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Whole Body Composition Analysis using Dual X-Ray Absorptiometry (DXA) or Bioelectrical Impedance Analysis (BIA)

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Related Policies (if applicable)
None

Disclaimer

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Coverage

Whole body composition analysis using dual-energy x-ray absorptiometry (DXA) or bioelectrical impedance analysis (BIA) **is considered experimental, investigational and/or unproven**.

Policy Guidelines

None.

Description

Body Composition Measurement
Body composition measurements can be used to quantify and assess the relative proportions of specific body compartments such as fat and lean mass (e.g., bones, tissues, organs, muscles).

These measurements may be more useful in informing diagnosis, prognosis, or therapy than standard assessments (e.g., body weight, body mass index) that do not identify the contributions of individual body compartments or their particular relationships with health and disease. While these body composition measurements have been most frequently utilized for research purposes, they may be useful in clinical settings to:

- Evaluate the health status of undernourished patients, those impacted by certain disease states (e.g., anorexia nervosa, cachexia), or those undergoing certain treatments (e.g., antiretroviral therapy, bariatric surgery).
- Evaluate the risk of heart disease or diabetes by measuring visceral fat versus total body fat.
- Assess body composition changes related to growth and development (e.g., infancy, childhood), aging (e.g., sarcopenia), and in certain disease states (e.g., human immunodeficiency virus (HIV), diabetes).
- Evaluate patients in situations where body mass index is suspected to be discordant with total fat mass (e.g., bodybuilding, edema).

A variety of techniques has been researched, 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, 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 anthropomorphics, 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 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 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 (UWW) requires the use of a specially constructed tank in which the subject is seated on a suspended chair. The subject is then submerged in the water while exhaling. While valued as a research tool, UWW is obviously not suitable for routine clinical use. This technique is based on the assumption that the body can be divided into 2 compartments with constant densities: adipose tissue, with a density of 0.9 g/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-Energy 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 also can 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 vary by disease state. Other assumptions used to derive body composition estimates are considered proprietary by DXA manufacturers.

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, Madison, WI), Hologic DXA systems (Hologic, Bedford MA), Mindways Software, Inc. systems (Mindways Software, Inc.) and Norland DXA systems (Norland, at Swissray, Fort Atkinson, WI).

Food and Drug Administration product code: KGI.

Rationale

Medical policies 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. Medical policies assess the evidence on whether a test is clinically valid and clinically useful.

Technical reliability is outside the scope of these policies, 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 abnormal body composition.

The question addressed in this medical policy 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 policy.

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 human immunodeficiency virus (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; and
- 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).

Systematic Reviews

A systematic review and meta-analysis comparing the accuracy of alternative comparators vs 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). (1) 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. (2) The use of DXA, ultrasound, and BIA for body composition analysis was investigated. Fifteen studies featuring comparisons of DXA to reference standard methods (e.g., 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[1]	N (Range)	Design	Duration
Murphy et al. (2019) (1)	1995-2018	23	Studies: • With IAAT quantified in humans by CT or MRI reference methods and one of DXA, ultrasound, BIA, or air displacement plethysmography • With reference and comparator methods that quantify IAAT at the same anatomical location in the same unit of measurement • With reported or quantifiable mean differences and SDs of IAAT quantity	6116 (29-2689)	Cross-sectional, diagnostic test accuracy studies Retrospective studies	NR
IAAT Area						

DXA	2012-2014	3	Included population groups: • Elderly adult men and women evaluated by DXA and CT at L4-L5 • Premenopausal women evaluated by DXA and CT at L4-L5 Premenopausal women evaluated by DXA and CT at L4	381 (115-135)	Cross-sectional, diagnostic test accuracy studies Retrospective studies	NR
BIA	2008-2018	9*	Included population groups: • Elderly Caucasian men and women evaluated by BIA and CT at L3-L4 • Elderly Korean adult men and women evaluated by BIA and CT at umbilicus • Elderly Korean adult men and women evaluated by BIA and CT at L4-L5 • Japanese outpatients with obesity evaluated by BIA and CT at umbilicus • Elderly, middle-aged, and adult Chinese men and women evaluated by BIA and CT at L4-L5 • Elderly adult men and women evaluated by BIA and MRI at L4-L5	2139 (100-1006)	Cross-sectional, diagnostic test accuracy studies Retrospective studies	NR

