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Submitted electronically

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Chiquita Brooks-LaSure, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Blvd
Baltimore, MD 21244

RE: CMS–1807–P
Medicare and Medicaid Programs; CY 2025 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Prescription Drug Inflation Rebate Program; and Medicare Overpayments

Dear Administrator Brooks-LaSure:

The Bone Health and Osteoporosis Foundation (BHOF) and the organizations listed below, thank the Centers for Medicare & Medicaid Services (CMS) for recognizing that post-fracture osteoporosis follow-up services are **"high-value, potentially underutilized services"** and inviting stakeholder input on payment policies and mechanisms that might address access barriers. We are encouraged that CMS seeks to address the significant care gap in secondary prevention of osteoporotic fractures and appreciate the opportunity to submit comments on the above-referenced proposed rule updating and refining payment policies under the Physician Fee Schedule (the Proposed Rule) for calendar year 2025. We once again strongly urge CMS to create sufficient payment mechanisms to ensure viability of the collaborative care delivery intervention known as Fracture Liaison Services (FLS) and proven to reduce costly subsequent osteoporotic fractures in individuals experiencing an initial fracture.

The BHOF is the nation's leading resource for patients, health care professionals and organizations seeking up-to-date, medically sound information and program materials on the causes, prevention, and treatment of osteoporosis. Established in 1984 as America's only voluntary, nonprofit health organization dedicated to reducing the widespread prevalence of osteoporosis, the foundation has grown to include a network of diverse stakeholders that support its goals to increase public awareness and knowledge, educate physicians and health care professionals, and support research activities concerning osteoporosis and bone health related areas.

CMS stated in its proposal that it is seeking to "understand more clearly how often evidence-based care for persons with fractures, for example, is not provided and the reasons for this, and how recent or new PFS codes, or their revaluation, might help resolve specific barriers to its provision." As more fully detailed below, the care gap in secondary prevention of osteoporotic fractures has been perpetuated and exacerbated by health system failures throughout the patient journey - from identifying patients with osteoporotic fractures requiring follow-up through development of personalized treatment plans and the necessary follow-up to ensure patients remain on treatment.

These failures in delivering adequate post-fracture care are also not unique to the U.S. A recent initiative led by the International Osteoporosis Foundation (IOF) examined the burden of osteoporosis and associated fragility fractures across Europe as well as service provision and care gaps.[1] The analysis noted that the proportion of European women at high fracture risk (defined in most European nations as having experienced a fragility fracture) but not receiving therapy for osteoporosis ranged from 32% to 87%. From 2010 to 2019, the number of untreated osteoporosis patients rose from 10.6 million to 14 million.[2] Data from another prospective observational study of over 60,000 older women recruited from primary care practices in 10 countries across US, Europe and Australia, demonstrated that more than 80% of women with a fragility fracture did not receive osteoporosis treatment.[3] A large retrospective analysis of U.S. patients, based on administrative insurance claims data of nearly 100,000 men and women aged 50 years or more who were hospitalized for hip fracture[4] revealed an estimated probability of receiving osteoporosis medication within 12 months after discharge of 28.5%; more alarming was the trend in such treatment, which declined from 40.2% in 2002 to 20.5% in 2011.[5]

As more fully detailed below, results from a study conducted by the actuarial firm Milliman and commissioned by BHOF suggest that low treatment rates noted in the *Solomon* study among patients at highest risk of a future fracture persist. Although there is broad agreement that primary care providers (PCPs) ***can*** play a critical role in ensuring that their patients receive osteoporosis-related follow-up after a fracture, recent advances in assessment, diagnosis, and treatment of osteoporosis as well as secondary fracture prevention strategies have not been incorporated into primary care clinical practice. This is likely due to time constraints and insufficient knowledge of treatment options to feel confident in prescribing therapies to address patient-specific fracture risk. [6]

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[1] Kanis JA, Norton N, Harvey NC, Jacobson T, Johansson H, Lorentzon M, et al. SCOPE 2021: a new scorecard for osteoporosis in Europe. *Archives of osteoporosis.* 2021;16(1):82.

[2] Id.

[3] Greenspan SL, Wyman A, Hooven FH, Adami S, Gehlbach S, Anderson FA, Jr, et al. Predictors of treatment with osteoporosis medications after recent fragility fractures in a multinational cohort of postmenopausal women. *Journal of the American Geriatrics Society.* 2012;60(3):455–61.

[4] Solomon DH, Johnston SS, Boytsov NN, McMorrow D, Lane JM, Krohn KD. Osteoporosis medication use after hip fracture in U.S. patients between 2002 and 2011. *J Bone Miner Res.* 2014;29(9):1929–37.

[5] Id.

[6] Singer AJ, Sharma A, Deignan C, Borgermans L. Closing the gap in osteoporosis management: the critical role of primary care in bone health. Curr Med Res Opin. 2023 Mar;39(3):387-398.

There is no easy fix to rapidly ensure that PCPs prioritize secondary osteoporotic fracture prevention and acquire the knowledge base necessary to deliver treatment plans that address patient-specific factors, including future fracture risk. The Medicare program's strategy of having fracture patients referred to primary care is, therefore, destined to fail in closing the bone health/post-fracture care gap. Maintaining the status quo, rather than directing fracture patients to coordinated care programs proven to increase access to evidence-based care, will, given the aging U.S. population, increase the patient and health system costs associated with preventable osteoporotic fractures. Our comments on this topic include:

- Providing information on how often evidence-based care for persons with fractures is not provided.

- Outlining evidence-based coordinated care interventions (known as Fracture Liaison Services (FLS)) that have been adopted globally, including within the U.S., to address the osteoporosis care gap.

- Summarizing our previous discussions with CMS on deficiencies in existing payment code sets and assessing potential that new coding proposals within the proposed rule will address the osteoporosis care gap.

- Recommending CMS creation of a payment code set reflecting the resources required to deliver high-quality care to Medicare beneficiaries suffering a fracture.

- Outlining CMS action, within the PFS rulemaking, essential to mitigate concerns BHOF expressed in connection with the episode-based payment and mandatory PCP referral for hip fracture patients within the CMMI TEAM initiative (articulated in the 2025 inpatient prospective payment system (IPPS) proposed and final rules).

We are hopeful that CMS will, in its final rule, acknowledge the deficit in osteoporotic fracture follow-up experienced by Medicare beneficiaries and ensure that providers delivering a coordinated care approach to secondary fracture prevention have, and are aware of, a set of appropriate coding and payment mechanisms to capture the time and resources required to deliver best practices in post fracture evidence-based care.

I. Despite the significant personal and financial burden of osteoporotic fractures, most Medicare beneficiaries fail to receive evidence-based care after a fracture to reduce risk of a subsequent osteoporotic fracture.

There are now approximately fifty-four million Americans who are at increased risk of a fracture due to osteoporosis or low bone mass, most of whom remain unaware of their fracture risk until they break a bone. Each year, there will be at least two million fractures, 432,000 hospital admissions and 180,000 nursing home admissions due to osteoporotic fractures. Outcomes for patients with osteoporosis, unlike those with other high-cost, debilitating conditions, can be

significantly improved using readily available screening, diagnostic and treatment tools. Unfortunately, most first-fracture patients fail to receive the post-fracture follow-up needed to prevent a future, potentially catastrophic osteoporotic fracture.

Over the past several years, BHOF, together with a diverse set of bone health stakeholders, has engaged with CMS on the disconnect between the evidence-based care Medicare beneficiaries should receive after a fracture and the real-world omission of osteoporosis-related services they experience.

- Medicare beneficiaries suffered approximately 2.1 million osteoporotic fractures in 2016.[7]
- Just 9% of female Medicare FFS beneficiaries were evaluated for osteoporosis with a bone mineral density (BMD) test within six months following a new osteoporotic fracture.[8]
- 77% of women aged 67 or older who have an osteoporotic fracture fail to receive medication to treat osteoporosis in the 6 months after their fracture.[9]
- Fewer than 50% of patients who receive osteoporosis treatment persist with their treatment plan beyond 6 months.[10] [11] [12]
- Although Black patients suffering an osteoporotic fracture have higher mortality, and a 2.3 times greater risk of destitution and debility:
    - just 5% receive any follow-up care (bone density testing and/or osteoporosis treatment) to address their underlying bone fragility.
    - Black patients are 30% less likely to receive post-fracture physical therapy.

CMS has prioritized reducing the Medicare costs associated with hip fractures through a Center for Medicare and Medicaid Innovation (CMMI) episode-based, mandatory payment model set for implementation in 2026.[13] The Transforming Episode Accountability Model (TEAM) will capture all Medicare beneficiary inpatient stays at participating hospitals that are related to hip fracture. BHOF and other stakeholders have expressed concerns that the TEAM initiative, including reliance on a PCP referral within 30 days of discharge, will perpetuate and likely worsen the care gaps that have prevailed for Medicare beneficiaries. We have engaged with CMS over the past several years to highlight the scope and breadth of the osteoporosis care gap, emphasizing that referring patients to primary care has not worked. Throughout these

[7] Milliman Research Report, Medicare cost of osteoporotic fractures – 2021 updated report, The clinical and cost burden of fractures associated with osteoporosis. Medicare Cost of Osteoporotic Fracture - 2021 Update (squarespace.com)
[8] Id.
[9] Yusuf A, et al. Presented at: ASBMR annual meeting. October 9-12, 2015; Seattle, WA. Abstract MO0350.
[10] Boudreau DM, Yu O, Balasubramanian A, et al. A survey of women's awareness of and reasons for lack of postfracture osteoporotic care. J Am Geriatr Soc. 2017;65(8):1829–1835.
[11] Rabenda V, Reginster J-Y. Overcoming problems with adherence to osteoporosis medication. Expert Rev Pharmacoecon Outcomes Res. 2010;10(6):677–689
[12] Kothawala P, Badamgarav E, Ryu S, et al. Systematic review, and meta-analysis of real-world adherence to drug therapy for osteoporosis. Mayo Clin Proc. 2007;82(12):1493–1501.
[13] 2024-17021.pdf (federalregister.gov), Section X.A (accessed August 6, 2024).

discussions, we have identified a coordinated care pathway known as Fracture Liaison Services (FLS) that is proven to reduce secondary osteoporotic fractures. The TEAM initiative will not only disrupt the referral pathway for these patients to existing FLS programs but compound the reimbursement impediments to FLS adoption that we have repeatedly asked CMS to address and discourage adoption of new FLS programs.

Once again, we strongly urge CMS to **prioritize reimbursement mechanisms** for post-fracture care proven to **prevent hip fractures** and their associated costs to Medicare and its beneficiaries, just some of which are highlighted below:

- Hip fractures, considered the most life altering and devastating of fractures, are projected to increase by 240% in women and 310% in men by 2050, globally, compared with 1990 rates.[14] [15]

- The total annual cost for osteoporotic fractures among Medicare beneficiaries was $57 billion in 2018.[16]

- Absent health system changes to detect, diagnose and treat the chronic, progressive disease of osteoporosis, annual costs of osteoporotic fractures are expected to grow to over $95 billion by 2040.[17]

- Patients suffering an osteoporotic fracture are likely to experience several other negative and costly health consequences, including:
    - hospitalizations (40% within 1 week after the fracture)
    - subsequent bone fractures (14% within the first year following the prevalent fracture)
    - institutionalization in nursing care facilities (3%)

- ***Preventing between 5% and 20% of subsequent fractures could have saved between $272 million and $1.1 billion for the Medicare FFS program.***

The burden of osteoporotic fractures falls disproportionately on women, who make up approximately 70.5% of osteoporotic fracture patients. In 2020, the National Committee for Quality Assurance (NCQA) reiterated the significant impact that osteoporotic fractures have on patients and their ability to maintain health, function, and independence:

> *Osteoporotic fractures, particularly hip fractures, are associated with limited mobility, chronic pain and disability, loss of independence and decreased quality*

[14] International Osteoporosis Foundation. Capture the fracture. [cited 2022 Jul 22]. https://www.capturethefracture.org/faq
[15] Gullberg B, Johnell O, Kanis JA. World-wide projections for hip fracture. Osteoporos Int. 1997;7(5):407–413.
[16] Lewiecki EM, Ortendahl JD, Vanderpuye-Orgle J, et al. Healthcare Policy Changes in Osteoporosis Can Improve Outcomes and Reduce Costs in the United States. JBMR Plus. May 2019. doi:10.1002/jbm4.10192.
[17] Id.

of life . . . Most hip fractures require surgery, yet 50% of hip fracture patients are unable to walk without assistance after surgery. Of those who survive the fracture, 40% never return to pre-fracture functional status—often needing long-term nursing home care.[18] (NCQA, 2020).

Fracture patients who fail to receive evidence-based post-fracture care remain at high risk of a future fracture; the patient journey in untreated osteoporosis often involves multiple fractures across decades.[19]

- Occurrence of a recent fracture is highly predictive of a second or subsequent fracture.[20] [21]
- According to a recent study, patients are at a five-fold higher risk of fracture in the first year following a prevalent fracture.[22]
- Early treatment to rapidly reduce fracture risk could prevent secondary fractures in high-risk individuals.[23]
    - This is particularly important for individuals over age 65 who have had a recent hip or vertebral fracture.[24] [25]

II. Evidence-based coordinated care interventions have been adopted globally and within the U.S. to successfully address the osteoporosis care gap.

Throughout the past several years, BHOF, together with its advocacy partners, has presented the stark statistics on the costs preventable osteoporotic fractures exact on the Medicare program, its beneficiaries, and their families. As outlined above, the care gap in post-fracture services is not unique to the U.S. in its scope, breadth, and associated costs to patients and health systems. **Experience in the U.S. and globally has demonstrated that maintaining the status quo, including initiatives prioritizing post-acute follow-up to PCPs, will not change the trajectory of rising costs associated with osteoporotic fractures as populations age**. In collaboration with our advocacy partners, we identified (and presented to CMS) a proven collaborative care coordination intervention, known as a Fracture Liaison Service (FLS) that is

[18] NCQA, Proposed New Measure for HEDIS®1 MY 2020 Osteoporosis Screening in Older Women (OSW), 20200212_09_Osteo.pdf (ncqa.org)
[19] Center JR, Bliuc D, Nguyen TV, et al. Risk of subsequent fracture after low-trauma fracture in men and women. JAMA. 2007;297(4):387–394.
[20] Balasubramanian A, Zhang J, Chen L, et al. Risk of subsequent fracture after prior fracture among older women. Osteoporos Int. 2019;30(1):79–92.
[21] Kanis JA, Harvey NC, McCloskey E, et al. Algorithm for the management of patients at low, high, and very high risk of osteoporotic fractures. Osteoporos Int. 2020;31(1):1–12.
[22] van Geel TACM, van Helden S, Geusens PP, et al. Clinical subsequent fractures cluster in time after first fractures. Ann Rheum Dis. 2009;68(1):99–102.
[23] Kanis JA, Harvey NC, McCloskey E, et al. Algorithm for the management of patients at low, high, and remarkably high risk of osteoporotic fractures. Osteoporos Int. 2020;31(1):1–12.
[24] Weaver J, Sajjan S, Lewiecki EM, et al. Prevalence and cost of subsequent fractures among U.S. patients with an incident fracture. J Manag Care Spec Pharm. 2017;23(4):461–471.
[25] Conley RB, Adib G, Adler RA, et al. Secondary fracture prevention: consensus clinical recommendations from a multistakeholder coalition. J Bone Miner Res. 2020;35(1):36–52.

recognized internationally as the "gold standard" for secondary prevention of osteoporotic fractures.[26]

A recent **Lancet *Diabetes & Endocrinology*** article discussed the utility of FLS in addressing the osteoporosis care gap in the U.S., noting:

> *The persistent divergence between real-world treatment experience and the standard of care following an osteoporotic fracture underscores the complex fragmentation of services for patients as they move from acute episode to rehabilitative care and community-based primary care. Fracture Liaison Services (FLS), which facilitate diagnosis, treatment planning, and long-term care management of patients with a fracture, are recognized internationally as the gold standard for secondary prevention of osteoporotic fractures.*[27]

Collaborative care coordination interventions such as FLS address care gaps by creating a protocol-driven infrastructure to identify individuals who have suffered an initial osteoporotic fracture and follow through on delivering the set of medically necessary services that gives patients the best chance possible of avoiding a subsequent and potentially catastrophic osteoporotic fracture**. BHOF, together with the American Society for Bone and Mineral Research (ASBMR), prepared a document outlining the significant disease burden associated with osteoporosis, existing care gaps, collaborative care coordination interventions to close the care gap, and a pragmatic Medicare coding approach to enable access to evidence-based care.**

The organizations listed below expressed their consensus on the need for collaborative care coordination interventions, including FLS, and joined us in urging CMS to implement reimbursement mechanisms to adequately capture the time and resources required to deliver evidence-based post-fracture care:

- American Association of Nurse Practitioners (AANP)
- American Association of Hip and Knee Surgeons (AAHKS)
- American Association of Orthopaedic Surgeons (AAOS)
- American Association of Physician Assistants (AAPA)
- American Bone Health (ABH)
- American Geriatric Society (AGS)
- American Orthopaedic Association (AOA)
- American Society for Bone and Mineral Research (ASBMR)
- American Society of Endocrine Physician Assistants (ASEPA)
- Bone Health and Osteoporosis Foundation (BHOF) (previously known as the National

[26] Barton DW, Piple AS, Smith CT, Moskal SA, Carmouche JJ. The Clinical Impact of Fracture Liaison Services: A Systematic Review. Geriatr Orthop Surg Rehabil. 2021 Jan 11;12:2151459320979978. doi: 10.1177/2151459320979978. PMID: 33489430; PMCID: PMC7809296.

[27] Osteoporosis in the USA: prevention and unmet needs - The Lancet Diabetes & Endocrinology

Osteoporosis Foundation (NOF)
- Fragility Fractures Alliance (FFxA) – American Academy of Orthopaedic Surgeons (AAOS), American Orthopaedic Association (AOA) & AOA Own the Bone, Orthopaedic Trauma Association (OTA), National Association of Orthopaedic Nurses (NAON), American Geriatrics Society (AGS), International Geriatric Fracture Society (IGFS), American Board of Orthopaedic Surgeons, U.S. Bone and Joint Initiative (UBJI)
- International Society for Clinical Densitometry (ISCD)
- National Spine Health Institute (NSHI)
- North American Spine Society (NASS)
- Orthopaedic Trauma Association (OTA)
- The Endocrine Society (TES)
- US Bone and Joint Initiative (USBJI)

FLS programs are usually led by an FLS coordinator (a physician, nurse practitioner, physician assistant) who utilizes established protocols to ensure that individuals who suffer an osteoporotic fracture are identified and receive appropriate diagnosis, evaluation, secondary prevention, treatment planning, follow-up, and support. Patient assessment and follow-up care are prompted through a database-driven, patient-specific timeline.

The patient journey starts with identifying suspected osteoporotic fracture patients, moves through clinician collection of medical history, evaluation and management services, diagnostic testing, and, for patients at high risk of fracture, results in treatment planning and initiation, and necessary follow-up. Given the high rate of discontinuation for patients taking osteoporosis medications, periodic follow-ups are essential to ensure that patients wishing to discontinue treatment due to side effects (or other reasons) are evaluated and offered alternative therapeutic options. FLS programs also reach out to other clinicians responsible for the patient's care (specialists, PCPs), and ascertain patient needs, including physical therapy, fall risk assessment and prevention, and caregiver support needs. The set of services is individualized to identify and fracture risk factors.

The first Fracture Liaison Services was established in the early 2000s, and FLS utility in reducing future fractures has been confirmed through multiple studies. A 2018 meta-analysis of FLS impact identified a total of 159 publications, including 74 controlled studies (16 RCTs; 58 observational studies). Compared with patients receiving usual care (or those in the control arm), patients receiving care from an FLS program had:

- Less than half the rates of subsequent fracture (13.4% among patients in the control arm and 6.4% in the FLS arm)
- Lower mortality (15.8% in the control arm and 10.4% in the FLS arm).
- Higher rates of BMD testing (48.0% vs 23.5%)
- Higher rates of treatment initiation (38.0% vs 17.2%)
- Greater adherence (57.0% vs 34.1%).

Although reimbursement uncertainties and deficiencies have impeded access to care through an FLS program in the U.S., leading U.S. health systems, including Geisinger and Kaiser Permanente, have successfully implemented the FLS framework to reduce repeat fractures and lower costs.

- The Healthy Bones Program run by the Kaiser Southern California health-maintenance organization led to a decrease of 37.2% in hip fractures with savings of $30.8 million.
- Geisinger Health System achieved $7.8 million in cost savings over 5 years with its FLS implementation.

The American Orthopaedic Association has offered an initiative known as Own the Bone® since 2009 to address the emerging epidemic of osteoporosis-related fragility fractures. Own the Bone enables hospitals and practices to help evaluate and treat fracture patients using a Fracture Liaison Service (FLS). AOA provides a toolkit, including a ten-step program and registry to document the bone health management of osteoporotic fracture patients.

- Over 320 hospitals and practices have participated in this program.
- Patients enrolled in the program by participating centers are twice as likely to receive bone health interventions post fracture.
- Recommendations for osteoporosis management (BMD testing and/or pharmacologic treatment), care coordination, and other secondary fracture prevention measures were addressed for these patients with 74-98% compliance.

The American Geriatrics Society's (AGS') CoCare®: Ortho is another example of a specialty society initiated, multi-disciplinary program to address post-fracture follow-up. This Geriatrics-Orthopedics Co-Management model integrates geriatrics professionals or specially trained geriatrics co-managers (e.g., hospitalists) into the care team with orthopedic surgeons to coordinate and improve the perioperative care of older adults with hip fractures.

- Because a geriatrics co-manager is involved in the older person's care immediately upon or soon after hospital admission, risk factors for harmful events such as delirium, falls, adverse drug events, or infections are identified and proactively addressed to prevent and optimally manage risks throughout the older adult's hospital stay.
- The AGS CoCare®: Ortho model of Geriatrics-Orthopedics Co-Management has been shown to reduce complications and enhance function after the older adult returns home, two goals at the heart of quality geriatrics care.
- This model also proactively facilitates referral for diagnosis, treatment, and management of osteoporosis to reduce future fracture risk.

A recent study exploring cost-effectiveness models for FLS confirm the assessment within the Milliman analysis that FLS programs could result in long-term health system savings.[28] According to Associate Professor Kassim Javaid, who co-authored the study, reimbursement deficiencies impede access to improved outcomes associated with FLS care:

> Although ***FLSs are highly effective in reducing the risk of subsequent fragility fractures and improving patient outcomes***, most healthcare settings that manage adult fracture patients do not have an FLS in place. In the European Union for example, 50% of countries reported FLS coverage in less than 10% of hospitals. ***We know that a major barrier to sustainable effective FLS implementation is a lack of national, regional, and local policy prioritization and reimbursement***. This new model makes visible both the invisible costs of fragility fracture and the expected net benefits from systematic FLS provision to patients and their families, clinicians, healthcare systems, and wider society.[29]

A June 2022 review article outlines osteoporosis care gaps and FLS program adoption efforts throughout Europe.[30] It notes the utility of FLS in addressing the UK osteoporosis crisis:

> *There is growing awareness that the FLS model is becoming a "standard of care." . . . An FLS should deliver a seamless journey for the patient from diagnosis of a fragility fracture onward. Delivering the right care close to patients' residences has been on the NHS agenda for years and there is an established framework of support to ensure local delivery meets expected benefits for patients.[31] (emphasis added)*

III. ***BHOF continues to assert that Medicare coding mechanisms do not accurately describe or capture the cost of providing evidence-based post-fracture care.***

Although post-fracture care programs that, like FLS, rely on collaborative care coordination are increasingly described as the "gold standard" for post-fracture follow-up, Medicare beneficiaries have limited access to these services. BHOF has been a key driver in encouraging FLS implementation and supporting clinicians and practices interested in offering evidence-based post-fracture care to their patient communities**. We have increasingly found that our efforts to close the osteoporosis care gap are impeded by the financial risks providers and health care systems perceive they will bear.** Existing FLS programs must rely primarily on

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[28] Milliman Research Report, Medicare cost of osteoporotic fractures – 2021 updated report, The clinical and cost burden of fractures associated with osteoporosis. Medicare Cost of Osteoporotic Fracture - 2021 Update (squarespace.com)

[29] New economic model finds Fracture Liaison Services are highly effective | International Osteoporosis Foundation

[30] Chesser T, et al., Overview of fracture liaison services in the UK and Europe: standards, model of care, funding, and challenges. OTA International: June 2022 - Volume 5 - Issue 3S - p e198 doi: 10.1097/OI9.0000000000000198

[31] Id.

Medicare payments to remain viable and avoid staffing and service reductions. Potential new FLS providers are increasingly, and understandably, wary of allocating financial resources to developing, staffing, and implementing an FLS program given the persistent coding uncertainties and payment deficiencies.

BHOF appreciates that CMS has (1) acknowledged the perceived coding and payment gap associated with FLS care and (2) seeks to identify mechanisms that will improve access to evidence-based post-fracture care. BHOF and ASBMR conducted a set of interviews with existing FLS programs to outline the services provided, the timeframe within which FLS services are provided, the clinician and clinical staff time required to deliver FLS care, and coding gaps or uncertainties that impede FLS function or adoption.

A. To assess the utility of existing (and new) payment codes in closing the osteoporosis care gap, it is important to identify the patient population, services provided, care timeline, and resources required to deliver evidence-based care.

The FLS patient population consists of individuals with a known or suspected fragility fracture within the previous 6 months (patients are ideally seen within several weeks and usually seen within 3 months of a fracture). The initial visit can, however, be delayed if the patient remains in a rehabilitation facility for an extended period.) FLS programs describe their services as:

- Patient identification and intake activities
- Initial direct patient encounter
- Medically appropriate evaluation and patient history (assessment of height/weight, balance, gait and fall risk assessment, fracture risk assessment)
- Review of medical history
- Patient education
- Caregiver education
- Appropriate coordination and communication with patient's primary care provider, coordination with patient's relevant specialists (including orthopaedic surgeon, geriatrician, physical rehabilitation, hematologist, oncologists, endocrinologist, psychiatrist, etc.)
- Coordination and communication with ancillary providers (including physical therapy, occupational therapy, nutrition)
- Ordering and reviewing imaging studies and laboratory tests as necessary to diagnosis osteoporosis and/or other conditions contributing to bone fragility.
- Shared decision making on creation of treatment plan, including development of pharmacological plan, updating current drugs and prescriptions, obtaining medication authorization.
- Follow up that incorporates patient's short-term goals and tasks that must be performed to attain such goals for reducing risk of future fractures.
- Periodic bone health follow-up to assess treatment adherence, tolerability, and referral back to primary care, when appropriate

There is wide divergence on when post-fracture services might be initiated, largely due to subsets of fracture patients remaining in acute rehabilitation facilities for an extended time. FLS programs agreed, however, that services are concentrated over the 45-day period that starts with an initial FLS visit. The goal of care is to ascertain and address future fracture risk, assess whether there are any secondary causes of bone fragility, develop and initiate a treatment plan, and ascertain patient tolerance of and adherence to treatment. Unlike care addressing, for example, chronic cardiovascular conditions, the bulk of FLS services are concentrated within a short timeframe rather than delivered over the course of several months or years. Periodic follow-up visits are adequately reimbursed through existing coding mechanisms.

B. <u>The list of services and encounters below details the time and resources FLS programs report as required to deliver the care outlined above.</u>

Below, we identify the coding and payment gaps impeding reimbursement for post-fracture care services and respond to CMS' inquiry on applicability of existing code sets highlighted in the proposed rule.

- Physician/Qualified Health Practitioner (QHP) time:
    - prior to initial encounter (non-face-to-face): 20 minutes (frequently unreimbursed)
        - Clinicians often perform services in advance of the patient visit, and this time cannot be included in evaluation and management services.
        - Chronic care management codes are inappropriate given that the clinician is focused on the single chronic condition of osteoporosis (rather than two or more chronic conditions) and collaborates with the patient's treating clinician(s) to address comorbidities. The concentrated timeline for services (45 days) differentiates post-fracture care from most chronic care management services that are billed over multiple months.
            - ***CMS could enable use of these codes by specifically including post-fracture care related to osteoporosis as sufficient, without other conditions, and enabling use of these codes by the various specialties (including orthopedic surgery) that might incorporate FLS into their practices.***
        - Principal care management codes are unavailable because the patient may not have been diagnosed with osteoporosis prior to the initial visit. The single chronic condition description within the code also appears to preclude use of the code for most patients requiring post-fracture osteoporosis care.

- ***Although untreated osteoporosis is associated with subsequent fractures and increased mortality, the timeline for fracture risk can be relatively long (i.e., extending beyond 1 year), which cuts against describing the care as having an urgency related to acuity.***
- ***Hospitalizations related to osteoporotic fractures are generally limited to hip fracture patients. FLS programs treat these patients as well as those with more common osteoporotic fractures that are even less likely to receive the post-fracture follow-up required to prevent a future fracture.***
- ***Osteoporosis patients often require changes or modifications in their prescribed treatment. It is, however, unlikely that there would be a "frequent" need to switch or adjust medications for any given FLS patient.***

  - Transition care management codes require an inpatient transition, limiting their potential utility to hip fracture patients. Unfortunately, most of these patients are unable to receive FLS care within the 14-day timeframe following their inpatient stay.
    - ***CMS could not adapt these codes to post-fracture care without fundamentally diverging from the original purpose of TCM codes, i.e., removing the need for an inpatient stay and extending the timeline for the initial visit to account for inpatient rehabilitation stays and patient mobility constraints.***
    - ***Internationally accepted key performance indicators for post-fracture care adopt a follow-up timeframe of 12 weeks.***

- initial face-to-face encounter: 53 minutes (either in person or via telehealth)
  - Evaluation and management codes are available but many clinicians (and most facilities contemplating starting an FLS program) have mentioned that their compliance teams believe that reporting a Level 5 E&M code based on time for each new patient would be a potential "red flag" regardless of the actual time spent and services provided.
    - ***Clear guidance from CMS explicitly stating that high-level E&M codes based on time are appropriate for post-fracture care within an FLS might, if accompanied by reimbursement mechanisms for non-face-to-face services, reduce barriers to access.***

    - 45-day-period-subsequent-to-initial-encounter period (non-face-to-face): 96 minutes (unreimbursed)
        - These services are not reportable through evaluation and management codes.
        - Chronic care management codes are inappropriate for the reasons outlined above given that the clinician is solely focused on the single chronic condition of osteoporosis (rather than two or more chronic conditions).
        - Principal care management codes are unavailable for the reasons stated above, including that the single chronic condition description within the code appears to preclude its use for post-fracture osteoporosis care.
        - Transition care management codes require an inpatient transition, limiting potential utility to hip fracture patients. Unfortunately, these patients are unable to receive FLS care within the 14-day timeframe following their inpatient stay.

