Effective November 1, 2023, refer to CMS Manual 100-02, Chapter 16-General Exclusions from Coverage for services included in this policy.

BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Ultrasonographic Evaluation of Skin Lesions

Policy #: 144
Latest Review Date: July 2023
Category: Radiology/Medicine
ARCHIVED EFFECTIVE 11/1/2023

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.

POLICY:

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

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

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.

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.

KEY POINTS:

The most recent update with literature review covers the period through July 7, 2022.

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.

CURRENT 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

REFERENCES:

1. Bakr M, et al. Ultrasound biomicroscopy in the diagnosis of skin diseases. Eur J Dermatol 2007; 17(6): 469-475.
2. Bessoud B, Lassau N, Koscielny S, et al. High frequency sonography and color Doppler in the management of pigmented skin lesions, Ultrasound Med Viol 2003; 29(6): 875-879.
3. Blue Cross Blue Shield Association. Ultrasonographic evaluation of skin lesions. Medical Policy Reference Manual, November 2009.
4. Bobadilla F, Wortsman X, et al. Pre-surgical high resolution ultrasound of facial basal cell carcinoma: Correlation with histology. Cancer Imaging, September 2008; 8: 163-172.
5. Cammarota T, Pinto F, Magliaro A et al. Current uses of diagnostic high-frequency US in dermatology. Eur J Radiol 1998; 27(suppl 2):S215-223.
6. Desai TD, Desai AD, et al. The use of high-frequency ultrasound in the evaluation of superficial and nodular basal cell carcinomas. Dermatol Surg, October 2007; 33(10): 1220-1227.
7. El-Zawahry MB, El-Hameed A, El-Cheweikh HM et al. Ultrasound biomicroscopy in the diagnosis of skin diseases. Eur J Dermatol 2007; 17(6):469-75.
8. Gambichler T, Moussa G, et al. Preoperative ultrasonic assessment of thin melanocytic skin lesions using a 100-MHz ultrasound transducer: A comparative study. Dermatol Surg, July 2007; 33(7): 818-824.
9. Harland, et al. High-frequency, high-resolution b-scan ultrasound in the assessment of skin tumors, British Journal of Dermatology, 1993; 128: 525-532.
10. IOM (Institute of Medicine). 2011. Clinical Practice Guidelines We Can Trust. Washington, DC: The National Academies Press.

11. Jambusaria-Pahlajani A, Schmults CD, et al. Test characteristics of high-resolution ultrasound in the preoperative assessment of margins of basal cell and squamous cell carcinoma in patients undergoing Mohs micrographic surgery. Dermatol Surg, January 2009; 35(1): 9-15.
12. Kaikaris V, Samsanavicius D, Maslauskas K et al. Measurement of melanoma thickness-comparison of two methods: ultrasound versus morphology. J Plast Reconstr Aesthet Surg 2011; 64(6): 796-802.
13. Kolbe L, Kligman AM, Schreiner V et al. Corticosteroid-induced atrophy and barrier impairment measured by non-invasive methods in human skin. Skin Res Technol 2001; 7(2):73-77.
14. Lassau N, et al. Prognostic values of high-frequency sonography and color Doppler sonography for the preoperative assessment of melanomas, American Journal of Radiology, 1999; 172: 457-461.
15. Machet L, Belot V, Naouri M, et al. Preoperative measurement of thickness of cutaneous melanoma using high-resolution 20 MHZ ultrasound imaging: a monocenter prospective study and systematic review of the literature. Ultrasound Med Biol; 2009; 35(9):1411-1420.
16. Mogensen M and Jemec GB. Diagnosis of nonmelanoma skin cancer/keratinocyte carcinoma: A review of diagnostic accuracy of nonmelanoma skin cancer diagnostic tests and technologies. Dermatol Surg, October 2007; 33(10): 1158-1174.
17. Music MM, Hertl K, Kadivec M et al. Pre-operative ultrasound with a 12-15 MHz linear probe reliably differentiates between melanoma thicker and thinner than 1mm. J Eur Acad Dermatol Venereol 2010; 24(9):1105-1108.
18. National Comprehensive Cancer Network. Melanoma. Clinical practice guidelines in oncology, v2.2020. Available online at: //www.nccn.org/professionals/physician_gls/PDF/melanoma.pdf.
19. Nessi R, et al. Skin ultrasound in dermatologic surgical planning, Journal of Dermatologic Surgical Oncology, 1991; 17: 38-42.
20. Olsen L, and Serup J. High-frequency ultrasound scan for non-invasive cross-sectional imaging of psoriasis, Acta Dermatology Venereol (Stock), 1993; 73: 185-187.
21. Partsch B, Binder M, Puspok-Schwarz M, et al. Limitations of high frequency ultrasound in determining the invasiveness of cutaneous malignant melanoma, Melanoma Res 1996; 6(5): 395-398.
22. Raju BI, Swindells KJ, Bonzalez S, et al. Quantitative ultrasonic methods for characterization of skin lesions in vivo, Ultrasound Med Biol 2003; 29(6): 825-838.
23. Ruocco E, Argenziano G, Pellacani G, et al. Non-invasive imaging of skin tumors, Dermatol Surg 2004; 30(2 pt 2): 301-310.
24. Semple J, Gupta AK, From L, et al. Does high-frequency (40 – 60 mhz) ultrasound imaging play a role in the clinical management of cutaneous melanoma? Annals of Plastic Surgery, June 1995, Vol. 34, No. 6.
25. Solivetti FM, Sidozzi A, et al. Sonographic evaluation of clinically occult in-transit and satellite metastases from cutaneous malignant melanoma. Radiol Med 2006; 111: 702-708.

26. Thiboutot D. Dermatological applications of high-frequency ultrasound, www.bioe.psu.edu/labs/NIH/main_pub.html.
27. Vaillant L, Berson M, Machet L, et al. Ultrasound imaging of psoriatic skin: A noninvasive technique to evaluate treatment of psoriasis, Int J Dermatol 1994; 33(11): 786-790.
28. Vergilio, M. M., Monteiro E Silva, S. A., Jales, R. M., & Leonardi, G. R. (2021). High-frequency ultrasound as a scientific tool for skin imaging analysis. Experimental dermatology, 30(7), 897–910.
29. Wortsman X, Wortsman J. Clinical Usefulness of variable-frequency ultrasound in localized lesions of the skin. J Am Acad Dermatol 2010; 62(2): 247-256.

POLICY HISTORY:

Adopted for Blue Advantage, March 2005
Available for comment May 1-June 14, 2005
Medical Policy Group, December 2005
Medical Policy Group, November 2007
Medical Policy Group, November 2009
Medical Policy Group, October 2010
Medical Policy Group, October 2011
Medical Policy Group, January 2013
Medical Policy Group, September 2016
Medical Policy Group, August 2019
Medical Policy Group, August 2021
Medical Policy Group, July 2022: Reviewed by consensus. There is no new published peer-reviewed literature available that would alter the coverage statement in this policy.
Medical Policy Group, July 2023: Reviewed by consensus. There is no new published peer-reviewed literature available that would alter the coverage statement in this policy.
Medical Policy Group, November 2023: Archived effective 11/1/2023.