			• Elderly, middle-aged, adult, and young men and women evaluated by BIA and CT at L4-L5			
IAAT Volume						
DXA	2012-2018	7**	Included population groups: • Adult men and women evaluated by DXA and CT from S1 to head region • Elderly adult men and women evaluated by DXA and CT from S1 to head region • Women with PCOS evaluated by DXA and MRI at L3 • Middle-Eastern adult men and women evaluated by DXA and MRI at android region • Adult men and women evaluated by DXA and MRI at L2-L3 with conversion to L1-L5	3410 (40-2689)	Cross-sectional, diagnostic test accuracy studies Retrospective studies	NR
IAAT Thickness						
US	2010-2014	4	Included population groups: • Obese women with infertility evaluated by US and CT at L4-L5 • Middle-aged men and women evaluated by US and CT at L2-L3 • Elderly and adult men and women	186 (29-74)	Cross-sectional, diagnostic test accuracy studies Retrospective studies	NR

			evaluated by US and MRI at L2-L3 • Elderly men and women evaluated by US and MRI at L4			
Sheean et al. (2019) (2) (ASPEN)	2001-2013	9	Studies: • With body compositions assessed in clinical populations via DXA and a reference standard method (e.g., MRI or CT) • With correlation analyses	1660 (39-625)	Cross-sectional, diagnostic accuracy studies Retrospective studies	NR
Abdominal FM in any disease via DXA	2004-2013	4	Included population groups: • Urban Asian Indians with type 2 diabetes • Premenopausal women with anorexia nervosa • Middle-aged Indian men with CVD • Multiethnic cohort of men and women with HIV	874 (39-625)	Cross-sectional, diagnostic accuracy studies Retrospective studies	NR
Total FM in any disease via DXA	2001-2013	7	Included population groups: • Women with CVD • Postmenopausal women with CVD • Men and women with CVD sub 96 • Middle-aged Indian men with CVD • Individuals with myosteatosis • Multiethnic cohort of men and women with HIV	1473 (66-625)	Cross-sectional, diagnostic accuracy studies Retrospective studies	NR

Total FM in CVD via DXA	2001-2013	5	Included population groups: • Men and women with CVD sub 96 (103), 92 • Postmenopausal women with CVD 132, 66 • Middle-aged Indian men with CVD 128	521 (66-132)	Cross-sectional, diagnostic accuracy studies Retrospective studies	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; M-A: meta-analysis; MRI: magnetic resonance imaging; NR: not reported; SD: standard deviation; SR: systematic review; US: ultrasound.

[1] 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.

** 1 of 8 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**
Murphy et al. (2019) (1)	DXA*	DXA	BIA	US
Total N	3410	381	2139	186
Pooled mean difference (95% LoA)	-10 (-280, 300) (cm^3)	8.09 (-98.88, 115.07) (cm^2)	-11.63 (-43.12, 19.85) (cm^2)	-0.32 (-3.82, 3.17) (cm)
Significance of mean difference (p)	p = 0.808	p = 0.061	p = 0.004	p = 0.400
I^2 (p)	99 (<0.001)	98 (<0.001)	94 (<0.001)	93 (<0.001)
Q	$Q_{(6)}$ =458	$Q_{(2)}$ = 31	$Q_{(11)}$ = 544	$Q_{(3)}$ = 41
Range of N	40-2689	115-135	100-1006	29-74
Range of pooled mean differences	(-451, 262) (cm^3)	(3.78, 16.70) (cm^2)	(-57.20, 10.96) (cm^2)	(-1.10, 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^3)	144.04 (-512.29, 800.38)	59.96 (-381.08, 492.99)	-41.15 (-881.96, 930.25)	49.52 (-498.42, 586323)
Significance for Subgroup comparison (p)	P=0.042		P=0.311	
I^2	95	90	100	90
Range of Subgroup N	20-1212	20-1477	109-145	40-2689
Range of Pooled mean differences (cm^3)	(-43, 379)	(4, 143)	(-451, 262)	(4, 104)
Sheean et al. (2019) (2) (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 (0.52-0.86)	0.71 (0.45-0.86)		0.71 (0.45-0.84)
I^2 (p)	87 (<0.01)	98 (<0.01)		95 (<0.01)
Range of N	39-625	66-625		66-132
Range of individual correlations	(0.52-0.86)	(0.49-0.80)		(0.49-0.87)