    - Subsequent face-to-face encounter): 26 minutes
        - Evaluation and management codes are sufficient to describe the services provided.

- Clinical staff time
    - prior to and on the day of initial encounter (non-face-to-face): 20 minutes
    - 45-day-period-subsequent-to-initial-encounter period (non-face-to-face): 145 minutes
    - subsequent encounter (when performed) (non-face-to-face): 30 minutes.

BHOF also reviewed and assessed the potential use of Community Health Integration (CHI) codes and notes that many of the services described in the CHI code set are valuable to fracture patients regardless of the presence of any social determinants of health (SDOH) needs. Post fracture patients certainly face substantial hurdles impeding diagnoses and treatment for their underlying osteoporosis. CHI services related to coordinating care, understanding, and participating in a treatment plan, caregiver communications, smoothing care transitions, educating the patient on their condition and how they can best participate in their treatment plan, and health system navigation are particularly relevant. **Unfortunately, even fracture patients with SDOH needs who might benefit from CHI services to obtain appropriate follow-up care are unlikely to be referred for, or qualify for, these services.** Given the system-wide failure to refer patients for post-fracture follow-up, and the fact that most healthcare encounters associated with fractures occur within settings ineligible to serve as CHI initiating visits, **we believe it is unlikely that CHI services will be helpful in reducing the osteoporosis care gap.**

Similarly, the Principal Illness Navigation (PIN) codes are unlikely to have a significant impact on closing the post-fracture care gap. This is disappointing given that care coordination and "navigation" services are a significant part of the unreimbursed care provided by FLS programs.

- PIN services require "One serious, high-risk condition expected to last at least 3 months and that places the patient at significant risk of hospitalization, nursing home placement, acute exacerbation/ decompensation, functional decline, or death."

- **Although osteoporosis is a serious, chronic condition associated with significant morbidity and mortality, CMS' examples of qualifying conditions appear to focus on risk acuity. Hip fracture patients may meet the requirements of this code, but for most patients treated within an FLS program, the significant risks associated with untreated osteoporosis are spread over a longer timeline than the conditions CMS lists as qualifying examples.**

- The system-wide failures to ensure that fracture patients receive appropriate follow-up care for osteoporosis are likely to function as similar impediments to PIN service access for post-fracture patients.

BHOF expects that a small subset of hip fracture patients may be referred for and receive PIN services and hopes that those services will focus beyond fracture recovery to include osteoporosis treatment and management.

C. <u>CMS' newly proposed code sets will have minimal impact in closing the care gap in secondary fracture prevention.</u>

BHOF appreciates that CMS highlighted its proposal to create additional codes and asked for feedback on the use of these codes in addressing the post-fracture care gap. At first glance, we had hoped that the new global post-operative add-on code, **HCPCS code GPOC1** would facilitate the transition from acute fracture care and follow-up clinicians to post-fracture follow-up for the chronic condition of osteoporosis. Upon review, we recognized that the proposed code does not envision what BHOF has described as a "warm handoff" from a clinician providing care related to the fracture event to a practice focused on the distinct, but associated, potential diagnosis of osteoporosis. **It is also important to note that the code does not address reimbursement deficiencies associated with the actual delivery of <u>post-fracture care related to osteoporosis as a chronic condition for which the fracture is a sentinel event</u>. Without also addressing these reimbursement deficiencies, this new code will not close the osteoporosis care gap or reduce the toll of fractures on Medicare beneficiaries.**

We also note that CMS identified the proposed advanced primary care management codes (GPCM1, GPCM2, and GPCM3) as potentially addressing the osteoporosis care gap. We have reviewed those codes and expect that their utility in post-fracture care would be severely limited as they are intended for use within advanced payment models and require the clinician to assume all primary care responsibilities for the patient. Moreover, while some post-fracture

care programs are provided within PCP practices, **most reside within other specialties, including orthopedics, rheumatology, and endocrinology.** Stakeholders, including the American Association of Orthopaedic Surgeons (AAOS) concur with our assessment of the utility of these codes to close the care gap in secondary prevention of osteoporotic fractures. AAOS has stated that it "***does not believe that that any of the proposed G codes in the CY 2025 proposed rule describe the services of managing fractures under a treatment plan, allow for use of these codes when those services are provided, nor address the longitudinal care management that is required to manage patients' bone health and fracture prevention."***

We do, however, urge CMS to (1) require that clinicians participating in APMs and delivering primary care for post-fracture patients provide evidence-based post-fracture services and (2) ensure that provider payment captures those care costs. Given the breadth and persistence of the care gap in post-fracture care to address osteoporosis, CMS cannot rely on its claim data to assess the cost of providing evidence-based care.

IV. BHOF strongly recommends that CMS create a payment code set reflecting the resources required to deliver high-quality care to Medicare beneficiaries suffering a fracture.

BHOF and ASBMR have met with CMS and outlined the coding and payment uncertainties FLS providers face. Throughout those discussions, we have reviewed existing code sets and concluded that CMS staff agreed with our assessment that existing codes are inappropriate due to either descriptors or requirements. We have, as outlined above, been unable to identify a single code or set of codes to capture post-fracture care services and their associated costs. We urge CMS to include in its final rule (or as an interim final section of the final rule) recognition of and adequate reimbursement for evidence-based post-fracture follow-up care by creating G-code(s) for a 45-day collaborative care intervention episode as described below.

The consensus "White Paper" (attached) has been provided to CMS and served as the basis of our presentation to CMS staff (attached). It outlines a pragmatic approach to encourage FLS program adoption that HHS could implement with the creation of "G" codes (G20XX1 and G20XX2) to describe an FLS care episode for typical and complex patients, respectively. The attached presentation provides further detail on proposed descriptors for these codes. CMS has used this approach to improve care for substance use disorder and pain management, and "Services Addressing Health-Related Social Needs." An FLS-specific payment mechanism would create an avenue for physicians and other health professionals to bill for evidence-based care in secondary prevention of osteoporotic fractures.

The two HCPCS G-codes differentiate payment based on patient complexity requiring significantly greater clinician time and practice resources. Our proposal to create a 45-day episode-based is based on information BHOF collected from existing FLS programs and other stakeholders suggesting that a 45-day episode aligns with the time in which services are

concentrated. The recommended codes for a 45-day episode would be reported once per beneficiary per fracture to reimburse for services provided from the initial encounter with the FLS provider through treatment plan development and implementation, as well as assessments to aid in development of the treatment plan, coordination with ancillary providers, collaboration and consultation with the beneficiary's care team and, as applicable, care plan discussions with caregivers. We expect that the high-complexity code would be billed in circumstances when effective assessment, care coordination, treatment planning, and treatment requires additional resources for a particular patient that substantially exceed the resources included in the base code.

The White Paper sets forth the general contours of integrated, collaborative care under the internationally accepted and proven FLS model, as well as the episode-based payment codes required to reimburse providers for delivering coordinated, high-quality care. The extent to which these codes are reported would inform CMS of its progress in ensuring that Medicare beneficiaries receive medically necessary follow-up care after an initial fracture. The document also identifies a set of FLS quality measures that FLS programs, CMS, and other payers could use for program evaluation and improvement.

Like providers performing SUD treatment and Chronic Pain Management and Treatment services, FLS programs are comprised of providers acting within the scope of their license to deliver coordinated care in collaboration with other clinicians to ensure that each patient receives the set of services they need. The set of services within FLS care are concentrated within a 45-day episode of care, and we proposed that the code would (a) be billable once per beneficiary per fracture episode (rather than monthly) and (b) describe FLS services over the 45-day day period from the initial visit through treatment planning and follow-up. These services are, like those included within CMS' SUD and pain management code sets, currently covered and reimbursed when reasonable and necessary. Implementation of episode-based payment codes to accurately describe the services that are part of evidence-based fracture care does not introduce new costs, new services, or newly covered services to the Medicare program that require budget neutrality assessments and/or adjustments.

The Bone Health and Osteoporosis Foundation (BHOF) and the American Society for Bone and Mineral Research (ASBMR) consulted an expert in coding and service valuation to estimate the time and resources associated with FLS care. The estimate was based on interviews with FLS programs located in various US regions, in various system settings (integrated health system, private practice, academic medical facilities), and with a variety of provider, staff, and patient population sizes).

Consistent with the methodology for pricing other services under the PFS, HCPCS code G20XX1 is valued based on stakeholder input and what we believe to be a typical case. In order to maintain the inherent advantages to the Medicare program of developing an episode-based payment, we recommend that the high-complexity code (HCPCS code G20XX2) would only be billed when (1) the total time spent in direct patient encounter(s) by the billing professional

and/or qualified nonphysician provider exceeds 75 minutes *and* the patient has more than one comorbidity complicating assessment, treatment planning, care coordination, or disease management. The high-complexity code is intended to address extraordinary situations where effective assessment, patient education, care coordination, and treatment requires additional resources that substantially exceed the resources included in HCPCS G20XX1. **BHOF expects that** practitioners would document both the medical necessity for the use of the high-complexity code, as well as the clinician time for direct patient encounter(s) in the patient's medical record.

We have proposed values for HCPCS codes G20XX1 and G20xx2 based on interviews with FLS programs and other stakeholder input, including estimates of time and resources required to deliver high-quality, evidence-based secondary fracture prevention services to Medicare beneficiaries. We used a crosswalk model to sum the work RVUs and direct PE inputs from codes CMS has previously used in valuing monthly care management services that include direct patient encounter services within the payment and adjusting for the 45-day episode proposed for FLS care.

As outlined in the discussion on applicability of existing codes, FLS care for a typical Medicare beneficiary includes 20 minutes of non-face-to-face pre-service time, 53 minutes of intra-service time spent in direct contact with patient (face-to-face in office or virtual), and 96 minutes of non-face-to-face post-service time. Pre-service time includes time spent by the FLS provider to identify and initiate contact with patients for program enrollment, reviewing and completing initial orders, referrals, requests for medical records, obtaining and preparing patient consent forms, and reviewing images and laboratory test results in advance of direct patient encounter.

Direct patient encounter time includes an appropriate medical examination that may include physical evaluation and patient history, review of medical history, assessment planning, patient education, shared decision making in creation of treatment plan and follow up that incorporate patient's short-term goals and tasks that must be performed to attain short-term goals for avoiding and reducing fractures, development of pharmacological plan including updating current drugs and prescriptions.

Follow-up, non-face-to-face clinician services include coordination and communication with the patient's primary care provider, coordination with patient's relevant specialists (including orthopaedic surgeon, physical rehabilitation, hematologist, oncologists, endocrinologist, psychiatrist, etc.), and coordination and communication with ancillary providers (including physical therapy, occupational therapy, speech therapy), ordering and reviewing of imaging, updating medical records, patient referrals, review of medical records, data registry entry and review, ongoing program evaluation, caregiver education and coordination, patient education,

coordination, and communication via email/portal/text messaging, and direction supervision and oversight of clinical and administrative staff work for each patient.

FLS care for complex patients, including those with multiple comorbidities, can require a longer initial patient encounter and/or substantial time in subsequent encounters. The additional time required to address the needs of complex patients was estimated at approximately 2-3 minutes of additional pre-service time, 26 minutes of additional intra-service time spent in direct contact with patient (face-to-face in office or virtual), and 5 minutes of non-face-to-face post-service time.

Our consultant looked for applicable codes to use within a crosswalk model and started with the assumption that most of the provider and clinical staff/administrative staff work would be similar to that described by CPT/HCPCS codes for cognitive services, including evaluation and management codes. The services provided in Fracture Liaison Service programs are, in many ways, similar to those within the Medicare PFS Substance Use Disorder bundle, Transitional Care Management, Chronic Care Management, Complex Chronic Care Management, and Principal Care Management. FLS care, however, differs from those services in that most services are performed within the initial 45 days of the initial patient encounter, and there is less need for significant time or resources in subsequent monthly follow-up.

The code set for principal care management physician/qualified healthcare professional (QH) (HCPCS 99224-99227) describes physician and clinical staff care for a patient with a high-risk condition. Post-fracture osteoporosis assessment, treatment planning, care management, and care coordination addresses care for patients at higher risk for hospitalizations, functional decline, and mortality in time increments that can be modeled for the services performed by providers in the 45-day (and in pre-time to the 45-day episode) for FLS care. In building the crosswalk, we used the initial 30 minutes of time and then added an additional four 30-minute increments to approximate the 154 minutes estimated for FLS services performed by a physician or QHP. Although HCPCS codes 99226 and 99227 slightly underestimate the intensity and complexity associated with FLS care, the codes can be used to capture the total time and resources required.

We also considered using the Transitional Care/Chronic Care Coordination Code model for valuation of a 45-day FLS episode of care. The Transitional Care codes and Chronic Care Coordination codes were established in 2017 and updated in 2019. These two sets of codes combine the direct patient encounter care surrounding a patient transitioning from inpatient care to outpatient clinic, along with the non-face-to-face care for coordination surrounding a patient with chronic conditions that require significant care plan management and monitoring. By combining the face-to-face encounter with the non-face-to-face care coordination these codes fully capture the services involved in the 45-day FLS care episode.

Specifically, HCPCS code 99495, Transitional Care Management Services, includes communication (direct contact, telephone, electronic) with the patient and/or caregiver within two business days of discharge, medical decision making of at least moderate complexity during the service period, a face-to-face visit within 14 calendar days of discharge. The 54 minutes of clinician time for a direct encounter approximates the 53-minute estimate for FLS care. Using the building block approach, we added chronic care management codes 99491, and 9943. These three codes provide 90 minutes of clinician services and care coordination time, closely approximating the estimated 96 minutes of clinician time required during the 45-day FLS episode.

To model the clinical staff time required for FLS care delivery, we used the practice expense for the transitional care management code 99495 to capture 100 minutes of clinical staff time and added HCPCS 99490 (chronic care management services, first 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month), HCPCS 99239 (x2) (chronic care management services, each additional 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month) to account for an additional 60 minutes of non-face-to-face clinical staff time. This closely approximates the estimated FLS clinical staff time for a 45-day FLS care episode.

In valuing HCPCS G20XX2 (complex patient) we used the two base models detailed above for HCPCS G20XX1 and added the total RVU value for HCPCS code 99213, (office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and low level of medical decision making). The estimated additional 20-29 minutes of clinician time for addressing the care needs of complex FLS patients is fully captured within HCPCS 99213.

BHOF is eager to meet with CMS to discuss the coding and payment options discussed above and ensure that providers delivering evidence-based post-fracture care have the guidance they need to obtain adequate reimbursement.

V. BHOF urges CMS to mitigate potential unintended consequences its CMMI TEAM initiative might have on post-fracture care providers, including FLS programs, and the beneficiaries they were intended to serve.

BHOF submitted comments to the IPPS proposed rule expressing its concern that the CMMI TEAM initiative will test use of episode-based payments to reduce costs and improve (or maintain) care for inpatient stays related to beneficiary hip fractures. Hip fractures are presumptive osteoporotic fractures. **The TEAM requirement that participating hospitals refer these patients to primary care is an authoritative mandate to providers that will disrupt the post-fracture referral and care pathway (i.e., FLS or other post-fracture care provider) BHOF, IOF, and other bone health stakeholders have diligently sought to bolster.**

We had urged CMS to configure TEAM to enable referral of hip fracture patients to an FLS practice as an alternative to primary care and remain hopeful that CMMI will consider this request before its 2026 TEAM implementation. We also asked that CMMI work with BHOF and other stakeholders as well as CMS' PFS team to identify and mitigate potential unintended consequences that might constrict access to evidence-based post-fracture care for patients within the TEAM initiative.

We strongly urge CMS to assign a specialty code or develop an alternative mechanism to identify FLS programs and other evidence-based post-fracture care interventions. Any new specialty code would be a secondary specialty since FLS programs are operated within orthopedic, endocrinology, rheumatology, women's health, primary care, and other practice types. We believe this will not only enable TEAM referral to evidence-based post-fracture care but allow CMS to specify codes and/or groups of codes that providers and claims processing contractors would accept as appropriate for claims reporting post-fracture care within a collaborative care intervention such as FLS.

Conclusion

BHOF has been a key driver in encouraging FLS implementation and supporting clinicians and practices interested in offering this evidence-based intervention for secondary prevention of osteoporotic fractures to their patient communities. We have increasingly found that our efforts to close the osteoporosis care gap requires us to acknowledge the financial risks these providers will bear.

The bone health community needs a clear statement from CMS acknowledging the perceived coding and payment gap associated with FLS care and providing clinicians with newly created payment mechanisms capturing the services and costs associated with evidence-based post-fracture care. If this cannot be done within the PFS final rule for 2025, we urge CMS to provide (1) interim guidance for claim submission throughout 2025, and (2) a statement of intent to implement sufficient coding mechanisms within the rulemaking cycle for CY2026.
Finally, if CMS is unwilling to consider adopting payment mechanisms to capture the cost of providing evidence-based post-fracture care, we ask that it provide a set of actionable instructions on the codes CMS *will* accept within the context of FLS care (e.g., permitting use of existing codes to receive reimbursement for FLS visits and non-face-to-face services performed on a day other than the date of the office visit, enabling use of principal care management or transition care management codes, including add-on codes, etc.)

Again, BHOF applauds CMS for prioritizing post-fracture care in the PFS rulemaking cycle for 2025. We appreciate the opportunity to offer our comments and recommendations and look forward to a continuing dialogue with CMS staff and leadership.

If you have any questions, please contact Claire Gill, CEO of BHOF at cgill@bonehealthandosteoporosis.org or 703-647-3025.

Sincerely,

Bone Health and Osteoporosis Foundation
American Society of Bone and Mineral Research
Alliance for Health Implementation Science
Alliance for Women's Health and Prevention
American Association of Nurse Practitioners
American Orthopaedic Association / Own the Bone®
Black Women's Health Imperative
Bronson Battle Creek
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GEISINGER
Global Healthy Living Foundation
HealthyWomen
International Geriatric Fracture Society
International Society for Clinical Densitometry
International Osteoporosis Foundation
KBJ Health Services
Lumbar Spine Research Society
National Association of Nurse Practitioners in Women's Health
National Caucus and Center for Black Aging
National Menopause Foundation
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National Spine Health Foundation
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Orthopaedic Trauma Division, University Hospitals of Cleveland
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Tigerlily Foundation

MEDICARE PAYMENT FOR POST-ACUTE OSTEOPOROSIS DETECTION, TREATMENT AND MANAGEMENT FOLLOWING A FRAGILITY FRACTURE

June 2021

The American Society for
Bone and Mineral Research

Executive Summary

Osteoporosis can be defined as "a bone disease that develops when bone mineral density and bone mass decreases, or when the quality or structure of bone changes." These, often degenerative, changes can increase fracture risk or the incidence of broken bones. Fractures due to osteoporosis occur without high-impact or -trauma events. Strikingly, 10 million Americans have osteoporosis, and 44 million Americans are at risk for fracture from low bone density. The current and future costs of fragility fractures, for both patients and the health care system, is staggering. A coordinated care approach utilizing the ***Fracture Liaison Service {FLS) model*** is a proven mechanism for reducing secondary fracture risk and the associated costs of subsequent fragility fractures.

Outcomes in osteoporosis can be significantly improved without substantial investment in research, new breakthrough therapies, or new legislative and/or regulatory provisions. Unfortunately,few patients receive the standard of care despite adequate clinical guidelines for the diagnosis and treatment of osteoporosis and osteoporotic fractures. Because of the under-utilization of bone density (DEXA) scans as a primary prevention tool, for many the first sign of osteoporosis is a fragility fracture event. The disease trajectory for osteoporosis can be disrupted through therapeutic and lifestyle modification interventions, but sadly most patients remain undiagnosed and unaware of both their increased risk for fracture and the availability of FDA-approved therapies to reduce that risk.

Osteoporotic fractures exact a huge quality of life toll on patients and a tremendous financial toll on the healthcare system. Medicare sustains significant costs related to both initial and subsequent osteoporotic fractures. Even modest reductions in secondary fractures could create significant savings for Medicare.

Leading US health systems, including Geisinger and Kaiser Permanente, have successfully implemented the FLSframework to reduce repeat fractures and lower costs. The FLS model has been shown to improve diagnosis and long-term treatment and to decrease morbidity in osteoporotic fracture patients. It also removes ambiguity regarding which specialty manages the disease and allows for efficient communication between multiple provider settings.

Although existing Medicare payment mechanisms and policies impede adoption of a FLS, there are significant advantages to such a framework:

- CMS has invested considerable time and resources into reducing preventable illnesses and injuries, and aligning incentives toward high- quality, cost-effective care. Without a reliable means for clinicians to secure adequate reimbursement for osteoporosis-related services, and sufficient incentives to drive cost-effective care, fragility fractures will continue to exact an ever- increasing cost on Medicare and its beneficiaries.

- Effective FLS care could be facilitated through CMS ***adoption of a code set*** with payment tailored to the resources required to effectively identify or refer post-acute fracture patients and ensure treatment planning and follow-up consistent with the standard of care for addressing osteoporosis and reducing the risk of a future fracture.

- The FLS framework is well suited to an episode-based payment.

- Unlike CMS' existing preventive care program for diabetes (Medicare Diabetes Prevention Program), the services within an FLS are Medicare-covered ***comprising the standard of care*** for osteoporosis and secondary prevention of fragility fractures.

The largely preventable human and economic tolls associated with fragility fractures can be addressed through simple solutions that are within CMS[1] rulemaking and administrative authority and leverage the tools already in existence.

Introduction

The National Institutes of Health (NIH) define osteoporosis as "a bone disease that develops when bone mineral density and bone mass decreases, or when the quality or structure of bone changes. This can lead to a decrease in bone strength that can increase the risk of fractures (broken bones)" (NIH, Osteoporosis Overview). Osteoporosis is the major cause of fractures in postmenopausal women and in older men, with fractures most frequently occurring in bones of the hip, vertebrae in the spine, and the wrist. These fractures occur without high-impact or high-trauma events, and often result from a fall from standing height. An estimated 10 million Americans have osteoporosis; an additional 44 million Americans have low bone density that places them at increased risk of a fracture (Looker, 2015).

Unlike many other debilitating conditions, outcomes in osteoporosis can be significantly improved without substantial investment in research, new breakthrough therapies, or new legislative and/or regulatory provisions. Therapeutic and lifestyle modification interventions, including prescription medications, can disrupt disease trajectory and significantly reduce the risk of osteoporotic fracture, under-utilization of DXA as a primary prevention tool means that

for many patients, the first sign of osteoporosis is a fragility fracture event. Even then, only 23% of women age 67 or older who have an osteoporotic fracture receive medication to treat osteoporosis in the 6 months after a fragility fracture (Yusef A, 2015; Faridi KF, 2016). Most patients remain undiagnosed and unaware of both their increased risk of a future fracture and the availability of FDA-approved therapies to reduce that risk.

- Medicare beneficiaries suffered approximately 2.1 million osteoporotic fractures in 2016 (Milliman, 2021);
- Analysis of 2016 claims data revealed that just 9% of female Medicare FFS beneficiaries were evaluated for osteoporosis with a bone mineral density (BMD) test within six months following a new osteoporotic fracture (Milliman, 2021);
- The total annual cost for osteoporotic fractures among Medicare beneficiaries was $57 billion in 2018 (Lewicki EM, et al., 2019);
- Absent health system changes to detect, diagnose and treat the chronic, progressive disease of osteoporosis, annual costs of fragility fractures are expected to grow to over $95 billion in 2040 (Lewicki EM, et al., 2019).

The National Committee for Quality Assurance (NCQA) recently (February 2020) articulated the significant impact that fragility fractures have on patients and their ability to maintain health, function, and independence:

> Osteoporotic fractures, particularly hip fractures, are associated with limited mobility, chronic pain and disability, loss of independence and decreased quality of life ... Most hip fractures require surgery, yet 50% of hip fracture patients are unable to walk without assistance after surgery. Of those who survive the fracture, 40% never return to pre-fracture functional status-often needing long-term nursing home care (NCQA, 2020).

As more fully detailed below, the current and future cost of fragility fractures, for both patients and the health care system, is staggering. The significant, and largely preventable, human and economic tolls associated with fragility fractures can be addressed through simple solutions that are within CMS' rulemaking and administrative authority and leverage the tools we already have. A coordinated care approach utilizing the Fracture Liaison Service (FLS) model is a proven mechanism for reducing secondary fracture risk and the associated costs of subsequent fragility fractures.

Leading US health systems, including Geisinger and Kaiser Permanente, have successfully implemented the FLS framework to reduce repeat fractures and lower costs. The patient journey within an FLS starts with identifying suspected fragility fracture patients for post-acute follow-up, moves through clinician collection of medical history, evaluation and management services, diagnostic testing, and, for patients at high risk of fracture, results in treatment planning and necessary follow-up. Unlike CMS' existing preventive care program for diabetes (Medicare Diabetes Prevention Program), the services within an FLS are Medicare-covered services comprising the standard of care for osteoporosis and secondary prevention of fragility

fractures. Unfortunately, existing Medicare payment mechanisms and policies impede adoption of FLS and existing sets of incentives and/or disincentives are ineffective in ensuring that fragility fracture patients receive any level of medical care for their underlying bone fragility. The logistic hurdles providers and patients currently face include:

- Acute hip fractures are reimbursed through bundled payments with 90-day global periods;
  Existing structures for treatment and follow-up in acute care settings approach fractures as any other acute episode rather than as a sentinel event indicative of underlying bone fragility;
  Multiple care settings complicate tracking and referral of patients with known or suspected osteoporotic fractures;
  Comprehensive care models and advanced payment models focus on acute episodes, do not account for osteoporosis as a chronic disease, and assess "cost" and "value" within timeframes too narrow to capture FLS cost-effectiveness;
- The limited sets of quality reporting mechanisms do not sufficiently incentivize the standard of care, and there is significant uncertainty as to which provider is ultimately responsible for delivering that care;
  Many patients are lost to follow-up due to care received within a rehabilitation hospital or other facility in the immediate post-acute period;
  Provider-assumed risk and quality reporting periods do not fully encompass the time period for heightened risk for a repeat fracture;
  Encouraging communication from acute to primary care has not closed the care gap in secondary prevention of fragility fractures. Efforts to date have failed to ensure that bone fragility follow-up is performed and/or that osteoporosis treatment is prescribed.

Any opportunity to transform our approach to osteoporotic fractures in the US requires the full partnership of CMS and the Medicare program. CMS has invested considerable time and resources into reducing preventable illnesses and injuries, and aligning incentives toward high-quality, cost-effective care. Unfortunately, without a sound, predictable, and reliable means for clinicians to secure adequate reimbursement for osteoporosis-related services, and sufficient incentives to drive cost-effective care, fragility fractures will continue to exact an ever-increasing cost on Medicare and its beneficiaries.

Effective FLS care could be facilitated through CMS adoption of a code set with payment tailored to the resources required to effectively identify and evaluate or refer post-acute fracture patients likely to have suffered a fragility fracture and ensure treatment planning and follow-up consistent with the standard of care for addressing osteoporosis and reducing the risk of a future fracture.

Osteoporotic fractures exact a tremendous toll on the health and lives of Medicare beneficiaries and their families.

According to the 2021 Milliman Report (based on 2016 data), Medicare fee-for-service beneficiaries with an osteoporotic fracture disproportionately suffered poor health outcomes, including significantly increased mortality, subsequent fractures, hospitalization, and loss of the ability to live independently.

The mortality rate for osteoporotic fracture patients is over three times that of the general Medicare FFS beneficiary population.

- Those with a hip fracture have the highest mortality; 30% died within 12 months of the fracture.
- Approximately 245,000 Medicare FFS beneficiaries (154,00 women and 91,000 men) or 19% of those with a new osteoporotic fracture died within 12 months.

41,900 Medicare FFS beneficiaries with osteoporotic fractures became institutionalized in nursing homes within three years of a new fracture.

Health system failures in delivering the standard of care in bone health for both primary and secondary fracture prevention disproportionate burden women. Female beneficiaries had 76% higher rates of new osteoporotic fracture than males, after adjusting for age and race.

Over 40% of osteoporotic fracture patients were hospitalized within one week after the fracture across all types of fractures studied.

- Over 90% of hip fracture patients were hospitalized within a week.

Osteoporotic fracture patients have three times the annual rate of new fractures within a year as compared to the overall Medicare FFS population.

Osteoporotic fracture patients had twice the annual rate of new pressure ulcers as the total Medicare FFS population (adjusted for age and sex).

- Approximately 20% of Medicare FFS beneficiaries who suffered a new osteoporotic fracture developed at least one pressure ulcer within three years.
- Pressure ulcers are a debilitating physical complication that require additional costly health care services.

