MEDICAL POLICY

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<tr>
<th>POLICY TITLE</th>
<th>WHOLE BODY DUAL X-RAY ABSORPTIOMETRY TO DETERMINE BODY COMPOSITION</th>
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<td>POLICY NUMBER</td>
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Original Issue Date (Created): 9/1/2011
Most Recent Review Date (Revised): 11/29/2016
Effective Date: 1/1/2017

POLICY
RATIONAL
DISCLAIMER
POLICY HISTORY

I. POLICY

Dual x-ray absorptiometry (DXA) body composition studies are considered investigational. There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

Cross-reference:
MP-5.046 Vertebral Fracture Assessment with Densitometry
MP-5.001 Bone Mineral Density Studies

II. PRODUCT VARIATIONS

This policy is applicable to all programs and products administered by Capital BlueCross unless otherwise indicated below.

BlueJourney HMO* BlueJourney PPO* FEP PPO**

*Refer to Centers for Medicare and Medicaid (CMS) National Coverage Determination (NCD) 150.3. Bone (Mineral) Density Studies and Medicare Benefit Policy Manual, Chapter 15, section 80.5 of Pub. 100-02, Bone Mass Measurements (BMMs). Also see chapter 13, section 140 of Pub. 100-04, Medicare Claims Processing Manual, Bone Mass Measurements (BMMs).

III. DESCRIPTION/BACKGROUND

Using low dose x-rays of two different energy levels, whole body dual x-ray absorptiometry measures lean tissue mass and total and regional body fat, as well as bone density.

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 such as occurs with acquired immune deficiency syndrome (AIDS) or post-bariatric surgery. A variety of techniques has been researched, including most commonly, anthropomorphic measures, bioelectrical impedance, and dual x-ray absorptiometry (DXA) 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, i.e., different age groups, ethnicities, or underlying conditions. Anthropomorphic, bioelectrical impedance, underwater weighing, and DXA techniques are briefly reviewed as followed.

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, measurement of skin-fold thickness is 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 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, weighing people underwater is obviously not suitable for routine clinical use. This technique is based on the assumption that the body can be divided into 2 compartments with constant densities: adipose tissue, with a density of 0.9 g/cm³, and lean body mass (i.e., 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, glycolipids).

**DXA**

While the cited techniques assume two body compartments, DXA 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, i.e., in 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 (i.e., Lunar, Hologic, and Norland.)

**Regulator Status**

Body-composition software for several bone densitometer systems have been approved by the U.S. Food and Drug Administration through the premarket approval process. This includes Lunar iDXA systems (GE Healthcare, Madison, WI), Hologic DXA systems (Hologic, Bedford MA), and Norland DXA systems (Norland, at Swissray, Fort Atkinson, WI).

**IV. RATIONALE**

The literature was reviewed through November 5, 2015. The key literature is described next.

Several different clinical roles for whole body dual x-ray absorptiometry (DXA) scans to assess body composition have been suggested. Each clinical application requires different data for analysis.

**Dual X-Ray Absorptiometry as a Diagnostic Test to Detect Abnormal Body Composition**

Most of the literature on dual x-ray absorptiometry (DXA) as a diagnostic test to detect abnormal body composition involves the use of the technology in the research setting, often as a reference test; studies have been conducted in different populations of patients and underlying disorders.\(^1\)\(^-\)\(^9\)

In some cases, studies compare other techniques with DXA to identify simpler methods of determining body composition. In general, these studies have shown that DXA is highly correlated to various methods of body composition assessment. For example, one study published in 2014 compared 2 bioelectrical impedance devices with DXA for the evaluation of
body composition in heart failure.\(^1\) Another 2014 study compared bioelectric impedance analysis with DXA for evaluating body composition in adults with cystic fibrosis.\(^2\) 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.

As a single diagnostic measure, it is important to establish diagnostic cutoff points for normal and abnormal values. This is problematic, because normal values will require the development of normative databases for the different components of body composition (i.e., bone, fat, lean mass) for different populations of patients at different ages. In terms of measuring bone mineral density (BMD), 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 BMD are primarily used for fracture risk assessment in postmenopausal women and to select candidates for various pharmacologic 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 patient management.

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

The ability to detect change in body composition over time 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% to 3% and, given the slow rate of change in BMD in postmenopausal women treated for osteoporosis, it is likely that DXA scans would only be able to detect a significant change in BMD in the typical patient after 2 years of therapy. Of course, changes in body composition are anticipated to be larger and more rapid than changes in BMD in postmenopausal women; therefore, precision errors in DXA scans become less critical in interpreting results.