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 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, 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 cut points 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). (3) A previous systematic review by Calella et al. (2018) presented on differences in body composition between patients with CF and healthy controls evaluated by DXA and other methods. (4) DXA was most frequently used to measure lean body or fat-free mass which was significantly reduced in CF patients. While several included studies showed a correlation between lower fat-free mass and impaired pulmonary function, application, 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. (5) Meta-analyses revealed that sarcopenia was associated with lower overall survival in both operable (harms ratio: 1.95; 95% confidence interval: 1.35-2.81; p<0.001) and unresectable patients (harms ratio: 2.49; 95% confidence interval: 1.38-4.48; p = 0.002). However, of the 42 included studies, only 1 utilized measurement 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. (6-18) 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. (6) Ziai et al. (2014) compared bioelectric impedance analysis with DXA for evaluating body composition in adults with cystic fibrosis. (7) The literature on DXA in population-based cohorts (e.g., National Health and Nutrition Examination Survey [NHANES], Prospective Epidemiological Risk Factor Study) (19, 20) 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 (e.g., BMI, relative fat mass [RFM]) is present (19) or absent. (20) 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 (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 an example regarding lean mass, Reina et al. (2019) conducted a case-control study to assess the correlation of body mass index (BMI) or serum albumin levels to DXA-derived parameters of nutritional status and sarcopenia in women (n=89) with rheumatoid arthritis. (21) 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 is calculated by dividing appendicular skeletal muscle mass by the square of the patient's height. A previously identified threshold of ≤5.75 kg/m^2 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. (22, 23)

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 (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: DXA 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.

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 medical policy 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 policy.

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
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; and
- 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).

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 two 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. (24)

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. (24-28) A long-term prospective study assessing the association between body fat and breast cancer risk in postmenopausal women with a normal BMI was published by Iyenagar et al. (2019), featuring the ad hoc secondary analysis of results from the Women's Health Initiative randomized clinical trial and observational study cohorts. (27) Women (n=3460) were assessed at baseline and during years 1, 3, 6, and 9 for BMI and via DXA. Multivariable-adjusted hazard ratios for the association of various body fat measures with the risk of developing invasive or estrogen receptor positive 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[a]	Reference Standard	Timing of Reference and Index Tests	Blinding of Assessors	Comment[b]
Iyengar et al. (2019) (27)	Postmenopausal women aged 50 to 79 years enrolled in the Women's Health Initiative (WHI) RCT or observational study was 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.

[a] Note 2 aspects of design: prospective, retrospective or nonconcurrent prospective and sample selection random or consecutive

[b] Note other characteristics that could cause bias or limit relevance such as timeframe or practice setting.

Table 4a. 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
Iyengar et al. (2019) (27) Invasive Breast Cancer	3464*	3460	4*	182
Whole body fat mass, kg (>25.1)	NR	NR	NR	57
Whole body fat, % (>41.3)	NR	NR	NR	52
Fat mass of trunk, kg (>11.4)	NR	NR	NR	50
Ratio of trunk fat mass to mean of legs (>2.6)	NR	NR	NR	43
Iyengar et al. (2019) (27) ER+ Breast Cancer	3464	3460	4*	146
Whole- body fat mass, kg (>25.1)	NR	NR	NR	48
Whole-body fat mass, kg (>41.3)	NR	NR	NR	44
Fat mass of trunk, kg (>11.4)	NR	NR	NR	41
Ratio of trunk fat mass to mean of legs (>2.6)	NR	NR	NR	34

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.
NR: not reported.