Over 4% (approximately 56,800 Medicare FFS beneficiaries) with an osteoporotic fracture became newly eligible for Medicaid within three years.

A July 2019 NOF report entitled "Patient Perception of Value in Healthcare: Osteoporosis and Bone Fragility" explored aspects of the osteoporosis patient experience not easily captured within claims data (NOF 2019). This report was derived from an NOF survey of individuals 50 years of age or older with a previous fragility fracture, a self-reported diagnosis of low bone density or osteoporosis, previous treatment or testing experience, or a clinician recommendation of one or more bone health interventions. Several overarching themes emerged that offer a contextual patient perspective to the Milliman findings, including:

Individuals at risk for a fragility fracture are primarily concerned that a fracture will trigger loss of the ability to live independently;
Over half of participants with a fracture history reported that they have curtailed their activity level due to concerns about a subsequent fracture. A significant proportion of participants with a fracture history reported that they:
    - Have been less active than previously due to fracture risk concerns;
    - Are concerned that bone fragility could contribute to a fracture that might make it difficult to live independently;

Despite participant knowledge of their increased fracture risk, concerns that a fracture could severely limit quality of life, and awareness of treatment options, the vast majority of patients, including those at highest risk of a fragility fracture (i.e., those who have experienced a previous fracture after age SO), remain untreated;

- Though overall treatment rates are low, participants with a fracture history were most likely to report a high level of willingness to consider starting an osteoporosis treatment regimen (as compared to those who had not fractured);
Over 22% of untreated individuals with a history of a previous fracture reported that they discontinued treatment due to side effects; and
Formulation and dosing frequency preferences were unexpectedly divergent, underscoring the importance of ensuring that individuals at greatest risk of fragility fracture have sufficient options to enable access to a treatment to which they will adhere.

Survey responses also revealed that health care providers may play a role in the osteoporosis care gap. The likelihood of having ***not*** been offered treatment in individuals with a fracture history was nearly double that of those with diagnosed osteoporosis or provider-identified fracture risk (24.1% and 13.3%, respectively). The NOF survey augments the Milliman report findings to underscore the very clear unmet need in osteoporosis care and secondary prevention of osteoporotic fractures that includes clear communication of all risks associated with osteoporosis and risks of no treatment, clear communication regarding benefits and risks of treatments, clinician consideration of patient preferences within the treatment plan, and follow-up to ascertain adherence to medication and/or the need to prescribe alternative therapies that the patient may be willing and able to continue.

Medicare expenditures associated with preventable osteoporotic fractures are significant.

Medicare sustains significant costs for both initial and subsequent osteoporotic fractures. The Milliman report found that the per patient, per month (PPPM) medical costs were over $2,000 per month between months 3 and 11 ($2,097 per month), nearly 20% greater than the average monthly allowed cost in the year prior to the new osteoporotic fracture event ($1,775 per month). Beneficiaries with a subsequent fracture within the three-year "episode" incurred

annual costs over $30,000 higher in the year following a new osteoporotic fracture compared to the year before the fracture.

- Annual allowed medical costs to Medicare for beneficiaries in the 12-month period beginning with the new osteoporotic fracture were more than twice their costs in the year prior to their fracture, with incremental annual allowed medical costs for those with an osteoporotic fracture of $21,564 per beneficiary covered by both Medicare Parts A and B in 2016.
- The incremental annual medical costs in the year following a new osteoporotic fracture increased 263% for skilled nursing facility (SNF) services compared to the year prior to the fracture, accounting for nearly 30% of the total incremental annual medical cost. Beneficiaries suffering a subsequent fracture within three years of an initial fracture accounted for an estimate $5.7 billion in Medicare FFS costs.
    - Actual total costs are significantly higher as these estimates do not include costs related to the loss of productivity, absenteeism, non-skilled home and nursing home care, or prescription drugs.

  Preventing between 5% and 20% of these subsequent fractures could have saved between $272 million and $1.1 billion for the Medicare FFS program during a follow up period that lasted up to three years after a new osteoporotic fracture in 2016.

The Milliman report found that the increased cost in the year following the new osteoporotic fracture was primarily attributable to increases for inpatient services and skilled nursing facilities (SNFs). Increased costs for these services accounted for over $16,000 of the total per beneficiary cost differential.

Substantial racial/ethnic disparities exist in fracture incidence, care, and deaths.

Although Black men and women are generally less likely to suffer from osteoporosis and sustain a fragility fracture, they are more likely to die from an osteoporotic fracture than their White counterparts. The Milliman report found that "fracture rates varied substantially by race/ethnicity," with North American Natives suffering fractures at a rate 20% higher than the national average. White beneficiaries had a fracture rate 6% higher than the national average. Black beneficiaries (50% lower), Asian beneficiaries (32% lower) and Hispanic beneficiaries (19% lower) had the lowest rates of new osteoporotic fractures.

Rates of subsequent fractures within 12 months following an initial osteoporotic fracture ranged from 11% of Black beneficiaries to 15% for White beneficiaries. Hispanic, Asian, and North American Native beneficiaries all suffered subsequent fractures within 12 months at the national average rate of 14%.

While suffering fewer initial fractures and subsequent fractures, Black Medicare FFS beneficiaries have higher hospitalization rates, higher death rates following fractures, and

lower bone mineral density (BMD) screening rates. Black patients suffering an osteoporotic fracture in 2016 had worse outcomes, including higher mortality, and were less likely to receive any follow-up care to address their underlying bone fragility:

45% were hospitalized within 7 days of the fracture, compared to a national average of 42%.

22% died within 12 months of an initial osteoporotic fracture, exceeding the national average rate of 19% and comparable rates for White (19%), Asian (16%), Hispanic (18%) and North American Native beneficiaries (18%).

- Just 5% were tested within six months of a new osteoporotic fracture - when the need for treatment and action is highest-versus 8% among all beneficiaries with a fracture.

The Milliman report noted that other studies have reported racial disparities in fracture incidence and post-fracture outcomes and have echoed the findings of higher rates of mortality and debility following a fracture among Black individuals versus the general population.

The report also found divergence across subpopulations with respect to the types of osteoporotic fractures likely to present as a sentinel event of osteoporosis. Secondary prevention strategies that fail to cast a wide net with respect to identifying osteoporotic fractures will likely perpetuate, and may even widen, racial disparities in access to care and outcomes related to bone fragility.

Black patients had a disproportionately high share of new osteoporotic fractures of the tibia/fibula;

- Asian beneficiaries had lower incidence of tibia/fibula fractures as a share of total fractures than the nationwide average.

Fractures of the spine were less common for Black and North American Native beneficiaries compared to nationwide average but were more common for Asian beneficiaries.

The real-world experience of Medicare beneficiaries indicates failures in delivering the standard of care for both primary and secondary prevention of osteoporotic fractures.

Although we have the ability to detect bone fragility early through non-invasive bone mineral density testing, and effective osteoporosis treatments are available to greatly reduce the risk of a fragility fracture, ***few patients receive the standard of care.***

The 2020 AACE/ACE Clinical Practice Guidelines for the Diagnosis and Treatment of Postmenopausal Osteoporosis recommend that all postmenopausal women aged 50 years undergo clinical assessment for osteoporosis and fracture risk, including a detailed history, physical examination, and clinical fracture risk assessment with FRAX™ or other fracture risk

assessment tool. The AACE/ACE 2020 Guidelines state that physicians should individualize treatment decisions based on patient preferences and circumstances and level of fracture risk. Patients at very high fracture risk may require more aggressive treatment to reduce that risk to an acceptable level as quickly as possible.

Although DXA testing is a covered Medicare benefit and recommended for older women, its use declined between 2009 and 2014 to 11.3% among women who were Medicare FFS beneficiaries aged 65 and older. The drop in DXA utilization coincided with a 70% reduction in Medicare reimbursement for office-based scans (from $139 in 2006 to $42 in 2015). Reimbursement cuts may have discouraged office-based providers from adopting, or continuing to maintain, DXA capabilities and potentially led to decreased patient access to this diagnostic service.

Primary prevention of high-cost events that, like osteoporotic fractures, can have catastrophic consequences for Medicare beneficiaries, is an important goal worthy of increased resources and attention. Unfortunately, the costs of system-wide failures in primary prevention of osteoporotic fractures are compounded by real-world failures in secondary prevention, particularly in light of the diagnostic and treatment tools that are available and within the standard of care.

Hip fracture patients, for example, have a risk of subsequent fracture that is similar to the risk of subsequent acute myocardial infarction (AMI) after initial AMI. For recent hip fracture, the risk of subsequent clinical fracture within 1 year is 8.3% (Balasubramanian A., 2016;). For initial acute myocardial infarction, the risk of subsequent AMI hospitalization within 1 year is 9.2% (Chaudhry SI, 2014). Only 23% of patients receive osteoporosis medication after an osteoporotic hip fracture, compared to 96% percent of patients receiving beta blockers after a myocardial infarction (Yusef A, 2015; Faridi KF, 2016). A fracture is to osteoporosis what an acute myocardial infarction is to cardiovascular disease, a sentinel event that requires treatment to prevent a recurrence that could have devastating consequences.

Both HEDIS and Medicare Part C STAR Ratings include a measure to rate quality of osteoporosis care: "Osteoporosis Management in Women Who Had a Fracture." The average 2020 Medicare STAR rating for this measure was 3.5/5 stars, indicating that 52% of women ages 67 to 85 did ***not*** receive a BMD test or prescription for a drug to treat osteoporosis within 6 months of a fracture.

The Quality Payment Program within Medicare Part B FFS includes a modest set of quality measures and practice improvement activities addressing bone health. Unfortunately, osteoporosis-related quality measures have not been sufficient to align with clinical guidelines or reflect the level of care required to reduce the incidence and consequence of osteoporotic fractures. The data, as reported by Milliman and discussed above, paint a stark picture of the real-world experience for Medicare patients suffering a fragility fracture, and the potentially catastrophic consequences on their health, independence, and longevity.

The low rates of osteoporosis diagnosis and treatment, particularly following a fracture, highlight the need for improved care coordination between acute care providers and clinicians able to guide patients through the transition from acute to chronic care, including appropriate osteoporosis treatment and management. In addition, the significant subset of patients discontinuing prescribed osteoporosis medication due to side effects or other factors underscores the need for osteoporosis-focused provider follow-up to assess treatment response and tolerability.

The Endocrine Society maintains guidelines on osteoporosis treatment and management. These guidelines are based on clinical trial data and insights from real-world experience, as well as patient preferences, adherence and persistence, and reflect four consensus principles:

- The risk of future fractures in postmenopausal women should be determined using country-specific assessment tools to guide decision-making.
- Patient preferences should be incorporated into treatment planning.
- Nutritional and lifestyle interventions and fall prevention should accompany all pharmacologic regimens to reduce fracture risk.
- Multiple pharmacologic therapies are capable of reducing fracture rates in postmenopausal women at risk with acceptable risk-benefit and safety profiles (Eastell, 2019; Shoback, 2020).

The National Osteoporosis Foundation (NOF) Guide to Prevention and Treatment of Osteoporosis offers concise recommendations regarding prevention, risk assessment, diagnosis, and treatment of osteoporosis in postmenopausal women and men age 50 and older. The Guide includes indications for bone densitometry and fracture risk thresholds for intervention with pharmacologic agents. The absolute risk thresholds at which consideration of osteoporosis treatment is recommended were guided by a cost-effectiveness analysis. We attach the NOF Clinician's Guide.

The American Society for Bone and Mineral Research Secondary Fracture Prevention Initiative has developed clinical recommendations for secondary fracture prevention. The ASBMR Secondary Fracture Prevention Initiative, with consensus from a broad multi-stakeholder coalition, in 2019 developed the Clinical Recommendations for clinical care for women and men, age 65 years or older with a hip or vertebral fracture. They are directed to all healthcare professionals who participate in the care of these patients. An important overarching principle for the recommendations is that these patients optimally should be managed in the context of a multidisciplinary clinical system that includes case management (one example is a fracture liaison service) to assure that they are appropriately evaluated and treated for osteoporosis and risk of future fractures (Conley, et al., 2020; ASBMR)/

Multidisciplinary approaches to improve outcomes in older fragility fracture patients include the American Geriatrics Society's (AGS') CoCare®: Ortho. This Geriatrics-Orthopedics Co-Management model integrates geriatrics professionals or specially trained geriatrics co-managers (e.g., hospitalists) with orthopedic surgeons to coordinate and improve the

perioperative care of older adults with hip fractures. Because a geriatrics co-manager is involved in the older person's care immediately upon or soon after hospital admission, risk factors for harmful events such as delirium, falls, adverse drug events, or infections are identified and proactively addressed to prevent and optimally manage risks throughout the older adult's hospital stay. The AGS CoCare®: Ortho model of Geriatrics-Orthopedics Co-Management has been shown to reduce complications and enhance function after the older adult returns home, two goals at the heart of quality geriatrics care through its cost-effective approach.

The American Academy of Orthopaedic Surgery, with support from the Orthopaedic Trauma Association, announced in 2020 the Fracture and Trauma Registry (FTR) to improve orthopedic care through data on five of the more common fractures in the United States: hip, distal radius, ankle, distal femur, proximal humerus. The data on the management of these fractures will be of great value in improving their care going forward. AAOS coordinates the Fragility Fracture Alliance of orthopaedic organizations and is a leading member of the ASBMR Secondary Fracture Prevention Initiative. The FTR joins the growing AAOS Registry Portfolio with over 2.2 million procedures across 1450 sites nationally.

NOF and ASBMR also acknowledge that it is unlikely that even a robust set of quality measures within the QPP would, alone, close the osteoporosis care gap. The gap in care following an osteoporotic fracture, i.e., patient receives quality care for their fracture but fails to receive follow-up within the standard of care for their underlying osteoporosis, has been described as the "Bermuda Triangle of Osteoporosis Care" made up of orthopedists, primary care physicians and osteoporosis experts into which the fracture patient disappears. Orthopedic surgeons view their role as managing the fracture, with primary care physicians responsible for managing osteoporosis. Following discharge, orthopedic surgeons will generally follow-up on an outpatient basis for 3-6 months following fracture care. The orthopedic surgery care timeline is not well-aligned with treatment planning and follow-up for a chronic condition like osteoporosis. There is also a great deal of ambiguity with respect to the specialty that does, or should, take on care responsibility and manage osteoporosis toward an acceptable fracture risk -- primary care, endocrinology, and/or rheumatology. The FLS model offers a solution to address the too-frequent discharge of osteoporotic fracture patients from acute care settings without a clear action plan for addressing their underlying bone fragility.

Medicare could recognize significant savings with a modest reduction in subsequent osteoporotic fractures.

The Milliman report used its estimates on the costs of secondary fractures and assumptions informed by the literature on secondary fracture prevention to model the potential savings to Medicare from preventing a portion of subsequent fractures in the Medicare FFS population. Table 15 in the Milliman report provides a summary of the estimated national savings under three scenarios that use different percentages for the subsequent fractures that would be

prevented and different percentages for additional BMD testing.

Preventing between 5% and 20% of subsequent fractures among FFS beneficiaries with both Part A and Part B coupled with performing BMD tests on an additional 10% to 50% of patients with new osteoporotic fractures, could have saved between $250 million (95% CI: $243 million to $258 million) and $990 million (95% CI: $962 million to $1,021 million) during a new osteoporotic fracture follow-up period of up to three years.

Extrapolating the estimated cost of Part A services associated with a subsequent fracture to beneficiaries covered only by Part A could have added between $23 million and $89 million in savings when preventing between 5% and 20% of subsequent fractures among beneficiaries covered only by Part A.

- Total Medicare savings under these scenarios is between $272 million and $1.1 billion for the Medicare FFS program.

NOF and ASBMR strongly believe that the predominantly-female patient population impacted by osteoporotic fractures are entitled to the standard of care in addressing osteoporosis and reducing the risk of future fractures, regardless of whether Medicare realizes a cost savings from ensuring that the care is received. Medicare has long prioritized avoiding poor health outcomes that are both preventable and costly. The savings associated with preventing osteoporotic fractures, combined with the clear, persistent, and potentially widening gap between the standard of care and the real-world experience of osteoporotic fracture patients, justifies payment policy refinements and mechanisms toward evidence-based interventions proven to close the care gap.

Fracture Liaison Services (FLS) to address the osteoporosis care gap and reduce osteoporotic fractures.

CMS has previously sought feedback on opportunities for payment mechanisms within the physician fee schedule that reflect the ongoing diagnostic, treatment, and disease management resources associated with high-impact diseases and conditions. This approach can be helpful in addressing care gaps for high-cost, high morbidity/mortality conditions for which there is an existing standard of care. CMS has recently implemented a payment approach to reimburse clinicians, on a monthly basis, for treating patients with opioid use disorders, and recently expanded applicability of the code set and payment mechanisms to accommodate office-based treatment for substance use disorders generally. NOF and ASBMR believe that a similar mechanism for post-fracture care could be structured to close the osteoporosis care gap, reduce Medicare expenses for preventable osteoporotic fractures, and ensure that patients receive the standard of care for addressing the underlying chronic condition of osteoporosis.

The Fracture Liaison Service (FLS) model is extremely well-suited to an episode-based payment since it is an easily-identified episode that requires information sharing among providers

directed toward both a population-health measure and patient-specific outcomes. FLS programs can be described as coordinated care systems headed by an FLS coordinator (a nurse practitioner, physician assistant, nurse, or other health professional) who utilizes established protocols to ensure that individuals who suffer a fragility fracture receive appropriate diagnosis, evaluation, secondary prevention, treatment, and support. Many FLS programs incorporate a pharmacist in the care team to enable prompt resolution of patient concerns related to prescribed medications and improved medication adherence. Patient assessment and follow-up care are generally prompted through a database-driven patient-specific timeline that can be adapted to a centralized care delivery model, incorporate telemedicine and operate as a "hub and spoke" care coordination and delivery system, or incorporate aspects of both models.

Since the first Fracture Liaison Services in the early 2000s, multiple studies have been conducted to investigate the utility of these fracture care models. The International Osteoporosis Foundation began a movement known as Capture the Fracture to endorse, implement and standardize Fracture Liaison Services and fragility fracture management. In the United States there are several programs to address the fragility fracture problem in at risk groups using the FLS model.

> The Healthy Bones Program run by the Kaiser Southern California health-maintenance organization led to a decrease of 37.2% in hip fractures with savings of $30.8 million.
>
> Geisinger Health System achieved $7.8 million in cost savings over 5 years with its FLS implementation.
>
> Since 2009, the American Orthopaedic Association has offered a quality improvement initiative known as Own the Bone® which provides a tool kit to set up an FLS, including a ten-step program and registry to document the bone health management of fragility fracture patients. Over 270 hospitals and practices have used the program. Patients enrolled in the program by participating centers are twice as likely to receive bone health interventions post fracture; over 53% had a BMD test ordered or pharmacologic therapy for osteoporosis prescribed. Recommendations for osteoporosis management (BMD testing and/or pharmacologic treatment), care coordination, and other secondary fracture prevention measures were addressed for these patients with 74-98% compliance.

The Fracture Liaison Service model has proven to improve diagnosis, improve long-term treatment and to decrease morbidity in osteoporotic fracture patients. It also takes away ambiguity regarding which specialty manages the disease and allows for efficient communication between multiple specialties and provider settings to reduce the chance a patient may get lost while navigating the current health care system.

There are several challenges to implementing and sustaining a viable FLS:

Covering the salary of a FLS provider within a healthcare system given payer reliance on a single payment provided under a global Diagnosis Related Group (DRG) for fracture repair.

In FFS, bundled payments must encompass all services and tend to disincentivize all 'extra' care not directly related to the fracture;

The "savings" accrues to payers, not providers, making it difficult for providers to justify the added expense of FLS. This contrasts with FLS programs in closed healthcare settings and in single payer healthcare systems, which have been shown to reduce costs;

Primary care providers are a needed partner to a FLS, but can present a hindrance if he or she does not understand the FLS, dismisses osteoporosis as simply a consequence of old age, or sees a fragility fracture as simply an unavoidable result of a fall;

Identifying osteoporotic fracture patients for FLS follow-up care can be a challenge that is resource-intensive without a clear and near-reflexive referral mechanism from the specialist responsible for acute fracture repair to the FLS;

For older patients with recent fractures, the fact of multiple care settings, including skilled nursing facilities, rehabilitation hospitals, memory care facilities, etc., for post-fracture care presents an additional layer of complication.

The patient journey in a FLS may vary depending upon the setting through which FLS is administered, but the following parameters and steps are common:

The patient is followed from the time of injury presentation through treatment planning, initiation and follow-up or until care is transitioned to the primary care provider.

The FLS team is frequently interdisciplinary with respect to care coordination and relies on a "coordinator" who may be a nurse practitioner, physician assistant, or other provider able to provide and bill for evaluation and management services;

When a patient presents to a hospital following a low-energy fracture, orthopedic surgery will treat the fracture and initiate the fracture liaison service in eligible patients;

Criteria for enrollment into an FLS might include being older than 50 years old and presenting with a fragility fracture of the wrist, humerus, hip and/or vertebrae.

Facilities that have implemented AGS CoCare or similar programs could integrate peri-operative risk reduction strategies with provision of, or referral to, FLS follow-up.

During the inpatient stay, or when the patient returns to the orthopedist for post-surgical follow-up, an FLS coordinator will meet with the patient to begin the process of coordinating osteoporosis education, evaluation and management;

The FLS will meet with the patient (and caregiver/family as appropriate) to evaluate the patient, develop a treatment plan, and facilitate coordination of other disciplines treating the patient (e.g., physical therapy, occupational therapy).

- This encounter would typically occur within 1-3 months following fracture repair, and may involve a face-to-face or telehealth visit, FLS review of medical records, laboratory and DXA testing, and coordination/consultation with other providers;
- The FLS will ensure that patient medical records are received and reviewed;
- Medical history will include questions on any
  - personal history of fracture, family history of fractures and other risk factors for osteoporosis.
  - comorbidities
  - prescription and non-prescription medications taken over the past 10 years
- Physical examination with emphasis on the spine to assess loss of height;
- Laboratory tests (obtained from medical records or performed if not previously performed)
- DXA imaging is performed or scheduled
- Physical therapy consultation, fall risk assessment, and fall prevention program
- Dietician consultation to assess for nutritional deficiencies contributing to fracture

The FLS may, depending on results and findings from evaluation, consult with other specialists or members of an interdisciplinary team; and coordinate with ancillary service providers as needed.

Educate the patient and, as appropriate, caregivers and family members, on osteoporosis, its risks and treatment options.

The coordinator individualizes the management of each patient including continuation of physical therapy or additional consultations, as well as development of a treatment plan to address the patient-specific fracture risk.

The FLS coordinator may transition care to the designated team (primary care or FLS) for long-term osteoporosis management as appropriate.

The bulk of services within an FLS occurs in the 30-45 days of FLS care (which may be 1-3 months following a fracture). This is similar to CMS' structure for the office-based substance use disorder treatment payment bundle. The initial month of care includes evaluation and management, care coordination with psychosocial providers as needed, review of medical records, ordering and reviewing tests, treatment planning and prescribing a treatment tailored to the patient's need. Like the substance use disorder payment bundle, payment to the clinician would be solely for the services and not encompass prescription drugs, testing, or services of other providers.

The structure would:

Ensure that care for the patient's underlying bone fragility is separate and apart from all mechanisms (payment, quality, costs) for the acute fracture episode.
Enable a payment to the provider performing services addressing the fracture, for referral and transition to FLS.
Enable FLS service performance within an orthopedic practice typically responsible for acute care, as well as other provider practices (hospital outpatient department, primary care, endocrinology, rheumatology);
Provide for an initial 45-day payment to reimburse FLS providers for the resources and services provided during assessment, treatment planning, treatment initiation, and initial follow-up;
Provide for subsequent-month payments when follow-up services are needed and performed (including follow-up through telemedicine and/or telephone consultation); medication management, treatment adherence, impact, etc.
Permit an add-on fee for each 15 minutes of clinician time in the initial and subsequent months of FLS services.
Ensure that calculations of practice expense include set-up and maintenance of the infrastructure required to identify osteoporotic fracture patients, and coordinate transition to FLS.

NOF consulted with coordinators within fully-implemented FLS programs within the U.S. to determine the clinician and staff time that is typical within an initial 30-45 day post-fracture FLS. The attached table reflects their findings.

Identifying Patients for FLS Care

The ICD-10-CM codes describing potential sentinel fractures indicative of osteoporosis include:

MS-DRGs (Hospital Inpatient)

453 Combined anterior/posterior spinal fusion w MCC
454 Combined anterior/posterior spinal fusion w CC
455 Combined anterior/posterior spinal fusion w/o CC/MCC
456 Spinal fus exc cerv w spinal curv/malig/infec or 9+ fus w MCC
457 Spinal fus exc cerv w spinal curv/malig/infec or 9+ fus w CC
458 Spinal fus exc cerv w spinal curv/malig/infec or 9+ fus w/o CC/MCC
459 Spinal fusion except cervical w MCC
460 Spinal fusion except cervical w/o MCC
469 Major Joint Replacement or Reattachment of Lower Extremity With MCC
470 Major Joint Replacement or Reattachment of Lower Extremity Without MCC
471 Cervical spinal fusion w MCC
472 Cervical spinal fusion w CC
473 Cervical spinal fusion w/o CC/MCC
480 Hip & femur procedures except major joint w MCC
481 Hip & femur procedures except major joint w CC
510 Shoulder, elbow or forearm proc,exc major joint proc w MCC

511 Shoulder, elbow or forearm proc,exc major joint proc w CC
512 Shoulder, elbow or forearm proc,exc major joint proc w/o CC/MCC
513 Hand or wrist proc, except major thumb or joint proc w CC/MCC
514 Hand or wrist proc, except major thumb or joint proc w/o CC/MCC
515 Other musculoskeletal system & connective tissue O.R. procedures with MCC
516 Other musculoskeletal system & connective tissue O.R. procedures with CC
517 Other musculoskeletal system & connective tissue O.R. procedures without CC
518 Back and neck procedure exc spinal fusion with MCC
519 Back and neck proc exc spinal fusion with CC
520 Back and neck proc exc spinal fusion without CC/MCC
533 Fractures of femur with MCC
534 Fractures of femur without MCC
535 Fractures of hip and pelvis with me
536 Fractures of hip and pelvis without mcc
542 Pathological fractures and musculoskeletal and connective tissue malignancy with MCC
543 Pathological fractures and musculoskeletal and connective tissue malignancy with CC
544 Pathological fractures and musculoskeletal and connective tissue malignancy CC/MCC
562 FX, sprain, strain and dislocation except femur, hip, pelvis & thigh with MCC
563 FX, sprain, strain and dislocation except femur, hip, pelvis & thigh without MCC
906 Hand procedures for injuries

ICD-10 Codes Potentially Indicative of a Fracture Requiring FLS Follow-up (Outpatient)

S22.XX Fractures of rib(s), sternum
S32.XX Fractures of lumbar spine and pelvis
S42.XX Fractures of shoulder and upper arm
S52.XX Fracture of forearm
S62.XX Fracture at wrist and hand level
S72.XX Fracture of femur
S79.XX Other injuries of hip and thigh
S82.XX Fracture of lower leg
M80.XXX Age-related osteoporosis with current pathological fracture
M84.30XA Stress fracture, pathological fracture
[from Milliman report table D3]

FLS Performance Indicators for Self-Evaluation and Quality Improvement

The NOF, in collaboration with the International Osteoporosis Foundation (IOF) Capture the Fracture® Campaign and the Fragility Fracture Network (FFN), recently developed a set of eleven patient-level key performance indicators (KPIs) to evaluate and guide quality improvement in FLS (Javaid 2020). The performance indicators include the proportion of patients:

- with non-spinal fractures;
- with spine fractures (detected clinically and radiologically);

- assessed for fracture risk within 12 weeks of sentinel fracture;
- having DXA assessment within 12 weeks of sentinel fracture;
- having falls risk assessment;
- recommended anti-osteoporosis medication;
- commenced strength and balance exercise intervention within 16 weeks of sentinel fracture;
- monitored within 16 weeks of sentinel fracture;
- started anti-osteoporosis medication within 16 weeks of sentinel fracture;
- prescribed anti-osteoporosis medication 52 weeks after sentinel fracture.

This KPI set is available to support FLS programs in examining their own performance using patient-level data and in guiding quality improvement activities.

About the National Osteoporosis Foundation

The National Osteoporosis Foundation (NOF) is the nation's leading resource for patients, health care professionals and organizations seeking up-to-date, medically sound information and program materials on the causes, prevention, and treatment of osteoporosis. Established in 1984 as America's only voluntary, nonprofit health organization dedicated to reducing the widespread prevalence of osteoporosis, the foundation has grown to include a network of diverse stakeholders that support its goals to increase public awareness and knowledge, educate physicians and health care professionals, and support research activities concerning osteoporosis and bone health related areas.

Our Policy Institute brings together the expertise, resources, and perspective of the full spectrum of bone health stakeholders to advocate for health policy initiatives that promote bone health and reduce both the personal and financial costs of fragility fractures. Although the breadth of our mission extends beyond the bone health concerns associated with advancing age, we are focused on protecting Medicare beneficiary access to osteoporosis treatment options and aligning CMS payment policies with our shared goal of reducing the incidence of and improving the care for fragility fractures in the Medicare population. Our patient population suffers debilitating pain and even death in large numbers, the Medicare reimbursement landscape deters providers from implementing evidence-based, innovative approaches to secondary prevention of fragility fractures.

About the American Society for Bone and Mineral Research

The American Society for Bone and Mineral Research (ASBMR) is a professional, scientific and medical society established to bring together clinical and experimental scientists who are involved in the study of bone and mineral metabolism.

