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## Medical Policy



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**\*Current Policy Effective Date: 3/1/22**  
(See policy history boxes for previous effective dates)

### **Title: Dual Energy X-Ray Absorptiometry (DXA) and Bioelectrical Impedance Analysis (BIA) to Determine Body Composition**

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#### **Description/Background**

##### **BODY COMPOSITION MEASUREMENT**

Body composition measurements can be used to determine the relative proportions of specific body components, usually fat versus lean body mass (ie, muscle, bone, organ tissue). These measurements may be more precise than standard non-specific assessments such as weight and body mass index (BMI). While these body composition measurements have been most frequently used for research, they may be useful in clinical settings to:

- Evaluate the health status of undernourished patients, those impacted by certain disease states (eg, anorexia nervosa, cachexia), or those undergoing certain treatments (eg, antiretroviral therapy, bariatric surgery).
- Predict the risk of heart disease or diabetes by measuring visceral fat versus total body fat.
- Monitor body composition changes during growth and development (eg, infancy, childhood), aging (eg, sarcopenia), and in certain disease states (eg, HIV, diabetes).
- Evaluate patients in whom BMI may be discordant with total fatty tissue mass (eg, bodybuilding, edema).

Various techniques have been used for body composition measurement, including most commonly, anthropomorphic measures, bioelectrical impedance, and dual energy 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, they will vary depending on their underlying assumptions and how those assumptions apply to different populations (ie, different age groups, ethnicities, or underlying conditions). The techniques of

anthropomorphics, bioelectrical impedance, underwater weighing, and DXA are briefly reviewed below.

### **Anthropomorphic Measurement**

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, even though this association may vary with age and sex.

### **Bioelectrical Impedance**

Bioelectrical impedance analysis is based on the relation among the volume of the conductor (ie, human body), the conductor's length (ie, height), the components of the conductor (ie, fat and fat-free mass), and its impedance. The technique involves attaching surface electrodes to various locations on the arm and foot. Alternatively, the patient can stand on pad electrodes.

Estimates of body composition are based on the assumption that the overall conductivity of the human body is closely related to lean tissue mass. The impedance value is then combined with anthropomorphic data to estimate body component measures.

### **Underwater Weighing**

Underwater weighing requires the use of a specially constructed tank in which the subject is suspended on a chair. The subject is submerged in the water while exhaling. This technique is based, on the assumption that the body can be divided into 2 compartments with constant densities: adipose tissue, which has a density of  $0.9 \text{ g/cm}^3$ , and lean body mass (ie, muscle and bone), with a density of  $1.1 \text{ g/cm}^3$ . One limitation of the underlying assumption is the variability in density between muscle and bone; bone has a higher density than muscle, and bone mineral density varies with age and other conditions. The density of body fat may vary as well, depending on its relative constituents (eg, glycerides, sterols, glycolipids). While valued as a research tool, underwater weighing is typically not suitable for routine clinical use.

### **Dual-energy X-Ray Absorptiometry**

While the techniques cited above measure two body components, DXA can estimate three body components: 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 soft tissue composition. When two x-ray energies are used, only two tissue compartments can be measured; therefore, soft tissue measurements (ie, 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 (ie, 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.

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## Regulatory Status

Body composition software for several bone densitometer systems have been approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process. They include the Lunar iDXA systems (GE Healthcare), Hologic DXA systems (Hologic), Mindways Software, Inc. Systems (Mindways Software, Inc.) and Norland DXA systems (Swissray).  
FDA product code: KGI.

Several body composition analyzers that use bioelectrical impedance analysis have been approved by the FDA through the premarket approval process. They include the BC1 Body Composition Analyzer (Stayhealthy Inc.) and the Bodystat 1500 Body Composition Monitoring Unit (Bodystat LTD).  
FDA product code MNW.

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## Medical Policy Statement

The DXA body composition system is considered experimental/investigational. While it may be safe, its utility in the medical management of the patient compared to standard currently available measurement methods has not been scientifically determined.

Bioelectrical impedance for body composition analysis is considered experimental/investigational. It has not been scientifically demonstrated to be an accurate and useful diagnostic tool.

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## Inclusionary and Exclusionary Guidelines (Clinically based guidelines that may support individual consideration and pre-authorization decisions)

N/A

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**CPT/HCPCS Level II Codes** *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

### Established codes:

N/A

### Other codes (investigational, not medically necessary, etc.):

76499

0358T

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## Rationale

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-ENERGY X-RAY ABSORPTIOMETRY AS A TEST TO DETECT ABNORMAL BODY COMPOSITION

### Clinical Context and Test Purpose

The purpose of dual-energy 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 PICO was used to select literature to inform this review.

### *Populations*

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 administered in an outpatient setting.

### *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. For patients with HIV who are treated with antiretroviral therapy, outcomes of interest would include lipodystrophy.