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

Study; Subgroup; Body Fat DXA	Clinical Validity Outcome: Multivariable Adjusted HR (95% CI)	
	Baseline Body Fat Measures	Serial Body Fat Measures

Measurement (Cutoff)					
Iyengar et al. (2019) (27) Invasive Breast Cancer	Highest Quartile	P-Value for trend	Per 5- Unit Increase	Cut-off	Time Dependent
Whole body fat mass, kg (>25.1)	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)	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)	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)	1.30 (0.83-2.02)	0.10	NR	NR	NR
Iyengar et al. (2019) (27) ER+ Breast Cancer	Highest Quartile	P- Value for trend	Per 5- unit in-crease	Cutoff	Time Dependent
Whole- body fat mass, kg (>25.1)	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 mass, kg (>41.3)	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)	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)	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.

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=10931), reporting additional associations between DXA-derived measures of body fat and breast cancer (BC) risk. (29) The multivariable-adjusted hazard ratio (HR) for risk of invasive BC per SD increase in trunk fat mass was HR = 1.21 (95% CI, 1.12 to 1.31) and whole body fat mass was HR = 1.21 (95% CI, 1.12 to 1.30). The multivariable-adjusted HR for risk of ER+ BC per SD increase in trunk fat mass was HR = 1.21 (95% CI, 1.11 to 1.31) and whole body fat mass was HR = 1.22 (95% CI, 1.11 to 1.33). Multivariable-adjusted HR for invasive BC 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. Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Duration of Follow-Up[e]
Arthur et al. (2020) (29)	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 the same purpose.	3, 5. Key clinical validity outcomes not reported; adverse events of the test not described.	
Iyengar et al. (2019) (27)	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 the 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.

[a] 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

[b] Intervention key: 1. Classification thresholds not defined; 2. Version used unclear; 3. Not intervention of interest.

[c] 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.

[d] 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).

[e] 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[a]	Blinding[b]	Delivery of Test[c]	Selective Reporting[d]	Data Completeness[e]	Statistical[f]
Arthur et al. (2020) (29)	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 pre-specified)		
Iyengar et al. (2019) (27)	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 pre-specified)	1. Inadequate description of indeterminate and missing samples.	2. Comparison with other tests not reported.

[a] Selection key: 1. Selection not described; 2. Selection not random or consecutive (i.e., convenience).
[b] Blinding key: 1. Not blinded to results of reference or other comparator tests.
[c] 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.
[d] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
[e] 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.
[f] Statistical key: 1. Confidence intervals and/or p values not reported; 2. Comparison with other tests not reported.

<u>Clinically Useful</u>

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 cannot be established, a chain of evidence cannot be constructed.

Section Summary: DXA as a Test to Monitor Changes in Body Composition
Studies assessing serial 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.

Bioelectrical Impedance Analysis
Bioelectrical impedance is a method of assessing body composition in relation to lean body mass. (30) However, the limited literature does not demonstrate the impact this testing may have on meaningful clinical outcomes.

In a systematic review published by Haverkort et al. (2015) the authors aim was to explore the variability of empirical prediction equations used in bioelectrical impedance analysis (BIA) estimations and to evaluate the validity of bioelectrical impedance estimations in adult surgical and oncological patients. (31) Studies developing new empirical prediction equations and studies evaluating the validity of BIA estimations compared with a reference method were included. Only studies using BIA devices measuring the entire body were included. To illustrate variability between equations, fixed normal reference values of resistance values were entered into the existing empirical prediction equations of the included studies. The validity was expressed by the difference in means between BIA estimates and the reference method, and relative difference in %. Substantial variability between equations for groups was found for total body water (TBW) and fat free mass (FFM). BIA mainly under-estimated TBW (range relative difference -18.8 % to +7.2 %) and FFM (range relative differences -15.2 % to +3.8 %). Estimates of the FM demonstrated large variability (range relative difference -15.7 % to +43.1 %). The authors concluded that application of equations validated in healthy subjects to predict body composition performs less well in oncologic and surgical patients. It was suggested that BIA estimations can only be useful when performed longitudinally and under the same standard conditions.

