6.01.40 Whole Body Dual X-Ray Absorptiometry to Determine Body Composition			
Original Policy Date:	April 5, 2007	**Effective Date:**	November 1, 2023
Section:	6.0 Radiology	**Page:**	Page 1 of 21

Policy Statement

I. Dual-energy x-ray absorptiometry body composition studies are considered **investigational**.

NOTE: Refer to Appendix A to see the policy statement changes (if any) from the previous version.

Policy Guidelines

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

- 76499: Unlisted diagnostic radiographic procedure

Description

Using low-dose x-rays of 2 different energy levels, whole-body dual-energy x-ray absorptiometry (DXA) measures lean tissue mass, total and regional body fat, as well as bone density. DXA scans have become a tool for research on body composition (e.g., as a more convenient replacement for underwater weighing). This evidence review addresses potential applications in clinical care rather than research use of the technology.

Related Policies

- Bone Mineral Density Studies
- Vertebral Fracture Assessment with Densitometry

Benefit Application

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

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

Regulatory Status

Body composition software for several bone densitometer systems has 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.

Rationale

Background

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).[1,] 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 certain disease states (e.g., HIV, diabetes).
- Evaluate patients in situations where body mass index is suspected to be discordant with total fat mass (e.g., body-building, edema).

A variety of techniques have 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.[1,2,] 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 1 of the most common techniques. The technique is based on the assumption that the subcutaneous adipose layer reflects total body fat but this association may vary with age and sex. Skinfold thickness measurement precision and utility can also be affected by operator experience and a lack of applicable reference data for specific patient populations or percentile extremes.

Bioelectrical Impedance

Bioelectrical impedance analysis is based on the relation between 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.[1,2,] 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. The impedance value is then combined with anthropomorphic data and certain other patient-specific parameters (e.g., age, gender, ethnicity) to give body compartment measures. These measures are calculated based on device manufacturer-specific regression models, which are generally proprietary. Bioelectrical impedance measures can be affected by fat distribution patterns, hydration status, ovulation, and temperature.

Underwater Weighing

Underwater weighing requires the use of a specially constructed tank in which the subject is seated on a suspended chair.[1,]The subject is then submerged in the water while exhaling; the difference between weight in air and weight in water is used to estimate total body fat percentage. While valued as a research tool, weighing people underwater is typically 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; e.g., bone has a higher density than muscle, and bone mineral density varies with age and other conditions. Also, the density of body fat may vary, depending on the relative components of its constituents (e.g., glycerides, sterols, glycolipids).

Dual-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.[1,2,] 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 soft tissue composition. When 2 x-ray energies are used, only 2 tissue compartments can be measured; therefore, soft tissue measurements (i.e., fat and lean body mass) can only be measured in areas in which no bone is present. DXA can also determine body composition in defined regions (i.e., the arms, legs, and trunk). DXA measurements are based in part on the assumption that the hydration of fat-free mass remains constant at 73%. Hydration, however, can vary from 67% to 85% and can vary by disease state. Other assumptions used to derive body composition estimates are considered proprietary by DXA manufacturers. The use of DXA for bone mineral density assessment in patients diagnosed with or at risk of osteoporosis is addressed separately in Blue Shield of California Medical Policy: Bone Mineral Density Studies. Vertebral fracture assessment with densitometry by DXA is addressed separately in Blue Shield of California Medical Policy: Vertebral Fracture Assessment with Densitometry.

Literature Review

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

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

Promotion of greater diversity and inclusion in clinical research of historically marginalized groups (e.g., People of Color [African-American, Asian, Black, Latino and Native American]; LGBTQIA (Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual); Women; and People with Disabilities [Physical and Invisible]) allows policy populations to be more reflective of and findings more applicable to our diverse members. While we also strive to use inclusive language related to these groups in our policies, use of gender-specific nouns (e.g., women, men, sisters, etc.) will continue when reflective of language used in publications describing study populations.

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 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.

