BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Ultrasonographic Evaluation of Skin Lesions

Policy #: 144
Category: Radiology/Medicine

Latest Review Date: August 2019
Policy Grade: **Effective October 2012: Active Policy but no longer scheduled for regular literature reviews and updates.**

Background:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Medicare the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational (exception: routine costs of qualifying clinical trial services with dates of services on or after September 19, 2000 which meet the requirement of the Clinical Trials NCD are considered reasonable and necessary);*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
   - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
   - *Furnished in a setting appropriate to the patient's medical needs and condition;*
   - *Ordered and furnished by qualified personnel;*
   - *One that meets, but does not exceed, the patient's medical need; and*
   - *At least as beneficial as an existing and available medically appropriate alternative.*

In accordance with Title XVIII of the Social Security Act, Section 1862 (a)(1)(K)(10) cosmetic surgery or expenses incurred in connection with such surgery is not covered except as required for the prompt repair of accidental injury or for improvement of the functioning of a malformed body member.

Description of Procedure or Service:

Ultrasonographic evaluation of skin lesions refers to the use of ultrasound to provide information about the margins and depth of surface tumors or inflammatory skin conditions. Several ultrasound systems using transducers of at least 20 MHz have been approved by the Food and Drug Administration (FDA) for visualizing skin; lower frequency ultrasound transducers (12-15 MHz) have also been used.

High-frequency ultrasound transducers (20-100 MHz) have been used in ophthalmology, endoscopic imaging systems, and to evaluate skin lesions. High frequency scanning provides a high degree of axial and lateral resolution, but limited penetration. High-frequency ultrasound can distinguish between the epidermis, dermis, and underlying connective tissue. Lower frequency ultrasound transducers (12-15 MHz) have also been used to evaluate skin layers. It gives information on the morphology of the lesion, such as the size, shape, and depth of the skin lesion. However, it does not give information on the diagnosis of the lesion.

The following applications of ultrasonic evaluation of skin lesions have been proposed:

- To assess the margins and depth of melanoma and non-melanoma skin cancers to aid in surgical planning.
- To assess actinic keratosis to determine if cryosurgery is an appropriate therapeutic option.
- To follow the course of connective tissue diseases of the skin, such as scleroderma, by evaluating the amount and location of collagen in the dermis.
- To assess inflammatory skin diseases, such as allergy reactions, psoriasis, and lichen planus.

This policy does not address the potential use of ultrasonographic detection for subcutaneous lesions including lipomas, epidermal cysts or ganglions or for detecting regional lymph nodes and subcutaneous metastases in patients with melanoma.

Policy:

Effective for dates of service on or after July 1, 2005:

Blue Advantage will treat **ultrasonic evaluation of skin lesions** as a **non-covered** benefit and is considered **investigational**.

Blue Advantage will treat **ultrasonic evaluation** as a technique to assess photoaging or skin rejuvenation techniques as a **non-covered** benefit and as **cosmetic**.

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

Key Points:

The evaluation of a new diagnostic technology typically focuses on the following 3 parameters: its technical performance, diagnostic parameters (sensitivity, specificity, positive and negative predictive value) in different populations of patients, and proof that the diagnostic information can be used to improve patient outcomes.

A number of studies reporting diagnostic accuracy of ultrasound have been published in a variety of patient populations, primarily including patients with malignant melanoma, inflammatory lesions, or connective tissue disorders. Several studies examined the correlation of the thickness of melanotic lesions as assessed histologically and with ultrasonography. Generally studies found a high degree of correlation, although some noted that the ultrasonographic assessment of the thickness of the lesion was often greater that that assessed histologically, perhaps due to shrinkage artifact in the histological specimen, or due to the inability of ultrasonography to distinguish an inflammatory reaction or normal nevus cells from malignant melanocytes.

A 2009 systematic review by Machet et al included 14 studies correlating high-resolution ultrasound with histological analysis in melanoma patients. The correlation coefficients in the studies ranged from 0.88 to 0.97 (median of 0.95). Data on the ability of ultrasound thickness to predict adequate surgical margins were available from 7 of the studies, with a total of 860 lesions. The proportion of lesions in the individual studies, that was well-classified by ultrasound, ranged from 72% to 89%. In addition to the systematic review, Machet et al conducted a prospective, single-center study in France that included 31 patients with suspected to confirmed primary cutaneous melanoma that had not been surgically removed. Average lesion thickness was 1.96 mm by ultrasound and 1.95 mm by histology. The correlation between ultrasound and histological findings was 94% and it was possible to predict appropriate surgical margins in 84% of patients.

A study published in 2009 investigated the optimal frequency of ultrasound machines for scanning thin melanocytic skin lesions (MSL). The study included 37 patients with 50 suspicious MSL of maximal vertical tumor thickness < 1mm. Compared to histology, 100 MHz was more accurate than 20 MHz, although both overestimated tumor thickness (mean of 16µm and 34µm overestimation of tumor thickness, respectively). This study suggests that a higher frequency transducer may be more accurate than a 20 MHz transducer which was used in many of the previously-reported case series.

