IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Measurements of body composition have been used to study how lean body mass and body fat change during health and disease and have provided a research tool to study the metabolic effects of aging, obesity, and various wasting conditions which may occur with AIDS or post-bariatric surgery, among others. A variety of techniques have been researched, including most commonly, anthropomorphic measures, bioelectrical impedance, and dual X-ray absorptiometry (DXA or DEXA) scans. All of these techniques are based in part on assumptions regarding the distribution of different body compartments and their density, and all rely on formulas to convert the measured parameter into an estimate of body composition. Therefore, all techniques will introduce variation based on how the underlying assumptions and formulas apply to different populations of subjects, e.g., different age groups, ethnicities, or underlying conditions. Anthropomorphic, bioimpedance, and DXA techniques are briefly reviewed below.

Anthropomorphic Techniques

Anthropomorphic techniques for the estimation of body composition include measurements of skin-fold thickness at various sites, bone dimensions, and limb circumference. These measurements are used in various equations to predict body density and body fat. Due to its ease of use, measurements of skin-fold
thickness are one of the most commonly used techniques. The technique is based on the assumption that the subcutaneous adipose layer reflects total body fat, but this association may vary with age and gender.

**Bioelectrical Impedance**

Bioelectrical impedance is based on the relationship between the volume of the conductor (i.e., the human body), the conductor’s length (i.e., height), the components of the conductor (i.e., fat and fat-free mass), and its impedance. Estimates of body composition are based on the assumption that the overall conductivity of the human body is closely related to lean tissue. The impedance value is then combined with anthropomorphic data to give body compartment measures. The technique involves attaching surface electrodes to various locations on the arm and foot. Alternatively, the patient can stand on pad electrodes.

**Underwater Weighing**

Underwater weighing (UWW) has generally been considered the reference standard for body composition studies. This technique requires the use of a specially constructed tank in which the subject is seated on a suspended chair. The subject is then submerged in the water while exhaling. While valued as a research tool, UWW is not suitable for routine clinical use. UWW is based on the assumption that the body can be divided into two compartments with constant densities, namely, adipose tissue with a density of 0.9 gm/cm³ and lean body mass (muscle and bone) with a density of 1.1 g/cm³. One limitation of the underlying assumption is the variability in density between muscle and bone; for example, bone has a higher density than muscle, and bone mineral density varies with age and other conditions. In addition, the density of body fat may vary, depending on the relative components of its constituents, e.g., glycerides, sterols, and glycolipids.

**Dual Energy X-ray Absorptiometry (DXA or DEXA)**

While the above techniques assume two body compartments, dual energy X-ray absorptiometry can estimate three body compartments consisting of fat mass, lean body mass, and bone mass. DXA systems use a source that generates X-rays at two energies. The differential attenuation of the two energies is used to estimate the bone mineral content and the soft tissue composition. When two X-ray energies are used, only two tissue compartments can be measured; therefore, soft tissue measurements (i.e., fat and lean body mass) can only be measured in areas where no bone is present. DXA also has the ability to determine body composition in defined regions, such as the arms, legs, and trunk. DXA measurements are based in part on the assumption that the hydration of fat-free mass remains constant at 73%. Hydration, however, can vary from 67%–85%, and can be variable in certain disease states. Other assumptions used to derive body composition estimates are considered proprietary by DXA manufacturers (e.g., Lunar, Hologic, and Norland).

**Regulatory Status**

Body composition software for several bone densitometer systems have been approved by the U.S. Food and Drug Administration through premarket approval process. This includes Lunar DXA systems (GE Healthcare, Madison, WI), Hologic DXA systems (Hologic, Bedford MA), and Norland DXA systems (Norland Corp., Fort Atkinson, WI), which are commercially available for use in measurement of bone mineral content, estimation of BMD, comparison of measurements with reference databases, estimation of fracture risk, body composition analysis, and measurement of periprosthetic BMD.
Note: DXA for screening for vertebral fracture is addressed separately in the plan’s Medical Policy, Radiology, No. 48

MEDICAL POLICY CRITERIA

Whole body dual x-ray absorptiometry (DXA) to determine body composition is considered investigational for all indications.

SCIENTIFIC EVIDENCE

Several different clinical roles for whole body dual x-ray absorptiometry (DXA or DEXA) scans to assess body composition have been suggested. In order to demonstrate how DXA scans to assess body composition could be used in the clinical setting to guide patient management and improve health outcomes, DXA needs to be compared with the other, simpler techniques for measurement of body composition (e.g., bioelectrical impedance, skin-fold thickness, anthropometric measures) in controlled clinical trials.

DXA as Reference Standard for Body Composition Assessment

In general, reference standards for diagnostic tests, often used primarily in research settings, serve to evaluate and verify the use of simpler and more convenient alternative tests that measure the same diagnostic parameter. For body composition studies, underwater weighing has been historically considered the reference standard. The emergence of DXA as a potential new reference standard reflects its ease of use and the fact that it provides a 3-compartment model of body density, i.e., lean body mass, bone mass, and fat mass, compared to the 2-compartment model of underwater weighing. More recently, a 4-compartment model has been suggested as the reference standard, consisting of measurements of bone/mineral, protein, water, and fat. Studies to evaluate different techniques of measuring the same parameter typically consist of correlation studies that compare values between the two techniques. However, correlation studies do not provide information on which diagnostic technique more closely represents the true value. For example, a lack of correlation between DXA and underwater weighing may reflect the lack of accuracy of underwater weighing, as opposed to any deficiency in the DXA technique. Furthermore, two diagnostic techniques may be highly correlated but produce different values of body composition. For example, compared to underwater weighing, DXA may identify different groups of patients as abnormal and normal.

