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Medical Benefit		Effective Date: 10/01/11	Next Review Date: 05/15
Preauthorization	No	Review Dates: 05/07, 07/08, 05/09, 05/10, 05/11, 05/12, 05/13, 05/14	

*The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. **Preauthorization is not required but is recommended if, despite this Protocol position, you feel this service is medically necessary.** Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.*

Description

Vertebral fracture assessment (VFA) with densitometry is a technique in which vertebral fractures are assessed at the same time as bone mineral density (BMD), by use of dual x-ray absorptiometry (DEXA). The addition of vertebral fractures to BMD may provide additional useful information on an individual's risk of fracture.

Background

Vertebral fractures are highly prevalent in the elderly population, and epidemiologic studies have found that these fractures are associated with an increased risk of future spine or hip fractures independent of bone mineral density (BMD). Only 20% to 30% of vertebral fractures are recognized clinically; the rest are discovered incidentally on lateral spine radiographs. Lateral spine radiographs have not been recommended as a component of risk assessment for osteoporosis because of the cost, radiation exposure, and the fact that the radiograph would require a separate procedure in addition to the BMD study using DEXA. However, several densitometers with specialized software are able to perform VFA in conjunction with DEXA. The lateral spine scan is performed by using a rotating arm; depending on the densitometer used, the patient can either stay in the supine position after the bone density study or is required to move onto the left decubitus position.

VFA differs from radiologic detection of fractures, as VFA uses a lower radiation exposure and can detect only fractures, while traditional radiograph images can detect other bone and soft tissue abnormalities in addition to spinal fractures. Manufacturers have also referred to this procedure as instant vertebral assessment, radiographic vertebral assessment, dual-energy vertebral assessment, or lateral vertebral assessment.

For both lateral spine radiographs and images with densitometry, vertebral fractures are assessed visually. While a number of grading systems have been proposed, the semiquantitative system of Genant is commonly used. This system grades the deformities from I to III, with grade I (mild) representing a 20% to 24% reduction in vertebral height, grade II (moderate) representing a 25% to 39% reduction in height, and grade III (severe) representing a 40% or greater reduction in height. The location of the deformity within the vertebrae may also be noted. For example, if only the midheight of the vertebrae is affected, the deformity is defined as an endplate deformity; if both the anterior and midheights are deformed, it is a wedge deformity; and if the entire vertebrae is deformed, it is classed as a crush deformity. A vertebral deformity of at least 20% loss in height is typically considered a fracture. Accurate interpretation of both lateral spine radiographs and VFA imaging is dependent on radiologic training. Thus, device location and availability of appropriately trained personnel may influence diagnostic accuracy.

Regulatory Status

To perform vertebral fracture assessment with a densitometer, additional software is needed, and it must have 510(k) marketing clearance from the U.S. Food and Drug Administration (FDA). Products that have received FDA clearance include Lunar Dual Energy Vertebral Assessment (DVA™) (General Electric Medical Systems) and Hologic Instant Vertebral Assessment™ (IVA™) software.

Policy (Formerly Corporate Medical Guideline)

Screening for vertebral fractures using dual x-ray absorptiometry (DEXA or DXA) is considered **investigational**.

Medicare Advantage

This may be a **medically necessary** service for Medicare Advantage when symptoms are present and the test results will be used in the management of the patient (such as specific treatment for a vertebral fracture). It is **not medically necessary** for screening to detect bone loss or determine bone quality.

Benefit Application

For all business if vertebral fracture assessment with densitometry is billed in addition to other services, it will be considered incidental to the other service(s).

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

1. National Osteoporosis Foundation. The Clinician's Guide to Prevention and Treatment of Osteoporosis 2013. Available online at: <http://nof.org/files/nof/public/content/resource/913/files/580.pdf>. Last accessed December, 2013.
2. Domiciano DS, Figueiredo CP, Lopes JB et al. Vertebral fracture assessment by dual X-ray absorptiometry: a valid tool to detect vertebral fractures in community-dwelling older adults in a population-based survey. *Arthritis Care Res (Hoboken)* 2013; 65(5):809-15.
3. Diacinti D, Del Fiacco R, Pisani D et al. Diagnostic Performance of Vertebral Fracture Assessment by the Lunar iDXA Scanner Compared to Conventional Radiography. *Calcif Tissue Int* 2012; 91(5):335-42.

