CLINICAL MEDICAL POLICY	
Policy Name:	Dual-Energy X-ray Absorptiometry (DXA) for Vertebral Fracture Assessment
Policy Number:	MP-106-MD-PA
Responsible Department(s):	Medical Management
Provider Notice/Issue Date:	11/01/2024; 11/01/2023; 11/01/2022; 11/19/2021; 11/23/2020; 01/20/2020
Effective Date:	12/01/2024; 12/01/2023; 12/01/2022; 12/20/2021; 12/21/2020; 01/20/2020
Next Annual Review:	09/2025
Revision Date:	09/18/2024; 09/20/2023; 09/21/2022; 09/15/2021; 09/16/2020
Products:	Highmark Wholecare℠ Medicaid
Application:	All participating hospitals and providers
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Policy History

Date	Activity
12/01/2024	Provider Effective date
10/07/2024	PARP Approval
09/18/2024	QI/UM Committee review
09/18/2024	Annual Review: No change to Experimental/Investigational clinical stance. Updated 'Reference Sources' section.
12/01/2023	Provider Effective date
10/11/2023	PARP Approval
09/20/2023	QI/UM Committee review
09/20/2023	Annual Review: No changes to E/I stance. Updated 'Summary of Literature' and 'Reference Sources' sections.
12/01/2022	Provider Effective date
10/07/2022	PARP Approval
09/21/2022	QI/UM Committee review
09/21/2022	Annual Review: No changes to clinical stance. Updated 'Summary of Literature' and 'Reference Sources' sections.
12/20/2021	Provider effective date
10/18/2021	PARP approval
09/15/2021	QI/UM Committee review

09/15/2021	Annual Review: No changes to clinical criteria. Added DHS TAG determination information. Updated Summary of Literature and Reference Sources sections.
08/28/2019	Initial policy developed

Disclaimer

Highmark Wholecare℠ medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

Policy Statement

Highmark Wholecare℠ does not provide coverage for the routine screening for vertebral fracture assessment by dual-energy x-ray absorptiometry (DXA) for all indications for the Company's Medicaid products. This policy does not address DXA used for the diagnostic assessment of symptomatic patients, routine bone mineral density screening, or DXA to determine body composition.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

(Current applicable Pennsylvania HealthChoices Agreement Section V. Program Requirements, B. Prior Authorization of Services, 1. General Prior Authorization Requirements.)

Definitions

Prior Authorization Review Panel (PARP) - A panel of representatives from within the PA Department of Human Services who have been assigned organizational responsibility for the review, approval and denial of all PH-MCO Prior Authorization policies and procedures.

Bone Mineral Density (BMD) - A measurement of the mineral content of bones useful for clinical diagnosis of osteoporosis and assessment of response to treatment.

Vertebral Fracture Assessment (VFA) - A densitometry technique to assess vertebral fractures at the same time as bone mineral density, using additional software with dual-energy x-ray absorptiometry.

Dual-Energy X-ray Absorptiometry (DXA or DEXA) - A testing method used to measure bone mineral density using a scanner that rapidly directs x-ray energy from two different sources towards the bone being examined in an alternating fashion at a set frequency.

Procedures

1. Vertebral fracture assessment screening by dual-energy x-ray absorptiometry (DXA) is considered experimental and investigational and therefore not medically necessary for all indications, including as a stand-alone procedure or in addition to standard bone mineral density (BMD) studies, and/or measurements. There is insufficient evidence to determine the effects of this technology on health outcomes.

2. Post-payment Audit Statement
   The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Highmark Wholecare℠ at any time pursuant to the terms of your provider agreement.

3. Place of Service
   The proper place of service for vertebral fracture assessment with DXA is in the outpatient setting.

Governing Bodies Approval

Vertebral fracture assessment is performed with a densitometer that requires additional software. There are several FDA approvals for DXA devices such as Hologic's Instant Vertebral Assessment (IVA) and General Electric Medical System's Lunar Dual Energy Vertebral Assessment (DVA).

The Centers for Medicare and Medicaid Services (CMS) has published the following guidance:

- National Coverage Determination (NCD) Bone (Mineral) Density Studies (150.3)

The Pennsylvania Department of Human Services Technology Assessment Group (TAG) workgroup meets quarterly to discuss issues revolving around new technologies and technologies or services that were previously considered to be a program exception. During this meeting, decisions are made as to whether or not certain technologies will be covered and how they will be covered. TAG's decisions are as follow:

- Option #1: Approved - Will be added to the Fee Schedule
- Option #2: Approved as Medically Effective - Will require Program Exception
- Option #3: Approved with (or denied due to) Limited/Minimal Evidence of Effectiveness - Will require Program Exception
- Option #4: Denied - Experimental/Investigational

On February 2008, the TAG workgroup assigned DXA scans for vertebral fractures an Option # 4, specifically for CPT codes 77085 & 77086.

Summary of Literature

According to the American Association of Neurological Surgeons (AANS), vertebral compression fractures (VCF) are most common in patients with osteoporosis and affect approximately 750,000 people annually. The occurrence of VCF increases with people as they age, with an estimated 40% of women aged 80 and older affected. However, 20% to 30% of vertebral fractures are recognized clinically, and the remaining are captured incidentally on lateral spine radiographs.

Standard methods of diagnosing vertebral fractures include the use of imaging technologies. The imaging methods can include CT scan, MRI, and radiology. Radiologic exams include anterior-posterior view and lateral view, with the lateral view as the gold standard. Bone mineral density studies can be measured either centrally by examining hip or spine, or peripherally testing wrist, finger, or heels. The central measurements of the hip and spine are the most predictive (Borges et al. 2017).