### Study Selection Criteria

For the evaluation of clinical validity of DXA body composition testing, studies that meet the following eligibility criteria were considered:

- Reported on the accuracy of the marketed version of the technology (including any algorithms used to calculate scores)
- Included a suitable reference standard
- Patient/sample clinical characteristics were described
- Patient/sample selection criteria were described.

### 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).

## REVIEW OF EVIDENCE

### Systematic Reviews

A systematic review and meta-analysis comparing the accuracy of alternative comparators versus reference standard computed tomography (CT) and magnetic resonance imaging (MRI) methods for the quantification of intra-abdominal adipose tissue (IAAT) was published by Murphy et al (2019).<sup>1</sup> This systematic review assessed the performance of DXA for IAAT volume quantification and compared the performance of both DXA and bioelectric impedance analysis (BIA) approaches for IAAT area quantification. The American Society for Parenteral and Enteral Nutrition (ASPEN) also conducted a systematic review to evaluate the validity of relevant body composition methods in various clinical populations.<sup>2</sup> The use of DXA, ultrasound, and BIA for body composition analysis was investigated. Fifteen studies featuring comparisons of DXA to reference standard methods (eg, MRI and CT) were identified. Nine studies using CT or MRI to validate DXA measures of abdominal fat mass (FM) or total body FM were used for pooled analyses. Characteristics and results of studies included for meta-analysis are summarized in Tables 1 and 2.

**Table 1. Systematic Review & Meta-Analysis Characteristics**

Study; Subgroup	Dates	Trials	Participants <sup>1</sup>	N (Range)	Design	Duration
Murphy et al (2019) <sup>1</sup>	1995-2018	23	Studies: <ul style="list-style-type: none"> <li>• With IAAT quantified in humans by CT or MRI reference methods and one of DXA, ultrasound, BIA, or air displacement plethysmography</li> <li>• With reference and comparator methods that quantify IAAT at the same anatomical location in the same unit of measurement</li> <li>• With reported or quantifiable mean differences and SDs of IAAT quantity</li> </ul>	6116 (29-2689)	Cross-sectional, diagnostic test accuracy studies  Retrospective studies	NR
IAAT Area						
DXA	2012-2014	3	Included population groups: <ul style="list-style-type: none"> <li>• Elderly adult men and women evaluated by DXA and CT at L4-L5</li> <li>• Premenopausal women evaluated by DXA and CT at L4-L5</li> <li>• Premenopausal women evaluated by DXA and CT at L4</li> </ul>	381 (115-135)	Cross-sectional, diagnostic test accuracy studies  Retrospective studies	NR
BIA	2008-2018	9*	Included population groups: <ul style="list-style-type: none"> <li>• Elderly Caucasian men and women evaluated by BIA and CT at L3-L4</li> <li>• Elderly Korean adult men and women evaluated by BIA and CT at umbilicus</li> <li>• Elderly Korean adult men and women</li> </ul>	2139 (100-1006)	Cross-sectional, diagnostic test accuracy studies  Retrospective studies	NR

			<ul style="list-style-type: none"> <li>evaluated by BIA and CT at L4-L5</li> <li>Japanese outpatients with obesity evaluated by BIA and CT at umbilicus</li> <li>Elderly, middle-aged, and adult Chinese men and women evaluated by BIA and CT at L4-L5</li> <li>Elderly adult men and women evaluated by BIA and MRI at L4-L5</li> <li>Elderly, middle-aged, adult, and young men and women evaluated by BIA and CT at L4-L5</li> </ul>			
IATT Volume						
DXA	2012-2018	7**	<p>Included population groups:</p> <ul style="list-style-type: none"> <li>Adult men and women evaluated by DXA and CT from S1 to head region</li> <li>Elderly adult men and women evaluated by DXA and CT from S1 to head region</li> <li>Women with PCOS evaluated by DXA and MRI at L3</li> <li>Middle-Eastern adult men and women evaluated by DXA and MRI at android region</li> <li>Adult men and women evaluated by DXA and MRI at L2-L3 with conversion to L1-L5</li> </ul>	3410 (40-2689)	<p>Cross-sectional, diagnostic test accuracy studies</p> <p>Retrospective studies</p>	NR
IATT Thickness						
US	2010-2014	4	<p>Included population groups:</p> <ul style="list-style-type: none"> <li>Obese women with infertility evaluated by US and CT at L4-L5</li> <li>Middle-aged men and women evaluated by US and CT at L2-L3</li> <li>Elderly and adult men and women evaluated by US and MRI at L2-L3</li> <li>Elderly men and women evaluated by US and MRI at L4</li> </ul>	186 (29-74)	<p>Cross-sectional, diagnostic test accuracy studies</p> <p>Retrospective studies</p>	NR
Sheean et al (2019) <sup>2</sup> (ASPEN)	2001-2013	9	<p>Studies:</p> <ul style="list-style-type: none"> <li>With body compositions assessed in clinical populations via DXA and a reference standard method (eg, MRI or CT)</li> <li>With correlation analyses</li> </ul>	1660 (39-625)	<p>Cross-sectional, diagnostic test accuracy studies</p> <p>Retrospective studies</p>	NR
Abdominal FM in any disease via DXA	2004-2013	4	<p>Included population groups:</p> <ul style="list-style-type: none"> <li>Urban Asian Indians with type 2 diabetes</li> <li>Premenopausal women with anorexia nervosa</li> <li>Middle-aged Indian men with CVD</li> <li>Multiethnic cohort of men and women with HIV</li> </ul>	874 (39-625)	<p>Cross-sectional, diagnostic test accuracy studies</p> <p>Retrospective studies</p>	NR
Total FM in any disease via DXA	2001-2013	7	<p>Included population groups:</p> <ul style="list-style-type: none"> <li>Women with CVD</li> <li>Postmenopausal women with CVD</li> <li>Men and women with CVD</li> <li>Middle-aged Indian men with CVD</li> <li>Individuals with myosteatosis</li> <li>Multiethnic cohort of men and women with HIV</li> </ul>	1473 (66-625)	<p>Cross-sectional, diagnostic test accuracy studies</p> <p>Retrospective studies</p>	NR
Total FM in CVD via DXA	2001-2013	5	<p>Included population groups:</p> <ul style="list-style-type: none"> <li>Men and women with CVD</li> <li>Postmenopausal women with CVD</li> <li>Middle-aged Indian men with CVD</li> </ul>	521 (66-132)	<p>Cross-sectional, diagnostic test accuracy studies</p> <p>Retrospective studies</p>	NR