Several studies have reported on DXA measurement of body composition changes over time in clinical populations; none of these studies used DXA findings to make patient management decisions or addressed how serial body composition assessment might improve health outcomes.\(^{10,11}\) For example, in 2014, Franzoni et al published a prospective study evaluating body composition in adolescent females with restrictive anorexia nervosa.\(^{11}\) Patients underwent DXA at baseline and 12 months after treatment for their eating disorder. A total of 46 of 79 patients (58%) completed the study. Mean total fat mass was 21% at baseline and 25% after 1 year, and this increase was statistically significant in all body regions. Change in fat mass percentage was significantly correlated with change in BMI.

**Ongoing and Unpublished Clinical Trials**

A search of ClinicalTrials.gov in November 2015 did not identify any ongoing or unpublished trials that would likely influence this review.
Summary of Evidence
The evidence for dual x-ray absorptiometry (DXA) body composition studies in patients who have a clinical condition associated with abnormal body composition includes several cross-sectional studies comparing DXA to other techniques. Relevant outcomes are symptoms and change in disease status. The available studies are primarily conducted in research settings and often use DXA body composition studies as a reference standard; these studies do not permit conclusions about the accuracy of DXA for measuring body composition. More importantly, no studies were identified in which DXA body composition measurements were actively used in patient management. The evidence is insufficient to determine the effects of the technology on health outcomes.

The evidence for DXA body composition studies in patients who have a clinical condition managed by monitoring changes in body composition over time includes several prospective studies monitoring patients over time. Relevant outcomes are symptoms and change in disease status. The studies used DXA as a tool to measure body composition and were not designed to assess the accuracy of DXA. None of the studies used DXA findings to make patient management decisions or addressed how serial body composition assessment might improve health outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

Practice Guidelines and Position Statements
In 2013, the International Society for Clinical Densitometry (ISCD) issued a statement on use of DXA for body composition. The statement included the following ISCD official positions regarding use of DXA total body composition with regional analysis:

- To assess fat distribution in patients with HIV who are using antiretroviral agents known to increase the risk of lipoatrophy. The statement noted that, although most patients who were taking medications known to be associated with lipoatrophy switched to other medications, some remain on these medications and DXA may be useful in this population to detect changes in peripheral fat before they become clinically evident.
- To assess fat and lean mass changes in obese patients undergoing bariatric surgery when weight loss exceeds approximately 10%. The statement noted that the impact of DXA studies on clinical outcomes in these patients is uncertain.
- To assess fat and lean mass in patients with risk factors associated with sarcopenia, including muscle weakness and poor physical functioning.

U.S. Preventive Services Task Force Recommendations
The U.S. Preventive Services Task Force (USPSTF) does not recommend DXA for body composition analysis. In 2012, USPSTF recommended screening all adults for obesity with body mass index (BMI). Its 2010 recommendation on obesity in children and adolescents recommends screening all children older than 6 years old using BMI. As of November 2015, the 2010 recommendation is in the process of being updated.
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Medicare National Coverage
There is no national coverage determination (NCD).

V. DEFINITIONS

**BODY COMPOSITION** is the relative percentage of bony minerals, cell mass, lean body mass, body fat, and body water in an organism, and their distribution through the body. Determination of the specific gravity of the body is done to estimate the percentage of fat. This may be calculated by various methods, including underwater weighing, which determines the density of the individual; use of radioactive potassium, measuring the total body water by dilution of tritium; and use of various anthropometric measurements such as height, weight, and skin fold thickness at various sites.

**BONE DENSITY OR BONE MINERAL DENSITY (BMD)** is the average mineral concentration of a specimen of bone; skeletal mass. Bone mineral density is reduced in osteopenia and osteoporosis.

**BODY FAT** also called adipose tissue is connective tissue that has been specialized to store fat.

**LEAN TISSUE MASS** is the weight of the body minus the fat content. It includes bones, muscles, and internal organs.

VI. BENEFIT VARIATIONS

The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member’s individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member’s benefit information or contact Capital for benefit information.

VII. DISCLAIMER

Capital’s medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member’s benefit information, the benefit information will govern. Capital considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.
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VIII. CODING INFORMATION

Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Investigational when used to report a DXA body composition study as noted in the policy guidelines above; therefore, not covered:

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IX. REFERENCES

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X. POLICY HISTORY

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<tr>
<th>MP 5.037</th>
<th>CAC 4/26/11 New Policy Adopt BCBSA. Information related to dual x-ray absorptiometry (DEXA) to determine body composition was extracted from MP 5.001 and a separate policy created. Added investigational policy statement.</th>
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<td>CAC 9/29/15 Consensus review. No change to the policy statement. Reference and rationale update. Coding reviewed.</td>
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<td>CAC 11/29/16 Consensus review. Abbreviation in policy statement changed to DXA. Abbreviation removed from Title. Variation reformatting completed. Regulatory Status section added. Description/Background, Rationale and Reference sections updated. Coding Reviewed.</td>
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