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 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
- 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).[3,] 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.[4,] 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 these meta-analyses 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)[3,]	1995-2018	23	Studies: • With IAAT quantified in humans by CT or MRI reference methods and 1 of DXA, ultrasound, BIA, or air displacement plethysmography	6116 (29 to 2689)	Cross-sectional, diagnostic test accuracy studies	NR

Study; Subgroup	Dates	Trials	Participants[1]	N (Range)	Design	Duration
			• 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		Retrospective studies	
IAAT Area						
DXA	2012-2014	3	Included population groups: • Elderly adult men and women evaluated by DXA and CT at L4 to L5 • Premenopausal women evaluated by DXA and CT at L4 to L5 • Premenopausal women evaluated by DXA and CT at L4	381 (115 to 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 to 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 to 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 to L5 • Elderly adult men and women evaluated by BIA and MRI at L4 to L5 • Elderly, middle-aged, adult, and young men and women evaluated by BIA and CT at L4 to L5	2139 (100 to 1006)	Cross-sectional, diagnostic test accuracy studies Retrospective studies	NR
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 to L3 with conversion to L1 through L5	3410 (40 to 2689)	Cross-sectional, diagnostic test accuracy studies Retrospective studies	NR

Study; Subgroup	Dates	Trials	Participants[1]	N (Range)	Design	Duration
IAAT Thickness						
US	2010-2014	4	Included population groups: • Obese women with infertility evaluated by US and CT at L4 to L5 • Middle-aged men and women evaluated by US and CT at L2 to L3 • Elderly and adult men and women evaluated by US and MRI at L2 to L3 • Elderly men and women evaluated by US and MRI at L4	186 (29 to 74)	Cross-sectional, diagnostic test accuracy studies Retrospective studies	NR
Sheean et al (2019)[4], (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 to 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 to 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 • Middle-aged Indian men with CVD • Individuals with myosteatosis • Multiethnic cohort of men and women with HIV	1473 (66 to 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 • Postmenopausal women with CVD • Middle-aged Indian men with CVD	521 (66 to 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; MRI: magnetic resonance imaging; NR: not reported; PCOS: polycystic ovarian syndrome; SD: standard deviation; 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)[3,]	DXA*	DXA	BIA	US
Total N	3410	381	2139	186
Pooled mean difference (95% LoA)	-10 (-280 to 300) (cm^3)	8.09 (-98.88 to 115.07) (cm^2)	-11.63 (-43.12 to 19.85) (cm^2)	-0.32 (-3.82 to 3.17) (cm)
Significance of mean difference (p)	.808	.061	.004	.400
I^2 (p)	99% (<.001)	98% (<.001)	94% (<.001)	93% (<.001)
Q	$Q_{(6)}$ = 458	$Q_{(2)}$ = 31	$Q_{(11)}$ = 544	$Q_{(3)}$ = 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^3)	(3.78 to 16.70) (cm^2)	(-57.20 to 10.96) (cm^2)	(-1.10 to 0.40) (cm)
DXA Subgroup Analysis	Mean Difference in IAAT Volumeby DXA and Gender		Mean Difference in IAAT Volumeby 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 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^2	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^3)	-43 to 379	4 to 143	451 to 262	4 to 104
Sheean et al (2019)[4,] (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^2 (p)	87% (<.01)	98% (<.01)	95% (<.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; MRI: magnetic resonance imaging; US: ultrasound; VAT: visceral adipose tissue.
* Results following the removal of a study due to identification as an outlier.

Because the analysis by Murphy et al (2019) aimed to evaluate agreement between DXA and CT or MRI, 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 via DXA 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. 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 cutpoints is also uncertain as these parameters were found to have applicability for women and cannot necessarily be extrapolated to mixed populations.