In 2019, Murphy et al. conducted a meta-analysis aimed to assess the agreement between intra-abdominal adipose tissue (IAAT) quantified by alternative methods and the reference standards, computed tomography (CT) and magnetic resonance imaging (MRI). (32) MEDLINE and EMBASE electronic databases were systematically searched to identify studies that quantified IAAT thickness, area, or volume by a comparator method and CT or MRI. Using an inverse variance weighted approach (random-effects model), the mean differences and 95%

limits of agreement (LoA) were pooled between methods. The meta-analysis included 24 studies using four comparator methods. The pooled mean differences were -0.3 cm (95% LoA: -3.4 to 3.2 cm; P = 0.400) for ultrasound and -11.6 cm^2 (95% LoA: -43.1 to 19.9 cm^2; P = 0.004) for bioelectrical impedance analysis. Dual-energy x-ray absorptiometry (DXA) quantified both IAAT area and volume with mean differences of 8.1 cm^2 (95% LoA: -98.9 to 115.1 cm^2; P = 0.061) and 10 cm^3 (95% LoA: -280 to 300 cm^3; P = 0.808), respectively. The study concluded ultrasound and DXA measure IAAT with minimal bias from CT or MRI, while bioelectrical impedance analysis systematically underestimates IAAT. However, with the exception of DXA for IAAT volume, the wide LoA caution against clinical or research use of the comparator methods and emphasize the need to optimize alternatives to the reference standards.

UpToDate

In an UpToDate (2023) publication titled "Determining body composition in Adults" (33) the authors note that dual-energy x-ray absorptiometry (DXA) is one of the more commonly used methods for determining body composition. This method is based on the attenuation of signals from two energy sources to provide a three-compartment model of body composition. In a study comparing DXA with a four-compartment model of body composition, estimates of mean percent body fat were similar between the two methods. However, there was considerable intraindividual variability, ranging from -3.0 to +4.0 percent, with DXA. However, there was considerable intraindividual variability, ranging from -3.0 to +4.0 percent, with DEXA. In addition, impedance measurement is widely used but has limitations. Impedance is measured by applying electrodes to one arm and one leg or by standing on the foot plates of a special scale. Impedance is proportional to the length of the conductor and inversely related to the cross-sectional area of the conductor. Accuracy in placement of electrodes is essential because variations can cause relatively large errors in the measurement of impedance and corresponding errors in the estimate of body water. A variety of formulas have been developed to convert impedance, which measures body water, into an estimate of fat. Most formulas for estimating fat from bioelectric impedance analysis underestimate body fat. As an example, in a study comparing two bioelectric impedance devices with DXA for the measurement of body fat, percent body fat measured with both bioelectric impedance devices were 2 to 6 percent lower in men and women with normal BMI. Among the overweight individuals, the values were lower in women but similar in men. In the summary of this article the authors note that other techniques to measure body composition (usually confined to research) may be appropriate for certain patients. For example, patients in whom BMI and adiposity are suspected as discordant, such as in sarcopenia with normal BMI, body builders, and people in whom visceral fat deposition occurs at lower BMI, may be candidates for a more rigorous assessment of body composition. Dual-energy x-ray absorptiometry (DEXA) is considered the preferred method to determine body composition when BMI and adiposity are considered discordant.

Summary of Evidence

For individuals who have a clinical condition associated with abnormal body composition who receive dual-energy x-ray absorptiometry (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 use 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 against reference methods for the quantification of intra-abdominal adipose tissue raised concerns regarding 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 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.

For individuals who have a clinical condition associated with abnormal body composition or who have a clinical condition managed by monitoring changes in body composition over time who receive bioelectrical impedance analysis, the evidence includes peer reviewed literature that does not establish its accuracy. Studies evaluating the diagnostic accuracy and clinical utility are lacking. The evidence is insufficient to determine the effects of the technology on health outcomes.

