovarali sa prevodiocem, nazovite 877-475-4799.

Thai: หากคุณ หรือผู้ที่คุณช่วยเหลือมีความสงสัยเกี่ยวกับ Blue Cross Blue Shield of Arizona คุณสามารถได้รับความช่วยเหลือและข้อมูลในภาษาของคุณได้โดยไม่เสียค่าใช้จ่าย โทร 877-475-4799.