The ASBMR membership comprises basic research scientists and clinical investigators in bone and mineral metabolism and related fields, along with physicians and other healthcare practitioners. Current worldwide membership numbers approximately 4,000 with interests in biomechanics, cell biology, molecular biology, dentistry, developmental biology, endocrinology, epidemiology, internal medicine, metabolism, molecular genetics, nephrology, obstetrics-gynecology, orthopaedics, pathology, pharmacology, physiology, rheumatology and other research/clinical areas.

ASBMR encourages and promotes the study of this expanding field through annual scientific meetings, two official journals ***(Journal of Bone and Mineral Research*** and ***JBMR Plus),*** the ***Primer on the Metabolic Bone Diseases and Disorders of Mineral Metabolism,*** advocacy, and interaction with government agencies and related societies.

To address the health crisis in the treatment of osteoporosis, the ASBMR Secondary Fracture Prevention Initiative was created in 2017 to bring together a Coalition of top bone health experts and health care professional organizations and patient advocacy organizations - more than 40 U.S. and international organizations - dedicated to reducing the number of avoidable second fractures in individuals with osteoporosis. In addition to a detailed Action Plan, the Coalition has developed Clinical Recommendations for health care professionals aimed at substantially reducing secondary fractures in men and women 65 years of age and older who have suffered a hip or vertebral fracture and are at very high risk for suffering another fracture.

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HS Patient Workflow Processes Time Study

Process	Time/Pt (Minutes)
Capture/Identification of patients/Spreadsheet Data/Initial orders if appropriate	15.0
Scheduling and coordinating FLS appointment to align with post fracture appt if possible (2 appts)	20.0
Chart review and prep/clinician and nurse collaboration for appointment prep	30.0
(Ave pt contact time (provider) (this would be covered by E&M visit)	(35-60)
Charting (EHR)/Prior Authorization/Appeals/Treatment initiation/Patient Education on treatment	60.0
Care Coordination with ancillary services or other specialist	20
Data Registry Entry (if established with organization)	15
Total Time (minutes)	**205.0**

** Our typical patient contact is 14- 90 days post op

****This set of time estimates is for initial 45-days of FLS**

Recommend registry for data with eventual plans for a national data registry in the near future

Recommend mandatory use of the NOF FLS pathway guide for KPI monitoring guidelines

Clinician's Guide to Prevention and Treatment of Osteoporosis

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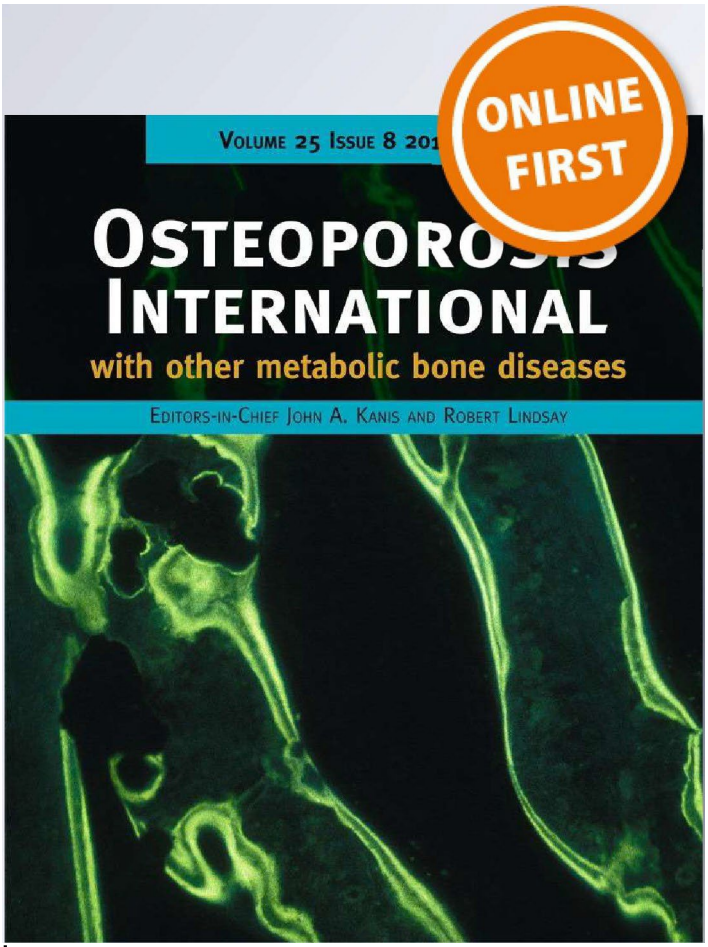

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POSITION PAPER

Clinician's Guide to Prevention and Treatment of Osteoporosis

F. Cosman • S. J. de Beur • M. S. LeBoff • E. M. Lewiecki • B. Tanner • S. Randall • R. Lindsay

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Abstract The Clinician's Guide to Prevention and Treatment of Osteoporosis was developed by an expert committee of the National Osteoporosis Foundation (NOF) in collaboration with a multispecialty council of medical experts in the field ofbone health convened by NOF. Readers are urged to consult current prescribing information on any drug, device, or procedure discussed in this publication.

Keywords Diagnosis • Guide • Osteoporosis • Prevention • Treatment

Executive summary

Osteoporosis is a silent disease until it is complicated by fractures-fractures that occur following minimal trauma or, in some cases, with no trauma. Fractures are common and place an enonnous medical and personal burden on the aging individuals who suffer them and take a major economic toll on the nation. Osteoporosis can be prevented, diagnosed, and treated before fractures occur. Importantly, even after the first fracture has occurred, there are effective treatments to decrease the risk of further fractures. Prevention, detection, and treatment of osteoporosis should be a mandate of primary care providers.

Since the National Osteoporosis Foundation (NOF) first published the Guide in 1999, it has become increasingly clear that many patients are not being given appropriate information about prevention and many patients are not receiving appropriate testing to diagnose osteoporosis or establish osteoporosis risk. Most importantly, many patients who have osteoporosis-related fractures are not being diagnosed with osteoporosis and are not receiving any of the Food and Drug Administration (FDA)-approved, effective therapies.

This Guide offers concise recommendations regarding prevention, risk assessment, diagnosis, and treatment of osteoporosis in postmenopausal women and men age 50 and older. It includes indications for bone densitometry and fracture risk thresholds for intervention with phannacologic agents. The absolute risk thresholds at which consideration of osteoporosis treatment is recommended were guided by a cost-effectiveness analysis.

Synopsis of major recommendations to the clinician

Recommendations apply to postmenopausal women and men age 50 and older.

Universal recommendations

Counsel on the risk of osteoporosis and related fractures. Advise on a diet that includes adequate amounts of total calcium intake (1000 mg/day for men 50- 70; 1200 mg/day

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for women 51 and older and men 71 and older), incorporating dietary supplements if diet is insufficient.
- Advise on vitamin D intake (800-1000 IU/day), including supplements if necessary for individuals age 50 and older.
- Recommend regular weight-bearing and muscle-strengthening exercise to improve agility, strength, posture, and balance; maintain or improve bone strength; and reduce the risk of falls and fractures.
- Assess risk factors for falls and offer appropriate modifications (e.g., home safety assessment, balance training exercises, corre(-1ion of vitamin D insufficiency, avoidance of central nervous system depressant medications, careful monitoring of antihypertensive medication, and visual correction when needed).
- Advise on cessation of tobacco smoking and avoidance of excessive alcohol intake.

Diagnostic assessment

- Measure height annually, preferably with a wall-mounted stadiometer.
- Bone mineral density (BMD) testing should be performed:

  In women age 65 and older and men age 70 and older
  In postmenopausal women and men above age 50-69, based on risk factor profile
  In postmenopausal women and men age 50 and older who have had an adult age fracture, to diagnose and determine degree of osteoporosis
  At dual-energy X-ray absorptiometry (DXA) facilities using accepted quality assurance measures

- Vertebral imaging should be performed:

  In all women age 70 and older and all men age 80 and older if BMD I-score is ::S-1.0 at the spine, total hip, or femoral neck
  In women age 65 to 69 and men age 70 to 79 ifBMD I-score is S-1.5 at the spine, total hip, or femoral neck
  In postmenopausal women and men age 50 and older with specific risk factors:

- Low-trauma fra(-ture during adulthood (age 50 and older)
- Historical height loss *(difference between the current height and peak height at age 20)* of 1.5 in. or more (4 cm)
- Prospective height loss *(difference between the current height and a previously documented height measurement)* of 0.8 in. or more (2 cm)
- Recent or ongoing long-term glucocorticoid treatment

  Ifbone density testing is not available, vertebral imaging may be considered based on age alone.

- Check for secondary causes of osteoporosis.
- Biochemical markers of bone turnover can aid in risk assessment and serve as an additional monitoring tool when treatment is initiated.

Monitoring patients

- Perform **BMD** testing I to 2 years after initiating medical therapy for osteoporosis and every 2 years thereafter.

  More frequent BMD testing may be warranted in certain clinical situations.
  The interval between repeat BMD screenings may be longer for patients without major risk factors and who have an initial I-score in the normal or upper low bone mass range.

- Biochemical markers can be repeated to determine if treatment is producing expected effect.

Pharmacologic treatment recommendations

- Initiate pharmacologic treatment:

  In those with hip or vertebral (clinical or asymptomatic) fractures
  In those with I-scores S-2.5 at the femoral neck, total hip, or lumbar spine by DXA
  In postmenopausal women and men age 50 and older with low bone mass (I-score between -1.0 and -2.5, osteopenia) at the femoral neck, total hip, or lumbar spine by DXA and a I0-year hip fracture probability 2:3 % or a IO-year major osteoporosis-related fracture probability 2:20 % based on the USA-adapted WHO absolute fracture risk model (Fracture Risk Algorithm (FRAX®); www.NOF.org and www.shef.ac.uk/FRAX)

- Current FDA-approved pharmacologic options for osteoporosis are bisphosphonates (alendronate, ibandronate, risedronate, and zoledronic acid), calcitonin, estrogen agonist/antagonist (raloxifene), estrogens and/or hormone therapy, tissue-selective estrogen complex (conjugated estrogens/bazedoxifene), parathyroid hormone 1-34 (teriparatide), and receptor activator of nuclear factor kappa-B (RANK) ligand inhibitor (denosurnab).
- No pharmacologic therapy should be considered indefinite in duration. After the initial treatment period, which depends on the pharmacologic agent, a comprehensive risk assessment should be performed. There is no uniform recommendation that applies to all patients and duration decisions need to be individualized.
- In adults age 50 and older, after a fracture, institute appropriate risk assessment and treatment measures for osteoporosis as indicated. Fracture liaison service (FLS) programs, where

patients with recent fractures may be referred for care coordination and transition management, have demonstrated improvement in the quality of care delivered.

Osteoporosis: impact and overview

Scope of the problem

Osteoporosis is the most common bone disease in humans, representing a major public health problem as outlined in Bone Health and Osteoporosis: A Report of the Surgeon General (2004) [l]. It is characterized by low bone mass, deterioration of bone tissue and disruption of bone architecture, compromised bone strength, and an increase in the risk of fracture. According to the WHO diagnostic classification, osteoporosis is defined by BMD at the hip or lumbar spine that is less than or equal to 2.5 standard deviations below the mean BMD of a young-adult reference population. Osteoporosis is a risk factor for fracture just as hypertension is for stroke. The risk of fractures is highest in those with the lowest BMD; however, the majority of fractures occur in patients with low bone mass rather than osteoporosis, because of the large number of individuals with bone mass in this range.

Osteoporosis affects an enormous number of people, of both sexes and all races, and its prevalence will increase as the population ages. Based on data from the National Health and Nutrition Examination Survey Ill (NHANES Ill), NOF has estimated that more than 9.9 million Americans have osteoporosis and an additional 43.1 million have low bone density [2]. About one out of every two Caucasian women will experience an osteoporosis-related fracture at some point in her lifetime, as will approximately one in five men [l]. Although osteoporosis is less frequent in African Americans, those with osteoporosis have the same elevated fracture risk as Caucasians.

Medical impact

Fractures and their complications are the relevant clinical sequelae of osteoporosis. The most common fractures are those of the vertebrae (spine), proximal femur (hip), and distal foreann (wri t). However, most fractures in older adults are due at lea t in part to low bone mass, even when they result from considerable trauma. A recent fracture at any major skeletal site in an adult older than 50 years of age should be considered a significant event for the diagnosis of osteoporosis and provides a sense of urgency for further assessment and treatment. The most notable exceptions are those of the fingers, toes, face, and skull, which are primarily related to trauma rather than underlying bone strength. Fractures may be followed by full recovery or by chronic pain, disability, and death [3].

Hip fractures are associated with an 8 to 36 % excess mortality within 1 year, with a higher mortality in men than in women [4]; additionally, hip fractures are followed by a 2.5-fold increased risk of future fractures [5]. Approximately 20 % of hip fracture patients require long-term nursing home care, and only 40 % fully regain their pre-fracture level of independence [l]. Although the majority of vertebral fractures are initially clinically silent, these fractures are often associated with symptoms of pain, disability, deformity, and mortality [3]. Postural changes associated with kyphosis may limit activity, including bending and reaching.

Multiple thoracic fractures may result in restrictive lung disease, and lumbar fractures may alter abdominal anatomy, leading to con tipation, abdominal pain, distention, reduced appetite, and premature satiety. Vertebral fractures, whether clinically apparent or silent, are major predictors of future fracture risk, up to 5-fold for subsequent vertebral fracture and 2- to 3-fold for fra(-tures at other sites. Wrist fractures are less disabling but can interfere with some activities of daily living as much as hip or vertebral fractures.

Pelvic fractures and humerus fractures are also common and contribute to increased morbidity and mortality. Fractures can also cause psychosocial symptoms, most notably depression and loss of self-esteem, as patients grapple with pain, physical limitations, and lifestyle and cosmetic changes.

Economic toll

Annually, two million fractures are attnbuted to osteoporosis, causing more than 432,000 hospital admissions, almost 2.5 million medical office visits, and about 180,000 nursing home admissions in the USA [l]. Medicare currently pays for approximately 80 % of these fractures, with hip fractures accounting for 72 % of fracture costs. Due in part to an aging population, the cost of care is expected to rise to $25.3 billion by 2025 [6].

Despite the availability of cost-effective and well-tolerated treatments to reduce fracture risk, only 23 % of women age 67 or older who have an osteoporosis-related fracture receive either a BMD test or a prescription for a drug to treat osteoporosis in the 6 months after the fracture [7].

Basic pathophysiology

Bone mass in older adults equals the peak bone mass achieved by age 18---25 minus the amount of bone subsequently lost. Peak bone mass is determined largely by genetic factors, with contnbutions from nutrition, endocrine status, physical activity, and health during growth [8].

The process of bone remodeling that maintains a healthy skeleton may be considered a preventive maintenance program, continually removing older bone and replacing it with new bone. Bone loss occurs when this balance is altered, resulting in greater bone removal than replacement. The

imbalance occurs with menopause and advancing age. With the onset of menopause, the rate ofbone remodeling increases, magnifying the impact of the remodeling imbalance. The loss of bone tissue leads to disordered skeletal architecture and an increase in fracture risk.

Figure 1 shows the changes within cancellous bone as a consequence of bone loss. Individual trabecular plates of bone are lost, leaving an architecturally weakened structure with significantly reduced mass. Increasing evidence suggests that rapid bone remodeling (as measured by biochemical markers of bone resorption or formation) increases bone fragility and fracture risk.

Bone loss leads to an increased risk of fracture that is magnified by other aging-associated declines in fum,,1ioning. Figure 2 shows the factors associated with an increased risk of osteoporosis-related fractures. These include general factors that relate to aging and sex steroid deficiency, as well as specific risk factors, such as use of glucocorticoids, which cause decreased bone formation and bone loss, reduced bone quality, and disruption of microarchitectural integrity. Fractures result when weakened bone is overloaded, often by falls or certain activities of daily living.

Approach to the diagnosis and management of osteoporosis

NOF recommends a comprehensive approach to the diagnosis and management of osteoporosis. A detailed history and physical examination together with BMD assessment, vertebral imaging to diagnose vertebral fractures, and, when appropriate, the WHO I0-year estimated fracture probability are utilized to establish the individual patient's fracture risk [11]. Therapeutic intervention thresholds are based on NOF's economic analysis that takes into consideration the cost-effectiveness of treatments and competition for resources in the USA l12, 13]. The clinician's clinical skills and past experience, incorporating the best patient-based research available, are used to determine the appropriate therapeutic intervention. The potential risks and benefits of all osteoporosis interventions should be reviewed with patients and the unique concerns and expectations of individual patients considered in any final therapeutic decision.

Risk assessment

All postmenopausal women and men age 50 and older should be evaluated for osteoporosis risk in order to determine the need for **BMD** testing and/or vertebral imaging. In general, the more risk factors that are present, the greater is the risk of fracture. Osteoporosis is preventable and treatable, but because there are no warning signs prior to a fracture, many people are not being diagnosed in time to receive effective therapy during the early phase of the disease. Many factors have been associated with an increased risk of osteoporosis-related fracture (Table I).

Since the majority of osteoporosis-related fractures result from falls, it is also important to evaluate risk factors for falling (Table 2). The most important of these are personal history of falling, muscle weakness and gait, selected medications, balance, and visual deficits [15]. Dehydration is also a risk factor for falls.

Several of these risk factors have been included in the WHO IO-year fracture risk model (Table 3). As suggested by the WHO l11J, this set of risk fa(.,1ors increases frd(.,1ure risk independently of BMD and can be combined with BMD measurements to assess an individual patient's risk of future fracture.

Diagnostic assessment

Consider the possibility of osteoporosis and fracture risk based on the presence of the risk factors and conditions outlined in Tables I and 3. Metabolic bone diseases other than m,teoporosis, such as hyperparathyroidism or osteomalacia, may be associated with low **BMD.** Many of these diseases have very specific therapies, and it is appropriate to complete a history and physical examination before making a diagnosis of osteoporosis on the basis of a low **BMD** alone. In patients in whom a specific secondary, treatable cause of osteoporosis is being considered (Table 1), relevant blood and urine studies (see below) should be obtained prior to initiating therapy. Any adulthood fracture may be an indication of osteoporosis and should be evaluated accordingly. Consider hip and vertebral fractures as indications of

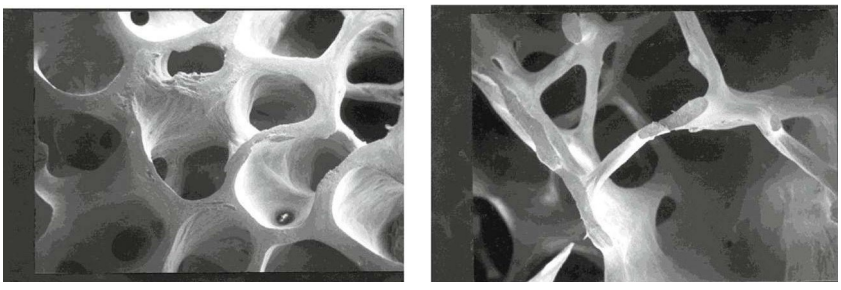


Fig. I Micrographs ofnormal vs. osteoporotic bone [9], from Demp ter et al., with permission of The American Society for Bone and Mineral Research [9]

osteoporosis unless excluded by the clinical evaluation and imaging. Fractures present a sense of urgency as they signify increased fracture risk over the subsequent 5 years [16]. Patients with recent fractures, multiple fractures, or very low BMD should be evaluated for secondary etiologies.

Osteoporosis affects a significant number of men, yet the condition often goes undetected and untreated. The evaluation of osteoporosis in men requires special consideration as some of the laboratory testing to assess underlying causes in men differs from those in women. Screening BMD and vertebral imaging recommendations for men life outlined in Table 8. The 2012 Endocrine Society's *Osteoporosis in Men: An Endocrine Society Clinical Practice Guideline* provides a detailed approach to the evaluation and treatment of osteoporosis in men [I7].

Diagnosis

The diagnosis of osteoporosis is established by measurement of **BMD** or by the occurrence of adulthood hip or vertebral fracture in the absence of major trauma (such as a motor vehicle accident or multiple story fall). Laboratory testing is indicated to exclude secondary causes of osteoporosis [1, 14, 17] (Table 4).

BMD measurement and classification

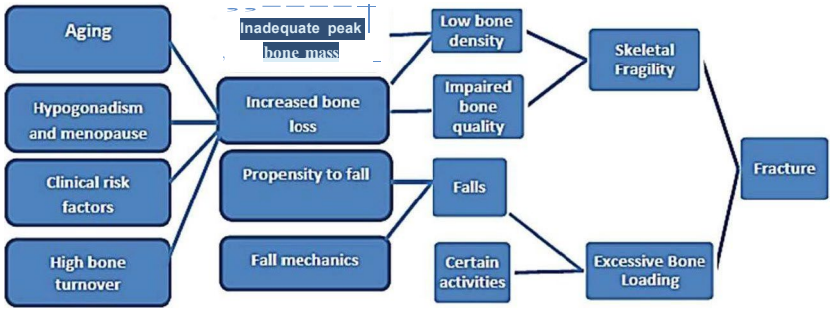
DXA measurement of the hip and spine is the technology used to establish or confirm a diagnosis of osteoporosis, predict future fracture risk, and monitor patients. Areal BMD is expressed in absolute terms of grams of mineral per square centimeter scanned (g/cm^2) and as a relationship to two norms: compared to the **BMD** of an age-, sex-, and ethnicity-matched reference population (Z-score) or compared to a young-adult reference population of the same sex (T-score). The difference between the patient's BMD and the mean *BMD* of the reference population, divided by the standard deviation (SD) of the reference population, is used to calculate T-scores and Z-scores. Peak bone mass is achieved in early adulthood, followed by a decline in BMD. The rate of bone loss accelerates in women at menopause and continues to progress at a slower pace in older postmenopausal women (see Fig. 3) and in older men. An individual's BMD is presented as the standard deviation above or below the mean BMD of the reference population, as outlined in Table 5. The BMD diagnosis of normal, low bone mass (osteopenia), osteoporosis, and severe or established osteoporosis is based on the WHO diagnostic classification (Table 5) [18].

BMD testing is a vital component in the diagnosis and management of osteoporosis. *BMD* has been shown to correlate with bone strength and is an excellent predictor of future fracture risk. Instead of a specific threshold, fracture risk increases exponentially as BMD decreases. Although available technologies measuring central (lumbar spine and hip) and peripheral skeletal sites (forearm, heel, fingers) provide site-specific and global (overall risk at any skeletal site) asses ment of future fracture risk, DXA measurement at the hip is the best predictor of future hip fracture risk. DXA measurements of the lumbllf spine and hip must be performed by appropriately trained technologists on properly maintained instruments. DXA scans are associated with exposure to trivial amounts of radiation.

In postrnenopausal women and men age 50 and older, the WHO diagnostic T-score criteria (normal, low bone mass, and osteoporosis) are applied to BMD measurement by central DXA at the lumbar spine and femoral neck [18]. BMD measured by DXA at the one-third (33 %) radius site can be used for diagnosing osteoporosis when the hip and lumbar spine cannot be measured or are unusable or uninterpretable [19]. In premenopausal women, men less than 50 years of age, and children, the WHO BMD diagnostic classification should not be applied. In these groups, the diagnosis of osteoporosis should not be made on the basis of densitometric criteria alone. The International Society for Clinical Densitometry (ISCD) recommends that instead of T-scores, ethnic or race-adjusted Z-scores should be used, with Z-scores of -2.0 or lower defined as either "low bone mineral density for chronological age" or "below the expected range for age" and those above -2.0 being "within the expected range for age" [19].

Who should be tested?

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



.Fig. 2 Pathogenesis of o teoporosis-related fm(.,tures, from Cooper and Mehon, with modification LIOJ

Table 1 Conditions, diseases, and medications that cause or contribute to osteoporosis and fractures

Lifestyle ra<.,1ors		
Alcohol abuse	Excessive thinness	Excess vitamin A
Frequent fulling	High salt intake	lmmobiliz.ation
Inadequate physical a<.,1ivity	Low calcium intake	Smoking (active or passive)
Vitamin D insufficiency		
Genetic diseases		
Cy 1ic fibrosis	Ehlers-Danlos	Gaucher's disease
Glycogen stornge diseases	Hemochromatosis	Homocystinuria
Hypopho 1Jhatasia	Marfan syndrome	Menkes steely hair syndrome
Osteogenesis imperfecta	Parental history of hip trdcture	Porphyria
Riley-Day syndrome		
Hypogonadal states		
Androgen insensitivity	Anorexia nervosa	Athletic amenorrhea
Hyperprola<.,1inemia	Panhypopituitarism	Premature menopause (<40 years)
Turner's and Klinefelter's syndromes		
Endocrine disorders		
Centr.:il obesity	Cushing's syndrome	Diabetes mellitus (types 1 and 2)
Hyperparnthyroidi ID	Thyrotoxicosis	
Gastrointestinal disorders		
Celiac disease	Ga 1ric bypass	Gastrointestinal surgery
Inflammatory bowel disease	Malabsorption	Pancreatic disease
Primary biliary cirrhosis		
Hematologic disorders		
Hemophilia	Leukemia and lymphomas	Monoclonal gammopathies
Multiple myeloma	Sickle cell disease	Systemic mastocytosis
Thalassemia		
Rheumatologic and autoimmune diseases		
Ankylosing 1)0ndylitis	Other rheumatic and autoimmune diseases	
Rheumatoid arthritis	Systemic lupus	
Neurological and musculoskeletal risk factors		
Epilepsy	Multiple sclerosis	Musmlar dystrophy
Parkinson's disease	Spinal cord injury	Stroke
Miscellaneous conditions and diseases		
AIDS/ffiV	Amyloidosis	Chronic metabolic acidosis
Chronic obstructive lung disease	Congestive heart fuilure	Depression
End-stage renal disease	Hypercalciuria	Idiopathic scoliosis
Po 1-tr.:msplant bone disease	Sarcoidosis	Weight loss
Medications		
Aluminum (in antacids)	Anticoagulants (heparin)	Anticonvulsants
Aromatase inhibitors	Barbiturntes	Cancer chemotherapeutic drugs
Depo-medroxyprogesterone (premenopausal contrnception)	Glucocorticoids (2:5 mg/day prednisone or equivalent for 2:3 months)	GnRH (gonadotropin-releasing hormone) agonists
Lithium cyclo 'Porine A and ta<.,Tolimus	Methotrexate	Parental nutrition
Proton pump inhibitors	Selective serotonin reuptake inhibitors	
Tamoxifen® (premenopausal use)	Thiazolidinediones (such as Actos® and Avandia®)	Thyroid hormones (in excess)

From: The Surgeon Genernl's Report LlJ, with modification

density is not indicated unless the results will influence the patient's treatment decision. The US Preventive Services Task Force recommends testing of all women age 65 and older and younger women whose fracture risk is equal to or greater than that of a 65-year-old white woman who has no additional risk factors [20].

Table 2 Risk factors for falls

Environmental risk factors	
Lack ofassistive devices in bathrooms	Obstacles in the walking path
Loose throw rugs	Slippery conditions
Low level lighting	
Medical risk factors	
Age	Medications causing sedation (narcotic analgesics, anticonvulsants, psychotropics)
Anxiety and agitation	Ortho iatic hypotension
Anhythmias	Poor vision
Dehydrntion	Previous falls or fear of falling
Depression	Reduced problem solving or mental acuity and diminished cognitive skills
Vitamin D insufficiency [serum 25-hydroxyvitamin D (25(OH)D)<30 ng,'ml (75 nmol/L)J Mainutrition	Urgent urinary incontinence
Neurological and musculoskeletal risk fa1.-iors	
Kyphosis	Reduced proprioception
Poor balance	Weak muscles/sarcopenia
Impaired transfer and mobility	Deconditioning
Diseases listed in Table 1	

From: *Health Professionals Guide tu the Rehabilitation ufthe Patient with Osteoporosis* [14]

Table 6 outlines the indications for BMD testing. BMD measurement is not recommended in children or adolescents and is not routinely indicated in healthy young men or premenopausal women unless there is a significant fracture history or there are specific risk factors for bone loss.

Vertebral imaging

A vertebral fracture is consistent with a diagnosis of osteoporosis, even in the absence of a bone density diagnosis, and is an indication for pharmacologic treatment with osteoporosis medication to reduce subsequent fracture risk [18, 21J. Most vertebral fractures are asymptomatic when they first occur and often are undiagnosed for many years. Proactive vertebral imaging is the only way to diagnose these fractures. The finding of a previously unrecognized vertebral fracture may change the diagnostic classification, alter future fracture risk calculations, and affect treatment decisions [22].

Independent of BMD, age, and other clinical risk factors, radiographically confirmed vertebral fractures (even if completely asymptomatic) are a sign ofimpaired bone quality and strength and a strong predictor of new vertebral and other fractures. The presence of a single vertebral fracture increases the risk of subsequent fractures 5-fold and the risk of hip and other fractures 2- to 3- fold [23]. Vertebral imaging can be performed using a lateral thoracic and lumbar spine X-ray or lateral vertebral fracture assessment (VFA), available on most modem DXA machines. VFA can be conveniently performed at the time of BMD assessment, while conventional X-ray may require referral to a standard X-ray facility.

