

Submitted electronically

September 11, 2023

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

**RE: CMS–1784–P
Medicare and Medicaid Programs; CY 2024 Payment Policies Under the
Physician Fee Schedule and Other Changes to Part B Payment and Coverage
Policies; Medicare Shared Savings Program Requirements; Medicare
Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies;
and Basic Health Program**

Dear Administrator Brooks-LaSure:

The Bone Health and Osteoporosis Foundation (BHOFF) and the American Society for Bone and Mineral Research (ASBMR) are joined by the undersigned leading national bone health, women's health, family caregiver and aging patient advocacy in submitting submit comments on the above-referenced proposed rule updating and refining payment policies under the Physician Fee Schedule (the Proposed Rule) for calendar year 2024. We are, once again, asking that the Centers for Medicare & Medicaid Services (CMS) recognize, prioritize, and address the significant care gap in secondary prevention of osteoporotic fractures.

The BHOFF 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.

The 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. ASBMR membership comprises basic research scientists and clinical investigators in bone and mineral metabolism and related fields, along with physicians and other healthcare practitioners. ASBMR encourages and promotes the study of this expanding field through annual scientific meetings, two peer-reviewed 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.

As CMS stated in its proposal to create three new sets of “G” codes to enable reimbursement for “Services Addressing Health-Related Social Needs,” the Agency has, in recent years, “sought to recognize significant changes in health care practice and been engaged in an ongoing, incremental effort to identify gaps in appropriate coding and payment for care management/coordination and primary care services under the PFS.” As discussed below, we have engaged with CMS on these efforts and are, once again, disappointed to find that the Agency has neither prioritized nor mentioned the glaring and persistent osteoporosis care gap. This lack of attention is especially notable given the cost of preventable fractures and the number of beneficiaries, mostly women, suffering poor outcomes that simple access to the standard of care might have avoided.

Our comments provide:

- An overview of our efforts over the past several years, including information on the “problem” of preventable osteoporotic fractures and the consensus-based proposed solution presented to CMS staff and leadership.
- A discussion of the gap in appropriate coding and payment for the care management/coordination services required to deliver post-fracture follow-up services.
- Our support for the sets of proposed “G” codes generally, together with a discussion on why these codes describe a set of services analogous to those provided within a Fracture Liaison Service (FLS) program yet are insufficient to enable reporting by FLS providers.
- Our concern that several proposed refinements to the Quality Payment Program will deter osteoporosis diagnosis and impede beneficiary access to FDA approved treatments.

We respectfully request that CMS’ final rule acknowledge the deficit in follow up care for the nearly 2 million Medicare beneficiaries who suffer osteoporotic fractures, recognize the utility of FLS care in addressing those deficits, and articulate whether, when, and how the Medicare program will ensure that FLS providers have, and are aware of, a set of appropriate coding mechanisms to obtain reimbursement for the time and resources required to deliver quality care.

Background

The BHOFF and ASBMR, together with a diverse set of bone health stakeholders, have focused considerable effort on informing CMS of the continuing chasm between the evidence-based care Medicare beneficiaries **should** receive following a fracture indicative of low bone density and the lack of osteoporosis-related services they **actually** experience. We have 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). FLS programs 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. FLS is recognized internationally as the “gold standard” for secondary prevention of osteoporotic fractures; it should be recognized by CMS and available to Medicare beneficiaries.

Finally, we prepared a document (Attachment 1) outlining a pragmatic Medicare coding approach to enable FLS care. The organizations listed below expressed their support for the coding proposal and 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 (BHOFF) (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, BHOFF and ASBMR facilitated meetings between CMS and their policy experts, together with Dr. Andrea Singer (Chief Medical Officer for BHOFF) 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 BHOFF and ASBMR, with sign-on from 28 national bone health, women’s health, aging and health equity stakeholders, submitted comments (Attachment 2) 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 on 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 (see Presentation, Attachment 3). 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 clinician 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’ Proposed Rule reinforces 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 intends 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.

The BHOF, ASBMR and their advocacy partners have urged CMS to acknowledge and address the growing problem preventable osteoporotic fractures present to Medicare and its beneficiaries.

Unlike many other high-cost, debilitating conditions, outcomes in osteoporosis can be significantly improved through effective screening, osteoporosis diagnosis and fracture risk assessment, and treatment planning and follow-up services to ensure that patients receive appropriate therapeutic and lifestyle modification interventions, including prescription medications. Ideally, patients would receive these services early, before decreases in bone density lead to an osteoporotic fracture. Unfortunately, for many Medicare beneficiaries, the first sign of osteoporosis is an osteoporotic fracture event, and most patients fail to receive the post-fracture follow-up needed to prevent a future, potentially catastrophic osteoporotic fracture.