ASPEN: American Society for Parenteral and Enteral Nutrition; BIA: bioelectrical impedance analysis; CT: computed tomography; CVD: cardiovascular disease; DXA: dual-energy x-ray absorptiometry; FM: fat mass; HIV: human immunodeficiency virus; IAAT: intra-abdominal adipose tissue; MRI: magnetic resonance imaging; NR: not reported; PCOS: polycystic ovarian syndrome; SD: standard deviation; US: ultrasound.

<sup>1</sup> Key study eligibility criteria and demographics of included subgroup participants.

\* 3 of 9 trials were sampled twice for a total of 12 result sets due to use of multiple techniques for IAAT quantification via BIA.  
 \*\* one of eight trials was categorized as an outlier and excluded from pooled analysis.

**Table 2. Systematic Review & Meta-Analysis Results**

Study	Mean Difference in IAAT Volume	Mean Difference in IAAT Area		Mean Difference in IAAT Thickness
		DXA	BIA	
Murphy et al (2019) <sup>1</sup>	DXA*	DXA	BIA	US
Total N	3410	381	2139	186
Pooled mean difference (95% LoA)	-10 (-280 to 300) (cm <sup>3</sup> )	8.09 (-98.88 to 115.07) (cm <sup>2</sup> )	-11.63 (-43.12 to 19.85) (cm <sup>2</sup> )	-0.32 (-3.82 to 3.17) (cm)
Significance of mean difference (p)	.808	.061	.004	.400
I <sup>2</sup> (p)	99% (<0.001)	98% (<0.001)	94% (<0.001)	93% (<0.001)
Q	Q <sub>(6)</sub> = 458	Q <sub>(2)</sub> = 31	Q <sub>(11)</sub> = 544	Q <sub>(3)</sub> = 41
Range of N	40 to 2689	115 to 135	100 to 1006	29 to 74
Range of pooled mean differences	(-451 to 262) (cm <sup>3</sup> )	(3.78 to 16.70) (cm <sup>2</sup> )	(-57.20 to 10.96) (cm <sup>2</sup> )	(-1.10 to 0.40) (cm)
DXA Subgroup Analysis	Mean Difference in IAAT Volume by DXA and Gender		Mean Difference in IAAT Volume by DXA and Reference Method	
Subgroup	Men	Women	CT	MRI
Subgroup N (Total N)	1483 (3287)	1804 (3287)	377 (3410)	3033 (3410)
Pooled mean difference (95% LoA) (cm <sup>3</sup> )	144.04 (-512.29 to 800.38)	59.96 (-381.08 to 492.99)	-41.15 (-881.96 to 930.25)	49.52 (-498.42 to 586.23)
Significance for subgroup comparison (p)	.042		.311	
I <sup>2</sup>	95%	90%	100%	90%
Range of Subgroup N	20 to 1212	20 to 1477	109 to 145	40 to 2689
Range of pooled mean differences (cm <sup>3</sup> )	-43 to 379	4 to 143	451 to 262	4 to 104
Sheean et al (2019) <sup>2</sup> (ASPEN)	DXA-derived Abdominal FM	DXA-derived Total FM		
	DXA vs CT-derived VAT in any disease	DXA vs CT/MRI-derived VAT in any disease	DXA vs CT/MRI-derived VAT in CVD	
Total N	874	1473	521	
Pooled random effects correlation (95% CI)	0.74 (0.52 to 0.86)	0.71 (0.45 to 0.86)	0.71 (0.45 to 0.84)	
I <sup>2</sup> (p)	87% (<0.01)	98% (<0.01)	95% (<0.01)	