There is extensive literature comparing DXA to other techniques for assessing body composition, most commonly underwater weighing, bioelectrical impedance, or skin-fold thickness in different populations of patients with differing age groups, ethnicities, and underlying disorders. In general, these studies have shown that DXA is highly correlated to various methods of body composition assessment. Detailed review of this extensive literature is beyond the scope of this discussion; however, it is apparent that many authors would consider a DXA body composition study the reference standard. For example, in various research studies, the results of DXA body composition have been included as an intermediate outcome in studies of nutrition and various metabolic disorders.

An updated search of the current literature found that dual-energy x-ray absorptiometry continues to be used as the reference standard for whole body composition analysis in research studies. Active research
areas include comparison of established clinical measures of body composition (body mass index or BMI, anthropomorphic measurements, and bioelectrical impedance analysis) with this “gold standard” and improvement of equations for more accurate clinical assessment of lean and fat body mass.[26] Regardless of whether a DXA scan is considered the reference standard, the key consideration regarding its routine clinical use is whether the results of the scan can be used in the management of the patient to improve health outcomes.

**DXA as a Diagnostic Test to Detect Abnormal Body Composition**

As a single diagnostic measure, it is important to establish diagnostic cutoff points for normal and abnormal values. This is problematic, since normal values will require the development of normative databases for the different components of body composition (bone, fat, and lean mass) for different populations of patients at different ages. In terms of measuring bone mineral density, normative databases have largely focused on postmenopausal white women, and these values cannot necessarily be extrapolated to either men or to different races. DXA determinations of bone mineral density are primarily used for fracture risk assessment in postmenopausal women and to select candidates for various pharmacological therapies to reduce fracture risk. In addition to the uncertainties of establishing normal values for other components of body composition, it also is unclear how a single measure of body composition would be used in the medical management of the patient.

**DXA as a Technique to Monitor Changes in Body Composition**

Changes in body composition over time may provide useful information. The ability to detect changes is related in part to the precision of the technique, defined as the degree to which repeated measurements of the same variable give the same value. For example, DXA measurements of bone mass are thought to have a precision error of 1%–3%, and given the slow rate of change in bone mineral density in postmenopausal women treated for osteoporosis, it is likely that DXA scans would only be able to detect a significant change in bone mineral density in the typical patients after two years of therapy. Of course, changes in body composition are anticipated to be larger and more rapid than changes in bone mineral density in postmenopausal women; therefore, precision errors in DXA scans become less critical in interpreting results. Many studies have used DXA to monitor changes in body composition, and the precision is similar to that estimated for DXA measurements of bone mineral density. While measuring changes in body composition is widely used in athletes for training purposes, it is still unclear how monitoring changes in body composition could be used in the medical management of the patient.

DXA measurements of body mass continue to be included as outcomes measures in various trials, frequently focusing on HIV-associated lipodystrophy.[27-30] With regard to patient management, a few reports suggested that DXA may have clinical utility for diagnosis of lipodystrophy in patients with HIV, for predicting metabolic insulin sensitivity in older men and women, for characterizing changes in body composition during chemotherapy for head and neck cancer[31], for predicting glomerular filtration rate in dialysis patients[32-35], and for assessing changes in fat mass and bone mineral density in renal transplant subjects.[36] Research in these specific clinical applications of DXA is at an early stage and studies have not shown if use of this test in clinical care improves health outcomes.

**Clinical Practice Guidelines**

U.S. Preventive Services Task Force[37]
The 2014 U.S. Preventive Services Task Force (USPSTF) Guide to Clinical Preventive Services addresses DXA only for measurements of the hip and lumbar spine for osteoporosis screening. The guide does not address DXA for body composition.

American Dietetic Association (ADA)\textsuperscript{[38]}

In 2010, the ADA issued HIV/AIDS evidence-based nutrition practice guidelines. The society recommended the use of dual x-ray absorptiometry (DXA) as one of several tests included in an initial dietitian assessment. A grade I and II recommendation was given to the following statement:

“(M)easurements of body compartment estimates should also be included, such as circumference measurements (mid-arm muscle, waist, hip, and waist-to-hip ratio) or measurements of body cell mass and body fat (measured with dual energy x-ray absorptiometry [DXA], bioelectrical impedance analysis [BIA], bioimpedance spectroscopy or skinfold thickness measurements). Baseline anthropometric measurements provide information for the nutrition assessment and the majority of research in men, women, children and adolescents reports that fat-free mass and fat mass are altered in people with HIV infection.”

Although the evidence used to support the ADA recommendation was graded as good/strong (grade I) and fair (grade II), supportive studies were not cited within the published guideline, precluding a review or analysis of the evidence used to establish the ADA’s recommended use of DXA in patients with HIV/AIDS.

Summary

Whole body dual x-ray absorptiometry (DXA or DEXA) body composition studies have emerged as a potential new reference standard for body composition studies, replacing underwater weighing. However, it is unclear how information regarding body composition could be used in the active medical management of the patient to improve health outcomes. Literature searches failed to identify any controlled clinical utility studies in which DXA body composition measurements were actively used in patient management compared with the use of other, simpler techniques of body composition assessment. Therefore, DXA to determine body composition is considered investigational for all indications.

REFERENCES


**CROSS REFERENCES**

Virtual Colonoscopy/CT Colonography, Radiology, Policy No. 36

Whole Body CT Screening, Radiology, Policy No. 40

Screening for Vertebral Fracture with Dual X-ray Absorptiometry (DXA), Radiology, No. 48

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