BlueCross BlueShield of Alabama

Name of Policy:

Whole Body Dual X-Ray Absorptiometry (DEXA) to Determine Body Composition

Policy #: 194
Category: Radiology

Latest Review Date: October 2018
Policy Grade: A

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:

Using low dose x-rays of two different energy levels, whole body dual x-ray absorptiometry (DXA) measures lean tissue mass and total and regional body fat as well as bone density. DXA scans have become a tool for research on body composition e.g. as a more convenient replacement for underwater weighing. This review addresses potential applications in clinical care rather than research use of the technology.

Body Composition Measurement

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 AIDS or post-bariatric surgery. A variety of techniques have been researched, including most commonly, anthropomorphic measures, bioelectrical impedance, and dual X-ray absorptiometry (DXA). 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 how the underlying assumptions and formulas apply to different populations of subjects, (i.e., different age groups, ethnicities, or underlying conditions). Techniques using anthropomorphics, bioelectrical impedance, underwater weighing, and DXA 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, a 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 two compartments with constant densities: adipose tissue with a density of 0.9gm/cm^3 and lean body mass (i.e., muscle and bone) with a density of 1.1 g/cm^3. 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. Also, the

density of body fat may vary, depending on the relative components of its constituents, (e.g., glycerides, sterols, and glycolipids).

Dual X-Ray Absorptiometry (DXA)
While the cited techniques assume 2 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 in which 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% to 85% and can be variable in certain disease states. Other assumptions used to derive body composition estimates are considered proprietary by DXA manufacturers.

Policy:

Dual x-ray absorptiometry (DXA) body composition studies do not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage and is considered **investigational**.

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 member's 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 most recent literature review was updated through July 26, 2018.

Evidence reviews assess whether a medical test is clinically useful. A useful test provides information to make a clinical management decision that improves the net health outcome. That is, the balance of benefits and harms is better when the test is used to manage the condition than when another test or no test is used to manage the condition.

The first step in assessing a medical test is to formulate the clinical context and purpose of the test. The test must be technically reliable, clinically valid, and clinically useful for that purpose. Evidence reviews assess the evidence on whether a test is clinically valid and clinically useful. Technical reliability is outside the scope of these reviews, and credible information on technical reliability is available from other sources.

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

Clinical Context and Test Purpose

The purpose of dual x-ray absorptiometry (DXA) body composition studies is to improve the diagnosis and management of patients who have a clinical condition associated with an abnormal body composition.

The question addressed in this evidence review is: Does the use of DXA improve the net health outcome in patients with clinical conditions associated with abnormal body composition?
The following PICOTS were used to select literature to inform this review.

Patients

The relevant population of interest is individuals with clinical conditions associated with abnormal body composition.

Interventions

The test being considered is DXA body composition studies.

Comparators

The following practices are currently being used to make decisions in this patient group: standard of care without DXA or an alternative method of body composition analysis.

Outcomes

The general outcomes of interest include symptom management and change in disease status. For patients at risk of osteoporosis, outcomes of interest would include fracture incidence.

Timing

The time frame for measuring outcome varies by the specific disease process

Setting

DXA testing is administered in an outpatient setting.

Technically Reliable

Assessment of technical reliability focuses on specific tests and operators and requires review of unpublished and often proprietary information. Review of specific tests, operators, and unpublished data are outside the scope of this evidence review and alternative sources exist. This evidence review focuses on the clinical validity and clinical utility.

Clinically Valid

A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse).

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. 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 two bioelectrical impedance devices with DXA for the evaluation of body composition in heart failure. Another 2014 study compared bioelectric impedance analysis with DXA for evaluating body composition in adults with cystic fibrosis. 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, since normal values will require the development of normative databases for the different components of body composition (i.e., bone, fat, and lean mass) for different populations of patients at different ages. Regarding 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 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 management of the patient.

Clinically Useful
A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if patients receive correct therapy, or more effective therapy, or avoid unnecessary therapy, or avoid unnecessary testing.

Direct Evidence
Direct evidence of clinical utility is provided by studies that have compared health outcomes for patients managed with and without the test. Because these are intervention studies, the preferred evidence would be from randomized controlled trials.

No randomized controlled trials were identified to support the utility of DXA for this indication.

Chain of Evidence
Indirect evidence on clinical utility rests on clinical validity. If the evidence is insufficient to demonstrate test performance, no inferences can be made about clinical utility.

Because the clinical validity of DXA for this population cannot be established, a chain of evidence cannot be constructed.

<u>Section Summary: Dual X-Ray Absorptiometry as a Test to Detect Abnormal Body Composition</u>
The available evidence was generated primarily in research settings and often used DXA body composition studies as a reference standard; these studies do not permit conclusions about the accuracy of DXA for measuring body composition. Additionally, no studies were identified in which DXA body composition measurements were actively used in patient management.

DXA as a Test to Monitor Changes in Body Composition

Clinical Context and Test Purpose

The purpose of serial DXA body composition studies in patients who have a clinical condition managed by monitoring body composition changes over time is to improve disease management. The question addressed in this evidence review is: Does serial DXA improve the net health outcome in patients with clinical conditions managed by monitoring body composition changes over time?

