BlueCross BlueShield of Alabama

Name of Policy:
Ultrasonographic Evaluation of Skin Lesions

Policy #: 144
Category: Radiology/Medicine

Latest Review Date: October 2011
Policy Grade: **Effective October 2012: Active Policy but no longer scheduled for regular literature reviews and updates.**

Background/Definitions:
As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. *The technology must have final approval from the appropriate government regulatory bodies;*
2. *The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;*
3. *The technology must improve the net health outcome;*
4. *The technology must be as beneficial as any established alternatives;*
5. *The improvement must be attainable outside the investigational setting.*

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. *In accordance with generally accepted standards of medical practice; and*
2. *Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient's illness, injury or disease; and*
3. *Not primarily for the convenience of the patient, physician or other health care provider; and*
4. *Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.*

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.

The FDA has cleared numerous ultrasound systems that include sin ultrasound as one of many indications. In addition, several ultrasonic systems that specialize in imaging skin have been cleared for marketing by the FDA through the 510(k) process. The Episcan® I-200, Ultrasound System (Longport, Inc.) which uses either a 20 MHz transducer, was cleared for marketing in November, 2006. Its intended use is medical/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 was cleared in 1999. This 20 MHz transducer is intended to be used to visual the layers of the skin to make approximate measurement of dimensions of skin layers and blood vessels.

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:

Ultrasonic evaluation of skin lesions does not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage and is considered **investigational**.

Ultrasonic evaluation as a technique to assess photoaging or skin rejuvenation techniques **does not meet** Blue Cross and Blue Shield of Alabama's medical criteria for coverage and will be considered as **not medically necessary**.

Blue Cross and Blue Shield of Alabama 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 Cross and Blue Shield of Alabama administers benefits based on the members' contract and corporate 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.

The skin is the largest organ in the body and can produce a large variety of both benign and malignant tumors. At present, excision-biopsy is the gold standard for analysis of such lesions. This is an expensive and time-consuming practice, especially since the majority of skin tumors are benign. Ultrasonography allows non-invasive assessment of the skin. Sound waves are beamed into the skin and reflected at structural interfaces between or within tissues.

There are several studies looking at the use of ultrasound to evaluate various skin lesions, such as skin tumors, psoriasis, and melanomas. Some compared ultrasound results with the histologic exam. There are no controlled studies looking at the clinical use of ultrasound in the management of the patients.

Harland et al examined 16 skin tumors and one BCG vaccination granuloma with a 20-MHz B-scan ultrasound and compared the images with corresponding histological section of the excised lesions. The ultrasound exam reliably showed the lesion margin and overall architecture. The correlation between ultrasound and histology was excellent for maximum tumor depth measurements but not as good for tumor width. The echogenicity of the lesions was determined by the content, configuration, and distribution of the collagen bundle fibers. The authors concluded that the accuracy of B-scanning in the assessment of skin tumors requires further study. It is a potentially valuable technique for the preoperative assessment of skin cancers such as melanoma.

Olsen et al used high frequency ultrasound (20 MHz) to study seventeen patients with psoriasis vulgaris. 42 of 44 psoriasis plaques showed a characteristic echo – lucent band, which represented acanthotic epidermal thickening and inflammation.

Semple et al used high frequency (40 – 60 MHz) B-scan ultrasound system to assess 10 cutaneous melanomas and 7 benign pigmented lesions. Vertical height was documented and compared with histopathological findings. There was good correlation with the ultrasound heights and the standard measurement of Breslow's thickness only in the mid-range (1.0 – 3.0 mm) lesions. Thick keratin layers, such as those on the feet, can block the ultrasound beam. The authors concluded that this ultrasound imaging does not replace the need for biopsy of a pigmented lesion.

Lassau et al looked at the efficacy of high frequency sonography for the preoperative assessment of melanomas and to determine the prognostic valve of tumor vascularity measured by color Doppler sonography. Twenty-seven patients with melanomas were examined with high frequency (20 MHz) sonography prior to surgery. After surgical resection, histologic analysis was done to determine the Breslow index valve. Sonography measurements and Breslow index values were strongly correlated. On color Doppler sonography, vessels were visualized in 10 melanomas and correlated significantly with histologic findings. The authors concluded that high frequency sonography is a reliable, noninvasive method for preoperative measurement of melanoma thickness.