Range of N	39 to 625	66 to 625	66 to 132
Range of individual correlations	0.52 to 0.86	0.49 to 0.80	0.49 to 0.87

ASPEN: American Society for Parenteral and Enteral Nutrition; BIA: bioelectrical impedance analysis; CI: confidence interval; CT: computed tomography; CVD: cardiovascular disease; DXA: dual-energy x-ray absorptiometry; FM: fat mass; IAAT: intra-abdominal adipose tissue; LoA: limits of agreement; M-A: meta-analysis; MRI: magnetic resonance imaging; SR: systematic review; US: ultrasound; VAT: visceral adipose tissue.

\* Results following the removal of a study due to identification as an outlier.

While this analysis was primarily focused on the utilization of the different body composition methods for the management of obesity, direct effects on key health outcomes were not explored and patient populations included for analysis displayed extensive heterogeneity and largely featured healthy populations. Measurements of IAAT volume were deemed comparable to the reference methods, however, 95% limits of agreement (LoA) were wide and these results were not seen until the removal of an outlying study. Rationale for identifying the study as an outlier and removing it from the meta-analysis was limited. Prior to the removal of the outlier, the pooled mean difference was significant compared to the reference methods at  $-124 \text{ cm}^3$  (95% LoA:  $[-479, 230]$ ;  $p = 0.013$ ;  $I^2 = 99\%$  [ $p < 0.001$ ];  $Q_{(7)} = 773$ ). Performance of DXA for the measurement of IAAT volume also varied significantly between male and female subgroups. Furthermore, included studies did not pre-determine clinically meaningful LoA. The authors' further caution that DXA measurement of IAAT volume has the capacity to differ from reference methods by more than 100%, however, the clinical significance of these margins of error are uncertain in individuals with obesity. While IAAT area cutoff points have been described for the determination of metabolic risk and visceral obesity based on single-slice CT computed tomography, the authors do not recommend utilization of DXA IAAT area measurements for this purpose due to wide LoA. The clinical utility of existing IAAT area cutpoints is also uncertain as these parameters were found to have applicability for women and cannot necessarily be extrapolated to mixed populations.

ASPEN recommends the use of DXA for the assessment of FM in patients with a specific disease or clinical outcome with a strong recommendation rating based on their analysis. Due to the lack of studies reporting on the validity of DXA for lean mass measurements, no recommendations could be made for assessments of this body compartment. The systematic review acknowledges that while the quality of the included evidence was low, the strong recommendation rating was applied with the rationale that the net benefits of FM assessment via DXA outweigh potential harms. However, the use of DXA findings to make patient management decisions and reporting of adverse events was not featured in the included studies.

Calella et al (2019) performed a systematic review exploring various methods for body composition analysis in patients with cystic fibrosis (CF).<sup>3</sup> A previous systematic review by Calella et al (2018) presented on differences in body composition between patients with CF cystic fibrosis and healthy controls evaluated by DXA and other methods.<sup>4</sup> DXA was most frequently used to measure lean body or fat-free mass (FFM) which was significantly reduced in CF patients. While several included studies showed a correlation between lower fat-free mass FFM and impaired pulmonary function, and use of this measure in patient management and its impact on health outcomes was not explored and requires further clarification. As these reviews featured qualitative analyses, data on clinical validity could not be extracted.



A systematic review by Bundred et al (2019) evaluated body composition assessment and sarcopenia in patients with pancreatic ductal adenocarcinoma.<sup>5</sup> Meta-analyses revealed that sarcopenia was associated with lower overall survival in both operable (harms ratio: 1.95; 95% confidence interval [CI], 1.35-2.81;  $p < .001$ ) and unresectable patients (harms ratio: 2.49; 95% CI, 1.38-4.48;  $p = .002$ ). However, of the 42 included studies, only one utilized measurements obtained by DXA, limiting the relevance of the overall findings to this technology and preventing extraction of pertinent clinical validity data. Furthermore, the authors caution that many studies failed to account for variation introduced by gender, race, tumor stage, and other factors. Additionally, clear criteria for the diagnosis of sarcopenia or cachexia via body composition assessments with DXA are lacking.

### **Cross-Sectional Studies**

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.<sup>6-15</sup> 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, a study by Alves et al (2014) compared two bioelectrical impedance devices with DXA for the evaluation of body composition in heart failure.<sup>6</sup> Ziai et al (2014) compared bioelectric impedance analysis with DXA for evaluating body composition in adults with CF.<sup>7</sup> The literature on DXA in population-based cohorts (eg, National Health and Nutrition Examination Survey [NHANES], Prospective Epidemiological Risk Factor Study)<sup>16,17</sup> involves the use of the technology to predict risk of overall mortality or cancer incidence. These studies often use DXA as a reference test to assess whether agreement with anthropometric measures (eg, body mass index [BMI], relative fat mass [RFM]) is present<sup>16</sup> or absent.<sup>17</sup> 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.

