



## FEP Medical Policy Manual

### FEP 6.01.40 Whole Body Dual X-Ray Absorptiometry to Determine Body Composition

**Annual Effective Policy Date: January 1, 2024**

**Original Policy Date: March 2013**

**Related Policies:**

6.01.01 - Bone Mineral Density Studies

6.01.44 - Vertebral Fracture Assessment with Densitometry

## Whole Body Dual X-Ray Absorptiometry to Determine Body Composition

### Description

#### 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 (eg, as a more convenient replacement for underwater weighing). This evidence review addresses potential applications in clinical care rather than research use of the technology.

#### OBJECTIVE

The objective of this evidence review is to determine whether the use of dual-energy x-ray absorptiometry improves the net health outcome in individuals with a condition associated with abnormal body composition.

#### POLICY STATEMENT

Dual-energy x-ray absorptiometry body composition studies are considered **not medically necessary**.

## POLICY GUIDELINES

None

## BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

## FDA 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

### 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 used DXA body composition studies as a reference standard. Systematic reviews with meta-analyses exploring the clinical validity of DXA measurements against reference methods for the quantification of fat mass 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. More importantly, no studies were identified in which DXA body composition measurements were actively used in patient management. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have a clinical condition managed by monitoring changes in body composition over time who receive serial DXA body composition studies, the evidence includes several prospective studies monitoring patients over time. Relevant outcomes are symptoms and change in disease status. The studies used DXA as a tool to measure body composition and were not designed to assess the accuracy of DXA. None of the studies used DXA findings to make patient management decisions or addressed how serial body composition assessment might improve health outcomes. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

## SUPPLEMENTAL INFORMATION

### 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.<sup>36</sup> Table 1 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 [m<sup>2</sup>]), 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 1. American Association of Clinical Endocrinology/American College of Endocrinology Recommendations for Diagnosis of Overweight and Obesity**

Recommendation	Quality of evidence <sup>a</sup>	Grade of recommendation <sup>b</sup>
All adults should be screened annually using a BMI measurement; in most populations a cutoff point of $\geq 25$ kg/m <sup>2</sup> 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/m <sup>2</sup> ) or obesity (BMI $\geq 30$ kg/m <sup>2</sup> ), 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.	2 (upgraded due to high relevance)	A
When evaluating patients for adiposity-related disease risk, WC should be measured in all patients with BMI $< 35$ kg/m <sup>2</sup> .	2 (upgraded due to high relevance)	A
In many populations, a WC cutoff point of $\geq 94$ cm in men and $\geq 80$ 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 $\geq 102$ cm for men and $\geq 88$ 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.

<sup>a</sup>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.

<sup>b</sup>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.<sup>37</sup> 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

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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).<sup>4</sup> 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 multicompartments models. Anthropometric measurements "were not included since these are considered surrogate measures of body composition." Table 2 describes relevant recommendations from the ASPEN guideline.

**Table 2. 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.<sup>38</sup> 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 lipotrophy.
- To assess fat and lean mass changes in obese patients undergoing bariatric surgery (or medical, diet, or weight loss regimens with anticipated large weight loss) when weight loss exceeds approximately 10%. The statement noted that the impact of DXA studies on clinical outcomes in these patients is uncertain.
- To assess fat and lean mass in patients with muscle weakness and poor physical functioning. The impact on clinical outcomes is uncertain.

Of note, pregnancy is a contraindication to use of DXA to measure body composition. The statement also adds that the clinical utility of DXA measurements of adiposity and lean mass (eg, visceral adipose tissue, lean mass index, fat mass index) is uncertain. Furthermore, while the use of DXA adiposity measures such as fat mass index may be useful in risk-stratifying patients for cardio-metabolic outcomes, specific thresholds to define obesity have not been established.

## 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.

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## POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
March 2013	New policy	
March 2014	Replace policy	Policy updated with literature review. References 25 and 27 added. Policy statement unchanged.
March 2015	Replace policy	Policy updated with literature review. References 1-2, 7-9, 12-13 added. Policy statement unchanged.
December 2018	Replace policy	Policy updated with literature review through July 26, 2018; reference 12 added. Policy statement unchanged.
December 2019	Replace policy	Policy updated with literature review through June 26, 2019; references added. Policy statement unchanged.
December 2020	Replace policy	Policy updated with literature review through June 19, 2020; references added. Policy statement unchanged.
December 2021	Replace policy	Policy updated with literature review through July 23, 2021; no references added. Policy statement unchanged.
December 2022	Replace policy	Policy updated with literature review through July 21, 2022; references added. Policy statement unchanged.
December 2023	Replace policy	Policy updated with literature review through July 18, 2023; references added. Policy statement unchanged.

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