A study published in 2006 from Italy cited a retrospective review of 600 patient's records with cutaneous malignant melanoma. Ultrasound identified malignant nodules during follow-up in 63 patients, suggesting that ultrasound maybe useful for detecting in-transit and satellite metastases during follow-up. Improvement in clinical outcomes needs to be tested in a randomized controlled trial. The non-coverage statement of this policy remains unchanged.

November 2009 Update

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 study that included 57 patients assessed whether ultrasound biomicroscopy (50 MHz) could aid in the diagnosis of 8 non-melanocytic skin disorders. There was a difference in thickness between lesional and normal skin for morphea, seborrheic keratosis, and psoriasis, and a correlation coefficient of 0.002 between the psoriatic area and severity index and ultrasound measurements. Dermal thickness could not be consistently assessed with ultrasound biomicroscopy for eczema, lichen planus, and seborrheic keratosis and skin thickness was not different between port wine and normal skin.

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.

Two studies have examined the role of ultrasound inpatient management among patients with non-melanoma skin cancer; the study by Jambusaria-Pahlajani used more rigorous methods. This study included 100 patients with biopsy-proven BCC or squamous cell carcinoma (SCC) 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. An earlier study by Desei et al compared the results from a 20 MHz scanner with clinically and histologically delineated margins for 50 superficial and nodular basal cell carcinomas (BCCs), excluding those in locations difficult to image. Ultrasound measurements were correlated ($r > 0.70$) with clinical measurements prior to excision, with a mean 20% to 25% increase in size compared to naked eye measurements; 10% of ultrasound measurements showed clinical extension findings with preoperative clinical measurements was not clearly describe and patients health outcomes were not evaluated.

In summary, the evidence is insufficient for determining whether the use of ultrasound leads to improved health outcomes in patients with skin lesions. No studies were identified that examined the impact of ultrasonographic findings on the management of patients with melanoma, actinic keratoses, inflammatory skin diseases or connective skin diseases. Moreover, no study identified examined whether the use of ultrasonography preoperatively resulted in improved health outcomes such as lower rates of disease recurrence or increased survival. Two studies used appropriate study designs to evaluate clinical utility, a comparison of estimates of the margins of non-melanoma skin carcinomas by ultrasonography and clinical examination with histological verification, to evaluate whether ultrasound scanning aids in surgical planning. Both were small and subject to limitations. Given the lack of sufficient high-quality evidence on the impact of ultrasound skin imaging on patient management, 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.

October 2010 Update
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.

Wortsman and Wortsman conducted a retrospective single-center study in Chile. The authors compared ultrasound diagnoses of 4338 skin lesions with clinical diagnosis, using histology as the reference standard. Frequencies of 14-15 MHz were used to observe skin layers. Of the 4338 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 histological 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 ultrasound was statistically significant ($p< 0.001$). IN 735 of the 4338 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. The evidence remains insufficient for determining whether this procedure improves health outcomes.

October 2011 Update
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.

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

Summary
The evidence is insufficient for determining whether the use of ultrasound leads to improved health outcomes in patients with skin lesions. No study identified examined whether the use of ultrasonography preoperatively resulted in improved health outcomes, such as 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, 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.

Key Words:
Ultrasonography, ultrasound, skin lesions, melanoma, psoriasis, skin

Approved by Governing Bodies:
FDA approved

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

ITS: Home Policy provisions apply
BellSouth/AT&T contracts: Considers investigational
FEP contracts: FEP does not consider investigational. Will be reviewed for medical necessity
Wal-Mart: Special benefit consideration may apply. Refer to member's benefit plan.
Pre-certification/Pre-determination requirements: Not 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:

Medical Policy Group, November 2003 **(1)**
Medical Policy Administration Committee, December 2003
Available for comment December 16, 2003-January 29, 2004
Medical Policy Group, November 2005 **(1)**
Medical Policy Administration Committee, December 2005
Medical Policy Group, November 2007 **(1)**
Medical Policy Group, November 2009 **(1)**
Medical Policy Group, October 2010 **(1)** Updated Key Points and References, no policy statement change
Medical Policy Group, October 2011 **(1)** Updated Descriptions, Key Points and References; no change in policy statement
Medical Policy Group, January 2013: Effective October 2012 this policy will no longer be scheduled for regular literature reviews and updates.