### **Case-Control Studies**

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 (ie, 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. 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. In an example regarding lean mass, Reina et al (2019) conducted a case-control study to assess the correlation of BMI or serum albumin levels to DXA-derived parameters of nutritional status and sarcopenia in women ( $n=89$ ) with rheumatoid arthritis (RA).<sup>18</sup> While 44% of cases met diagnostic criteria for sarcopenia based on quantification of the skeletal muscle index, a reference technique was not clearly identified in this study. Skeletal muscle index MI is calculated by dividing appendicular skeletal muscle mass by the square of the patient's height. A previously identified threshold of  $\leq 5.75$  kg/m<sup>2</sup> in women was applied, however, this metric was established through the use of BIA in a slightly older patient population. Given that DXA

provides measures of lean mass which may be influenced by body compartments other than skeletal muscle, the relevance of this diagnostic cutoff point is uncertain. Furthermore, the study utilized a control group composed of patients affected by non-inflammatory rheumatic disorders as opposed to healthy controls, further limiting the relevance of applied cutoff points. In addition to the aforementioned uncertainties of establishing and applying normal values for components of body composition, it also is unclear how a single measure of body composition would be used in patient management. Studies discussing appropriate use and determination of DXA-derived lean mass cutoffs for sarcopenia in various populations of patients and underlying disorders continue to be featured in the literature.<sup>19,20</sup>

### **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 RCTs.

No RCTs 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 is limited, a chain of evidence cannot be constructed.

## **Section Summary: Dual-energy 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. A systematic review exploring the clinical validity of DXA measurements against reference methods for the quantification of intra-abdominal adipose tissue raised concerns regarding precision and reliability. Additionally, no studies were identified in which DXA body composition measurements were actively used in patient management.

## **DUAL-ENERGY X-RAY ABORPTIOMETRY 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 PICO was used to select literature to inform this review.

### **Populations**

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.

### **Study Selection Criteria**

See information under the first indication.

#### **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. However, precision errors for other body compartments such as lean and fat mass may differ and impact clinical validity. Coefficients of variation as high as 42.2% have been reported for fat mass.<sup>21</sup>

## **REVIEW OF EVIDENCE**

### **Prospective Studies**

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 and few addressed how serial body composition assessment might improve health outcomes.<sup>22,23,21,24</sup> A long-term prospective study assessing the association between body fat

and BMI) was published by Iyengar et al (2019), featuring the ad hoc secondary analysis of results from the Women's Health Initiative RCT and observational study cohorts.<sup>24</sup> Women (N=3460) were assessed at baseline and during years 1, 3, 6, and 9 for BMI and via DXA. Multivariable-adjusted hazard ratios (HR) for the association of various body fat measures with the risk of developing invasive or estrogen receptor positive (ER+) breast cancer were reported. Median follow-up duration was 16.9 years. Characteristics and results of clinical validity for breast cancer risk assessment are summarized in Tables 3 and 4.

**Table 3. Study Characteristics of Clinical Validity of Risk Assessment**

Study	Study Population	Design <sup>a</sup>	Reference Standard	Timing of Reference and Index Tests	Blinding of Assessors	Comment <sup>b</sup>
Iyengar et al (2019) <sup>24</sup>	Postmenopausal women aged 50 to 79 years enrolled in the Women's Health Initiative (WHI) RCT or observational study were considered for study. Women from 3 WHI trial centers were assessed longitudinally for body fat composition. Data from women with normal BMIs were assessed for correlations with breast cancer outcomes.	Prospective, sample selection NR	Clinical outcomes were confirmed via questionnaires. Breast cancer cases were confirmed via review of medical records and pathology reports.	NR	NR	Risk outcomes for women in the RCT and observational cohorts were not analyzed separately. Given that treatments utilized in the RCT group may have had an impact on breast cancer risk and outcomes, the relevance and utility of this study is uncertain.

BMI: body mass index; NR: not reported; RCT: randomized controlled trial.

<sup>a</sup>Note 2 aspects of design: prospective, retrospective or nonconcurrent prospective and sample selection random or consecutive

<sup>b</sup>Note other characteristics that could cause bias or limit relevance such as timeframe or practice setting.