Table 3 Risk factors included in the WHO Frncture Risk Assessment Model

Clinical risk factors included in the FRAX Tool	
Current age	Rheumatoid arthritis
Gender	Secondary causes of o ieoporosis: type 1 (insulin dependent) diabetes, osteogenesis irnperlecta in adults, untreated long-standing hyperthyroidism, hypogonadism or premature menopause (<40 years), chronic malnutrition or malabsorption, and chronic liver disease
A prior osteoporotic fracture (including clinical and asymptomatic vertebrnl fractures)	Parental history of hip frdcture
Femornl neck BMD	Current smoking
Low body mass index (BMI, kg/m^2)	Alcohol intake (3 or more drinks/day)
0ml glucocorticoids 2:5 mg/d of prednisone for >3 months (ever)	

From: WHO Technical Report [11]

Table 4 Exclusion of secondary causes of osteoporosis

Consider the following cliagno 1ic stuclies for secondary causes of osteoporosis
Blood or serum
Complete blood count (CBC)
Chemistry levels (calcium, renal function, pho phorus, and magnesium)
Liver function tests
Thyroid-stimulating hormone (TSH) +/- free T_4
25(OH)D
Parnthyroid hormone (PTH)
Total testosterone and gonadotropin in younger men
Hone turnover mai:kers
Consider in selected patients
Serum protein electrophoresis (SPEP), serum immunofixation, serum-free light chains
Tissue transglutaminase antibodies (IgA and IgG)
Iron and ferritin levels
Homocysteine
Prolae,1in
Tryptase
Urine
24-h urinary calcium
Consider in selected patients
Protein electrophoresis (lJPEP)
Urinary free cortisol level
Urinary histamine

Indications for vertebral imaging

Because vertebral fractures are so prevalent in older individuals and most produce no acute symptoms, vertebral imaging tests are recommended for the individuals defined in Table 7.

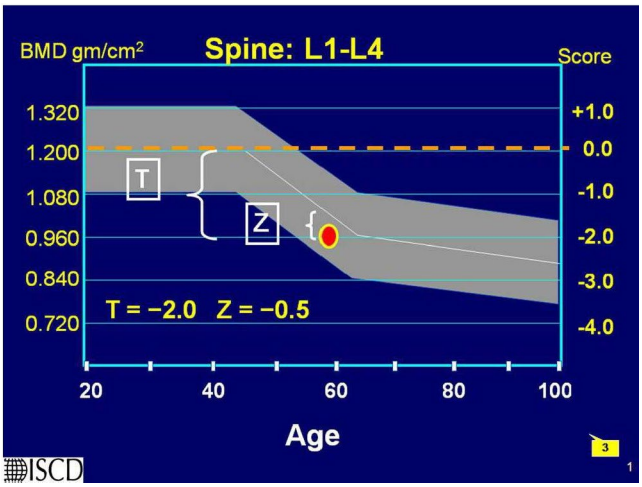


Fig. 3 Z- and T-scores in women, from ISCD Bone Densitometry Clinician Course, Lecture 5 (2008), with permission of the International Society for Clinical Densitometry

Once a first vertebral imaging test is done, it only needs to be repeated if prospective height loss is documented or new back pain or postural change occurs [3, 24]. A follow-up vertebral imaging test is also recommended in patients who are being considered for a medication holiday, since stopping medication would not be recommended in patients who have recent vertebral fractures.

Biochemical markers of bone turnover

Bone remodeling (or turnover) occurs throughout life to repair fatigue damage and microfractures in bone and to maintain mineral homeostasis. Biochemical markers of bone remodeling [e.g., resorption markers-serum C-telopeptide (CTX) and urinary N-telopeptide (NTX}-and formation markers-serum bone-specific alkaline phosphatase (BSAP), osteocalcin (OC), and aminoterminal propeptide of type I procollagen (PINP)] are best collected in the morning while patients are fasting.

Biochemical markers of bone turnover may [25]:

- Predict risk of fracture independently of bone density in untreated patients
- Predict rapidity of bone loss in untreated patients
- Predict extent of fracture risk reduction when repeated after 3--6 months of treatment with FDA-approved therapies
- Predict magnitude of BMD increases with FDA-approved therapies
- Help determine adequacy of patient compliance and persistence with osteoporosis therapy
- Help determine duration of"drug holiday" and when and if medication should be restarted. (Data are quite limited to support this use, but studies are underway.)

Use of WHO FRAX® in the USA

FRAX® was developed to calculate the 10-year probability of a hip fracture and the 10-year probability of a major osteoporotic fracture (defined as clinical vertebral, hip, forearm, or proximal humerus fracture), taking into account femoral neck BMD and the clinical risk factors shown in Table 3 LllJ. The FRAX® algorithm is available at www.no£org as well as at www.shef.ac.uk/FRAX. It is also available on newer DXA machines or with software upgrades that provide the FRAX® scores on the bone density report.

The WHO algorithm used in this Guide was calibrated to US fracture and mortality rates; therefore, the fracture risk figures herein are specific for the US population. Economic modeling was performed to identify the I 0-year hip fracture risk above which it is cost-effective, from the societal perspective, to treat with pharmacologic agents. The US-based economic modeling is descnbed in one report [12], and the US-

Table 5 Defining obieoporosis by BMD

WHO definition of Obieoporosis based on BMD		
Classification	BMD	I-score
Normal	Within 1 SD of the mean level for a young-adult reference population	T-score at - 1.0 and above
Low bone mass (osteopenia)	Between 1.0 and 2.5 SD below that of the mean I eve) for a young-adult reference population	T-score between - 1.0 and -2.5
Osteoporosis	2.5 SD or more below that of the mean level for a young-adult reference population	T-score at or below -2.5
Severe or established osteoporosis	2.5 SD or more below that of the mean level for a young-adult reference population with frdctures	T-score at or below -2.5 with one or more frd(,iureS

Although these definitions are necessary to establish the presence of osteoporosis, they should not be used as the sole determinant of treatment decisions

adapted WHO algorithm and its clinical application are illustrated in a companion report [13].

The latter analyses generally confirm the previous NOF conclusion that it is cost-effective to treat individuals with a prior hip or vertebral fm(,ture and those with a DXA femoral neck T-score :S-2.5. Previous analyses have established that a lumbar spine T-score :S-2.5 also warrants treatment [26].

FRAX underestimates fracture risk in patients with recent fractures, multiple osteoporosis-related fractures, and those at increased risk for falling. FRAX® is most useful in patients with low femoral neck BMD. Utilizing FRAX® in patients with low BMD at the lumbar spine but a relatively normal BMD at the femoral neck underestimates fracture risk in these individuals. Specifically, the WHO algorithm has not been validated for the use oflumbar spine BMD. NOF recommends treatment ofindividuals with osteoporosis of the lumbar spine as well as the hip.

Application of US-adapted FRAX® in the USA

- FRAX® is intended for postmenopausal women and men age 50 and older; it is not intended for use in younger adults or children.
- The FRAX® tool has not been validated in patients currently or previously treated with pharmacotherapy for osteoporosis. In such patients, clinical judgment must be exercised in interpreting FRAX® scores. Patients who have been off osteoporosis medications for I to 2 years or more might be considered untreated [27].
- FRAX® can be calculated with either femoral neck BMD or total hip BMD, but, when available, femoral neck BMD is preferred. The use of BMD from nonhip sites is not recommended.
- The WHO determined that for many secondary causes of osteoporosis, fracture risk was mediated primarily through impact on BMD [28]. For this reason, when femoral neck BMD is inserted into FRAX®, the secondary causes of osteoporosis button are automatically inactivated.

The therapeutic thresholds proposed in this Guide are for clinical guidance only and are not rules. All treatment decisions require clinical judgment and consideration of individual patient fa(,tors, including patient preferences, comorbidities, risk factors not captured in the fRAX® model (e.g., frailty, falls), recent decline in bone density, and other sources of posSible under- or overestimation of fracture risk by FRAX®.

The therapeutic thresholds do not preclude clinicians or patients from considering intervention strategies for those who

Table 6 Indications for HMD testing

Consider BMD testing in the following individuals:

- Women age 65 and older and men age 70 and older, regardless of clinical risk factors
- Younger postrnenopausal women, women in the menopausal transition, and men age 50 to 69 with clinical risk factors for fracture
- Adults who have a fmcture at or after age 50
- Adults with a condition (e.g., rheumatoid arthritis) or taking a medication (e.g., glucocorticoids in a daily dose 2:5 mg prednisone or equivalent for 2:3 months) associated with low bone mass or bone loss

Table 7 Indications for vertebrnl imaging

Consider vertebrnl imaging tebis for the following individuals[3]:

- All women age 70 and older and all men age 80 and older if HMD I-score at the spine, total hip, or femornl neck is - 1.0
- Women age 65 to 69 and men age 70 to 79 ifBMD I-score at the spine, total hip, or femoral neck is -1.5
- Postrnenopausal women and men age 50 and older with specific risk factors:
  - Low-trnuma :frd(,iure during adulthood (age 50 and older)
  - Historical height loss of 1.5 in. or more (4 cml
  - Prospective height loss of0.8 in. or more (2 cm)"
  - Recent or ongoing long-term glucocorticoid treatment

• If bone density testing is not available, vertebral imaging may be considered based on age alone

b Current height compared to peak height during young adulthood

c Cumulative height loss measured during interval medical assessment

do not have osteoporosis by BMD (WHO diagnostic criterion ofT-score S-2.5), do not meet the cut points after FRAX(!l;, or are not at high enough risk of fracture despite low BMD. Conversely, these recommendations should not mandate treatment, particularly in patients with low bone mass above the osteoporosis range. Decisions to treat must still be made on a case-by-case basis.

Additional bone densitometry technologies

The following bone mass measurement technologies included in Table 8 are capable of predicting both site-specific and overall fracture risk. When performed according to accepted standards, these densitometric techniques are accurate and highly reproducible [19]. However, T-scores from these technologies cannot be used according to the WHO diagnostic classification because they are not equivalent to T-scores derived from DXA.

Table 8 Additional bone densitometry technologies

CT-based absorptiometry: Quantitative computed tomogrnphy (QCT) measures volumetric integrnl, trabecular, and cortical bone density at the spine and hip and can be used to determine bone strength, whereas pQCT measures the same at the forearm or tibia. High-resolution pQCT (HR-pQCT) at the rndius and t:toia provides measures of volumetric density, bone stru(,1ure, and microarchitecture. In po 'trneno-pausal women, QCT measurement of spine trabecular HMD can predi(,1 vertebrnl fractures, whereas pQCT of the forearm at the ultradistal rndius predicts hip but not vertebrnl fractures. There is insufficient evidence for frdcture prediction in men. QCI' and pQCT are associated with greater amounts of rndiation exposure than centrnl DXAorpDXA.

Trabecular Bone Score (TBS) is an FDA-approved technique which is available on some densitometers. It may measure the microarchitectural ifU(,1ure of bone tissue and may improve the ability to predi(,1 the risk of frdc.1ure.

The following technologies are often used for community-based sc.Teening programs because of the portability of the equipment. Results are not equivalent to DXA and abnormal results should be confirmed by physical examination, risk asses ment, and centrnl DXA.

Peripheral dual-energy x-rny absorptiomet:ty (pDXA) measures areal bone density of the forearm, finger, or heel. Measurement by validated pDXA devices can be used to assess vertebral and overnll fracture risk in postrnenopausal women. There is insufficient evidence for fracture prediction in men. pDXA is associated with exposure to trivial amounts ofrndiation. pDXA is not appropriate for monitoring HMD after treatment.

Quantitative ultrnsound densitomet:ty (QUS) does not measure BMD dire(,1ly but rnther JJeed of sound (SOS) and/or broadband ultrnsound attenuation (BUA) at the heel, t:toia, patella, and other peripheral skeletal sites. A composite parnmeter using SOS and BUA may be used clinically. Validated heel QUS devices predict fra(,1ures in post-menopausal women (vertebral, hip, and overall fracture risk) and in men 65 and older (hip and nonvertebrnl fractures). QUS is not associated with any rndiation exposure.

Universal recommendations for all patients

Several interventions to preserve bone strength can be recommended to the general population. These include an adequate intake of calcium and vitamin D, lifelong participation in regular weight-bearing and muscle-strengthening exercise, cessation of tobacco use, identification and treatment of alcoholism, and treatment of risk factors for falling.

Adequate intake of calcium and vitamin D

Advise all individuals to obtain an adequate intake of dietary calcium. Providing adequate daily calcium and vitamin D is a safe and inexpensive way to help reduce fracture risk. Controlled clinical trials have demonstrated that the combination of supplemental calcium and vitamin D can reduce the risk of fracture [29]. A balanced diet rich in low-fat dairy products, fruits, and vegetables provides calcium as well as numerous nutrients needed for good health. If adequate dietary calcium cannot be obtained, dietary supplementation is indicated up to the recommended daily intake.

Lifelong adequate calcium intake is necessary for the acquisition of peak bone mass and subsequent maintenance of bone health. The skeleton contains 99 % of the body's calcium stores; when the exogenous supply is inadequate, bone tissue is resorbed from the skeleton to maintain serum calcium at a constant level.

NOF supports Institute of Medicine (IOM) recommendations that men age 50- 70 consume 1000 mg/day of calcium and that women age 51 and older and men age 71 and older consume 1200 mg/day of calcium [30]. There is no evidence that calcium intake in excess of these amounts confers additional bone strength. Intakes in excess of 1200 to 1500 mg/day may increase the risk of developing kidney stones, cardiovascular disease, and stroke. The scientific literature is highly controversial in this area l31-34J.

Table 9 illustrates a simple method for estimating the calcium content of a patient's diet. The average daily dietary calcium intake in adults age 50 and older is 600 to 700 mg/day. Increasing dietary calcium is the first-line approach, but calcium supplements should be used when an adequate dietary intake cannot be achieved.

Vitamin D plays a major role in calcium absorption, bone health, muscle performance, balance, and risk of falling. NOF recommends an intake of 800 to 1000 international units (IU) of vitamin **D** per day for adults age 50 and older. Institute of Medicine Dietary Reference Intakes for vitamin **D** are 600 IU/day until age 70 and 800 IU/day for adults age 71 years and older [30].

Chief dietary sources of vitamin D include vitamin D-fortified milk (400 IU/quart, although certain products such

Table 9 Estimating daily dietary calcium intake

Step 1: Estimate calcium intake from calcium-rich foodsa			
Produ<,1	# of servings/day	Estimated calcium/serving, in mg	Calcium in mg
Milk (8 oz.)	_____	x3()()	_____
Yogurt (6 oz.)	_____	x3()()	_____
Cheese (1 oz. or 1 cubic in.)	_____	x2()()	_____
Fortified foods or juices	_____	x8Q to 1,000b	_____
			Subtotal= _____
Step 2: Add 250 mg for nondairy sources to subtotal above			+250
			Total calcium, in mg= ____ _

a About 75 to 80 % of the calcium consumed in American diets is from dairy produ<,18

b Calcium content of fortified foods varies

as soy milk are not always supplemented with vitamin D), some fortified juices and cereals (40 to 50 ID/serving or more), salt water fish, and liver. Some calcium supplements and most multivitamin tablets also contain vitamin D. Supplementation with vitamin D_2 (ergocalciferol) or vitamin D_3 (cholecalciferol) may be used. Vitamin D_2 is derived from plant sources and may be used by individuals on a strict vegetarian diet.

Many older patients are at high risk for vitamin D deficiency, including patients with malabsorption (e.g., celiac disease) or other intestinal diseases (e.g., inflammatory bowel disease, gastric bypass surgery), chronic renal insufficiency, patients on medications that increase the breakdown of vitamin D (e.g., some antiseizure drugs), housebound patients, chronically ill patients and others with limited sun exposure, individuals with very dark skin, and obese individuals. There is also a high prevalence of vitamin D deficiency in patients with osteoporosis, especially those with hip fractures, even in patients taking osteoporosis medications [35, 36].

Since vitamin D intakes required to correct vitamin D deficiency are so variable among individuals, serum 25(OH)D levels should be measured in patients at risk of deficiency. Vitamin D supplements should be recommended in amounts sufficient to bring the serum 25(OH)D level to approximately 30 ng/ml (75 nmol/L) and a maintenance dose recommended to maintain this level, particularly for individuals with osteoporosis. Many patients with osteoporosis will need more than the general recommendation of 800-1000 IU/day. The safe upper limit for vitamin D intake for the general adult population was increased to 4000 IU/day in 2010 [30].

Treatment of vitamin D deficiency

Adults who are vitamin D deficient may be treated with 50,000 IU of vitamin D_2 or vitamin D_3 once a week or the equivalent daily dose (7000 IU vitamin D_2 or vitamin D_3) for 8-12 weeks to achieve a 25(OH)D blood level *of approximately* 30 ng/ml. This regimen should be followed by maintenance therapy of 1500-2000 IU/day or whatever dose is needed to maintain the target blood level [37, 38].

Regular weight-bearing and muscle- trengthening exercise

Recommend regular weight-bearing and muscle-strengthening exercise to reduce the risk of falls and fractures [39--42]. Among the many health benefits, weight-bearing and muscle-strengthening exercise can improve agility, strength, posture, and balance, which may reduce the risk of falls. 1n addition, exercise may modestly increase bone density. NOF strongly endorses lifelong physical activity at all ages, both for osteoporosis prevention and overall health, as the benefits of exercise are lost when people stop exercising.

Weight-bearing exercise (in which bones and muscles work against gravity as the feet and legs bear the body's weight) includes walking, jogging, Tai Chi, stair climbing, dancing, and tennis. Muscle-strengthening exercise includes weight training and other resistive exercises, such as yoga, Pilates, and boot camp programs. Before an individual with osteoporosis initiates a new vigorous exercise program, such as running or heavy weight-lifting, a clinician's evaluation is appropriate.

Fall prevention

Major risk factors for falling are shown in Table 2. In addition to maintaining adequate vitamin D levels and physical activity, as described above, several strategies have been demonstrated to reduce falls. These include, but are not limited to, multifactorial interventions such as individual risk assessment, Tai Chi and other exercise programs, home safety assessment, and modification especially when done by an occupational therapist, and gradual withdrawal of psychotropic medication if possible. Appropriate correction of visual impairment may improve mobility and reduce risk of falls.

There is a lack of evidence that the use of hip protectors by community-dwelling adults provides statistically significant reduction in the risk of hip or pelvis fractures. Also, there is no evidence that the use of hip protectors reduces the rate of falls. In long-term care or residential care settings, some studies

have shown a marginally significant reduction in hip fracture risk There are no serious adverse effects of hip protectors; however, adherence to long-term use is poor [43]. There is additional uncertainty as to which hip protector to use, as most of the marketed products have not been tested in randomized clinical trials.

Cessation of tobacco use and avoidance of excessive alcohol intake

Advise patients to stop tobacco smoking. The use of tobacco products is detrimental to the skeleton as well as to overall health [44--47]. NOF strongly encourages a smoking cessation program as an osteoporosis intervention.

Recognize and treat patients with excessive alcohol intake. Moderate alcohol intake has no known negative effect on bone and may even be associated with slightly higher bone density and lower risk of fracture in postmenopausal women. However, alcohol intake of more than two drinks per day for women or three drinks a day for men may be detrimental to bone health, increases the risk of falling, and reguires further evaluation for possible alcoholism [48].

Table IO Clinical approach to managing osteoporosis in postmenopausal women and men age 50 and older

General prim.iples:

- Obtain a detailed patient history pertaining to clinical risk faL1ors for o 1eoporosis-related frdL1ures and falls
- Perform physical examination and obtain diagnostic studies to evaluate for signs of o 1eoporosis and its secondary causes
- Modify diet/supplements, life 1yle, and other modifiable clinical risk factors for frdL1ure
- Estimate patient's 10-year probability of hip and any major o 1eoporosis-related frdL1ure using the US-adapted FRAX and perform vertebral imaging when appropriate to complete risk assessment
- Decisions on whom to treat and how to treat should be based on clinical judgment using this Guide and all available clinical information

Consider .FDA-approved medical therapies based on the following:

- Vertebrnl frdcture (clinical or asymptomatic) or hip fiaL1ure
- Hip D.XA (femoral neck or total hip) or lumbar spine I-score :::-2.5
- Low bone mass (osteopenia) and a US-adapted WHO JO-year probability ofa hip frdcture 2:3 % or 1()..year probability of any major o 1eoporosis-related fiaL1ure 2:20 %
- Patient preferences may indicate treatment for people with I0-year fraL1ure probabilities above or below these levels

Consider nonmedical therapeutic interventions:

- Modify risk factors related to falling
- Referrals for physical and/or occupational therapy evaluation (e.g., walking aids and other assistive devices)
- Weight-bearing, muscle-strengthening exercise, and balance training

Follow-up:

- Patients not requiring medical thernpies at the time of initial evaluation should be clinically re-evaluated when medically appropriate
- Patients taking FDA-approved medications should have laboratory and bone density re-evaluation after 2 years or more frequently when medically appropriate
- Vertebral imaging should be repeated if there is documented height loss, new back pain, postural change, or S 1)icious finding on chest X-ray, following the last (or first) vertebral imaging test or in patients being considered for a tempordry cessation of drug therapy to make sure no new vertebral fiaL1ures have occurred in the interval
- Regularly, and at least annually, assess compliance and persistence with the therapeutic regimen

Pharmacologic therapy

All patients being considered for treatment of osteoporosis should also be counseled on risk factor reduction including the importance of calcium, vitamin D, and exercise as part of any treatment program for osteoporosis. Prior to initiating treatment, patients should be evaluated for secondary causes of osteoporosis and have BMD measurements by central DXA, when available, and vertebral imaging studies when appropriate. Biochemical marker levels should be obtained if monitoring of treatment effects is planned. An approach to the clinical assessment of individuals with osteoporosis is outlined in Table 10.

The percentage of risk reductions for vertebral and nonvertebral fractures cited below are those cited in the FDA-approved prescribing information. In the absence of head-to-head trials, direct comparisons of risk reduction among drugs should be avoided.

Who should be considered for treatment?

Postrnenopausal women and men age 50 and older presenting with the following should be considered for treatment:

- A hip or vertebral fracture (clinically apparent or found on vertebral imaging). There are abundant data that patients with spine and hip fractures will have reduced fracture risk if treated with pharmacologic therapy. This is true for fracture patients with BMD in both the low bone mass and osteoporosis range [49--58]. In patients with a hip or spine fracture, the T-score is not as important as the fracture itself in predicting future risk of fracture and antifracture efficacy from treatment.
- T-score :::-2.5 at the femoral neck, total hip, or lumbar spine. There is abundant evidence that the elevated risk of fracture in patients with osteoporosis by BMD is reduced with pharmacotherapy [52, 57, 59--70].
- Low bone mass (T-score between - 1.0 and -2.5 at the femoral neck or lumbar spine) and a I0-year probability of a hip fracture 2:3 % or a I0-year probability of a major

osteoporosis-related fracture 2':20 % based on the US-adapted WHO algorithm [13, 15, 71, 72].

Although FRAX calculated fracture risk prediction has been confirmed in multiple studies, there are relatively few data confirming fracture risk reductions with pharmacotherapy in this group of patients.

US FDA-approved drugs for osteoporosis

Current FDA-approved pharmacologic options for the prevention and/or treatment of postmenopausal osteoporosis include, in alphabetical order: bisphosphonates (alendronate, alendronate plus D, ibandronate, risedronate and zoledronic acid), calcitonin, estrogens (estrogen and/or hormone therapy), estrogen agonist/antagonist (raloxifene), tissue-selective estrogen complex (conjugated estrogens/bazedoxifene), parathyroid hormone (PTH [1-34], teriparatide), and the receptor activator of nuclear factor kappa-B (RANK) ligand (RANKL) inhibitor denosumab. Please see prescribing information for specific details of their use.

The antifracture benefits of FDA-approved drugs have mostly been studied in women with postmenopausal osteoporosis. There are limited fracture data in glucocorticoid-induced osteoporosis and in men. FDA-approved osteoporosis treatments have been shown to dec.,Tease fracture risk in patients who have had fragility fractures and/or osteoporosis by DXA. Pharmacotherapy may also reduce vertebral fractures in patients with low bone mass (osteopenia) without fractures, but the evidence supporting overall antifracture benefit is not as strong. Thus, the clinician should assess the potential benefits and risks of therapy in each patient and the effectiveness of a given osteoporosis treatment on reduction of vertebral and nonvertebral fractures.

Note that the intervention thresholds do not take into account the nonskeletal benefits or risks associated with specific drug use. NOF does not advocate the use of drugs not approved by the FDA for prevention and treatment of osteoporosis. Examples of these drugs are listed in Table 11 for information only.

Table 11 Non-FDA-approved drugs for obieoporosis

These drugs are libied for information only. Nonapproved agents include:

Calcitriol: This synthetic vitamin D analogue, which promotes calcium absmption, has been approved by the FDA for managing hypocalcemia and metabolic bone disease in renal dialysis patients. It is also approved for use in hypoparnthyroidism, both surgical and idiopathic, and pseudohypoparnthyroidism. No reliable data demonstrate a reduction of risk for osteoporotic fm<.,iure.

Genistein: An isoflavone phytoestrogen which is the main ingredient in the prescription "medical food" product fosteum® and generally regarded as safe by the FDA. Genistein may benefit bone health in postmenopausal women but more data are needed to fully understand its effects on bone health and fm<.,iufe risk.

Other bib1Jhosphonates (etidronate, pamidronate, tiludronate): These medications vary chemically from alendronate, ibandronate, risedronate, and zoledronic a<.,id but are in the same drug class. At this time, none is approved for prevention or treatment of Obieoporosis. Most of these medications are currently approved for other conditions (e.g., Paget's disease, hypercalcemia ofmalignan<.,y, myositis ossificans).

PlH (1-84): This medication is approved in some countries in Europe for treatment of osteoporosis in women. In one clinical study, PTH(l-84) etle<.,iively reduced the risk of vertebral fractures at a dose of 100 mcg/day.

Sodium fluoride: Through a process that is still unclear, sodium fluoride stimulates the formation of new bone. The quality ofbone mass thus developed is uncertain, and the evidence that fluoride reduces fracture risk is confli<.,1ing and controversial.

Strontium ranelate: This medication is approved for the treatment of osteoporosis in some countries in Europe. Strontium ranelate reduces the risk of both spine and nonvertebrnl frdctures, but the mechanism is unclear. lncmporntion of strontium into the <.,,ystal structure replacing calcium may be part of its mechanism of effe<.,1. These effe<.,is have only been documented with the pharmaceutical grnde agent produced by Servier. This effe<.,1 has not been studied in nutritional supplements containing strontium salts.

Tibolone: Tibolone is a tissue-b1Jecific, eb1rogen-like agent that may prevent bone loss and reduce menopausal symptoms. It is indicated in Europe for the treatment of vasomotor symptoms of menopause and for prevention of ob1eoporosis, but it is not approved for use in the USA.

Bisphosphonates

Drug efficacy

Alendronate, brand name: Fosamax®, Fosamax Plus D, Binosto™, and generic alendronate Alendronate sodium is approved by the FDA for the prevention (5 mg daily and 35 mg weekly tablets) and treatment (10 mg daily tablet, 70 mg weekly tablet, 70 mg weekly tablet with 2,800 or 5,600 IU of vitamin D_3, and 70 mg effervescent tablet) of postmenopausal osteoporosis. Alendronate is also approved for treatment to increase bone mass in men with osteoporosis and for the treatment of osteoporosis in men and women taking glucocorticoids [73].

Alendronate reduces the incidence of spine and hip fractures by about 50 % over 3 years in patients with a prior vertebral fracture or in patients who have m,teoporosis at the hip site [49, 59]. It reduces the incidence of vertebral fractures by 48 % over 3 years in patients without a prior vertebral fracture [74].

Ibandronate, brand name: Boniva® and generic ibandronate Ibandronate sodium is approved by the FDA for the treatment (150 mg monthly tablet and 3 mg every 3 months by intravenous injection) ofpostmenopausal osteoporosis. Ibandronate is available as a generic preparation in the USA The oral preparations are also approved for the prevention of postmenopausal osteoporosis.

Ibandronate reduces the incidence of vertebral fractures by about 50 % over 3 years, but reduction in risk of nonvertebral fracture with ibandronate has not been documented [50].

Risedronate, brand name: Actonel®, Atelvia™, and generic risedronate Risedronate sodium is approved by the FDA for the prevention and treatment (5 mg daily tablet; 35 mg weekly tablet; 35 mg weekly delayed release tablet; 35 mg weekly tablet packaged with six tablets of 500 mg calcium carbonate; 75 mg tablets on two consecutive days every month; and 150 mg monthly tablet) of postmenopausal osteoporosis. Risedronate is also approved for treatment to increase bone mass in men with osteoporosis and for the prevention and treatment of osteoporosis in men and women who are either initiating or taking glucocorticoids L7 5 J.

Risedronate reduces the incidence of vertebral fractures by 41 to 49 % and nonvertebral fractures by 36 % over 3 years, with significant risk reduction occurring within I year of treatment in patients with a prior vertebral fracture [51, 52].

Zoledronic acid, brand name: Reclast® Zoledronic acid is approved by the FDA for the prevention and treatment (5 mg by intravenous infusion over at least 15 min once yearly for treatment and once every 2 years for prevention) of osteoporosis in postmenopausal women. It is also approved to improve bone mass in men with osteoporosis and for the prevention and treatment of osteoporosis in men and women expected to be on glucocorticoid therapy for at least 12 months. Zoledronic acid is also indicated for the prevention of new clinical fractures in patients (both women and men) who have recently had a low-trauma (osteoporosis-related) hip fracture [58].

Zoledronic acid reduces the incidence of vertebral fractures by 70 % (with significant reduction at I year), hip fractures by 41 %, and nonvertebral fractures by 25 % over 3 years in patients with osteoporosis defined by prevalent vertebral fractures and osteoporosis by BMD of the hip [66].

Drug administration

Alendronate (generic and Fosamax) and risedronate (Actonel) tablets must be taken on an empty t.tomach, fiTht thing in the morning, with 8 oz of plain water (no other liquid). Binot.to mut.t be dissolved in 4 oz of room tempernture water taken on an empty stomach, first thing in the morning. Delayed release risedronate (Atelvia) tablets must be taken immediately after breakfast with at least 4 oz of plain water (no other liquid). After taking these medications, patients must wait at least 30 min before eating, drinking, or taking any other medication. Patients should remain upright (sitting or standing) during this interval.

