BlueCross BlueShield of Arizona
An Independent Licensee of the Blue Cross and Blue Shield Association

MEDICAL COVERAGE GUIDELINES	**ORIGINAL EFFECTIVE DATE: 03/05/13**
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OPTICAL DIAGNOSTIC DEVICES FOR EVALUATING SKIN LESIONS SUSPECTED OF MALIGNANCY

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.

OPTICAL DIAGNOSTIC DEVICES FOR EVALUATING SKIN LESIONS SUSPECTED OF MALIGNANCY (cont.)

Description:

Dermatoscopy:
Dermatoscopy, also known as dermoscopy, describes noninvasive techniques that allow in vivo microscopic examination of skin lesions to distinguish between benign and malignant pigmented skin lesions. The technique involves application of immersion oil to the skin, which eliminates light reflection from the skin surface and renders the stratum corneum transparent. Using a magnifying lens, the structures of the epidermis and epidermal-dermal junction can then be visualized.

A handheld or stereomicroscope may be used for direct visual examination. Handheld dermatoscopy may also be referred to as handheld dermoscopy, epiluminescence microscopy and magnified oil immersion diascopy.

Photography is a component of dermatoscopy. Specific lesions or whole body images may be taken. Computer-assisted dermatoscopy devices are tools that photograph and digitize images typically after initial visual assessment to permit storage and facilitate retrieval for subsequent monitoring. Computer-assisted dermatoscopy may also be referred to as computer-assisted dermoscopy, computer-assisted skin surface microscopy, computer-assisted direct skin microscopy or computer-assisted skin videomicroscopy.

Teledermatoscopy describes sending the images to other medical providers, such as dermatologists, for evaluation and management recommendations. May also be referred to as teledermoscopy.

Specialized clinics have been developed specifically to offer dermatoscopy. The evaluation may be marketed as a “melanomagram”.

Dermatoscopy has been investigated as a noninvasive technique to improve the diagnosis of malignant skin lesions and in the serial assessment of lesions over time and for defining peripheral margins prior to surgical excision of skin tumors.

OPTICAL DIAGNOSTIC DEVICES FOR EVALUATING SKIN LESIONS SUSPECTED OF MALIGNANCY (cont.)

Description: (cont.)

Dermatoscopy: (cont.)

Dermatoscopic devices cleared by the U.S. Food and Drug Administration (FDA) include:

- Dermascope™
- DermLite®
- DermoGenius®
- Episcope™
- MoleMax™
- Nevoscope™

Computer-assisted dermatoscopic devices cleared by the FDA include:

- MoleMax™ II
- SolarScan® Skin Cancer Detection System, also referred to as Solar Scan

Optical Coherence Tomography (OCT):
OCT has been investigated as a noninvasive technique using an imaging technology based on light and optics. OCT uses eye-safe infrared light to obtain a 3D block of image data at a higher resolution compared to other modalities. OCT is indicated for use in the two-dimensional, cross-sectional, real-time imaging of external tissues of the human body. This allows imaging of the tissue microstructure, including skin, to aid trained and competent clinicians in their assessment of clinical conditions. The VivoSight™ has received FDA-510(k) approval.

Reflectance Confocal Microscopy (RCM):
RCM, also known as confocal scanning laser microscopy, uses a near-infrared laser beam projected through a lens to obtain images of the top layers of the skin. The images are magnified and information regarding cell structure and the surrounding tissues is evaluated. The system is intended to acquire, store, retrieve, display and transfer in vivo images of tissue, including blood, collagen and pigment, in exposed unstained epithelium and the supporting stroma for review by physicians to assist in forming a clinical judgement.

Reflectance confocal laser scanning microscopy devices cleared by the FDA include:

- VivaScope®

OPTICAL DIAGNOSTIC DEVICES FOR EVALUATING SKIN LESIONS SUSPECTED OF MALIGNANCY (cont.)

Criteria:

Dermatoscopy:

- Dermatoscopy, using either direct inspection, digitization of images, or computer-assisted analysis, for the following 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.

  These indications included, *but are not limited to*:

  - As a technique to evaluate or serially monitor pigmented skin lesions
  - As a technique to define peripheral margins of skin lesions suspected of malignancy prior to surgical excision

Optical Coherence Tomography:

- Optical coherence tomography devices for the following indications are 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.

  These indications included, *but are not limited to*:

  - As a technique to evaluate or serially monitor pigmented skin lesions
  - As a technique to define peripheral margins of skin lesions suspected of malignancy prior to surgical excision

OPTICAL DIAGNOSTIC DEVICES FOR EVALUATING SKIN LESIONS SUSPECTED OF MALIGNANCY (cont.)

Criteria: (cont.)

Reflectance Confocal Microscopy:

- Reflectance confocal microscopy optical imaging devices (e.g. multilaser cellular) for the following indications are 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.