Calella et al (2019) performed a systematic review exploring various methods for body composition analysis in patients with cystic fibrosis (CF).[5,] 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.[6,] 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. Since 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.[7,] Meta-analyses revealed that sarcopenia was associated with lower overall survival in both operable (harms ratio, 1.95; 95% confidence interval [CI], 1.35 to 2.81; p<.001) and unresectable patients (harms ratio, 2.49; 95% CI, 1.38 to 4.48; p=.002). However, of the 42 included studies, only 1 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.[8,-,23,]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.[8,] Ziai et al (2014) compared bioelectric impedance analysis with DXA for evaluating body composition in adults with CF.[9,] The literature on DXA in population-based cohorts (e.g., National Health and Nutrition Examination Survey [NHANES], Prospective Epidemiological Risk Factor Study)[24,25,] 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., body mass index [BMI], relative fat mass [RFM]) is present.[24,] or absent.[25,] 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 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 BMI or serum albumin levels to DXA-derived parameters of nutritional status and sarcopenia in women (N=89) with rheumatoid arthritis.[26,] 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.[27,28,]

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.

Pooled analyses indicate that there is generally strong correlation between estimates of FM as assessed by DXA versus CT or MRI, particularly in populations with clinical conditions for which risk of adverse outcomes associated with visceral adiposity may be of particular importance.[4,] In a broader population, including healthy individuals, while there remains a strong overall correlation between these methods of FM estimation, significant variability suggests that there are some subpopulations in whom DXA may perform poorly as an estimate of adiposity compared to CT or MRI.[3,] Additionally, there is a lack of evidence to indicate that evaluation of body composition via DXA changes clinical management.

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. Systematic reviews with meta-analyses exploring the clinical validity of DXA measurements against reference methods for the quantification of FM indicate strong overall agreement between these modalities, but raise concerns regarding precision and reliability in some populations, particularly those without existing clinical conditions for which risk of adverse outcomes is influenced by abnormal visceral adiposity. Additionally, no studies were identified in which DXA body composition measurements were actively used in patient management.

Dual-energy X-ray Absorptiometry 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 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
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).

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 FM.[29,]

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.[30,31,29,32,-,34,] 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 Iyengar et al (2019), featuring the ad hoc secondary analysis of results from the Women's Health Initiative RCT and observational study cohorts.[32,] 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[a]	Reference Standard	Timing of Reference and Index Tests	Blinding of Assessors	Comment[b]
Iyengar et al (2019)[32],	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.
[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 4. Clinical Validity of Breast Cancer Risk Assessment with Dual-Energy X-ray Absorptiometry

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)[32],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 to 2.95)	.004	1.28 (1.10 to 1.49)	≥22.1	1.43 (1.06 to 1.93)
Whole-body fat, % (>41.3)	NR	NR	NR	52	1.79 (1.14 to 2.83)	.03	1.19 (1.03 to 1.37)	≥38.0	1.45 (1.07 to 1.95)
Fat mass of trunk, kg (>11.4)	NR	NR	NR	50	1.88 (1.18 to 2.98)	.002	1.46 (1.14 to 1.87)	≥9.4	1.50 (1.12 to 2.03)
Ratio of trunk fat mass to mean of legs (>2.6)	NR	NR	NR	43	1.30 (0.83 to 2.02)	.10	NR	NR	NR
Iyengar et al (2019)[32],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 to 3.67)	.002	1.35 (1.14 to 1.60)	≥22.1	1.41 (1.01 to 1.97)
Whole-body fat, % (>41.3)	NR	NR	NR	44	2.17 (1.29 to 3.66)	.01	1.27 (1.08 to 1.48)	≥38.0	1.50 (1.07 to 2.10)
Fat mass of trunk, kg (>11.4)	NR	NR	NR	41	1.98 (1.18 to 3.31)	.003	1.56 (1.18 to 2.06)	≥9.4	1.46 (1.05 to 2.04)
Ratio of trunk fat mass to mean of legs (>2.6)	NR	NR	NR	34	1.28 (0.78 to 2.10)	.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.[35,] The multivariable-adjusted HR for risk of invasive breast cancer per standard deviation (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 an HR of 1.19 (95% CI, 1.10 to 1.28). Trends of time-dependent analyses of anthropometric measures and overall ER + incident breast cancer cases were significant for BMI (p <.001) and waist circumference (p<.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[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Duration of Follow-Up[e]
Arthur et al (2020)[35,]	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)[32,]	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.
[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)[35,]	1. Selection not described.	1. Blinding not described.	1, 4. Timing of delivery of index or reference tests not clear;	2. Evidence of selective reporting		

Study	Selection[a]	Blinding[b]	Delivery of Test[c]	Selective Reporting[d]	Data Completeness[e]	Statistical[f]
			expertise of evaluators not described.	(covariates did not have to be pre-specified).		
Iyengar et al (2019)[32,]	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.