The following PICOTS were used to select literature to inform this review.

Patients

The relevant population of interest is individuals with clinical conditions managed by monitoring body composition changes over time.

Interventions

The test being considered is serial DXA body composition studies.

Comparators

The following practices are currently being used to make decisions in this patient group: standard of care without DXA or an alternative method of body composition analysis.

Outcomes

The general outcomes of interest include symptom management and change in disease status. For patients with anorexia nervosa, outcomes of interest would include disease-related morbidity, disease- related mortality, and rate of remission.

Timing

The time frame for measuring outcome varies by the specific disease process

Setting

DXA testing is administered in an outpatient setting.

Technically Reliable

Assessment of technical reliability focuses on specific tests and operators and requires review of unpublished and often proprietary information. Review of specific tests, operators, and unpublished data are outside the scope of this evidence review and alternative sources exist. This evidence review focuses on the clinical validity and clinical utility.

Clinically Valid

A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse).

The ability to detect a 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. For example, Franzoni et al (2014) conducted a prospective study evaluating body composition in adolescent girls with restrictive anorexia nervosa. Patients underwent DXA at baseline and 12 months after treatment for their eating disorder. A total of 46 (58%) of 79 patients 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 correlated significantly with change in BMD.

Clinically Useful

A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if patients receive correct therapy, or more effective therapy, or avoid unnecessary therapy, or avoid unnecessary testing.

Direct Evidence

Direct evidence of clinical utility is provided by studies that have compared health outcomes for patients managed with and without the test. Because these are intervention studies, the preferred evidence would be from randomized controlled trials.
No randomized controlled trials were identified to support the utility of DXA for this indication.

Chain of Evidence

Indirect evidence on clinical utility rests on clinical validity. If the evidence is insufficient to demonstrate test performance, no inferences can be made about clinical utility.
Because the clinical validity of DXA for this population cannot be established, a chain of evidence cannot be constructed.

Section Summary: DXA as a Test to Monitor Changes in Body Composition

Studies assessing DXA used it 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.

Summary of Evidence

For individuals who have a clinical condition associated with abnormal body composition who receive DXA body composition studies, the evidence includes several cross-sectional studies comparing DXA with 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.

For individuals who have a clinical condition managed by monitoring changes in body composition over time who receive serial DXA body composition studies, the evidence 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
The International Society for Clinical Densitometry (2015) updated its statements on the use of dual x-ray absorptiometry (DXA) for body composition. The following statements were made on the 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.
- To assess fat and lean mass changes in obese patients undergoing bariatric surgery (or medical, diet, or weight loss regimens with anticipated large weight loss) 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 muscle weakness and poor physical functioning. The impact on clinical outcomes is uncertain.

Of note, pregnancy is a contraindication to use of DXA to measure body composition.

U.S. Preventive Services Task Force Recommendations
No U.S. Preventive Services Task Force recommendations for whole body DXA have been identified

Key Words:
Dual X-ray absorptiometry (DXA), body composition assessment, anthropomorphic techniques, skin-fold thickness, body composition, DXA, Total Body DXA scan

Approved by Governing Bodies:
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 iDXA systems (GE Healthcare, Madison, WI), Hologic DXA systems (Hologic, Bedford MA), and Norland DXA systems (Norland Corp., Fort Atkinson, WI).

Benefit Application:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.
ITS: Home Policy provisions apply
FEP contracts: Special benefit consideration may apply. Refer to member's benefit plan. FEP does not consider investigational if FDA approved and will be reviewed for medical necessity.

Current Coding:

CPT:

76499 Unlisted diagnostic radiographic procedure

References:

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Policy History:

Medical Policy Group, August 2004 **(4)**
Medical Policy Administration Committee, August 2004
Available for comment August 24-October 7, 2004
Medical Policy Group, August 2006 **(1)**
Medical Policy Group, January 2007 **(2)**
Medical Policy Group, January 2009 **(1)**
Medical Policy Panel, February 2010
Medical Policy Group, June 2010 **(2)**
Medical Policy Group, June 2011; Added Key Word
Medical Policy Group, July 2011; Updated Key Points and References
Medical Policy Group, February 2012 **(2)**: 2012 Update-Key Points & References
Medical Policy Group, January 2013 **(2)**: 2013 Update to Key Points & References; policy statement remains unchanged
Medical Policy Panel, December 2014
Medical Policy Group, December 2014 **(4):** Update to Key Points, Approved Governing Bodies, and References. No change in policy statement.
Medical Policy Panel, December 2015

Medical Policy Group, December 2015 (**2**): 2015 Updates to Description, Key Points, and References; no change in policy statement.
Medical Policy Panel, September 2017
Medical Policy Group, September 2017 **(7)**: Updates to Description, Key Points, and References. Removed Previous Coding section (0028T deleted effective Jan 2009). No change in policy statement.
Medical Policy Panel, September 201
Medical Policy Group, October 2018 **(7)**: Updates to Key Points and References. No change in policy statement.