  These indications included, *but are not limited to*:

  - As a technique to evaluate or serially monitor pigmented skin lesions
  - As a technique to define peripheral margins of skin lesions suspected of malignancy prior to surgical excision

Teledermatoscopy:

- Teledermatoscopy is considered an electronic consultation and is a ***benefit plan exclusion*** and ***not eligible for coverage***.

OPTICAL DIAGNOSTIC DEVICES FOR EVALUATING SKIN LESIONS SUSPECTED OF MALIGNANCY (cont.)

Resources:

Literature reviewed 02/20/18. 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.

Resources prior to 03/05/13 may be requested from the BCBSAZ Medical Policy and Technology Research Department.

1. 2.01.42 BCBS Association Medical Policy Reference Manual. Optical Diagnostic Devices for Evaluating Skin Lesions Suspected of Malignancy. Re-issue date 09/11/2014, issue date 08/15/2001.

2. 2.01.101 BCBS Association Medical Policy Reference Manual. Multispectral Digital Skin Lesion Analysis. Re-issue date 01/11/2018, issue date 12/10/2015

3. Abignano G, Kapadia A, Lettieri G, et al. Use of optical coherence tomography for the diagnosis of preclinical lesions of circumscribed palmar hypokeratosis. *Clinical and experimental dermatology.* Mar 2017;42(2):192-195.

4. Braun RP, Gutkowicz-Krusin D, Rabinovitz H, et al. Agreement of dermatopathologists in the evaluation of clinically difficult melanocytic lesions: how golden is the 'gold standard'? *Dermatology (Basel, Switzerland).* 2012;224(1):51-58.

5. Guitera P, Menzies SW, Argenziano G, et al. Dermoscopy and in vivo confocal microscopy are complementary techniques for diagnosis of difficult amelanotic and light-coloured skin lesions. *The British journal of dermatology.* Dec 2016;175(6):1311-1319.

6. Guitera P, Menzies SW, Longo C, Cesinaro AM, Scolyer RA, Pellacani G. In vivo confocal microscopy for diagnosis of melanoma and basal cell carcinoma using a two-step method: analysis of 710 consecutive clinically equivocal cases. *The Journal of investigative dermatology.* Oct 2012;132(10):2386-2394.

7. Kadouch DJ, Wolkerstorfer A, Elshot Y, et al. Treatment of Basal Cell Carcinoma Using a One-Stop-Shop With Reflectance Confocal Microscopy: Study Design and Protocol of a Randomized Controlled Multicenter Trial. *JMIR research protocols.* 2015;4(3):e109.

8. Maher NG, Blumetti TP, Gomes EE, et al. Melanoma diagnosis may be a pitfall for optical coherence tomography assessment of equivocal amelanotic or hypomelanotic skin lesions. *The British journal of dermatology.* Nov 18 2016.

OPTICAL DIAGNOSTIC DEVICES FOR EVALUATING SKIN LESIONS SUSPECTED OF MALIGNANCY (cont.)

Resources: (cont.)

9. Meekings A, Utz S, Ulrich M, et al. Differentiation of Basal Cell Carcinoma Subtypes in Multi-Beam Swept Source Optical Coherence Tomography (MSS-OCT). *Journal of drugs in dermatology : JDD.* May 01 2016;15(5):545-550.

10. Nori S, Rius-Diaz F, Cuevas J, et al. Sensitivity and specificity of reflectance-mode confocal microscopy for in vivo diagnosis of basal cell carcinoma: a multicenter study. *Journal of the American Academy of Dermatology.* Dec 2004;51(6):923-930.

11. Pellacani G, Pepe P, Casari A, Longo C. Reflectance confocal microscopy as a second-level examination in skin oncology improves diagnostic accuracy and saves unnecessary excisions: a longitudinal prospective study. *The British journal of dermatology.* Nov 2014;171(5):1044-1051.

12. Pellacani G, Witkowski A, Cesinaro AM, et al. Cost-benefit of reflectance confocal microscopy in the diagnostic performance of melanoma. *Journal of the European Academy of Dermatology and Venereology : JEADV.* Mar 2016;30(3):413-419.

13. Rao BK, Mateus R, Wassef C, Pellacani G. In vivo confocal microscopy in clinical practice: comparison of bedside diagnostic accuracy of a trained physician and distant diagnosis of an expert reader. *Journal of the American Academy of Dermatology.* Dec 2013;69(6):e295-300.

14. UpToDate.com. Clinical features and diagnosis of cutaneous melanoma. 12/01/2016.

OPTICAL DIAGNOSTIC DEVICES FOR EVALUATING SKIN LESIONS SUSPECTED OF MALIGNANCY (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 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.

OPTICAL DIAGNOSTIC DEVICES FOR EVALUATING SKIN LESIONS SUSPECTED OF MALIGNANCY (cont.)

<u>Multi-Language Interpreter Services</u>: (cont.)

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