**Table 4. Clinical Validity of Breast Cancer Risk Assessment with DXA**

Study; Subgroup; Body Fat DXA Measurement (Cutoff)	Initial N	Final N Cases/ Person - Years	Excluded Samples	Prevalence of Condition	Clinical Validity Outcome: Multivariable Adjusted HR (95% CI)				
					Baseline Body Fat Measures			Serial Body Fat Measures	
Iyengar et al (2019) <sup>24</sup> Invasive Breast Cancer	3464*	3460	4*	182	Highest Quartile	P-value for trend	Per 5-unit increase	Cutoff	Time-Dependent
Whole-body fat mass, kg (>25.1)	NR	NR	NR	57	1.89 (1.21-2.95)	0.004	1.28 (1.10-1.49)	≥ 22.1	1.43 (1.06-1.93)
Whole-body fat, % (>41.3)	NR	NR	NR	52	1.79 (1.14-2.83)	0.03	1.19 (1.03-1.37)	≥38.0	1.45 (1.07-1.95)
Fat mass of trunk, kg (>11.4)	NR	NR	NR	50	1.88 (1.18-2.98)	0.002	1.46 (1.14-1.87)	≥ 9.4	1.50 (1.12-2.03)
Ratio of trunk fat mass to mean of legs (>2.6)	NR	NR	NR	43	1.30 (0.83-2.02)	0.10	NR	NR	NR
Iyengar et al (2019) <sup>24</sup> ER+ Breast Cancer	3464	3460	4*	146	Highest Quartile	P-value for trend	Per 5-unit increase	Cutoff	Time-Dependent
Whole-body fat mass, kg (>25.1)	NR	NR	NR	48	2.21 (1.23-3.67)	0.002	1.35 (1.14-1.60)	≥22.1	1.41 (1.01-1.97)

Whole-body fat, % (>41.3)	NR	NR	NR	44	2.17 (1.29-3.66)	0.01	1.27 (1.08-1.48)	≥38.0	1.50 (1.07-2.10)
Fat mass of trunk, kg (>11.4)	NR	NR	NR	41	1.98 (1.18-3.31)	0.003	1.56 (1.18-2.06)	≥9.4	1.46 (1.05-2.04)
Ratio of trunk fat mass to mean of legs (>2.6)	NR	NR	NR	34	1.28 (0.78-2.10)	0.13	NR	NR	NR

CI: confidence interval; DXA: dual-energy x-ray absorptiometry; ER+: estrogen receptor-positive; HR: hazard ratio; NR: not reported.

\* Excluded cases were lost to follow-up with ER+ status not reported.

These results suggest that standard BMI categorization may be inadequate for the risk assessment of invasive breast cancers in postmenopausal women. However, the clinical utility of DXA findings on patient management protocols and health outcomes requires further study.

Arthur et al (2020) published additional results from the Women's Health Initiative cohort of postmenopausal women (N=10,931), reporting additional associations between DXA-derived measures of body fat and breast cancer risk.<sup>25</sup> The multivariable-adjusted HR for risk of invasive breast cancer per SD increase in trunk fat mass was 1.21 (95% CI, 1.12 to 1.31) and whole body fat mass was 1.21 (95% CI, 1.12 to 1.30). The multivariable-adjusted HR for risk of ER+ breast cancer per SD increase in trunk fat mass was 1.21 (95% CI, 1.11 to 1.31) and whole body fat mass was 1.22 (95% CI, 1.11 to 1.33). Multivariable-adjusted HR for invasive breast cancer per SD increase in BMI was also significant, with a HR 1.19 (95% CI, 1.10 to 1.28). Trends of time-dependent analyses of anthropometric measures and overall and ER+ incident breast cancer cases was significant for BMI (P < 0.001) and waist circumference (P < 0.001). Therefore, the added clinical utility of DXA-derived fat measures is unclear for this population.

Relevance and study design and conduct limitations are summarized in Tables 5 and 6.

**Table 5. Study Relevance Limitations**

Study	Population <sup>a</sup>	Intervention <sup>b</sup>	Comparator <sup>c</sup>	Outcomes <sup>d</sup>	Duration of Follow-Up <sup>e</sup>
Arthur et al (2020) <sup>25</sup>	1. Study population is unclear	2. Version used unclear regarding both DXA and patient participation in RCT treatment or observational groups.	3. Not compared to other tests used for same purpose.	3,5. Key clinical validity outcomes not reported; adverse events of the test not described	
Iyengar et al (2019) <sup>24</sup>	1, 4. Study population is unclear; study population not representative of intended use.	2. Version used unclear regarding both DXA and patient participation in RCT treatment or observational groups.	3. Not compared to other tests used for same purpose.	3, 5. Key clinical validity outcomes not reported; adverse events of the test not described.	

DXA: dual-energy x-ray absorptiometry; RCT: randomized controlled trial.

The study limitations stated in this table are those notable in the current review, this is not a comprehensive gaps assessment.

<sup>a</sup> Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.

<sup>b</sup> Intervention key: 1. Classification thresholds not defined; 2. Version used unclear; 3. Not intervention of interest.

<sup>c</sup> Comparator key: 1. Classification thresholds not defined; 2. Not compared to credible reference standard; 3. Not compared to other tests in use for same purpose.