Ibandronate must be taken on an empty stomach, first thing in the morning, with 8 oz of plain water (no other liquid). After taking this medication, patients must remain upright and wait at least 60 min before eating, drinking, or taking any other medication. Ibandronate, 3 mg/3 ml prefilled syringe, is given by intravenous injection over 15 to 30 s, once every 3 months. Serum creatinine should be checked before each injection.

Zoledronic acid, 5 mg in 100 ml, is given once yearly or once every 2 years by intravenous infusion over at least 15 min. Patients should be well hydrated and may be pre-treated with acetaminophen to reduce the risk of an acute phase reaction (arthralgia, headache, myalgia, fever). These symptoms occurred in 32 % of patients after the first dose, 7 % after the second dose, and 3 % after the third dose.

Drug safety

Side effects are similar for all oral bisphosphonate medications and include gastrointestinal problems such as difficulty swallowing and inflammation of the esophagus and stomach.

All bisphosphonates can affect renal function and are contraindicated in patients with estimated GFR below 30-35 ml/min. Zoledronic acid is contraindicated in patients with creatinine clearance less than 35 mL/min or in patients with evidence of acute renal impairment. Healthcare professionals should screen patients prior to administering zoledronic acid in order to identify at-risk patients and should assess renal function by monitoring creatinine clearance prior to each dose of zoledronic acid [76]. Eye inflammation can also occur. Any such complication should be reported to the healthcare provider as soon as possible.

There have been rare reports of osteonecrosis of the jaw **(ONJ)** with long-term use of bisphosphonates for osteoporosis, though ONJ is much more common following high-dose intravenous bisphosphonate treatment for patients with cancer. The risk of **ONJ** appears to increase with duration of treatment beyond 5 years [77].

Although rare, low-trauma atypical femur fractures may be associated with the long-term use of bisphosphonates (e.g., >5 years of use). Pain in the thigh or groin area, which can be bilateral, often precedes these unusual fractures. Patients should be evaluated closely for these unusual fractures, including proactive questioning regarding thigh and groin pain. For patients with thigh and groin pain, a stress fracture in the subtrochanteric region or femoral shaft of the femur may be present. Bilateral X-ray of the femurs should be ordered when an atypical femur fracture is suspected, followed by an **MRI** or a radionuclide bone scan when clinical suspicion is high enough [78]. Surgical fixation is required in some cases, whereas medical conservative treatment is appropriate in other cases. Bisphosphonates should be stopped if atypical femur fractures have occurred.

Calcitonin

Drug efficacy

Brand name: Miacalcin® or Fortical® and generic calcitonin Salmon calcitonin is FDA-approved for the treatment of osteoporosis in women who are at least 5 years postmenopausal when alternative treatments are not suitable.

Miacalcin nasal spray has not been shown to increase bone mineral density in early postmenopausal women.

Calcitonin reduces vertebral fracture occurrence by about 30 % in those with prior vertebral fractures but has not been shown to reduce the risk of nonvertebral fractures [54, 79]. Due to the possible association between malignancy and calcitonin-salmon use, the need for continued thernpy should be re-evaluated on a periodic basis.

Drug administration

Two hundred international units delivered as a single daily intranasal spray. Subcutaneous administration by injection also is available.

Drug safety

Intranasal calcitonin can cause rhinitis, epistaxis, and allergic reactions, particularly in those with a history of allergy to salmon. The FDA has reviewed long-term post-marketing data concerning calcitonin and the very small increase in the risk of certain cancers. A meta-analysis of 21 randomized, controlled clinical trials with calcitonin-salmon (nasal spray and investigational oral forms) suggests an increased risk of malignancies in calcitonin-salmon-treated patients compared to placebo-treated patients. The overall incidence of malignancies reported in the 21 trials was higher among calcitonin-salmon-treated patients (4.1 %) compared with placebo-treated patients (2.9 %). The data were not sufficient for further analyses by specific type of malignancy. Although a definitive causal relationship between the calcitonin-salmon use and malignancies cannot be established from this meta-analysis, the benefits for the individual patient should be carefully evaluated againt.t all possible risks [80, 81].

Estrogen/hormone therapy (ET/HT)

Drug efficacy

ET brand names:e.g., Climara®, Estrace®, Estraderm®, Estratab®, Ogen®, Premarin®, Vivelle®; HT brand names: e.g., Activella®, Femhrt®, Premphase®, Prempro® Estrogen/hormone therapy is approved by the FDA for the prevention of osteoporosis, relief of vasomotor symptoms, and vulvovaginal atrophy associated with menopause. Women who have not had a hysterectomy require HT, which also contains progestin to protect the uterine lining. The Woman's Health Initiative (WHI) found that 5 years of HT (Prempro®) reduced the risk of clinical vertebral fractures and hip fractures by 34 % and other osteoporotic fractures by 23 % [69].

Drug administration

ET/HT is available in a wide variety of oral as well as transdermal preparations including estrogen only, progestin only, and combination estrogen-progestin. ET/HT dosages include cyclic, sequential, and continuous regimens. If and when treatment is stopped, bone loss can be rapid and alternative agents should be considered to maintain **BMD.**

Drug safety

The **WHI** reported increased risks of myocardial infarction, stroke, invasive breast cancer, pulmonary emboli, and deep vein thrombosis during 5 years of treatment with conjugated equine estrogen and medroxyprogesterone acetate (Prempro®) [69]. Subsequent analyses of these data showed no increase in cardiovascular disease in women starting treatment within 10 years of menopause [82]. ln the estrogen only arm ofWHI, no increase in breast cancer incidence was noted over 7.1 years of treatment. Other doses and combinations of estrogen and progestins were not studied and, in the absence of comparable data, their risks should be assumed to be comparable. Because of the risks, ET/HT should be used in the lowest effective doses for the shortest duration to treat moderately severe menopausal symptoms and should be considered primarily for women within the first few years of menopause. When ET/HT use is considered solely for prevention of osteoporosis, the FDA recommends that approved nonestrogen treatments should first be carefully considered. When ET/HT treatments are stopped, bone loss can be rapid and alternative agents should be considered to maintain BMD.

Estrogen agonist/antagonist (formerly known as SERMs): Raloxifene

Drug efficacy

Raloxifene, brand name: Evista® and generic raloxifene Raloxifene is approved by the FDA for both prevention and treatment of osteoporosis in postmenopausal women.

Raloxifene reduces the risk of vertebral fractures by about 30 % in patients with a prior vertebral fracture and by about 55 % in patients without a prior vertebral fracture over 3 years [55]. Reduction in risk ofnonvertebral fracture with raloxifene has not been documented. Raloxifene is also

inclicated for the reduction in risk of invasive breast cancer in postmenopausal women with osteoporosis [83-86]. Raloxifene does not reduce the risk of coronary heart disease.

Drug administration

Available in a 60-mg tablet form to be taken with or without food.

Drug safety

Raloxifene increases the risk of deep vein thrombosis to a degree similar to that observed with estrogen. It can also increase hot flashes and cause leg I.Tamps.

Tissue-selective estrogen complex: conjugated estrogens/bazedoxifene (conjugated estrogens paired with estrogen agonist/antagonist)

Drug efficacy

Conjugated estrogens/bazedoxifene, brand name: Duavee® Conjugated estrogens/bazedoxifene is approved by the FDA for women who suffer from moderate-to-severe hot flashes (vasomotor symptoms) associated with menopause and to prevent osteoporosis after menopause.

The medication combines conjugated estrogen with an estrogen agonist/antagonist (bazedoxifene). The bazedoxifene component reduces the risk of endometrial hyperplasia (excessive growth of the lining of the uterus) that can occur with the estrogen component of the drug. Therefore, progestins do not need to be taken with conjugated estrogens/bazedoxifene.

Use of this combination drug significantly increased mean lumbar spine BMD (treatment difference, 1.51 %), at 12 months compared to placebo in women who had been postmenopausal between 1 and 5 years. Treatment with conjugated e trogens/bazedoxifene also in1.Teased total hip BMD. The treatment difference in total hip BMD at 12 months was 1.21 % [87-90].

Drug administration

Available as a tablet containing conjugated estrogens and bazedoxifene 0.45 mg/ 20 mg, to be taken once daily without regard to meals.

Drug safety

Conjugated estrogens/bazedoxifene is intended only for postmenopausal women who still have a uterus. Like other products containing estrogen, it should be used for the shortest duration consistent with treatment goals and risks for the individual woman. When using this drug only for the prevention of osteoporosis, such use should be limited to women who are at significant risk of osteoporosis and only after carefully considering alternatives that do not contain estrogen.

Side effects of conjugated estrogens/bazedoxifene include muscle spasms, nausea, cliarrhea, dyspepsia, upper abdominal pain, oropharyngeal pain, dizziness, and neck pain. Because this product contains estrogen, it is approved with the same Boxed Warning and other Warnings and Precautions that have been approved with estrogen products.

Parnthyroid hormone: teriparatide

Drug efficacy

PTH(l-34), teriparatide, brand name: Forteo® Teriparatide is approved by the FDA for the treatment of osteoporosis in postmenopausal women and men at high risk for fracture. It is also approved for treatment in men and women at high risk of fracture with osteoporosis associated with sustained systemic glucocorticoid therapy [91]. Teriparatide reduces the risk of vertebral fractures by about 65 % and nonvertebral fragility fractures by about 53 % in patients with osteoporosis, after an average of 18 months of therapy [57].

Drug administration

Teriparatide is an anabolic (bone-building) agent administered by 20 µg daily subcutaneous injection. If and when treatment is stopped, bone loss can be rapid and alternative agents should be considered to maintain BMD. Treatment duration is recommended not to exceed 18 to 24 months.

Drug safety

Side effects of teriparatide include leg cramps, nausea, and dizziness. Because it caused an increase in the incidence of osteosarcoma in rats (high doses, long duration treatment in the rodent), patients with an in1.Teased risk of osteosarcoma (e.g., patients with Paget's clisease of bone and those having prior racliation therapy of the skeleton), bone metastases, hypercalcemia, or a history of skeletal malignancy should not receive teriparatide therapy. It is common pra1.,tice to follow teriparatide treatment with an antiresorptive agent, usually a bisphosphonate, to maintain or further increase BMD.

RANKL/RANKL inhibitor: denosumab

Drug efficacy

Denosumab, brand name Prolia® Denosumab is approved by the FDA for the treatment of osteoporosis in postmenopausal women at high risk of fracture. Denosumab reduces the incidence of vertebral fra1.,1ures by about 68 %, hip fra1.,1ures

by about 40 %, and nonvertebral fractures by about 20 % over 3 years [56]. Denosumab is also indicated to increase bone mass in men at high risk of fracture, treat bone loss in women with breast cancer on aromatase inhibitor therapies, and to treat bone loss in men receiving gonadotropin-reducing hormone treatment for prostate cancer who are at high risk for fracture.

Drug administration

Administered by a health professional, 60 mg every 6 months as a subcutaneous injection.

Drug safety

Denosumab may cause hypocalcemia. Hypocalcemia must be corrected before starting denosumab. Denosumab increased the risk of serious skin infections (cellulitis) and skin rash. Denosumab has been rarely associated with the development of ONJ, both when used to treat osteoporosis and to treat patients with cancer (at much higher doses), although it is much more common in the latter setting. Denosumab has also been associated rarely with the development of atypical femur fractures. If and when denosumab treatment is stopped, bone loss can be rapid and alternative agents should be considered to maintain BMD.

Sequential and combination therapy

When osteoporosis is diagnosed in young individuals, choices of osteoporosis medication may change over time to take advantage of the best benefit to risk ratio at each stage oflife (sequential monotherapy). For more severe osteoporosis, sequential treatment with anabolic therapy followed by an antiresorptive agent is generally preferred to concomitant combination therapy. However, combination therapy with teriparatide and an antiresorptive can be considered in a few clinical settings in patients with very severe osteoporosis such as spine and hip fractures. There are few indications for combining two antiresorptive treatments, but such options could be considered in the short term in women who are experiencing active bone loss while on low dose HT for menopausal symptoms or raloxifene for breast cancer prevention.

Duration of treatment

No pharmacologic therapy should be considered indefinite in duration. All nonbisphosphonate medications produce temporary effects that wane upon discontinuation. If these treatments are stopped, benefits rapidly disappear. In contrast, bisphosphonates may allow residual effects even after treatment discontinuation. Therefore, it may be possible to discontinue bisphosphonates and retain residual benefits against fracture at least for several years.

Evidence of efficacy beyond 5 years is limited, whereas rare safety concerns such as ONJ and atypical femur fractures become more common beyond 5 years [67, 92]. Since there is no extensive evidence base to guide treatment duration decisions, duration decisions need to be individualized [93]. After the initial 3- to 5-year treatment period, a comprehensive risk assessment should be performed. This should include interval clinical history, particularly with respect to intercurrent fracture history and new chronic diseases or medications, as well as height measurement, BMD testing, and vertebral imaging if there has been any documented height loss during the treatment period. It is reasonable to discontinue bisphosphonates after 3 to 5 years in people who appear to be at mode t risk of fracture after the initial treatment period. In contrast, for those who appear to be at high risk for fracture, continued treatment with a bisphosphonate or an alternative therapy should be considered [94].

Monitoring patients

It is important to ask patients whether they are taking their medications and to encourage continued and appropriate compliance with their osteoporosis therapies to reduce fracture risk. It is also important to review their risk factors and encourage appropriate calcium and vitamin D intakes, exercise, fall prevention, and other lifestyle measures. Furthermore, the need for continued medication to treat osteoporosis should be reviewed annually. Duration of treatment must be individualized. Some patients may be able to discontinue treatment temporarily after several years of therapy, particularly after bisphosphonate administration [95, 96]. Other patients will need to continue treatment If treatment is discontinued, serial monitoring should include clinical assessment for fractures, falling, any interval chronic disease occurrence and consideration of serial BMD testing, use of biochemical markers, and vertebral imaging in some patients.

Accurate yearly height measurement is a 1.,Titical determination of osteoporosis treatment efficacy. Patients who lose 2 cm (or 0.8 in.) or more in height either acutely or cumulatively should have a repeat vertebral imaging test to determine if new or additional vertebral fra1.,tures have occurred since the prior vertebral imaging test.

Serial central DXA testing is an important component of osteoporosis management. Measurements for monitoring patients should be performed in accordance with medical necessity, expected response, and in consideration of local regulatory requirements. NOF recommends that repeat BMD assessments generally agree with Medicare guidelines of every 2 years but recognizes that testing more frequently may be warranted in certain clinical situations.

The following techniques may be used to monitor the effectiveness of treatment:

Central DXA Central D.XA assessment of the hip or lumbar spine is the "gold standard" for serial assessment of BMD. Biological changes in bone density are small compared to the inherent error in the test itself, and interpretation of serial bone density studies depends on appreciation of the smallest change in BMD that is beyond the range of error of the test. This least significant change (LSC) varies with the specific instrument used, patient population being assessed, measurement site, technologist's skill with patient positioning and test analysis, and the confidence intervals used [97]. Changes in the BMD ofless than 3---6 % at the hip and 2--4 % at the spine from test to test may be due to the precision error of the testing itself Information on how to assess precision and calculate the LSC is available at www.ISCD.org.

QCT Volumetric **BMD** of the lumbar spine can be used to monitor age-, disease, and treatment-related BMD changes in men and women. Precision of acquisition should be established by phantom data and analysis precision by re-analysis of patient data.

pDXA, pQCT, and QUS Peripheral skeletal sites do not respond with the same magnitude as the spine and hip to medications and thus are not appropriate for monitoring response to therapy at this time.

Biochemical markers of bone turnover Suppression of biochemical markers of bone turnover after 3---6 months of treatment and biochemical marker increases after 1-3 months of anabolic therapy have been predictive of greater BMD responses and in some cases fracture risk reduction in large clinical trials. Biochemical marker changes in individuals must exceed the LSC in order to be clinically meaningful. The LSC is specific to the biomarker being utilized, which is calculated by multiplying the "precision error" of the specific biochemical marker (laboratory provided) by 2.77 (95 % confidence level). Biological variability can be reduced by obtaining samples in the early morning after an overnight fast. Serial measurements should be made at the same time of day at the same laboratory.

Vertebral imaging Once the fin,t vertebral imaging test has been performed to determine prevalent vertebral fractures (indications above), repeat testing should be performed to identify incident vertebral fractures if there is a change in the patient's status suggestive of new vertebral fracture, including documented prospective height loss, undiagnosed back pain, postural change, or a possible finding of new vertebral deformity on chest X-ray. If patients are being considered for a temporary cessation of drug therapy, vertebral imaging should be repeated to determine that no vertebral fractures have occurred in the interval off treatment. A new vertebral fracture on therapy indicates a need for more intensive or continued treatment rather than treatment cessation [95].

Implementation of fLS secondary fracture prevention programs

FLS programs have been implemented successfully in a number of closed and open settings over the last 15 years, both in the USA (including the American Orthopedic Association Own the Bone program) as well as abroad. These programs have accomplished a reduction in secondary fracture rates as well as health care cost savings [98, 99]. In the USA, Kaiser Permanente's *Healthy Bones* program has reduced the expected hip fracture rate by 38 % since 1998 llO0J; Geisinger Health System achieved $7.8 million in cost savings over 5 years llOIJ.

A Fracture Liaison Service is a coordinated care system headed by an FLS coordinator (a nurse practitioner, physician's assistant, nurse, or other health professional) who ensures that individuals who suffer a fra(-ture receive appropriate diagnosis, treatment, and support [I02]. The FLS uses established protocols to find and assess fracture patients. The program creates a population database of fracture patients and establishes a process and timeline for patient assessment and follow-up care. An FLS coordinator is frequently based in a hospital and requires support from a qualified physician or physician team.

Physical medidne and rehabilitation

Physical medicine and rehabilitation can reduce disability, improve physical function, and lower the risk of subsequent falls in patients with osteoporosis. Rehabilitation and exercise are recognized means to improve function, such as activities of daily living. Psychosocial factors also strongly affect functional ability of the patient with osteoporosis who has already suffered fractures.

Recommendations from the *Health Professional's Guide to Rehabilitation of the Patient with Osteoporosis* [14]:

- Evaluate and consider the patient's physical and functional safety as well as psychological and social status, medical status, nutritional status, and medication use before pre-Sl,nbing a rehabilitation program.
- Evaluate the patient and her/his current medication use and consider possible interactions and risk for altered mental status. Intervene as appropriate.
- Provide training for the performance of safe movement and safe activities of daily living, including posture, transfers, lifting, and ambulation in populations with or at high risk for osteoporosis. Intervene as appropriate, e.g., with prescription for assistive device for improved balance with mobility.
- Implement steps to correct underlying deficits whenever possible, i.e., improve posture and balance and strengthen quadriceps muscles to allow a person to rise unassisted

from a charr; promote use of assistive devices to help with ambulation, balance, lifting, and reaching.
- Evaluate home environment for risk factors for falls and intervene as appropriate.
- Based on the initial condition of the patient, provide a complete exercise recommendation that includes weight-bearing aerobic activities for the skeleton, postural training, progressive resistance training for muscle and bone strengthening, stretching for tight soft tissues and joints, and balance training.
- Advise patients to avoid forward bending and exercising with trunk in flexion, especially in combination with twisting.
- As long as principles of safe movement are followed, walking and daily activities, such as housework and gardening, are practical ways to contnbute to maintenance of fitness and bone mass. Additionally, progressive resistance training and increased loading exercises, within the parameter of the person's current health status, are beneficial for muscle and bone strength. Proper exercise may improve physical performance/function, bone mass, muscle strength, and balance, as well as reduce the risk of falling.
- Avoid long-term immobilization and recommend partial bed rest (with periodic sitting and ambulating) only when required and for the shortest periods possible.
- In patients with acute vertebral fractures or chronic pain after multiple vertebral fractures, the use of trunk orthoses (e.g., back brace, corset, posture training support devices) may provide pain reliefby reducing the loads on the fracture sites and aligning the vertebra. However, long-term bracing may lead to muscle weakness and further de-conditioning. Effective pain management is a cornerstone in rehabilitation from vertebral fractures. Pain relief may be obtained by the use of a variety of physical, pharmacological, and behavioral techniques with the caveat that the benefit of pain relief should not be outweighed by the risk of side effects such as disorientation or sedation which may result in falls.
- Individuals with recent, painful vertebral fractures that fail conservative management may be candidates for interventions, such as kyphoplasty or vertebroplasty, when performed by experienced practitioners.

Conclusions and remaining questions

The Guide has focused on the prevention, diagnosis, and treatment of osteoporosis in postmenopausal women and men age 50 and older using the most common existing diagnostic and treatment methods available. Many additional issues urgently need epidemiologic, clinical, and economic research. For example:

- How can we better assess bone strength using noninvasive technologies and thus further refine or identify patients at high risk for fracture?
- Can we expand the WHO FRAXTM algorithm to incorporate information on lumbar spine BMD and to consider multiple fractures and recency of fractures in quantitative risk assessment.
- Can we develop a fracture risk calculator for patients who have aheady initiated pharmacologic therapy.
- How can children, adolescents, and young adults maximize peak bone mass'!
- What are the precise components (type, intensity, duration, frequency) of an effective exercise program for osteoporosis prevention and treatment?
- What should be done to identify and modify risk factors for falling, and what would be the magnitude of effect on fracture risk in a population?
- How effective are different FDA-approved treatments in preventing fractures in patients with moderately low bone mass? Do benefits exceed risks?
- What approaches are most effective in treating osteoporosis in disabled populations?
- How can we make the diagnosis of vertebral fractures more accurate and consistent, particularly mild fractures?
- How long should antiresorptive therapies be continued, and are there long-term side effects as yet unknown? Are combination therapies useful and, if so, which drug combinations are best and when should they be used?
- Can we identify agents or medications that will return bone mass and bone structure to normal even in those starting with severe osteoporosis?
- Should we treat patients to a certain goal and then reconsider type and/or dose of therapy? If so, what should that goal be?
- How should therapeutic agents be sequentially prescribed in order to maximize benefits and minimize risks over the lifespan of the patient'!

NOF is committed to continuing the effort to answer these and other que tions related to this debilitating disease, with the goal of eliminating osteoporosis as a threat to the health of present and future generations. For additional resources on osteoporosis and bone health, visit www.noforg.

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Conflicts of interest None.

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The Clinician's Guide to Prevention and Treatment of Osteoporosis 2014 is endorsed by the following organizations: American Academy of Pain Medicine (AAPM), American Association of Clinical Endo(.,Tinologists (AACE), American Orthopaedic Association (AOA), American O teopathic Association (AOA), American Society for Hone and Mineral Research (ASBMR), and International Society for Clinical Densitometry (JSCD).

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Avoidable and Costly Secondary Osteoporotic Fractures

February 29, 2023

Andrea J. Singer, MD, FACP, CCD

Dr. Andrea Singer is Division Director of Women's Primary Care and is also the Director of the Bone Densitometry Program within the Department of Obstetrics and Gynecology at MedStar Georgetown University Medical Center. In addition, she serves as Chief Medical Officer for the Bone Health and Osteoporosis Foundation (BHOF). She is a national leader in primary care and women's health and has published and lectured extensively on such topics such as osteoporosis, the primary care of women, midlife women's health, obesity and weight management, female sexual dysfunction, fibromyalgia, regional pain syndromes, and depression in women. She is active in the education of both medical students and residents at Georgetown University Medical Center as well as in numerous regional and national continuing medical education programs. She is also an esteemed member of multiple medical advisory boards and consulting panels and is also a reviewer for several peer-reviewed journals.

Paul A. Anderson, M.D., M.S

Dr. Paul Anderson is a board-certified orthopaedic spine surgeon with special interest in spine trauma, tumors, cervical spine, and geriatric spinal diseases. He is an internationally recognized expert in the field of orthopaedic spinal surgery and currently holds academic positions as Professor of Orthopedic Surgery and Adjunct Professor in Neurological Surgery and Biomedical Engineering at the University of Wisconsin. Dr. Anderson has served as President of the Cervical Spine Research Society and President of the Lumbar Spine Research Society and has held various positions in a number of spinal and orthopaedic societies. He has served as a member as well as Chairman of the AAOS Biomedical Engineering Committee, Co-Chair of ASTM 04.25, and Clinical Chair of ASTM F04.

Most recently, Dr. Anderson chaired the “Own the Bone” Steering Committee of the American Orthopaedic Association which aims to educate medical practitioners and patients on the importance of bone health and promote fracture liaison services.

Broad Set of Stakeholders Urge CMS Adoption of Reimbursement Codes for a Post-Fracture Episode of Care Delivered within a Fracture Liaison Service

- **American Academy of Nurse Practitioners (AANP)**
- **American Association of Hip and Knee Surgeons (AAHKS)**
- **American Association of Orthopaedic Surgeons (AAOS)**
- **American Academy of Physician Assistants (AAPA)**
- **American Bone Health (ABH)**
- **American Geriatric Society (AGS)**
- **American Orthopaedic Association (AOA)**
- **American Society for Bone and Mineral Research (ASBMR)**
- **American Society of Endocrine Physician Assistants (ASEPA)**
- **Bone Health and Osteoporosis Foundation (BHOF) (previously known as the National Osteoporosis Foundation (NOF)**
- **Fragility Fractures Alliance (FFxA)** – American Academy of Orthopaedic Surgeons (AAOS), American Orthopaedic Association (AOA) & AOA Own the Bone, Orthopaedic Trauma Association (OTA), National Association of Orthopaedic Nurses (NAON), American Geriatrics Society (AGS), International Geriatric Fracture Society (IGFS), American Board of Orthopaedic Surgeons, U.S. Bone and Joint Initiative (UBJI)
- **International Society for Clinical Densitometry (ISCD)**
- **National Spine Health Institute (NSHI)**
- **North American Spine Society (NASS)**
- **Orthopaedic Trauma Association (OTA)**
- **The Endocrine Society (TES)**
- **US Bone and Joint Initiative (USBJI)**

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AGENDA

- Introductions
- Osteoporotic fracture care gap – significant, costly problem driving inequities in women and underserved populations, and compromising care
- Stakeholder consensus - Fracture Liaison Services
- Cross-walk model(s) to value evidence-based secondary prevention

ASBMR®
The American Society for Bone and Mineral Research

In 2016

1.8 Million

Medicare Beneficiaries

Suffered approximately

2.1 Million

Osteoporotic

Fractures

Milliman Report – 2021 Update (2016 claims data):

- 30% of hip fracture patients died within 12 months of fracture
- 19% of patients with any osteoporotic fracture died within 12 months
- 41,900 Medicare FFS beneficiaries with osteoporotic fractures became institutionalized in nursing homes within three years of a new fracture.
- Osteoporotic fracture patients have 3x the annual rate of new fractures within a year, compared to the overall Medicare FFS population.

The **predominately-female** osteoporotic fracture population routinely **fails to receive standard of care** and suffers compromised outcomes

	Patient pop.	Events/Year	1-year post-event risk	1-year post-event mortality	Diagnostics performed?	Treatment plan and follow-up
Osteoporotic Fractures	70.5% of patients are female	2.1 M osteoporotic fractures 300K hip fractures (Milliman, 2021 update)	14 % of patients have a risk of a subsequent fracture within 1 year of hip fracture	19% die within 12 months after any osteoporotic fracture 30% of hip fracture patients die within 12 months	9% of patients receive a bone mineral density test w/in 6 months	Approximately 20% of ***hip fracture*** patients (two studies with slightly different numbers) receive medication. Significant proportion of patients stop taking prescribed meds.
Acute Myocardial Infarction (AMI)	Approx. 70% of patients are male	805,000 AMIs (2020) (605K new; 200K recurrent) (AHA 2020)	9.2% of patients have a risk of subsequent AMI hospitalization within 1 year of their initial AMI	5-10% AMI patients surviving acute episode die w/in first year	Monitoring and assessment are performed to devise treatment plan for all/nearly all patients.	96% of patients receive medication (beta blockers) post AMI. Quality measures and evaluation drive quality care for patients.

High Relative Impact of Osteoporosis on Medicare Beneficiaries

New Cases and Deaths per 100,000 in Medicare

	New Cases	Deaths
Breast Cancer (women)	406	148
Lung Cancer (men and women)	389	311
Prostate Cancer (men)	786	216
Colorectal Cancer (men and women)	246	107
Hip Fractures (women 65+ only)	**776**	169

Based on SEER data from seer.cancer.gov/statfacts/html/breast.html. Cancer incidence and mortality rates may be overstated, as they may included cases outside Medicare FFS patients aged 65 and over.

Significant Disparities and Inequities Exist in Post-Fracture Care and Outcomes

While suffering fewer osteoporotic fractures, Black Medicare FFS beneficiaries have higher hospitalization rates, higher death rates following fractures, and lower bone mineral density (BMD) screening rates.

- ***22% died within 12 months*** of an initial osteoporotic fracture, exceeding the national average rate of 19%.
- ***35.4% died within 2-3 years*** post-fracture, which is ~10% higher than national average
- ***Just 5% were tested*** within six months of a new osteoporotic fracture – when the need for treatment and action is highest.
- ***30% less likely*** to receive post-fracture physical therapy
- ***2.3 times higher risk of destitutio***n in the year following vertebral fracture. *

*J Am Geriatr Soc. 2020 Apr 26. doi: 10.1111/jgs.16455.