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

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 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 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.

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 Association of Clinical Endocrinology et al

The American Association of Clinical Endocrinology (AACE) and American College of Endocrinology (ACE) clinical practice guideline on obesity was updated in 2016.[36,] Table 7 describes relevant recommendations for the diagnosis of overweight and obesity from the AACE/ACE guideline. The authors also state that "The DEXA [dual x-ray absorptiometry] scan also allows for calculation of the fat mass index (total body fat mass [kg] divided by height [m2]), which is a physiologic relevant measure of adiposity. The clinical utility of these measures is limited by availability, cost, and lack of outcomes data, but they have been applied extensively in research settings. Body fat percentage cut points for obesity have been proposed by the World Health Organization (WHO) to be 25% for men and 35% for women."

Table 7. American Association of Clinical Endocrinology/American College of Endocrinology Recommendations for Diagnosis of Overweight and Obesity

Recommendation	Quality of evidence[a]	Grade of recommendation[b]
All adults should be screened annually using a BMI measurement; in most populations a cutoff point of ≥25 kg/m² should be used to initiate further evaluation of overweight or obesity.	2 (upgraded due to high relevance)	A
BMI should be used to confirm an excessive degree of adiposity and to classify individuals as having overweight (BMI 25 to 29.9 kg/m²) or obesity (BMI ≥30 kg/m²), 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 athleses and those with sarcopenia.	2 (upgraded due to high relevance)	A
When evaluating patients for adiposity-related disease risk, WC should be measure in all patients with BMI <35 kg/m².	2 (upgraded due to high relevance)	A
In many populations, a WC cutoff point of ≥94 cm in mean and ≥80 cm in women should be considered at risk and consistent with abdominal obesity; in the U.S. and Canada, cutoff points that can be used to indicate increased risk are ≥102 cm for men and ≥88 cm for women.	2 (upgraded due to high relevance)	A
Other measurements of adiposity (e.g., bioelectric impedance, air/water displacement plethysmography, or dual-energy X-ray absorptiometry [DEXA]) may be considered at the clinician's discretion if BMI and physical examination results are equivocal or require further evaluation.	2 (downgraded due to evidence gaps)	C
However, the clinical utility of these measures [listed in the above recommendation] is limited by availability, cost, and lack of outcomes data for validated cutoff points.	2	B

BMI: body mass index; WC: waist circumference.
[a] Evidence quality 2 indicates intermediate-level evidence, including meta-analyses of nonrandomized prospective or case-controlled trials, nonrandomized controlled trials, prospective cohort studies, and/or retrospective case-control studies.
[b] Grade A, B, and C indicate strong, intermediate, and weak recommendations, respectively.

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.[37,] Dual-energy x-ray 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.

American Society for Parenteral and Enteral Nutrition

The American Society for Parenteral and Enteral Nutrition (ASPEN) published clinical guidelines on the validity of body composition assessment in clinical populations in 2019, as a complement to the Global Leadership Initiative on Malnutrition (GLIM) criteria for malnutrition (described below).[4,] The systematic review with meta-analysis used to develop these guidelines is described above. The target population of the guideline was adults "with a potentially inflammatory condition or pathological end point associated with a specific disease or clinical condition such as cancer, cardiovascular disease (CVD), cardiac failure, diabetes, hepatic or renal disease, human immunodeficiency virus, or possessing a condition that requires surgical intervention." The target population did not include healthy individuals or those with obesity, except when "linked to a clinical condition such as metabolic syndrome, hypertension, etc." Studies evaluated for guideline development involved specific body composition assessment methodologies (DXA, bioelectrical impedance analysis, or ultrasound) and were required to use a more precise comparator; for studies evaluating DXA, these included computed tomography, magnetic resonance imaging, or multicompartment models. Anthropometric measurements "were not included since these are considered surrogate measures of body composition." Table 8 describes relevant recommendations from the ASPEN guideline.