<sup>d</sup> Outcomes key: 1. Study does not directly assess a key health outcome; 2. Evidence chain or decision model not explicated; 3. Key clinical validity outcomes not reported (sensitivity, specificity, and predictive values); 4. Reclassification of diagnostic or risk categories not reported; 5. Adverse events of the test not described (excluding minor discomforts and inconvenience of venipuncture or noninvasive tests).

<sup>e</sup> Follow-Up key: 1. Follow-up duration not sufficient with respect to natural history of disease (true-positives, true-negatives, false-positives, false-negatives cannot be determined).

**Table 6. Study Design and Conduct Limitations**

Study	Selection <sup>a</sup>	Blinding <sup>b</sup>	Delivery of Test <sup>c</sup>	Selective Reporting <sup>d</sup>	Data Completeness <sup>e</sup>	Statistical <sup>f</sup>
Arthur et al (2020) <sup>25</sup>	1. Selection not described.	1. Blinding not described.	1, 4. Timing of delivery of index or reference tests not clear; expertise of evaluators not described.	2. Evidence of selective reporting (covariates did not have to be prespecified).		
Iyengar et al (2019) <sup>24</sup>	1. Selection not described.	1. Blinding not described.	1, 4. Timing of delivery of index or reference tests not clear; expertise of evaluators not described.	2. Evidence of selective reporting (covariates did not have to be prespecified).	1. Inadequate description of indeterminate and missing samples.	2. Comparison with other tests not reported.

The study limitations stated in this table are those notable in the current review, this is not a comprehensive gaps assessment.

<sup>a</sup>Selection key: 1. Selection not described; 2. Selection not random or consecutive (ie, convenience).

<sup>b</sup>Blinding key: 1. Not blinded to results of reference or other comparator tests.

<sup>c</sup>Test Delivery key: 1. Timing of delivery of index or reference test not described; 2. Timing of index and comparator tests not same; 3. Procedure for interpreting tests not described; 4. Expertise of evaluators not described.

<sup>d</sup> Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.

<sup>e</sup> Data Completeness key: 1. Inadequate description of indeterminate and missing samples; 2. High number of samples excluded; 3. High loss to follow-up or missing data.

<sup>f</sup> Statistical key: 1. Confidence intervals and/or p values not reported; 2. Comparison with to other tests not reported.

## 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 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 RCTs.

No RCTs 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-energy X-ray Absorptiometry 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.

## **BIOIMPEDANCE AS A TEST TO DETECT ABNORMAL BODY COMPOSITION**

Talma et al (2013) performed a review of 50 studies to assess validity, responsiveness, reliability and measurement error of bioelectrical impedance analysis (BIA) in estimating percent body fat in children and adolescents.<sup>26</sup> There was strong evidence for good reliability. However, test-retest mean differences ranges from 7.5% to 13.4% of total percent body fat in the included study samples, indicating considerable measurement error. The review suggested that BIA is a practical method to estimate percent body fat in children and adolescents; however, noted that validity and measurement error are not satisfactory.

Haverkort et al (2015) performed a systematic review to explore the variability of empirical prediction equations used in BIA estimations and to evaluate the validity of BIA estimations in adult surgical and oncological patients.<sup>27</sup> The reviewers found that BIA underestimated the total body water and fat free mass; and, estimates of the fat mass demonstrated large variability. The reviewers concluded that application of equations validated in healthy subjects to predict body composition is not as accurate in this population. They recommended that BIA estimations can only be useful when performed longitudinally and under the same conditions.

### **Section Summary: Bioimpedance to Detect Abnormal Body Composition**

The peer reviewed medical literature does not support that BIA is a reliable indicator of body composition. Also, no studies have been identified in which BIA measurements were actively used in patient management. The evidence is insufficient to determine the effects of the technology on net 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 systematic reviews and 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. A systematic review exploring the clinical validity of DXA measurements against reference methods for the quantification of intra-abdominal adipose tissue raised concerns for precision and reliability. More importantly, no studies were identified in which DXA body composition measurements were actively used in patient management. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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 that the technology results in an improvement in the net health outcome.

For the use of bioelectrical impedance analysis in determining body composition, there are no studies identified in which BIA measurements were actively used in patient management. The

evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

## **SUPPLEMENTAL INFORMATION**

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

### **Practice Guidelines and Position Statements**

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

### **American College of Radiology et al**

The American College of Radiology (ACR), the Society for Pediatric Radiology (SPR), and the Society of Skeletal Radiology (SRR) (2018) issued a collaborative practice parameter to assist practitioners in providing appropriate radiologic care for their patients.<sup>28</sup> Dual-energy absorptiometry (DXA) was described as a "clinically proven, accurate and reproducible method of measuring bone mineral density (BMD) in the lumbar spine, proximal femur, forearm, and whole body," that "may also be used to measure whole-body composition, including nonbone lean mass (LM) and fat mass (FM)." DXA measurement of BMD, LM, or FM is indicated whenever a clinical decision is likely to be directly influenced by the test result. In particular, LM and FM may be useful in assessing conditions such as sarcopenia and cachexia. Specifically, DXA may be indicated as a tool for the measurement of regional and whole body FM and LM in patients afflicted with conditions such as malabsorption, cancer, or eating disorders.

