Vertebral assessment using dual-energy x-ray absorptiometry for osteoporotic fracture risk assessment

BlueCross BlueShield Association

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Citation

Authors' objectives
The objective of this Assessment is to determine whether vertebral assessment with dual X-ray absorptiometry (DXA) will improve patient outcomes. This technique has capability to identify vertebral fractures. Vertebral fractures are a result of osteoporosis and are strong risk factors for future vertebral and other osteoporotic fractures. Identification of those persons with vertebral fractures might more accurately determine future risk of fracture and change management decisions for certain patients.

Authors' conclusions
1. The technology must have final approval from the appropriate governmental regulatory bodies.

Many dual energy radiographic absorptiometry devices have received 510(k) marketing clearance from the U.S. Food and Drug Administration (FDA). To perform vertebral fracture assessment on the DXA devices, additional software is needed and it must have 510(k) marketing clearance from the FDA as well. Some examples of vertebral fracture assessment application packages that have received 510(k) marketing clearance are GE LUNAR Corporations Dual Energy Vertebral Assessment (DVA) (previously known as Lateral Vertebral Assessment or LVA), and Hologics Instant Vertebral Assessment or IVA.

2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes.

The available evidence is insufficient to assess what health outcomes would result from using vertebral assessment using DXA as a screening test for osteoporosis. Currently, there is no direct evidence linking the use of vertebral assessment to health outcomes. The case for using vertebral assessment lies in evaluating the strength of evidence underlying 4 critical assumptions: 1) prevalent vertebral fractures predict future osteoporotic fractures; 2) vertebral assessment identifies additional patients who are potential candidates for pharmacologic treatment based on presence of fracture; 3) vertebral fractures are accurately identified with vertebral assessment using DXA; and 4) patients identified benefit from pharmacologic treatment.

Regarding the first assumption, several observational studies show that prevalent vertebral fractures are a risk factor for future fractures of various types. This risk prediction persists even after accounting for bone mineral density, and the risk appears to be high, greater than 4-fold for further vertebral fractures, and close to doubling for hip fractures. The evidence behind the first assumption is strong and consistent.

Regarding the second assumption, 2 studies have examined the prevalence of patients without osteoporosis who may have undetected vertebral fractures. These patients may be candidates for pharmacologic therapy even though they do not meet criteria for treatment based on bone mineral density. Both of these studies found substantial numbers of persons who may have vertebral fractures but bone mineral density levels above treatment thresholds.
Regarding the third assumption, 4 studies examine the accuracy of vertebral assessment compared to a reference standard of plain X-ray assessment. Sensitivity of vertebral assessment ranges from 54% to 79%, with specificities in the range of 88% to 99%. The diagnostic performance is reasonable in making the diagnosis of vertebral fracture, and even with the diagnostic errors, risk stratification could be achieved using DXA. However, evidence supporting the fourth assumption is lacking. There is a lack of clinical trial evidence showing that patients with vertebral fractures but with bone mineral density levels above treatment thresholds benefit from treatment. Most clinical trials have enrolled patients with very low bone mineral density levels. The 1 clinical trial that enrolled significant numbers of persons with higher bone mineral density levels (but without vertebral fractures) appeared to show that treatment was only effective among those persons with osteoporotic bone mineral density levels.

In sum, then, the evidence supporting the argument for use of vertebral assessment is not strong enough to make conclusions about its effect on health outcomes.

3. The technology must improve the net health outcome.

The evidence does not permit conclusions that vertebral assessment using DXA improves the net health outcome.

4. The technology must be as beneficial as any established alternatives.

The evidence does not permit conclusions that vertebral assessment using DXA improves net health outcomes over the current practice of assessing osteoporosis risk using bone mineral density measurement alone.

5. The improvement must be attainable outside the investigational settings.

Whether vertebral assessment using DXA improves health outcomes has not been established in the investigational setting.

Based on the above, vertebral assessment using DXA does not meet the TEC criteria.

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