**Policy Statement**

Dual x-ray absorptiometry (DXA) body composition studies are considered **investigational**.

**Policy Guidelines**

This service should be billed using the following unlisted CPT code:

- **76499**: Unlisted diagnostic radiographic procedure

**Description**

Using low-dose x-rays of 2 different energy levels, whole body dual x-ray absorptiometry (DXA) measures lean tissue mass, 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 evidence review addresses potential applications in clinical care rather than research use of the technology.

**Related Policies**

- Vertebral Fracture Assessment With Densitometry

**Benefit Application**

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

**Regulatory 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. They include the Lunar iDXA systems (GE Healthcare), Hologic DXA systems (Hologic), and Norland DXA systems (Swissray). Food and Drug Administration product code: KGI.

**Rationale**

**Background**

**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 occur with AIDS or...
after bariatric surgery. A variety of techniques has 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 about 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). Techniques using anthropometrics, bioelectrical impedance, underwater weighing, and DXA are briefly reviewed below.

**Anthropomorphic Techniques**

Anthropomorphic techniques for the estimation of body composition include measurements of skinfold 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 skinfold thickness is one of the most common 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 sex.

**Bioelectrical Impedance**

Bioelectrical impedance is based on the relation among the volume of the conductor (i.e., 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 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; e.g., 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, glycolipids).

**Dual X-Ray Absorptiometry**

While the cited techniques assume 2 body compartments, DXA can estimate 3 body compartments consisting of fat mass, lean body mass, and bone mass. DXA systems use a source that generates x-rays at 2 energies. The differential attenuation of the 2 energies is used to estimate the bone mineral content and the soft tissue composition. When 2 x-ray energies are used, only 2 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 can also determine body composition in defined regions (i.e., 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 vary by disease state. Other assumptions used to derive body composition estimates are considered proprietary by DXA manufacturers.

**Literature Review**

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 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 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 have compared 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, a study by Alves et al. (2014) compared 2 bioelectrical impedance devices with DXA for the evaluation of body composition in heart
failure. Ziai et al (2014) compared bioelectric impedance analysis with DXA for evaluating body composition in adults with cystic fibrosis. Whether or not 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 to manage the patients and 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. Regarding measuring bone mineral density (BMD), normative databases have largely focused on postmenopausal white women, and these values cannot necessarily be extrapolated to 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.

**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: Dual X-Ray Absorptiometry as a Test to Detect Abnormal Body Composition**
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 were primarily conducted 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. 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.

**Supplemental Information**

**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.\(^\text{12}\) 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.

**Medicare National Coverage**
There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

**Ongoing and Unpublished Clinical Trials**
A search of ClinicalTrials.gov in July 2018 did not identify any ongoing or unpublished trials that would likely influence this review.

**References**

**Documentation for Clinical Review**

- No records required

**Coding**

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of codes does not constitute or imply member coverage or provider reimbursement.

IE

The following services may be considered investigational.

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**Policy History**

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

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<tr>
<th>Effective Date</th>
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<td>04/05/2007</td>
<td>BCBSA Medical Policy adoption</td>
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<td>01/07/2011</td>
<td>Policy revision without position change</td>
<td>Medical Policy Committee</td>
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<tr>
<td>06/30/2015</td>
<td>Coding update</td>
<td>Administrative Review</td>
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| 10/30/2015     | Policy title change from Whole Body Dual X-Ray Absorptiometry (DEXA) to Determine Body Composition  
Policy revision without position change | Medical Policy Committee |
| 03/01/2016     | Policy revision without position change                                           | Medical Policy Committee        |
| 06/01/2017     | Policy revision without position change                                           | Medical Policy Committee        |
| 11/01/2017     | Policy revision without position change                                           | Medical Policy Committee        |
| 11/01/2018     | Policy revision without position change                                           | Medical Policy Committee        |

**Definitions of Decision Determinations**

**Medically Necessary:** A treatment, procedure, or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

**Investigational/Experimental:** A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation:** Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions,
but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

**Prior Authorization Requirements (as applicable to your plan)**

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department. Please call (800) 541-6652 or visit the provider portal at www.blueshieldca.com/provider.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.