Draft Simplified Specs.
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DXA: Improving Reporting of True Change in Bone Mineral Density

Measure Purpose	To improve the accuracy and clinical usefulness of serial DXA reports by ensuring that radiologists clearly distinguish true changes in bone mineral density (BMD) from normal measurement variation. This improves patient care by informing treatment decisions.
Measure Type	Intermediate Outcome
Measure Level	Individual or Group Practice
Measure Rationale	Osteoporosis and low BMD are major public health issues for millions of Americans aged 50 and older. Approximately 1.8 million Medicare beneficiaries sustained approximately 2.1 million osteoporotic fractures in 2016.[1] Further, one in every two women will develop a fragility fracture after age 50. Although osteoporosis is often considered a silent disease, its impact is not. Approximately 24% of those with a hip fracture will die within a year of the fracture. With about 20% of those sustaining a hip fracture requiring a nursing home stay and 60% do not return to pre-fracture functional level.[2] In addition to the morbidity and mortality burden, the economic costs of osteoporotic fractures are substantial, being projected to reach $25.3 billion annually by 2025, an increase of 50%.[3] Osteoporotic fragility fractures lead to more hospitalizations and hospital costs than myocardial infarction, stroke, or breast cancer.[4] Clearly, optimal management of this substantial health problem is essential. Osteoporosis diagnosis and management are currently suboptimal. Accurate DXA reporting is an essential component of high-quality osteoporosis detection and follow-up care. Radiologists now interpret most of these exams in the U.S.[5], yet research demonstrates DXA interpretation errors are common.[6-9] In one study, interpretation errors were present in 80% of patients; 42% of errors were likely to impact patient management decisions. The most common major errors were reporting incorrect information on BMD change (70%) and incorrect diagnosis (22%).[10] To improve DXA quality, it is imperative to mitigate such errors. This includes applying established best practices to correctly report BMD changes. A critical reporting element includes describing the widespread performance of precision assessment and including this into routine DXA reporting. The standard precision metric in BMD measurement is the repeatability coefficient, known as the least significant change (LSC). Many final DXA reports do not currently include this metric[11, 12] and therefore do not adequately communicate the significance of BMD measurement changes or the technical quality of the acquisition.[8, 13-15] The appropriate use of precision assessment in clinical practice is essential to determine if a measured BMD numerical difference in serial DXA exams is due to true physiological change or is due to unavoidable, random measurement error. This can be accomplished by understanding and measuring both inter- and intra-system measurement variations of DXA scanners.[13, 15, 16]

Measure Description	Percentage of final reports for serial DXA exams (those with a comparable prior DXA) that include: 1. The facility's least significant change (LSC) value for the scanned site, and 2. A statement indicating whether the difference between the current and prior bone mineral density (BMD) is or is not statistically significant based on the LSC.
Denominator	All DXA exams that have a prior DXA exam on the same skeletal site and were performed on the same system or an appropriately cross-calibrated system.
Denominator Exceptions	Cases where the exams cannot be meaningfully compared due to medical or technical issues, such as artifacts, fractures, arthroplasty, severe degenerative changes, or technical problems impacting measurement accuracy.
Numerator	DXA reports that include both: 1. A statement referencing the facility's LSC value, and 2. A statement indicating whether the difference between the current and prior BMD is or is not statistically significant based on the LSC.
Guidance	The following information supports appropriate interpretation and reporting of statistically significant changes in bone mineral density. To aid in determining the statistical significance of clinical measurement differences, the precision error in the form of the LSC should be calculated for each clinical DXA system and skeletal site. • The LSC represents the smallest difference between two clinical BMD measurements on a single scanner that can be considered statistically significant with 95% confidence. When monitoring patients, the comparison should be made to prior DXA examinations of the same skeletal site and region of interest. • The precision error and LSC[iii] of the specific scanner(s) and skeletal site should be ascertained and documented to determine if measured changes are statistically significant.[14, 15] • A statement comparing the current study to prior available studies should include assessment of whether any change in measured BMD is statistically significant.[14, 17] • Technologist precision and quantitative BMD comparisons in clinical practice should use the LSC expressed as an absolute value in grams per square centimeter.[15] This is preferable to using %CV as it is less affected by the baseline BMD value ◦ For example, the same absolute change in BMD with a very low baseline BMD would represent a greater percentage change compared with a higher baseline BMD. DXA precision calculators are available online to calculate precision as either grams per square centimeter or %CV.[18] The International Society for Clinical Densitometry provides minimum precision values; therefore, it is possible to determine whether a technologist meets these standards.[16] • If a technologist has exceeded acceptable values, retraining is necessary.[16] • If the LSC is inappropriately large, then changes in BMD over time with aging, disease or treatment cannot be detected within a clinically useful time interval.[16]

	Facility LSC should be updated when a new DXA system is installed, a new technologist begins scanning patients, or a technologist's skill level has changed.[16] • If a DXA facility has not performed precision assessment, then quantitative comparison of serial BMD measurements is not possible.[8, 12, 15] **Follow-up DXA Report:** Minimum Requirements Statement about the LSC at your facility and the statistical significance of the comparison.[17] • The manufacturer's LSC should not be used, because it does not account for differences in patients who will be tested and the performance and skill of the technologist.[15] • It is not possible to quantitatively compare BMD or to calculate a LSC between densitometers or facilities without cross-calibration.[16] • When possible, patients should return to the same DXA device that was used to perform their most recent prior study, provided that the facility in vivo precision and LSC values are known and do not exceed established maximum values.19 • If a prior study is available, but not an appropriate comparison[ii], a statement should be included in the report as to why the exams are not comparable. • If no prior studies with an appropriate comparison are available, a statement can be included to the effect: Limited availability of data related to the prior exam prohibit direct comparison and assessment of change. *Content below is an example of acceptable documentation included in the final report:* At *Facility Name* the least significant change in BMD with 95% confidence is 0.020gm/cm2 at the mean total femur or 0.025 gm/cm2 at a single total femur. At *Facility Name* the least significant change in BMD with 95% confidence is 0.035 gm/cm2 at the L1-4 region **OR** 0.040 gm/cm2 at the L2-4 region **OR** 0.045 gm/cm2 at the L1-3 region **OR** 0.055 gm/cm2 at the L1-2 region. At *Facility Name* the least significant change in BMD with 95% confidence is 0.040 gm/cm2 at the 1/3 radius.
Definitions	i. Serial exams are DXA studies in which there is a previous exam performed on the same skeletal site. ii. Comparable exams are studies performed using the same DXA system or a system that has been appropriately cross calibrated with the current DXA system. iii. Least significant change (LSC) is a precision value that determines whether a measured BMD difference is statistically significant between DXA exams; therefore, representing a true change rather than random measurement error. LSC values are distinct for each anatomic site routinely evaluated (i.e., lumbar spine L1-L4, hip and forearm). When multiple technologists are performing exams within a facility, it is acceptable to establish the facility LSC for a specific anatomic site from the pooled average LSC values of all facility technologists, assuming values are similar.15 This should be updated continuously as technologists change.

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