Several recent studies conducted outside of the United States have evaluated skin lesions using ultrasound machines with transducer frequencies lower than 20 MHz. In 2010, Music et al in Slovenia preoperatively evaluated 69 patients with suspicious pigmented skin lesions with ultrasound (12-15 MHz). There was a high correlation between ultrasound and histologic tumor thickness (correlation coefficient=0.82). Using histologic diagnosis as the reference standard, ultrasound had a sensitivity of 92% and a specificity of 92% for detecting melanoma with a thickness greater than 1 mm. In 2011, Kaikaris et al in Lithuania published findings from 100 patients with a clinical diagnosis of stage I-II cutaneous melanoma who underwent preoperative ultrasound examination with a 14-MHz transducer. There was a high correlation between ultrasound and histologic findings when melanoma lesions were thicker than 2 mm (correlation

coefficient0.87). Histologic findings did not correlate well with ultrasound for thinner lesions (1-2 mm), correlation coefficient=0.28.

Clinical Utility

Several studies have evaluated the role of ultrasound in patient management among patients with skin lesions. A 2009 study by Jambusaria-Pahlajani and colleagues included 100 patients with biopsy-proven basal cell carcinoma or squamous cell carcinoma scheduled to undergo Mohs micrographic surgery. Patients received a preoperative high-resolution (40MHz) ultrasound scan after the surgeon initially drew a proposed surgical margin. The ultrasound technician identified any area of tumor that extended outside the proposed margin, and these areas were verified by histology. The sensitivity of ultrasound for correctly identifying areas of tumor extension beyond those proposed by the surgeon was low, 32% (95% CI=15-54%). Ultrasound was more sensitive for the 43 larger tumors above the median of 1.74 sq cm than for the 41 smaller tumors (55% versus 33%, respectively). The authors concluded that the sensitivity of high-frequency ultrasound was too low to be clinically useful. They noted, however, that the overall low sensitivity might be due in part from their decision to optimize the image of the dermis with greater resolution than the epidermis, thereby limiting the accuracy of imaging of the epidermis.

Another study on patient management using ultrasound was published in 2010 by Wortsman and Wortsman in Chile. In a retrospective single-center study, the authors compared ultrasound diagnoses of 4,338 skin lesions with clinical diagnosis, using histology as the reference standard. Frequencies of 14-15 MHz were used to observe skin layers. Of the 4,338 lesions, 75 (2%) were malignant tumors, and 677 (16%) were inflammatory or infectious lesions. (The majority of the skin lesions were benign nonvascular tumors, such as enlarged lymph nodes and lipomas.) All patients were referred to a department of radiology for further testing; specific reasons for referral were not provided. Clinicians did not have the ultrasound results available at the time of diagnosis, but they did have access to findings from laboratory tests. Ultrasound technicians were aware of the referring diagnosis. The referring diagnosis agreed with the histologic diagnosis in 87% of the 75 malignant tumor cases, and the addition of ultrasound findings increased the percentage to 91%. The referring diagnosis was correct in 77% of the inflammatory/infectious lesions, and ultrasound increased this percentage to 99%. In both types of lesions, the increase in the proportion of correct diagnoses by ultrasound was statistically significant ($p<0.001$). In 735 of the 4,338 lesions (17%), including 3 malignant lesions, only ultrasound correctly identified the diagnosis. The authors said that the treatment plans were modified in all of these cases but did not provide details on the modifications. All ultrasound examinations were performed by the same physician, which, although increasing the consistency of interpretation, may not be generalizable to findings by other clinicians. As noted above, the study was retrospective; prospective studies evaluating larger numbers of skin conditions relevant to this policy are needed.

Summary of Evidence

The evidence is insufficient for determining the clinical utility of ultrasonic evaluation of skin lesions. No published studies were identified that prospectively examined whether the use of ultrasonography resulted in improved health outcomes, such as higher treatment success rates, lower rates of disease recurrence or increased survival. Given the lack of sufficient high-quality evidence on the impact of ultrasound skin imaging on patient management and health outcomes,

this technology is considered investigational. In addition, due to the cosmetic nature of the application, ultrasound skin imaging is considered not medically necessary to assess photoaging or skin rejuvenation techniques.

Practice Guidelines and Position Statements
The National Comprehensive Cancer Network (NCCN) melanoma guideline does not mention use of ultrasonography for evaluating known or suspected melanomas.

Key Words:
Ultrasonography, ultrasound, skin lesions, melanoma, psoriasis, skin, Episcan I-200, DermaScan

Approved by Governing Bodies:
The FDA has cleared numerous ultrasound systems that include skin ultrasound as one of many indications. In addition, several ultrasonic systems that specialize in imaging skin have been cleared for marketing by the FDA though the 510(k) process. The Episcan® I-200, Ultrasound System (Longport, Inc., Glen Mills, PA), which uses either a 20-MHz or 30-MHz transducer, was cleared for marketing in November 2006. Its intended use is medical/surgical dermatology assessment and diagnosis (aesthetic and therapeutic), plastic/reconstructive surgical planning, wound assessment and management, skin assessment for pressure ulcer detection and prevention, and superficial musculoskeletal diagnosis.

Another specialized system, the DermaScan™ C Ultrasonic System (Cortex Technology, Denmark) was cleared in 1999. This 20-MHz transducer is intended to be used to visualize the layers of the skin to make approximate measurement of dimensions of skin layers and blood vessels.

Benefit Application:
Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

Coding:
CPT codes: There are no specific CPT codes describing ultrasonographic evaluation of skin lesions. These codes might be used.

17999	Unlisted procedure, skin, mucous membrane and subcutaneous tissue
76999	Unlisted ultrasound procedure
96999	Unlisted special dermatological service or procedure

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Policy History:

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Medical Policy Group, December 2005
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Medical Policy Group, October 2011
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