Table 8. American Society for Parenteral and Enteral Nutrition Clinical Guideline Recommendations for Body Composition Assessment in Adult Clinical Populations

Recommendation	Quality of evidence	Strength of recommendation
We recommend the use of DXA for assessing fat mass in patients with clinical conditions.	Low	Strong
No recommendation can be made at this time to support the use of ultrasound in a clinical setting for assessing body composition.	Very low	Weak
No recommendations can be made regarding the validity of using bioelectrical impedance analysis in clinical populations.	Low	Weak

DXA: dual-energy x-ray absorptiometry.

International Society for Clinical Densitometry

The International Society for Clinical Densitometry (2019) updated its statements on the use of DXA for body composition.[38,] Use of DXA for measurement of body composition was suggested for use in the following clinical conditions:

- To assess fat distribution in patients with human immunodeficiency virus (HIV) who are using antiretroviral agents known to increase the risk of lipoatrophy.
- To assess fat and lean mass changes in obese patients undergoing bariatric surgery (or medical, diet, or weight loss regimens with anticipated large weight loss) when weight loss exceeds approximately 10%. The statement noted that the impact of DXA studies on clinical outcomes in these patients is uncertain.
- To assess fat and lean mass in patients with muscle weakness and poor physical functioning. The impact on clinical outcomes is uncertain.

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

U.S. Preventive Services Task Force Recommendations

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

Medicare National Coverage

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

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 9.

Table 9. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT03621306	Precision and Reliability of Dual X-ray Absorptiometry (DXA) Testing	400	Aug 2028
NCT05639556	Strength and Muscle Related Outcomes for Nutrition and Lung Function in CF	300	Dec 2028
NCT05879692	Response of Irritable Bowel Syndrome to Abdominal Fat Reduction	60	Dec 2023
NCT05699863	A Multidisciplinary Approach to Screening for Obesity Complications - The MULTISITE Study	90	Dec 2025
NCT05885672	A Multi-Modal Approach to Improving the Early Detection of Cardiometabolic Disease Risk	200	Jul 2024

NCT: national clinical trial.
[a] Denotes industry-sponsored or cosponsored trial.

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Documentation for Clinical Review

- No records required

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.

The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.

Type	Code	Description
CPT®	76499	Unlisted diagnostic radiographic procedure
HCPCS	None	

Policy History

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

Effective Date	Action
04/05/2007	BCBSA Medical Policy adoption
01/07/2011	Policy revision without position change
06/30/2015	Coding update
10/30/2015	Policy title change from Whole Body Dual X-Ray Absorptiometry (DEXA) to Determine Body Composition Policy revision without position change
03/01/2016	Policy revision without position change
06/01/2017	Policy revision without position change
11/01/2017	Policy revision without position change
11/01/2018	Policy revision without position change
12/01/2019	Policy revision without position change
11/01/2023	Policy reactivated. Previously archived from 08/01/2020 to 10/31/2023.

Definitions of Decision Determinations

Medically Necessary: Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

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

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

Prior Authorization Requirements and Feedback (as applicable to your plan)

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

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

We are interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration.

For utilization and medical policy feedback, please send comments to: MedPolicy@blueshieldca.com

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

Appendix A

POLICY STATEMENT	
BEFORE	AFTER Blue font: Verbiage Changes/Additions
Reactivated Policy **Policy Statement:** N/A	**Whole Body Dual X-Ray Absorptiometry to Determine Body Composition 6.01.40** **Policy Statement:** I. Dual-energy x-ray absorptiometry body composition studies are considered **investigational**.