OPTICAL DIAGNOSTIC DEVICES FOR EVALUATING SKIN LESIONS SUSPECTED OF MALIGNANCY

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.

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.

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

**Description** (cont.)

**Dermatoscopy** (cont.)
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.

Computer-based optical diagnostic devices have been investigated for defining peripheral margins of lesions suspected of malignancy. A multispectral digital skin lesion analysis (MSDCLA) device uses a handheld scanner to shine visible light on the suspicious lesion. MelaFind is an FDA-approved computer-based optical imaging device. MelaFind includes computerized algorithms to evaluate specific pigmented lesions with clinical or histological characteristics suggestive of melanoma.

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
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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 include, 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

- Computer-based optical imaging devices (e.g., multispectral digital skin lesion analysis) 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 include, 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:

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