Number of Osteoporotic Fractures Likely to INCREASE by 68% by 2040 with Associated Cost Exceeding 95 Billion*

Milliman Report – 2021 Update (2016 claims data):

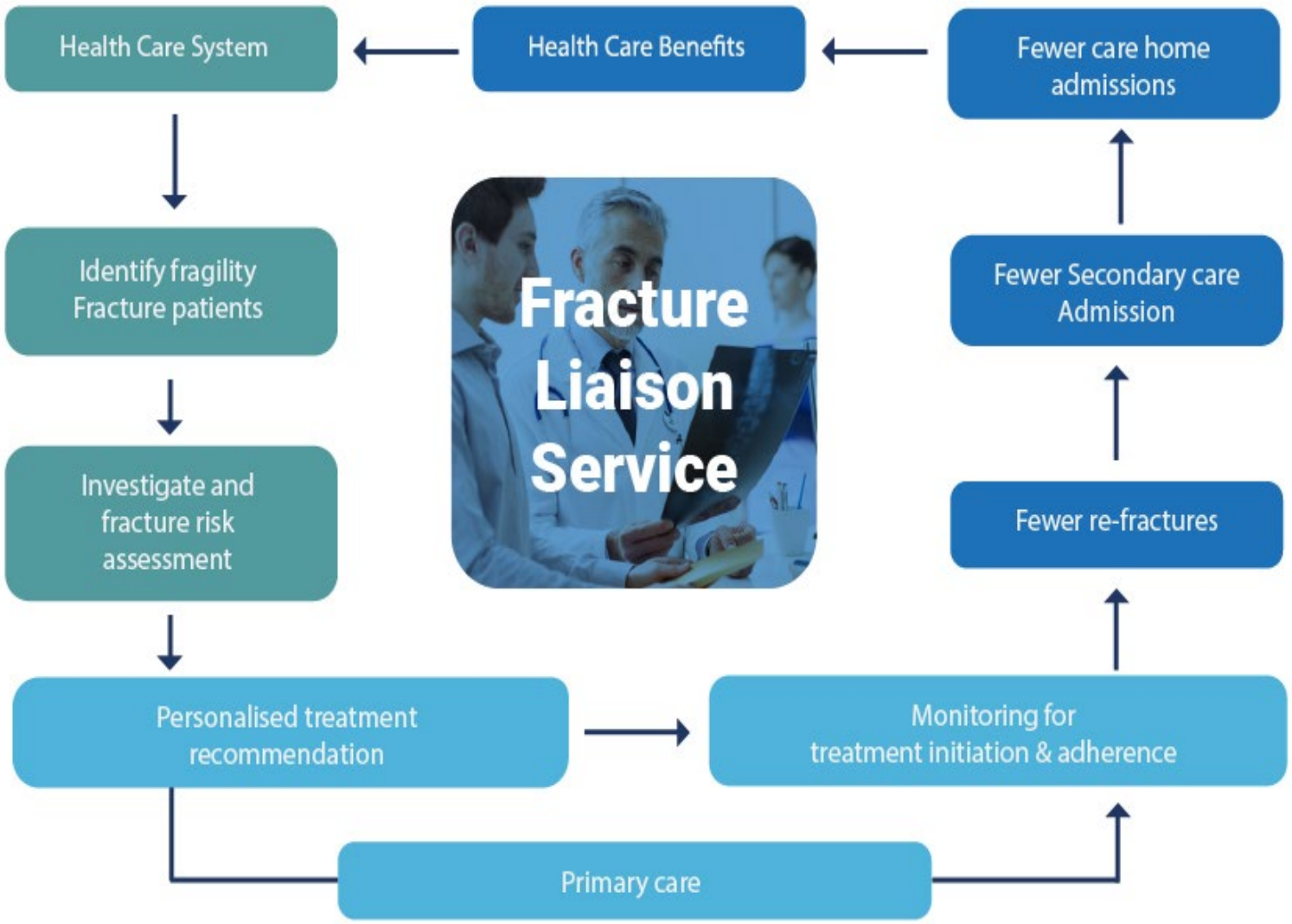
- $21,564 incremental cost for EACH osteoporotic fracture
- For secondary osteoporotic fractures, cost exceeds $30,000
- Secondary osteoporotic fractures cost $5.7 billion in 2016 among 290,000 Medicare FFS beneficiaries

- ***Actual total costs are significantly higher as these estimates do not include costs related to the loss of productivity, absenteeism, non-skilled home and nursing home care, or prescription drugs.***

*Lewiecki, et al. 2019.

Fracture Liaison Services are a proven intervention to close care gap, a well-established model internationally, and supported by decades of evidence

- Coordinated care systems headed by a coordinator (a physician, nurse practitioner, physician assistant, or other health professional).
- Delivers patient-centered secondary prevention of osteoporotic fractures.
- Utilizes established protocols to ensure that osteoporotic fracture patients receive appropriate diagnosis, evaluation, secondary prevention, treatment, and support.
- Patient assessment and follow-up care are generally prompted through a database-driven patient-specific timeline.
- Can be adapted to a centralized care delivery model, incorporate telemedicine and operate as a "hub and spoke" care coordination and delivery system, or incorporate aspects of various care delivery models.



FLS is not a new intervention for Medicare to “test.” It is an internationally-recognized coordinated care intervention grounded in decades of strong evidentiary support.

A 2018 meta-analysis of FLS impact identified a total of 159 publications , including 74 controlled studies (16 RCTs; 58 observational studies). (Wu C-H, Tu S-T, Chang Y-F, et al.)

Compared with patients receiving usual care (or those in the control arm), patients receiving care from an FLS program had:

- Less than half the rates of subsequent fracture (13.4% among patients in the control arm and 6.4% in the FLS arm)
- Lower mortality (15.8% in the control arm and 10.4% in the FLS arm.
- Higher rates of BMD testing (48.0% vs 23.5%)
- Higher rates of treatment initiation (38.0% vs 17.2%)
- Greater adherence (57.0% vs 34.1%).

US FLS Programs Have Successfully Closed Osteoporosis Care Gap, Reduced Fractures and Lowered Costs

"Closed" systems adopting FLS demonstrate improved outcomes and cost savings

GEISINGER: Prescription treatment rates in FLS were 75.4% among drug-eligible patients, compared to only 13.8% of patients in primary care. Between 2006 and 2010, the percentage of women 65+ who had a BMD test within the prior three years increased from 40% to 74%. Achieved **$7.8 million in cost savings from 1996-2000**

KAISER: Healthy Bones program **reduced the hip fracture rate expected by over 40%** (since 1998) If implemented nationally, Kaiser estimates a similar effort could **reduce the number of hip fractures by over 100,000 (and save over $5 billion/year)**

AOA: Own the Bone program at over 190 sites led to high rates of BMD testing and osteoporosis pharmacotherapy in patients aged 50 and older following an osteoporotic fracture, with **over 60% of patients treated for osteoporosis** after an osteoporotic fracture in 2015.

Reducing Secondary Osteoporotic Fractures by Just 20% Could Save Medicare $1.2 Billion (Milliman)

Effective post-fracture secondary prevention requires a specific knowledge base and protocol-driven patient identification and follow-up.

As with primary prevention, there is a systemic disconnect on which provider and/or specialty is “responsible” for osteoporosis diagnosis and treatment. FLS addresses post-fracture “Bermuda Triangle.”

Orthopedic specialists encountering fracture focus on acute episode

- Follow-up focuses on recovery from fracture (and that is what they are paid to do).
- Most FLS w/in orthopedics are practice-within-a-practice.
- Global periods, etc., deter orthopedic surgeon follow-up on osteoporosis

MIPS quality measures have not been effective in encouraging post-fracture osteoporosis follow-up.

- Referral to primary care in MIPS measure does not improve real-world care.
- Claims-driven quality measures reduce provider burden and are more reliable.

FLS requires an infrastructure to identify osteoporotic fracture patients, and ensure follow-up to an effective treatment plan. Health systems resist start-up because FLS are not viewed as self-sustaining.

Existing Codes Do Not Adequately Describe the Patients or the Encounters in FLS

Current Codes like Principal Care Management or Chronic Care Coordination do Not Sufficiently Describe and Capture the work for FLS coordination

- HCPCS codes 99437, 99490, 99494 require management of multiple chronic conditions which may not apply for FLS patients
- HCPCS codes 99224 and 99225 do not accurately capture the patient encounters and care coordination within FLS. This crosswalk slightly underestimates the intensity and complexity provided in the FLS. However, it does model the total time of the episode fairly well.
- HCPCS code 99227 can only be billed twice, which represents significantly less clinical staff time than was found to be typical for FLS services

Specific codes for FLS services allow for more efficient and accurate coding and reimbursement

- Use of current codes *would require physicians to bill multiple times* and will *increase administrative complexity, denials and appeals*
- Use of current codes could lead to *under-coding because of overlapping global periods*
- New codes would allow accurate tracking of utilization of FLS services and increase certainty that FLS programs can be self-sustaining.
- Increased adoption of FLS is best way to ensure that fracture patients receive standard of care to prevent potentially catastrophic subsequent fracture.

Our proposal will lead to Increased adoption of FLS, ensuring our health systems are equipped with infrastructure to respond to increasing osteoporotic fractures due to aging population.

Proposed Coding and Reimbursement

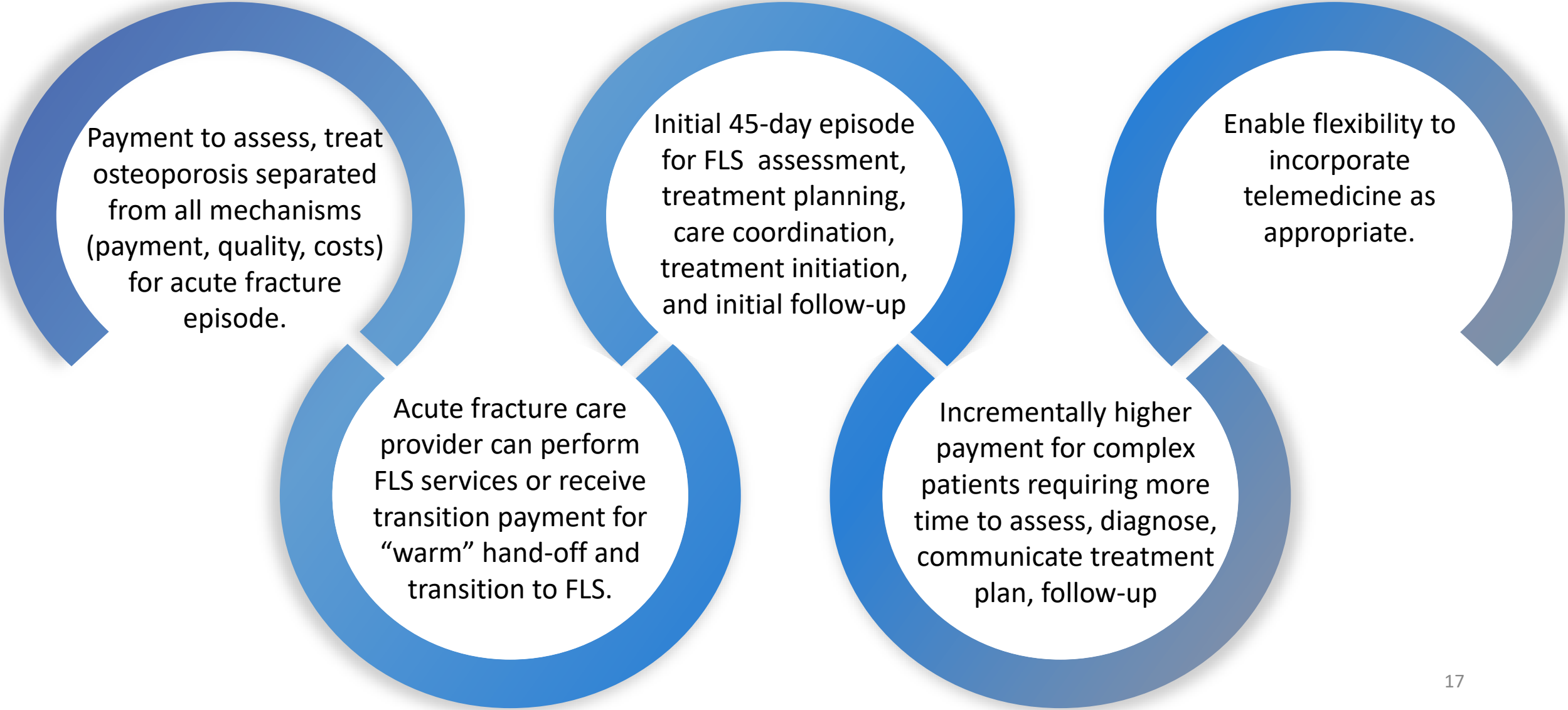
Two separate Medicare G-Codes to describe the 45-day episode of care from the initial patient encounter and capture all clinical work.

CMS-identified coding for “warm hand-off” from acute care provider if different from FLS provider

Our model proposes separate codes based on the patient complexity and increased clinician time.

Medicare currently has a similar episode-based bundle for treatment planning and management in substance use disorder patients.

Broad Set of Stakeholders Urge CMS to Adopt Reimbursement Codes for a Post-Fracture FLS Episode of Care



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Preventing Avoidable and Costly Secondary Osteoporotic Fractures

Backup/Reference Slides

Despite its Utility in Improving Care and Reducing Costs, Providers Face Challenges in Implementing and Sustaining a Viable FLS

- In FFS, payment mechanisms tend to disincentivize all ‘extra’ care not directly related to the fracture;
- The FLS “savings” accrues to payers, not providers, making it difficult for providers to justify the added expense of FLS, e.g., infrastructure set-up, patient identification, acquiring and reviewing records.
- Quality/cost metrics do not capture a sufficient time period to demonstrate real-world savings.
- Patients recovering from hip fracture in SNF’s are often delayed in receiving osteoporotic care as the SNF is unlikely to transport patients for visits or include osteoporosis medications that are not separately reimbursed.
- Primary care providers are a needed partner to FLS but can present a hindrance if he or she does not understand the FLS, dismisses osteoporosis as simply a consequence of old age, or sees an osteoporotic fracture as simply an unavoidable result of a fall.
- Identifying osteoporotic fracture patients for FLS follow-up care can be a challenge that is resource-intensive without a clear and near-reflexive referral mechanism from the specialist responsible for acute fracture repair to the FLS.
- For older patients with recent fractures, the fact of multiple care settings, including skilled nursing facilities, rehabilitation hospitals, memory care facilities, etc., for post-fracture care presents an additional layer of complication.
- Prior authorization for osteoporosis medications can absorb hours of office staff and clinician time each day.

A Survey of health professionals reiterated our findings of significant barriers in initiating/maintaining a viable FLS program

BHOF and AOA distributed a survey to approximately 2k healthcare professionals who have expressed interest in FLS

- 308 survey responses were received in November/December 2021/
- 172 respondents said they have an active FLS or have one in progress
- Respondents = wide range of healthcare institutions, including Academic Medical Centers, Community Hospitals, Group/Private Practice, Acute Care, Rehab Hospital, and 340B Covered

Existing and in-process FLS programs expressed significant frustration in maintaining programs

- Getting referrals to the FLS program
- Costs for maintaining or hiring FLS coordinators
- Billing issues/prior authorization issues
- Coding issues
- Lack of Medicare policies with incentives/disincentives to promote FLS program

Respondents who did not have an FLS highlighted several reasons why

- Need for buy-in from hospital administration
- Cost for personnel and administration
- Inter-departmental support
- Lack of awareness about post-fracture care needs

Delivering the Post-Fracture Standard of Care Would Result In Substantial Medicare Savings

- The gap in care following an osteoporotic fracture has been described as the “Bermuda Triangle of Osteoporosis Care” made up of orthopedists, primary care physicians and osteoporosis experts into which the fracture patient disappears.
- Both HEDIS and Medicare Part C STAR Ratings include a measure to rate quality of osteoporosis care: “Osteoporosis Management in Women Who Had a Fracture.”
  - The average 2020 Medicare STAR rating for this measure was 3.5/5 stars, indicating that 52% of **women** ages 67 to 85 did not receive a BMD test or prescription for a drug to treat osteoporosis ***within 6 months of a fracture***.
- **Only 23% of patients receive osteoporosis medication after an osteoporotic hip fracture, compared to 96% percent of patients receiving beta blockers after a myocardial infarction**

The real-world experience of Medicare’s osteoporotic fracture patients falls far short of the standard of care and fails to deliver secondary fracture prevention services that would save both lives and money.

Part II

Medicare codes and payments should recognize evidence-based post-fracture care management and coordination to reduce future fracture risk

Data Collection Informed Our Proposed Reimbursement for FLS Specific Codes

Detailed set of questions was provided to interviewees and interviewers walked through each question and response and recorded interviewee time and resource estimates and descriptions

7 programs were from different regions of the United States and included programs within Academic Medical Centers, Integrated Health Systems, and Private Practices.

- Median program annual volume was approximately 850 new patients a year
- Median number of Physician/QHP providers in practice was 2
- Median years of program experience/age was 8

Methodology/ Background

Using the median times from our survey interviews, we created crosswalk models for the underlying Work, Practice Expense (PE) and Malpractice Relative Value Units (RVU) for G20XX1 and G20XX2 to create a reimbursement range

- We multiplied our estimated RVUs by the Medicare Physician Fee Schedule Conversion Factor as published in the 2022 Medicare Physician Fee Schedule Final Rule on November 2, 2021
- Work RVUs represent the RVUs for the time/resources of the Physician/QHP
  - Combines the face-to-face and non-face-to-face time/resources of the Physician/QHP
- PE RVUs represent the RVU for the time/resources of the clinical/administrative staff

We chose comparable HCPCS codes from the Medicare Physician Fee Schedule with similar descriptions of work and similar times to what our interview surveys estimated as their median times for Fracture Liaison Services

- Principal Care codes crosswalk model
- Transitional Care Management/Chronic Care Coordination Codes crosswalk model

Key Findings

Physician/QHP time

- prior to initial encounter (non-face-to-face): 20 minutes
- initial face-to-face encounter: 53 minutes (either in person or via telehealth)
- 45-day-period-subsequent-to-initial-encounter period (non-face-to-face): 96 minutes
- subsequent face-to-face encounter (when performed): 26 minutes

60% of patients required at least one additional direct (face-to-face) encounter subsequent to the initial encounter within the 45-day period after initial encounter.

- The time for this encounter was incorporated into payment level for both complex and non-complex patients.

Clinical/Admin time

- prior to and on the day of initial encounter (non-face-to-face): 20 minutes
- 45-day-period-subsequent-to-initial-encounter period (non-face-to-face): 145 minutes
- subsequent encounter (when performed) (non-face-to-face): 30 minutes

Proposed Reimbursement Based on Cross-Walk Methodology

Code	Descriptor	Range (Assumes a Medicare conversion factor equal to the final 2022 Medicare Conversion Factor of 34.606 as published in the amended 2022 Medicare Physician Fee Schedule Final Rule on December 21, 2021)
G20XX1	Initial 45-day period, patient (initial encounter only)	$413.54
G20XX2	Initial 45-day period, complex patient (requiring additional face-to-face encounter time day of and/or subsequent encounters)	$505.69

Proposed Code Descriptors Outline Required Services

- **G20XX1:** *Fracture Liaison Services for **45-day period** in a patient with a known or suspected fragility fracture **within the previous 6 months**, including patient identification and intake activities, **initial direct patient encounter between 45-60 minutes** that includes **medical examination** with **physical evaluation** when appropriate and **initial assessment** conducted by a program physician or qualified health care professional that includes a **medically appropriate evaluation** and **patient history**, review of medical history, **assessment planning**, **patient education**, shared decision making in **creation of treatment plan** and follow up that incorporate patient's short-term goals and tasks that must be performed to attain short-term goals for avoiding and reducing fractures. Includes, as appropriate, **assessment of height/weight, balance, gait and fall risk assessment** , **fracture risk assessment**, **fall risk assessment** and plan, shared decision making and development of pharmacological plan including updating current drugs and prescriptions and follow-up, **non-face-to-face physician/QHP and clinical staff services** in the 45-days after the initial encounter that includes appropriate coordination and **communication with patient primary care** provider, **coordination with patient's relevant specialists** (including orthopaedic surgeon, geriatrician, physical rehabilitation, hematologist, oncologists, endocrinologist, psychiatrist, etc.), and **coordination and communication with ancillary providers** (including physical therapy, occupational therapy, speech therapy), ordering and reviewing of imaging studies and laboratory tests as necessary to diagnosis osteoporosis or other condition contributing to bone fragility, updating medical records, patient referrals, review of medical records, data registry entry and review, ongoing program evaluation, caregiver education and coordination, patient education, coordination, and communication via email/portal/text messaging, and direction supervision and oversight of clinical and administrative staff work for each patient.*

- **G20XX2:** *Fracture Liaison Services for 45-day period in a **complex patient** with multiple co-morbidities along with a known or suspected fragility fracture within the previous 6 months, including patient identification and intake activities, either an initial direct patient encounter **greater than 75 minutes** and/or follow-up direct patient encounters . . .*

Discussion of Crosswalk Codes for G20XX1- Non-complex Patient

We looked for applicable codes to use to crosswalk and build our RVU and reimbursement models.

We started with the assumption that most of the provider and clinical staff/admin staff work would be similar to that described by CPT/HCPCS codes for cognitive services like evaluation and management codes.

The services provided in Fracture Liaison Service programs are similar to services like the CMS Opioid Use Disorder bundle, Transitional Care Management, Chronic Care Management, Complex Chronic Care Management, and Principal Care Management.

There are dozens of CPT/HCPCS codes in this family of services, and we sought to create our models based on similarity of service(s) and the times assigned to the services in the Medicare Physician Fee Schedule to match the times reported in our interviews for both face-to-face and non-face-to-face provider and clinical/administrative staff work in the 45-day episode.

Crosswalk Codes for G20XX1- Non-complex Patient

Transitional Care Management/Chronic Care Coordination Codes crosswalk model:

- HCPCS code 99495 work RVU + HCPCS code 99491 work RVU+ HCPCS code 99437 work RVU (x2); 2.78 + 1.50 + 2.00= 6.28
- HCPCS code 99495 PE RVU + HCPCS code 99490 PE RVU + HCPCS code 99439 PE RVU (x2); = 3.01 + 0.78 + 1.30 = 3.48
- HCPCS code 99495 malpractice RVU + HCPCS code 99491 malpractice RVU+ HCPCS code 99437 malpractice RVU (x4); 0.19+ 0.07 + 0.32= 0.58

Total RVUs: 11.95 (6.28 work RVU +5.09 PE RVU +0.58 Malpractice RVU)

Crosswalk Codes for G20XX2- Complex Patient (single initial encounter + subsequent encounter(s))

- **Total RVUs: 14.61**
  - **adds an additional 2.49 total RVU with a crosswalk to HCPCS code 99213**

Discussion of Crosswalk Codes for Physician/QHP work for G20XX1

- The Transitional Care codes and Chronic Care Coordination codes were established in 2017 and updated in 2019. These two sets of codes combine the direct patient encounter care surrounding a patient transitioning from inpatient care to outpatient clinic, along with the non-face-to-face care for coordination surrounding a patient with chronic conditions that require significant care plan management and monitoring. By combining the face-to-face encounter with the non-face-to-face care coordination these codes capture the services involved in the 45-day Fracture Liaison Service care model fully.
  - These four new codes are HCPCS 99495, HCPCS 99491, HCPCS 99437
    - 99495 has 54 minutes of physician/qhp time for a direct encounter which matches the initial face-to-face encounter estimated of 53-minutes from our provider surveys.
    - 99495 also requires a face-to-face patient encounter similar to the FLS patient encounters
    - 99491 and 99437 both describe non-face-to-face work by a physician/qhp
    - We used the initial 30 minutes of time described in 99491 and then added an additional four 30-minutes increments to get close to the 154 minutes time estimated for non-face-to-face fracture care liaison services by a physician or qhp.

Discussion of Crosswalk Codes for Physician/QHP and Clinical Staff work for G20XX1 continued

- A separate code set that was created for CPT 2022 also has similarities to G20XX1.
  - This set of four new codes was created for CPT 2022 and incorporated into the 2022 Medicare Physician Fee Schedule describing provider and clinical staff work done in principal care management.
  - These four new codes are HCPCS 99224-Physician/QHP Primary Initial Encounter, HCPCS 99225-Physician QHP Additional time, HCPCS 99226-Clinical/Admin Staff Initial time, HCPCS 99227-Clinical/Admin Staff Additional time
  - HCPCS codes 99224 and 99225 do not specify in-person patient encounters are required, whereas the initial assessment visit in the Fracture Liaison Services model would be face-to-face and thus this crosswalk slightly underestimates the intensity and complexity provided in the Fracture Liaison model. However, it does model the total time of the episode fairly well.
  - In addition, HCPCS code 99227 can only be billed twice, which represents significantly less clinical staff time than was found to be typical for FLS services

Discussion of Crosswalk Codes for Clinical/Admin staff work for G20XX1

- To model the clinical staff time estimated by our survey of FLS programs, we used the practice expense for the transitional care management code 99495 to capture 100 minutes of clinical staff time and added 99490, *Chronic care management services with the following required elements: multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, comprehensive care plan established, implemented, revised, or monitored; first 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month plus* and 99239 (x2) *Chronic care management services with the following required elements: multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, comprehensive care plan established, implemented, revised, or monitored; each additional 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month (List separately in addition to code for primary procedure)* to account for an additional 60 minutes of clinical staff time non-to-face.

- This combines to closely match the total clinical staff time from our program survey.

Discussion of Crosswalk Codes for Physician/QHP and Clinical/Admin staff work for G20XX2-Complex Patient

- For the complex patient code, we have used the two base models used for the straightforward patient and added the total RVU value for HCPCS code 99213, *Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and low level of medical decision making.*

- By looking at the time that our surveys estimated is spent in a face-to-face subsequent patient encounter it is a straight crosswalk for the direct face-to-face encounter with 99213 describing 20-29 minutes of a direct patient encounter which our median survey result falls into.

- HCPCS code 99213 has a total RVU of 2.66 (work RVU=1.30; PE RVU=1.26; malpractice RVU=.10) which can be added onto the RVUs in both models for the straightforward patient and creates the proposed range for G20XX2.

Principal Care codes crosswalk model:

Crosswalk Codes for G20XX1- Non-complex Patient

- HCPCS code 99424 work RVU+ HCPCS 99245 work RVU (x4); 1.45 + 4.00= 5.45
- HCPCS code 99426 PE RVU+ HCPCS 99427 PE RVU (x4); 0.75 + 2.56= 3.31
- HCPCS code 99424 malpractice RVU+ HCPCS 99245 work RVU (x4); 0.10 + 0.32= 0.42

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Submitted electronically

June 10, 2024

Chiquita Brooks-LaSure, Administrator
Centers for Medicare & Medicaid Services Department of Health and Human Services
7500 Security Blvd
Baltimore, MD 21244

RE: CMS–1808–P
Medicare and Medicaid Programs and the Children's Health Insurance Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long- Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2025 Rates; Quality Programs Requirements; and Other Policy Changes

Dear Administrator Brooks-LaSure:

The Bone Health and Osteoporosis Foundation (BHOF) appreciates the opportunity to submit comments on the above-referenced proposed rule updating and refining payment policies under the Hospital Prospective Payment System (IPPS proposed rule). We have, for the past several years, submitted comments to the Physician Fee Schedule proposed rules asking that the Centers for Medicare & Medicaid Services (CMS) recognize, prioritize, and address the significant care gap in secondary prevention of osteoporotic fractures by implementing mechanisms to facilitate a widely adopted care coordination model known as Fracture Liaison Services (FLS).

The BHOF is the nation's leading resource for patients, health care professionals and organizations seeking up-to-date, medically sound information and program materials on the causes, prevention, and treatment of osteoporosis. Established in 1984 as America's only voluntary, nonprofit health organization dedicated to reducing the widespread prevalence of osteoporosis, the foundation has grown to include a network of diverse stakeholders that support its goals to increase public awareness and knowledge, educate physicians and health care professionals, and support research activities concerning osteoporosis and bone health related areas.

Our comments to this IPPS proposed rule focus on CMS' proposal to address high costs associated with hip and vertebral fractures through a Transforming Episode Accountability Model (TEAM) initiative. As further detailed below, BHOF is disappointed that CMS intends to

focus on these presumptive osteoporotic fractures through the narrow lens of an acute episode rather than as sentinel events indicative of a treatable chronic condition (osteoporosis) that dramatically increases the risk of subsequent, preventable fractures. We fear that the model will work as intended – to shape the care this predominantly female population receives in the wake of an osteoporotic fracture – and that any episode-based savings within the TEAM initiative will be outpaced by the lost opportunity to avoid the cost of subsequent, preventable fractures suffered by beneficiaries.

Our comments provide:

- Background on the care gap in osteoporotic fracture prevention, its costs in terms of Medicare spending and beneficiary lives, and the significant savings that might accrue if Medicare implemented effective secondary fracture prevention strategies.

- A discussion of the historic failure to resolve the osteoporosis care gap through reliance on post-fracture referral to primary care practitioners and an overview of the FLS coordinated care model, its implementation in the U.S. and throughout the world, and the likely roadblocks to use of this proven model if TEAM is implemented as proposed.

- An outline of our interactions with CMS over the past several years, including the consensus-based proposal to improve health outcomes and reduce costs associated with osteoporotic fractures.

- Recommendations on refinements to the TEAM proposal that align its contours and goals with quality care for beneficiaries suffering an osteoporotic fracture of the hip or vertebrae, including:

    - Recognizing the deficit in osteoporotic fracture follow-up experienced by Medicare beneficiaries.
    - Designating an alternative pathway that facilitates evidence-based FLS secondary fracture prevention care.
    - Creating a separate "specialty code" for FLS practices so that CMS and its claims processing contractors recognize these services (and practitioners) as a preferred care pathway for post-fracture follow-up.
    - Ensuring that FLS practices are appropriately reimbursed for their services and that acute care practitioners and providers are incentivized, or at a minimum not disincentivized, for FLS referrals.