Practice Guidelines and Position Statements

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. (34)https://www.evidencepositioningsystem.com/_w_ac9051e13413c0dabe095753720ea2704b3fafb568cc43e2/bcbsa_html/BCBSA/html/_blank 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 (ISCD)

The International Society for Clinical Densitometry (2019) updated its statements on the use of DXA for body composition. (35) Use of DXA for measurement of body composition was suggested for use in the following clinical conditions:

1. To assess fat distribution in patients with HIV who are using antiretroviral agents known to increase the risk of lipoatrophy.
2. To assess fat and lean mass changes in obese patients undergoing bariatric surgery when weight loss exceeds approximately 10%. The statement noted that the impact of DXA studies on clinical outcomes in these patients is uncertain.
3. 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 (e.g., 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 task force in 2018. (36) 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:

- 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 (e.g., falls, fractures, lowered physical performance, mobility).

National Institute for Health and Care Excellence (NICE)

NICE published a clinical guideline regarding obesity: identification, assessment and management in 2006, amended in 2022. The recommendations for adults and children do not use bioimpedance as a substitute for body mass index (BMI) as a measure of general adiposity in children and young people. (37)

American Association of Clinical Endocrinologists (AACE) and American College of Endocrinology (ACE)

In 2016, the AACE and ACE published clinical practice guidelines for comprehensive medical care of patients with obesity. In the executive summary of the clinical practice guidelines the question was asked, what are the best anthropomorphic criteria for defining excess adiposity in the diagnosis of overweight and obesity in the clinical setting? (38) The following recommendations were made:

1. "BMI should be used to confirm an excessive degree of adiposity and to classify individuals as having overweight (BMI 25-29.9 kg/m^2) or obesity (BMI ≥30 kg/m^2), after taking into account age, gender, ethnicity, fluid status, and muscularity; therefore, clinical evaluation and judgment must be used when BMI is employed as the anthropometric indicator of excess adiposity, particularly in athletes and those with sarcopenia (Grade A; BEL 2, upgraded due to high relevance).
2. Other measurements of adiposity (e.g., bioelectric impedance, air/water displacement plethysmography, or dual-energy x-ray absorptiometry) may be considered at the clinician's discretion if BMI and physical examination results are equivocal or require further evaluation (Grade C, BEL 2, downgraded due to evidence gaps). However, the clinical utility of these measures is limited by availability, cost, and lack of outcomes data for validated cutoff points (Grade B; BEL 2)."

The best evidence level (BEL) is accompanied by a recommendation grade (A, B, C, or D). This recommendation grade maps to the BEL and can be adjusted upward or downward by 1 level. Final recommendation grades may be interpreted as being based on strong (Grade A), intermediate (Grade B), weak (Grade C), or no (Grade D) scientific substantiation.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this policy are listed in Table 7.

Table 7. Summary of Key Trials

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

NCT: national clinical trial.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	76499, 0358T
HCPCS Codes	None

*Current Procedural Terminology (CPT®) ©2023 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision	
Date	**Description of Change**
12/15/2024	Reviewed. No changes.
07/01/2023	Document updated with literature review. Coverage unchanged. References 16-18, 28 and 32 added; others removed.
12/01/2022	Reviewed. No changes.
11/01/2021	Document updated with literature review. Coverage unchanged. References 16, 17, 25, 29, and 30 added.
01/15/2021	Reviewed. No changes.
10/01/2020	Document updated with literature review. Coverage unchanged. References 1-5, 15-19, 22, 27-28 added.
06/15/2019	Reviewed. No changes.
07/01/2018	Document updated with literature review. Coverage unchanged. References 14 and 17-18 added.
03/01/2017	Reviewed. No changes.
04/15/2016	Document updated with literature review. Coverage unchanged.
06/01/2015	Reviewed. No changes.
07/01/2014	Document updated with literature review. Whole body composition analysis using bioelectrical impedance was added to the experimental, investigational and/or unproven coverage statement. Title changed from: Whole Body Composition Analysis using Dual X-Ray Absorptiometry (DEXA). CPT/HCPCS code(s) updated.
10/15/2013	Document updated with literature review. Coverage unchanged.
08/15/2007	Revised/updated entire document
04/01/2005	New medical document