BONE DENSITY STUDIES  
RAD601.036 

COVERAGE: 

Bone density measurements may be eligible for coverage where osteoporosis is a crucial factor in making the decision to initiate or monitor estrogen replacement therapy and other preventive or therapeutic measures.

There is a legislative mandate adopted by the Texas Department of Insurance, regarding required coverage for individuals for bone mass measurement for the detection of low bone mass and determine the person's risk of osteoporosis. Bone density measurements, therefore, are eligible for coverage.

DESCRIPTION: 

Bone Density Studies are non-invasive measurements of bone mass. Either bone mineral content (BMC), bone mineral density (BMD), or both can be assessed by these technologies. Radiologic testing more frequently diagnoses osteoporosis (low bone mass leading to an increased risk of fragility fractures) and evaluation of skeletal mass. There are no blood or urine quantitative tests which establishes specifically the diagnosis of primary osteoporosis, but such tests may exclude secondary causes.

Current practice guidelines published by the National Osteoporosis Foundation (NOF) recommend that measurement of BMD be performed:

- In all postmenopausal women under the age of 65 who have one or more risk factors includes a personal history of fracture as an adult, history of fracture in a first degree relative, current cigarette smoker, and low (less than 127 pounds) body weight;

- In all women aged 65 and older regardless of additional risk factors;

- In women who have been on hormone replacement therapy for prolonged periods; and,

- As part of the initial workup prior to the initiation of glucocorticoid therapy.

There are additional recommendations made by clinical practitioners to perform BMD when estrogen replacement therapy is not contraindicated for the individual and to use BMD results as an integral part of the individual receiving counseling about the benefits and risks of estrogen replacement therapy.

Therefore, BMD measurements are often performed in patients prior to initiating therapy OR for those patients who have not been previously measured. Serial monitoring of BMD to determine treatment response is also commonly performed.
BMD can be measured with a variety of techniques in a variety of sites. Sites are broadly subdivided into central sites (hip or spine) and peripheral sites (wrist, finger, heel). While BMD measurements are predictive of fragility fractures at all sites, central measurements of the hip and spine are most predictive. In addition, fractures of the hip and spine (vertebral fractures) are the most clinically relevant. The following techniques are used.

- **DUAL ENERGY X-RAY (RADIOGRAPHIC) ABSORPTIOMETRY (DEXA),** also known as:
  - dual energy radiography (DER),
  - dual energy radiography absorptiometry (DRA),
  - quantitative digital radiography (QDR), and
  - dual x-ray absorptiometry (DXA), is used to measure BMC and BMD in the spine, hip, wrist, or total body. The x-ray source provides a resolution compared to radioisotopic sources of photons used in other methods listed below. These measurements may be done for estrogen-deficient women for whom the decision to use estrogen replacement therapy depends on information regarding the probability of future fractures. DEXA is an effective tool to provide bone density measurements and is probably the most commonly used because it is easy to use, has low radiation exposure, and has the ability to measure both the hip and spine.

- **QUANTITATIVE COMPUTED TOMOGRAPHY (QCT)** is used to measure bone mass in the spine and, on some occasions, the hip. It is the only non-invasive method for directly measuring bone volume. Compared to DEXA, QCT is less readily available to the individual variability in soft tissue content around the hip and spine.

- **SINGLE PHOTON ABSORPTIOMETRY (SPA)** is used to measure peripheral bone mass, e.g., the wrist. SPA is rarely used.

- **DUAL PHOTON ABSORPTIOMETRY (DPA)** is used to measure bone mass in the spine and hip and to measure total body calcium. DEXA is commonly replacing DPA. DPA is rarely used and may even be considered obsolete.

- **RADIOGRAPHIC ABSORPTIOMETRY (RA)** is used to measure bone mass in the hand or heel. Computerized image processing has been applied to radiography. Current RA techniques applicable to a routine clinical setting are as precise and accurate as DEXA.

- **BROADBAND ULTRASOUND ATTENUATION (BUA) or ULTRASOUND DENSITOMETRY (UD)** is the first diagnostic tool which does not involve the use of x-rays. UD is intended for use in women at risk for bone fracture, not as a general screening tool. UD is a portable device that transmits high frequency sound waves through the patient's heel for about 10 seconds and automatically analyzes the results. According to the FDA (03/13/98) this ultrasound device was shown to be as good as x-ray bone density measurements for diagnosing osteoporosis and predicting fracture risk. UD has no radiation exposure, and machines may be purchased for use in an office setting.

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**RATIONALE:**
The National Osteoporosis Foundation (NOF) guidelines exist in two formats:

- a formal background report and
- a summary version presented as a Physician's Guide.

Although BMD measurements at the clinically relevant central sites (hip and spine) are most predictive of future fracture risk, the Physician's Guide does not recommend one particular type or site of BMD testing technology. However, the background report does state that hip measurements are preferred.

The 1999 BCBSA TEC Assessment specifically addresses the use of UD of the heel, not only to determine fracture risk, but to predict response to drug treatment history. Although these outcomes may seem the same, there is a subtle but important distinction. This TEC Assessment concluded that while both DEXA and UD were equivalent in predicting fracture risk, the correlation coefficient was only modest, suggesting that the two techniques identified different populations of at-risk patients.

The NOF guidelines did not address serial monitoring to assess treatment response. However, serial monitoring using DEXA was the subject of the 2000 TEC Assessment that offered the following conclusions:

1. There is no direct evidence regarding the utility of BMD in patients undergoing treatment of osteoporosis.

2. Lacking this direct evidence, the chain of logic supporting BMD monitoring is very weak and does not indicate a benefit. Given the precision of BMD measurement using DEXA, the expected changes in BMD and variability of those changes as a result of treatment, it is only possible under situations where there is a great loss of bone where it is possible to identify a patient who is not responding to treatment. Even then, the patients may actually be responding by losing less BMD than they would have without treatment.

3. There is no direct evidence that alternative treatments or adjustments in management will be effective in those judged to be a nonresponder in their treatment.

4. Based on these above considerations, serial monitoring with DEXA did not meet the TEC criteria.

The above TEC assessment only addressed the use of DEXA as a technique for serial monitoring. However, for unknown reasons, treatment related changes in BMD are not observed at peripheral sites. Thus, ultrasound densitometry of the heel cannot be used for serial monitoring. This suggests that if serial monitoring is considered a central DEXA BMD measurement should be the initial BMD test performed in patients at risk for osteoporosis. A central DEXA measurement will simultaneously establish the diagnosis of osteoporosis and provide a baseline.

DEXA is probably the most commonly used technique for measuring BMD,
but QCT, BUA, SPA, and RA may also be used. UD is a new office based technology and it is unknown whether it can be used to predict response to pharmacologic therapy. On this basis, DEXA may be preferred.

DISCLAIMER:

State and federal law, as well as contract language, including definitions and specific inclusions/exclusions, takes precedence over Medical Policy and must be considered first in determining coverage. The member’s contract benefits in effect on the date that services are rendered must be used. Any benefits are subject to the payment of premiums for the date on which services are rendered. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

HMO Blue Texas physicians who are contracted/affiliated with a capitated IPA/medical group must contact the IPA/medical group for information regarding HMO claims/reimbursement information and other general polices and procedures.

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