Dual x-ray absorptiometry is one of the most commonly used techniques to measure BMD. DXA has lower radiation exposure and is capable of measuring BMD of the hip and spine. Vertebral fracture assessment with DXA is performed at the same time as BMD with the use of additional software. It is believed that this combination may augment diagnostic information on fracture risk.

The International Society for Clinical Densitometry (2019) recommends lateral spine imaging with either standard radiography or densitometric VFA, indicated for patients with a T score of < -1.0 and one or more of the following is present:

- Women age ≥ 70 years or men ≥ 80 years
- Historical height loss > 4 cm (>1.5 inches)
- Self-reported but undocumented prior vertebral fracture
- Glucocorticoid therapy equivalent to ≥ 5 mg of prednisone or equivalent, per day for ≥ 3 months

The U.S. Preventive Services Task Force (USPSTF) has two recommendations for osteoporosis screening. The first recommendation is screening for osteoporosis with bone measurement testing to prevent osteoporotic fractures in postmenopausal women younger than 65 years who are at increased risk of osteoporosis, as determined by a formal clinical risk assessment tool. The second recommendation addresses women aged 65 years and older that indicates screening for osteoporosis with bone measurement testing to prevent osteoporotic fractures. Both recommendations were graded B, defined as a high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial. In addition, the USPSTF treatment guidelines recommend using BMD, as measured by central DXA, to define osteoporosis and the treatment threshold to prevent osteopathic fractures. Peripheral DXA and quantitative ultrasound are listed as common BMD testing. (USPSTF, 2018).

A symposium found that vertebral fracture assessment (VFA) of acute fractures using dual-energy X-ray absorptiometry (DXA) was not superior to VFA assessed by lateral X-ray, according to a follow-up study of fracture risk in patients with normal bone mineral density (BMD) (Ginther, 2017).

The decision to perform bone density assessment should be based on an individual's fracture risk profile and skeletal health assessment. Utilizing any procedure to measure bone density is not indicated unless the results will influence the patient's treatment decision. (Cosman, de Beur, et al., 2014).

Commonly evaluated clinical risk assessment instruments each showed high sensitivity approaching or exceeding 90 % for identifying individuals with DXA-determined osteoporosis or low BMD at certain

thresholds in different population. Simpler instruments, such as osteoporosis self-assessment tool (OST), generally performed as well as or better than more complex instruments, such as DXA. Additional studies are also needed to evaluate the comparative effectiveness and cost-effectiveness of use of clinical risk assessment instruments for initial prescreening of individuals for osteoporosis or low BMD compared with other screening strategies. (Nayak, Edwards, Saleh, Greenspan, 2015).

DXA has been recognized as the reference method to measure BMD with acceptable accuracy errors and good precision and reproducibility. The World Health Organization (WHO) has established DXA as the best densitometric method for assessing BMD in postmenopausal women and based the definitions of osteopenia and osteoporosis on its results. DXA provides for accurate diagnosis of osteoporosis, estimation of fracture risk and monitoring of patients undergoing treatment. However, when DXA studies are performed incorrectly, it can lead to major mistakes in diagnosis and therapy (El Maghraoui & Roux, 2008).

Coding Requirements

Non-covered Procedure Codes
These procedure codes will not be reimbursed without Medical Director approval.

CPT Code	Description
77085	Dual-energy x-ray absorptiometry (DXA), bone density study, 1 or more sites; axial skeleton (e.g., hips, pelvis, spine), including vertebral fracture assessment
77086	Vertebral fracture assessment via dual-energy x-ray absorptiometry (DXA)

Reimbursement

Participating facilities will be reimbursed per their Highmark Wholecare℠ contract.

Reference Sources

Pennsylvania Department of Human Services. Technology Assessment Group Coverage Decisions. Managed Care Operations Memorandum: OPS # 02/2008-004 from February 5, 2008, Option #4. Accessed on September 2, 2022.

Borges JLC, de M Mirnada IS, Lewiecki EM. The clinical utility of vertebral fracture assessment in predicting fractures. J Clin Densitom. July 2017. Accessed on August 28, 2019.

U.S. Preventive Services Task Force (USPSTF). Osteoporosis to prevent fractures: screening. June 2018. Accessed on September 5, 2024.

American Association of Neurological Surgeons (AANS). Vertebral compression fractures: incidence and prevalence. No date. Accessed on August 9, 2021.

National Osteoporosis Foundation. Clinician's guide to prevention and treatment of osteoporosis 2014. Accessed on August 30, 2019.

International Society for Clinical Densitometry. 2019 ICCD Official Positions-adult. 2019. Accessed on August 9, 2021.

Ginther J, Ginther A. Vertebral compression deformities in patients with normal bone mineral densities. Presented at: Clinical Osteoporosis 2017: A Joint ISCD/NOF Symposium; April 22, 2017. Accessed on July 9, 2020.

Cosman F, de Beur SJ, et al. Clinician's Guide to Prevention and Treatment of Osteoporosis. Osteoporosis Int. 2014. Accessed July 10, 2020.

Nayak S, Edwards DL, Saleh AA, Greenspan SL. Systematic review and meta-analysis of the performance of clinical risk assessment instruments for screening for osteoporosis or low bone density. Osteoporos Int. 2015. Accessed July 14, 2020.

The Centers for Medicare and Medicaid Services (CMS). National Coverage Determination (NCD) Bone (Mineral) Density Studies (150.3). Effective date January 1, 2007. Implementation date July 2, 2007. Accessed on September 5, 2024.

El Maghraoui A, Roux C. DXA scanning in clinical practice, QJM: An International Journal of Medicine, Volume 101, Issue 8. August 2008. Accessed on September 2, 2022.