Given the significant deficiencies U.S. patients experience in both primary and secondary osteoporotic fracture prevention services, it is not surprising that hip fracture and vertebral fractures were identified as drivers of high costs to the Medicare program and selected for inclusion in the TEAM initiative. Unfortunately, CMS is focusing on the wrong "problem" and devising a solution that could all but halt the efforts BHOF and other bone health stakeholders have prioritized to reduce **both** the costs and suffering associated with fractures through

effective delivery of secondary fracture prevention services.

I. BACKGROUND

Despite availability of screening, diagnostic, and treatment tools, most Medicare beneficiaries with osteoporosis fail to receive care that might prevent osteoporotic fractures.

The National Institutes of Health (NIH) defines osteoporosis as "a bone disease that develops when bone mineral density and bone mass decrease, or when the quality or structure of bone changes. This can lead to a decrease in bone strength that can increase the risk of fractures (broken bones)"[1] Osteoporosis is the major cause of fractures in postmenopausal women and in older men, with fractures most frequently occurring in bones of the hip, vertebrae in the spine, and the wrist. These fractures occur without high-impact or high-trauma events, and often result from a fall from standing height. An estimated 10 million Americans have osteoporosis; an additional 44 million Americans have low bone density that places them at increased risk of a fracture.[2]

Unlike many other debilitating conditions, outcomes in osteoporosis can be significantly improved without substantial investment in research, new breakthrough therapies, or new legislative and/or regulatory provisions. Therapeutic and lifestyle modification interventions, including prescription medications, can change disease trajectory and significantly reduce the risk of osteoporotic fracture. Unfortunately, under-utilization of DXA as a primary prevention tool means that for many patients, the first sign of osteoporosis is a fragility fracture. Even then, only 23% of women aged 67 or older who have an osteoporotic fracture receive medication to treat osteoporosis in the 6 months after the fracture.[3] Most patients remain undiagnosed and unaware of both their increased risk of a future fracture and the availability of FDA-approved therapies to reduce that risk.

- Medicare beneficiaries suffered approximately 2.1 million osteoporotic fractures in 2016.[4]
- Analysis of 2016 claims data revealed that just 9% of female Medicare FFS beneficiaries were evaluated for osteoporosis with a bone mineral density (BMD) test within six months following a new osteoporotic fracture despite CMS' reinforcement of this standard of care through quality measures.[5]

[1] Osteoporosis Causes & Symptoms | NIAMS (nih.gov)
[2] Wright N.C., et al. (2014). The Recent Prevalence of Osteoporosis and Low Bone Mass in the United States Based on Bone Mineral Density at the Femoral Neck or Lumbar Spine. *Journal of Bone and Mineral Research, 29*(11), 2520-2526. DOI: 10.1002/jbmr.2269.
[3] Yusuf AA, et al**.,** Utilization of osteoporosis medication after a fragility fracture among elderly Medicare beneficiaries. *Arch Osteoporos.* 2016; 11: 31.
[4] Medicare cost of osteoporotic fractures: 2021 updated report (milliman.com)
[5] Id.

The statistics confirming the care gap in both primary and secondary osteoporotic fracture prevention reflect real world experience for Medicare beneficiaries when CMS directs post-fracture follow-up through "referral to primary care." It is the status quo that the TEAM initiative will likely cement despite its failure to curb the staggering cost of fragility fractures. Under this care delivery model, Medicare fee-for-service beneficiaries with an osteoporotic fracture disproportionately suffered poor health outcomes, including significantly increased mortality, subsequent fractures, hospitalization, and loss of the ability to live independently.

- The mortality rate for osteoporotic fracture patients is over three times that of the general Medicare FFS beneficiary population.

    - ***Those with a hip fracture have the highest mortality; 30% died within 12 months of the fracture.***[6]
    - Approximately 245,000 Medicare FFS beneficiaries (154,00 women and 91,000 men) or 19% of those with a new osteoporotic fracture died within 12 months.[7]

- 41,900 Medicare FFS beneficiaries with osteoporotic fractures became institutionalized in nursing homes within three years of a new fracture.

- Health system failures in delivering the standard of care in bone health disproportionately burden women. Female beneficiaries had 76% higher rates of new osteoporotic fracture than males, after adjusting for age and race.

- Osteoporotic fracture patients have three times the annual rate of new fractures within a year as compared to the overall Medicare FFS population.

- Over 4% (approximately 56,800 Medicare FFS beneficiaries) with an osteoporotic fracture became newly eligible for Medicaid within three years.[8]

These outcomes are neither anticipated by nor accounted for within the framework of TEAM and most will occur well after the 30-day TEAM episode has concluded.

The table below was presented to CMS staff and included in our comments to both the 2023 and 2024 PFS proposed rules. It delineates the real-world failures in secondary prevention of osteoporotic fractures. This care gap has persisted despite incremental efforts directing communication from the practitioner treating the fracture to the patient's primary care practitioner. Unfortunately, primary care physicians, even when informed of a fracture, may not see the patient in the near-term or inquire beyond the patient's recovery from the acute episode.

[6] Id.
[7] Id.
[8] Id.

Heart attack and fractures are both acute, sentinel events within a chronic underlying condition and both have established care pathways to mitigate the risk of future events and poor health outcomes. Although nearly all of the predominantly male heart attack patient population receives the standard of care, the same cannot be said about the primarily female osteoporotic fracture patient population. Failures in delivering the right care at the right time means that these patients remain at high risk of a future fracture. The TEAM initiative is more likely to widen than address this care gap as it focuses on the acute episode and cost-reduction in a chronic condition that has long been and remains under-diagnosed and under-treated.

	Events/Year	**1-year post-event risk**	**Diagnostics performed?**	**Treatment plan and follow-up**
Osteoporotic Fractures ***70.5% of patients are female***	2.1 M osteoporotic fractures 300K hip fractures (Milliman, 2021 update)	14 % of patients have a risk of a subsequent fracture within 1 year of hip fracture. 19% die within 1 year after any osteoporotic fracture 30% of hip fracture patients die within 1 year of their fracture	9% of patients receive a bone mineral density test w/in 6 months	Approximately 20% of ***hip fracture*** patients (two studies with slightly different numbers) receive medication.
Acute Myocardial Infarction (AMI) ***Approx. 70% of patients are male***	805,000 AMIs (2020) (605K new; 200K recurrent) (AHA 2020)	9.2% of patients have a risk of subsequent AMI hospitalization within 1 year of their initial AMI 5-10% AMI patients surviving acute episode die w/in first year	Monitoring and assessment are performed to devise treatment plan for all/nearly all patients.	96% of patients receive medication (beta blockers) post AMI. Quality measures and evaluation drive quality care for patients.

Medicare expenditures associated with preventable osteoporotic fractures are significant and could be reduced with greater focus on identifying and managing underlying osteoporosis.

Medicare sustains significant costs for both initial and subsequent osteoporotic fractures. A report by the actuarial firm, Milliman, found that the per patient, per month (PPPM) medical costs were over $2,000 per month between months 3 and 11 ($2,097 per month), nearly 20% greater than the average monthly allowed cost in the year prior to the new osteoporotic fracture event ($1,775 per month).[9] Beneficiaries with a subsequent fracture within the three-year "episode" incurred annual costs over $30,000 higher in the year following a new osteoporotic fracture compared to the year before the fracture.

- The total annual cost for osteoporotic fractures among Medicare beneficiaries was $57 billion in 2018.[10]

- Absent health system changes to detect, diagnose and treat the chronic, progressive disease of osteoporosis, annual costs of fragility fractures are expected to grow to over $95 billion in 2040).[11]

- Annual allowed medical costs to Medicare for beneficiaries in the 12-month period beginning with the new osteoporotic fracture were more than twice their costs in the year prior to their fracture, with incremental annual allowed medical costs for those with an osteoporotic fracture of $21,564 per beneficiary covered by both Medicare Parts A and B in 2016.[12]

- The incremental annual medical costs in the year following a new osteoporotic fracture increased 263% for skilled nursing facility (SNF) services compared to the year prior to the fracture, accounting for nearly 30% of the total incremental annual medical cost.
- Beneficiaries suffering a subsequent fracture within three years of an initial fracture accounted for an estimated $5.7 billion in Medicare FFS direct costs.

    - Actual total costs are significantly higher as these estimates do not include costs related to the loss of productivity, absenteeism, non-skilled home and nursing home care, or prescription drugs[13].

The Milliman report used its estimates on the costs of secondary fractures and assumptions informed by the literature on secondary fracture prevention to model the potential savings to Medicare from preventing a portion of subsequent fractures in the Medicare FFS population. Table 15 in the Milliman report provides a summary of the estimated national savings under

[9] Medicare cost of osteoporotic fractures: 2021 updated report (milliman.com)
[10] Lewiecki EM , et al. Hip fracture trends in the United States, 2002 to 2015**.** *Osteoporos Int.* 2018; 29: 717-722
[11] Id.
[12] Milliman, supra.
[13] Id.

three scenarios that use different percentages for the subsequent fractures that would be prevented and different percentages for additional BMD testing.

- Preventing between 5% and 20% of subsequent fractures among FFS beneficiaries with both Part A and Part B coupled with performing BMD tests on an additional 10% to 50% of patients with new osteoporotic fractures, could have saved between $250 million (95% CI: $243 million to $258 million) and $990 million (95% CI: $962 million to $1,021 million) during a new osteoporotic fracture follow-up period of up to three years.

- Extrapolating the estimated cost of Part A services associated with a subsequent fracture to beneficiaries covered only by Part A could have added between $23 million and $89 million in savings when preventing between 5% and 20% of subsequent fractures among beneficiaries covered only by Part A.

- Total Medicare savings under these scenarios is between $272 million and $1.1 billion for the Medicare FFS program.

Substantial inequities and disparities exist in fracture incidence, care, and deaths.

Although Black men and women are generally less likely to suffer from osteoporosis and sustain a fragility fracture, they are more likely to die from an osteoporotic fracture than their White counterparts. The Milliman report found that "fracture rates varied substantially by race/ethnicity," with North American Natives suffering fractures at a rate 20% higher than the national average. White beneficiaries had a fracture rate 6% higher than the national average. Black beneficiaries (50% lower), Asian beneficiaries (32% lower) and Hispanic beneficiaries (19% lower) had the lowest rates of new osteoporotic fractures.

Rates of subsequent fractures within 12 months following an initial osteoporotic fracture ranged from 11% of Black beneficiaries to 15% for White beneficiaries. Hispanic, Asian, and North American Native beneficiaries all suffered subsequent fractures within 12 months at the national average rate of 14%.

While suffering fewer initial fractures and subsequent fractures, Black Medicare FFS beneficiaries have higher hospitalization rates, higher death rates following fractures, and lower bone mineral density (BMD) screening rates. Black patients suffering an osteoporotic fracture in 2016 had worse outcomes, including higher mortality, and were less likely to receive any follow-up care to address their underlying bone fragility. Once again, this data reflects the real-world care Medicare beneficiaries receive when the CMS-directed post-fracture follow-up is a primary care referral.

- 45% were hospitalized within 7 days of the fracture, compared to a national average of 42%.

- 22% died within 12 months of an initial osteoporotic fracture, exceeding the national average rate of 19% and comparable rates for White (19%), Asian (16%), Hispanic (18%) and North American Native beneficiaries (18%).

- ***Just 5% were tested within six months of a new osteoporotic fracture – when the need for treatment and action is highest – versus 8% among all beneficiaries with a fracture.***

The Milliman report noted that other studies have reported racial disparities in fracture incidence and post-fracture outcomes and have echoed the findings of higher rates of mortality and debility following a fracture among Black individuals versus the population as a whole. The report also found divergence across subpopulations with respect to the types of osteoporotic fractures likely to present as a sentinel event of osteoporosis. Secondary prevention strategies that fail to cast a wide net with respect to identifying osteoporotic fractures will likely perpetuate, and may even widen, racial disparities in access to care and outcomes related to bone fragility.

”Fracture Liaison Services” (FLS) are an effective, evidence-based intervention for preventing secondary osteoporotic fractures. The TEAM initiative will threaten existing FLS programs and deter initiation of new ones.

It has become clear that encouraging communication from acute to primary care has not closed the care gap in secondary prevention of fragility fractures. Efforts to date have relied on primary care yet failed to ensure that bone fragility follow-up is performed and/or that osteoporosis treatment is prescribed. The TEAM initiative would penalize facilities for the added cost of performing even a cursory inquiry into osteoporosis or other underlying causes of bone fragility, despite acknowledgment among bone health experts that a hip fracture in an individual over age 50 is clearly indicative of osteoporosis warranting timely, aggressive treatment and ongoing disease management.

It is worth noting that the osteoporosis care gap is not unique to the US; the United Kingdom (UK) and European Union (EU) have become increasingly concerned about the rising incidence of osteoporotic fractures. This concern, however, has been accompanied by a recognition that focusing solely on the acute, sentinel event of a fracture and/or relying on primary care practitioners to assess and respond to fracture risk is not the solution. Systemic changes must be implemented to reduce the potential that preventable fractures associated with aging populations could exceed health care resources. A recent report from the International Osteoporosis Foundation entitled ‘Osteoporosis in Europe: A Compendium of Country-Specific Reports’ reveals that in several European countries the high burden of osteoporosis combined with suboptimal osteoporosis care, service provision, and treatment uptake mirrors that of the US health care system. A June 2022 review article outlines osteoporosis care gaps and FLS

program adoption efforts throughout Europe.[14] It notes the utility of FLS in addressing the UK osteoporosis crisis:

> There is growing awareness that the FLS model is becoming a "standard of care." . . . An FLS should deliver a seamless journey for the patient from diagnosis of a fragility fracture onward. Delivering the right care close to patients' residences has been on the NHS agenda for years and there is an established framework of support to ensure local delivery meets expected benefits for patients. With Integrated Care Systems becoming active in UK planning of health and social care, FLSs are optimally placed to identify those patients who have complex needs. There are clear whole system benefits available from identifying this cohort of patients as they have an associated high health resource requirement.[15]

Similarly, a recent **Lancet *Diabetes & Endocrinology*** article discussed the osteoporosis care gap in the U.S., noting:

> The persistent divergence between real-world treatment experience and the standard of care following an osteoporotic fracture underscores the complex fragmentation of services for patients as they move from acute episode to rehabilitative care and community-based primary care. Fracture Liaison Services (FLS), which facilitate diagnosis, treatment planning, and long-term care management of patients with a fracture, are recognized internationally as the gold standard for secondary prevention of osteoporotic fractures.[16]

The first Fracture Liaison Service was established in the early 2000s, and FLS utility in reducing future fractures has been confirmed through multiple studies. A 2018 meta-analysis of FLS impact identified a total of 159 publications, including 74 controlled studies (16 RCTs; 58 observational studies). Compared with patients receiving usual care (or those in the control arm), patients receiving care from an FLS program had:

- Less than half the rates of subsequent fracture (13.4% among patients in the control arm and 6.4% in the FLS arm)
- Lower mortality (15.8% in the control arm and 10.4% in the FLS arm.
- Higher rates of BMD testing (48.0% vs 23.5%)
- Higher rates of treatment initiation (38.0% vs 17.2%)
- Greater adherence (57.0% vs 34.1%).

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[14] Chesser T, et al., Overview of fracture liaison services in the UK and Europe: standards, model of care, funding, and challenges. OTA International: June 2022 - Volume 5 - Issue 3S - p e198 doi: 10.1097/OI9.0000000000000198

[15] Id.

[16] . Osteoporosis in the USA: prevention and unmet needs - The Lancet Diabetes & Endocrinology

This coordinated care intervention is usually headed by an FLS coordinator (a physician, nurse practitioner, physician assistant) who utilizes established protocols to ensure that individuals who suffer a fragility fracture are identified and receive appropriate diagnosis, evaluation, secondary prevention, treatment planning, follow-up, and support. The patient journey starts with identifying suspected fragility fracture patients for post-acute follow-up, moves through collection of medical history, evaluation and management services, diagnostic testing, and, for patients at high risk of fracture, results in treatment planning and necessary follow-up to ensure that patients remain adherent to medications or are offered alternative therapeutic options if needed. FLS programs also reach out to other practitioners responsible for the patient's care, and ascertain patient needs, including physical therapy, fall risk assessment and prevention, and caregiver support needs with a goal of addressing fracture risk factors. Patient assessment and follow-up care are generally prompted through a database-driven, patient-specific timeline.

Unfortunately, existing Medicare payment mechanisms and policies impede adoption of FLS. The TEAM initiative will not only disrupt the referral pathway upon which FLS programs rely, but act as an implicit, if not explicit, CMS endorsement of post-fracture care that ignores the underlying cause of the fracture and diverts referrals away from bone health professionals and FLS programs.

BHOF recently surveyed existing and potential FLS practices on the logistic hurdles they face in implementation. Virtually all of these impediments will be exacerbated with TEAM implementation as proposed:

- Acute hip fractures are reimbursed through bundled payments with 90-day global periods and do not account for secondary fracture prevention follow-up.

- Existing structures for treatment and follow-up in acute care settings approach fractures as any other acute episode rather than as a sentinel event indicative of underlying bone fragility.

- Multiple care settings complicate tracking and referral of patients with known or suspected osteoporotic fractures.

- Comprehensive care models and advanced payment models focus on acute episodes, do not account for osteoporosis as a chronic disease, and assess "cost" and "value" within timeframes too narrow to capture FLS cost-effectiveness.

- The limited sets of quality reporting mechanisms do not sufficiently incentivize the standard of care in preventing a subsequent fracture, and there is significant uncertainty as to which practitioner is ultimately responsible for delivering that care.

- Many patients are lost to follow-up due to care received within a rehabilitation hospital or other facility in the immediate post-acute period.

- Provider-assumed risk and quality reporting periods do not fully encompass the time period for heightened risk for a repeat fracture.

Despite these impediments, leading U.S. health systems, including Geisinger and Kaiser Permanente, have successfully implemented the FLS framework to reduce repeat fractures and lower costs.

- The Healthy Bones Program run by the Kaiser Southern California health-maintenance organization led to a decrease of 37.2% in hip fractures with savings of $30.8 million.
- Geisinger Health System achieved $7.8 million in cost savings over 5 years with its FLS implementation.

The American Orthopaedic Association has offered an initiative known as Own the Bone® since 2008 to address the emerging epidemic of osteoporosis-related fragility fractures. Own the Bone enables hospitals and practices to help evaluate and treat these patients using a Fracture Liaison Service (FLS). AOA provides a toolkit, including a ten-step program and registry to document the bone health management of osteoporotic fracture patients.

- Over 270 hospitals and practices have participated in this program.

- Patients enrolled in the program by participating centers are twice as likely to receive bone health interventions post fracture; over 53% had a BMD test ordered or were prescribed pharmacologic therapy for osteoporosis.

- Recommendations for osteoporosis management (BMD testing and/or pharmacologic treatment), care coordination, and other secondary fracture prevention measures were addressed for these patients with 74-98% compliance.

- ***The TEAM initiative's referral pathway will deter access to FLS for patients at highest risk of a future fracture, i.e., hip and vertebral fracture patients. Rather than receiving coordinated post-fracture follow-up from an Own the Bone® practitioner, beneficiaries within the model would have their episode of care closed by the hospital after 30 days and referral to a primary care practitioner.***

The American Geriatrics Society's (AGS') CoCare®: Ortho is another example of a specialty society initiated, multi-disciplinary program to address post-fracture follow-up. This Geriatrics-Orthopedics Co-Management model integrates geriatrics professionals or specially trained geriatrics co-managers (e.g., hospitalists) into the care team with orthopedic surgeons to coordinate and improve the perioperative care of older adults with hip fractures.

- Because a geriatrics co-manager is involved in the older person's care immediately upon or soon after hospital admission, risk factors for harmful events such as delirium, falls,

adverse drug events, or infections are identified and proactively addressed to prevent and optimally manage risks throughout the older adult's hospital stay.

- The AGS CoCare®: Ortho model of Geriatrics-Orthopedics Co-Management has been shown to reduce complications and enhance function after the older adult returns home, two goals at the heart of quality geriatrics care.

- This model also proactively facilitates referral for diagnosis, treatment, and management of osteoporosis to reduce future fracture risk.

- ***Although geriatricians are primary care practitioners, the CoCare® model delivers enhanced services directed beyond the acute fracture episode. The costs of these services are not accurately reflected in aggregate data CMS will use to benchmark costs for an episode of care. We expect that the TEAM initiative will drive unintentional disincentives that deter practitioners and facilities from using CoCare®-Ortho.***

BHOF provides an FLS Training Program. This On-Demand program includes 23 individual sessions (synchronized slide/audio presentations) from the 2022 Interdisciplinary Symposium on Osteoporosis (ISO2022), held virtually in May 2022. Participants much complete each session, including post-test and session evaluation, to receive BHOF's FLS Certificate of Completion. The program emphasizes the importance of appropriate patient assessment, treatment initiation, medical follow-up, and care coordination for the post-fracture patient. In addition, the BHOF Guide to Prevention and Treatment of Osteoporosis offers concise recommendations regarding prevention, risk assessment, diagnosis, and treatment of osteoporosis in postmenopausal women and men aged 50 and older. The Guide includes indications for bone densitometry and fracture risk thresholds for intervention with pharmacologic agents.

Throughout the past several years, BHOF and its advocacy partners have urged CMS to adopt a consensus-based proposal to improve health outcomes and reduce costs associated with osteoporotic fractures.

The BHOF, together with a diverse set of bone health stakeholders, has focused considerable effort on informing CMS of the continuing disparity between the evidence-based care Medicare beneficiaries ***should*** receive following a fracture and the lack of osteoporosis-related services they ***actually*** receive. We have met with CMS staff numerous times and presented the stark statistics on the costs preventable osteoporotic fractures exact on the Medicare program, its beneficiaries, and their families. In collaboration with our advocacy partners, we identified (and presented to CMS) a proven collaborative care coordination intervention, known as Fracture Liaison Services (FLS) that is recognized internationally as the "gold standard" for secondary

prevention of osteoporotic fractures.

We have urged CMS to recognize the FLS coordinated care intervention by identifying appropriate coding and payment mechanisms so that FLS programs could identify individuals who have suffered an initial osteoporotic fracture and provide the set of medically necessary services to give them the best chance possible of avoiding a subsequent and potentially catastrophic osteoporotic fracture. Finally, together with the American Society for Bone and Mineral Research (ASBMR), we prepared a document (Attachment 1) outlining a pragmatic Medicare coding approach to enable FLS care. The organizations listed below expressed their support for incorporating FLS care into the Medicare program as well as for the coding proposal. These stakeholders joined us in urging CMS to implement a set of payment codes to adequately capture the time and resources required to deliver evidence based FLS care:

- American Academy of Nurse Practitioners (AANP)
- American Association of Hip and Knee Surgeons (AAHKS)
- American Association of Orthopaedic Surgeons (AAOS)
- American Academy of Physician Assistants (AAPA)
- American Bone Health (ABH)
- American Geriatric Society (AGS)
- American Orthopaedic Association (AOA)
- American Society for Bone and Mineral Research (ASBMR)
- American Society of Endocrine Physician Assistants (ASEPA)
- Bone Health and Osteoporosis Foundation (BHOF) (previously known as the National Osteoporosis Foundation (NOF)
- Fragility Fractures Alliance (FFxA) – American Academy of Orthopaedic Surgeons (AAOS), American Orthopaedic Association (AOA) & AOA Own the Bone, Orthopaedic Trauma Association (OTA), National Association of Orthopaedic Nurses (NAON), American Geriatrics Society (AGS), International Geriatric Fracture Society (IGFS), American Board of Orthopaedic Surgeons, U.S. Bone and Joint Initiative (UBJI)
- International Society for Clinical Densitometry (ISCD)
- National Spine Health Institute (NSHI)
- North American Spine Society (NASS)
- Orthopaedic Trauma Association (OTA)
- The Endocrine Society (TES)
- US Bone and Joint Initiative (USBJI)

Throughout 2021, BHOF and ASBMR facilitated meetings between CMS and their policy experts, together with Dr. Andrea Singer (Chief Medical Officer for BHOF) and Dr. Paul Anderson (former chair of the “Own the Bone” Steering Committee of the American Orthopaedic Association). When the 2022 PFS proposed rule failed to include any discussion on the care gaps in post-fracture osteoporosis follow-up, the BHOF and ASBMR, with sign-on from 28 bone health, women’s health, and health equity stakeholders, submitted comments reiterating the impact that preventable fractures have on Medicare and its beneficiaries. We further noted that

"[e]ffective FLS care could be facilitated through CMS adoption of a code set with payment tailored to the resources required to effectively identify or refer post-acute fracture patients and ensure treatment planning and follow-up consistent with the standard of care for addressing osteoporosis and reducing the risk of a future fracture." Neither our engagement throughout the year nor our comments to the proposed rule were acknowledged or discussed within CMS' discussion of comments and Agency determinations in the final PFS rule for 2023.

Discussions with CMS and HHS staff and leadership continued throughout the remainder of 2022 and early 2023. These discussions reiterated and reinforced our messages from 2021, focusing on the alignment between our FLS coding and payment proposal and the Administration's interest in reducing health disparities, particularly within the context of under-utilized services. Our clinical and scientific experts, as well as our health policy and coding/payment consultants, answered questions related to the lack of sufficient coding mechanisms, the uniquely "concentrated" nature of FLS care making chronic care management payment mechanisms insufficient or inappropriate, and CMS leadership interest in the utility of FLS to address high-priority Agency and Administration concerns such as fall prevention, reduction in nursing home admissions, and curbing high-dose and/or long-term opioid use related to fractures.

Although CMS' 2024 Proposed Rule reinforced the utility of Medicare-specific code sets (G codes) to address coding and payment gaps that compromise care for Medicare beneficiaries, there was, again, no indication that the Agency intended to address gaps related to the uniquely-Medicare problem of preventable osteoporotic fractures. Similarly, CMS has not asserted the existence of, much less identified, a set of existing codes that could be used by FLS programs seeking Medicare reimbursement.

Throughout our discussions with CMS, we have emphasized that the primary care referral pathway reinforced in CMS' sets of quality measures has proven to be ineffective. FLS programs have one overarching purpose - to ensure that patients at high risk of a future fracture (hip fracture patients are at highest risk) are identified and can receive the standard of care to address their long- and short-term future fracture risk. Unless CMS refines the TEAM initiative, the Medicare program will be taking the unique position of proactively discouraging and impeding access to the practitioners best positioned to deliver secondary fracture prevention services.

CMS should refine the TEAM initiative to facilitate, rather than impede, access to evidence based FLS secondary fracture prevention services.

The BHOF urges CMS to implement a set of pragmatic refinements to the TEAM initiative as applied to episodes involving hip fractures and spinal fusion procedures in patients with known or suspected osteoporosis. These refinements include:

- Enabling referral to an FLS practice as an alternative to primary care. FLS programs coordinate with primary care practitioners as well as other specialties in delivering secondary fracture prevention care.

- Exempt episodes for which an FLS referral is made and FLS services are initiated from the model.

    - Since benchmark costs will reflect the existing deficiencies in secondary fracture prevention, including cases with referral to FLS would ultimately deter access.
    - In addition, FLS care goals focus beyond the acute episode and "quality" cannot be determined within a 30-day episode.
    - We believe this approach is more workable than benchmarking FLS costs and assigning differential episode payment amounts, and more likely to benefit CMS than simply excluding all hip fractures, and spinal fusions in individuals with known or suspected osteoporosis from the model.

- Assigning a specialty code to identify FLS practices. This would be a secondary specialty since FLS programs are operated within orthopedic, endocrinology, rheumatology, women's health, primary care, and other practice types. The specialty code would be reported by FLS practices, including those that:

    - Participate in AOS' Own the Bone initiative, OR
    - Deliver FLS care through participation in AGS CoCare-Ortho, OR
    - Have received a certificate of completion for training administered through BHOF or the International Osteoporosis Foundation and deliver FLS care.

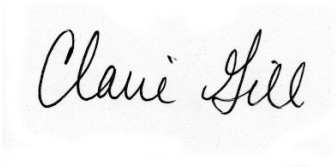
- Work with BHOF and the CMS Physician Fee Schedule team to identify or create a reimbursement mechanism that captures the services delivered within evidence based FLS programs. BHOF and its advocacy partners have interviewed FLS programs, ascertained the set of services provided by these programs, and developed crosswalk scenarios reflecting the time and resources required in a typical FLS care episode.

Finally, the bone health community needs a clear statement from CMS acknowledging existing deficiencies in secondary fracture prevention as well as the perceived coding and payment gap associated with FLS care. Practitioners and facilities contemplating continuing or starting an FLS program need either (a) a set of actionable instructions on the codes CMS will accept within the context of FLS care, e.g., permitting use of existing codes to receive reimbursement for FLS visits and non-face-to-face services performed on a day other than the date of the office visit, enabling use of principal care management or transition care management codes, including add-on codes, etc., or (b) interim guidance for claim submission throughout 2024 and 2025, with an intent to implement sufficient coding mechanisms in a future rulemaking cycle.

Conclusion

BHOF appreciates the opportunity to submit its comments to the 2025 IPPS Proposed Rule. While we are disappointed that our advocacy efforts to date failed to gain CMS' attention and action, we remain hopeful that the TEAM initiative will be implemented to facilitate rather than impede quality care for beneficiaries suffering an osteoporotic fracture.

If you have any questions, please contact me at 703.647.2025 or cgill@bonehealthandosteoporosis.org if you or your staff have questions or would like to discuss these issues in greater detail.



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Bone Health and Osteoporosis Foundation