### **International Society for Clinical Densitometry**

The International Society for Clinical Densitometry (2019) statements on the use of DXA for body composition.<sup>29</sup> Use of DXA for measurement of body composition was suggested for use in the following clinical conditions:

- To assess fat distribution in patients living with human immunodeficiency virus (HIV) who are using anti-retroviral agents known to increase the risk of lipotrophy.
- 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. The statement also adds that the clinical utility of DXA measurements of adiposity and lean mass (eg, visceral adipose tissue, lean mass index, fat mass index) is uncertain. Furthermore, while the use of DXA adiposity measures such as fat mass index may be useful in risk-stratifying patients for cardio-metabolic outcomes, specific thresholds to define obesity have not been established.



### International Conference on Sarcopenia and Frailty Research Task Force

Evidence-based clinical practice guidelines for the screening, diagnosis, and management of sarcopenia were developed by the International Conference on Sarcopenia and Frailty Research (ICSFR) task force in 2018.<sup>30</sup> The following recommendations were made:

- Screening for sarcopenia can be performed using gait speed analysis or SARC-F questionnaire.
- Individuals screened as positive for sarcopenia should be referred for further assessment to confirm the presence of the disease.
- DXA imaging should be used to determine low levels of lean body mass when diagnosing sarcopenia.

The recommendation regarding the diagnostic use of DXA received a conditional (weak) recommendation. The certainty of the evidence for DXA assessment was ranked low due to the following:

- DXA studies featuring populations from low-middle income countries are lacking.
- DXA measurement of lean body mass rather than muscle mass may potentially misclassify body composition in certain individuals.
- Incorporation of DXA measurements of lean body mass may have limited additional benefit for the prediction of relevant health outcomes (eg, falls, fractures, lowered physical performance, mobility).

### U.S. Preventive Services Task Force Recommendations

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

### Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 7.

**Table 7. Summary of Key Trials**

NCT Number	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
NCT03621306	Precision and Reliability of Dual X-ray Absorptiometry (DXA) Testing	400	Aug 2028 (recruiting)

NCT: national clinical trial

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## Government Regulations

### National:

There is no national coverage determination on this topic.

### Local:

There is no local coverage determination on this topic.

**Wisconsin Physicians Service Insurance Corporation**  
**Local Coverage Article: Billing and Coding: Category III Codes (A56902)**

Original effective date: 08/29/2019

Revision effective date: 04/25/2021

Code 0358T is not listed as a reasonable and medically necessary code.

*(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)*

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## **Related Policies**

- Bioelectrical Impedance for Body Composition Analysis (Retired)
  - Bone Density Studies (Retired)
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*The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 10/5/21, the date the research was completed.*

### Joint BCBSM/BCN Medical Policy History

<b>Policy Effective Date</b>	<b>BCBSM Signature Date</b>	<b>BCN Signature Date</b>	<b>Comments</b>
12/8/05	12/9/05	12/1/05	Joint policy established
3/1/07	12/28/06	1/14/07	Routine maintenance
1/1/09	10/13/08	12/30/08	Routine maintenance
9/1/11	6/21/11	6/21/11	Routine maintenance. CPT code 0028T deleted; NOC code 76499 added
11/1/12	8/21/12	8/21/12	Routine maintenance
3/1/14	12/10/13	1/6/14	Routine maintenance
1/1/16	10/13/15	10/27/15	Routine maintenance
1/1/17	10/11/16	10/11/16	Routine maintenance
1/1/18	10/19/17	10/19/17	Routine maintenance
1/1/19	10/16/18	10/16/18	Routine maintenance
1/1/20	10/15/19		Routine maintenance
1/1/21	10/20/20		Routine maintenance Ref 16,17,25,26,28 added
11/1/21	8/17/21		Integrated IMP Bioelectrical Impedance for Body Composition Analysis. Ref 26, 27 added
3/1/22	12/14/21		Routine maintenance

Next Review Date: 4<sup>th</sup> Qtr, 2022

**BLUE CARE NETWORK BENEFIT COVERAGE**  
**POLICY: BODY COMPOSITION STUDIES – DUAL ENERGY X-RAY ABSORPTIOMETRY (DXA) AND BIOELECTRICAL IMPEDANCE**

**I. Coverage Determination:**

<b>Commercial HMO (includes Self-Funded groups unless otherwise specified)</b>	Not covered.
<b>BCNA (Medicare Advantage)</b>	See Government Regulations section.
<b>BCN65 (Medicare Complementary)</b>	Coinsurance covered if primary Medicare covers the service.

**II. Administrative Guidelines:**

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.