Preventable osteoporotic fractures are a significant health concern for Medicare and its beneficiaries:

- According to a report prepared by the actuarial firm, Milliman, based on 2016 Medicare fee-for-service claims data, 1.8 million Medicare beneficiaries suffered approximately 2.1 million osteoporotic fractures in 2016.¹
 - 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.²
- Death rates among women over age 65 with hip fractures are **higher than those facing breast cancer**.
- A recent study revealed that 23% of opioid-naïve hip fracture patients became chronic opioid users after surgery.³
- Total costs associated with osteoporotic fractures were over \$57 billion in 2018.⁴
- The number of osteoporotic fractures is projected to increase by 68% and cost Medicare over \$95 billion by 2040.
- ***Preventing between 5% and 20% of subsequent fractures could have saved between \$272 million and \$1.1 billion for the Medicare FFS program, yet just 9% of Medicare beneficiaries with a fracture are screened for osteoporosis. 80% of Medicare osteoporosis patients with a hip fracture do not receive osteoporosis treatment despite having the highest risk of another fracture.***

The table below was presented to CMS staff and included in our comments on the 2023 PFS proposed rule. It delineates the real-world failures in secondary prevention of osteoporotic fractures. This care gap has persisted despite incremental efforts to reinforce osteoporosis awareness through quality measures directing communication from the clinician treating the fracture to the patient’s primary care provider. 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. Heart attack and fractures are both acute, sentinel events within a chronic condition and both have established care pathways to mitigate the risk of future 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.

¹ 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)

² Milliman Report (2021 Update).

³ Hereford, et al., Prevalence of Chronic Opioid Use in the Elderly After Hip Fracture Surgery, [Prevalence of Chronic Opioid Use in the Elderly After Hip Fracture Surgery - The Journal of Arthroplasty \(arthroplastyjournal.org\)](https://arthroplastyjournal.org) (Feb 2022).

⁴ 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.

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

It is, unfortunately, difficult to parse out disparities and inequities suffered by subpopulations within the context of a condition for which care deficiencies are overwhelmingly suffered over the entire disease population. We strongly believe that poor health outcomes due to care failures specific to a particular condition are inherently inequitable in light of Medicare’s mission to provide healthcare access for the nation’s elderly and disabled. It is, however, important to note that while Black men and women are generally less likely to suffer from osteoporosis and sustain a fragility fracture than White women and men, they are more likely to die as a result of an osteoporotic fracture than their White counterparts.

- Compared to White women, Black women with postmenopausal osteoporosis experience worse outcomes after sustaining hip and several other types of fractures.⁵
- Up to 75% of Black Americans are lactose-intolerant. This can prevent them from consuming dairy products—an excellent source of bone-strengthening calcium and Vitamin D. In fact, Black women's calcium intake is 50% less than the Recommended Dietary Allowance.
- A recent study found that Black patients were at greater risk for delayed surgery following a hip fracture.
- The Milliman report found that Black patients suffering an osteoporotic fracture in 2016 had worse outcomes, including:
 - higher mortality (22% die within 12 months and 35.4% die within 2-3 years post-fracture)
 - just 5% of Black osteoporotic fracture patients receive any follow-up care to address their underlying bone fragility
 - Black patients were 30% less likely to receive post-fracture physical therapy
 - Black patients have a 2.3 times higher risk of destitution, debility and death in the year following vertebral fracture.^{6 7}

FLS programs are designed to close the osteoporosis care gap by replacing fragmented care delivery with a collaborative, coordinated, protocol-driven care approach. Lack of sufficient coding and payment mechanisms impedes existing programs and discourages broader FLS implementation.

The marked and persistent divergence between real-world patient experience and the standard of care for post-fracture osteoporosis follow-up is likely due to a complex set of factors, including care fragmentation as patients move from acute episode to rehabilitative care and, at some later point in time, to community-based primary care. A July 2019 BHOF report entitled “Patient Perception of Value in Healthcare: Osteoporosis and Bone Fragility” explored aspects of the post-fracture patient experience not readily captured within claims data.⁸ It was derived from results of a BHOF 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. The BHOF survey highlights the need for patient-centered care that includes timely intervention from a bone health clinician, clear communication of all risks associated with osteoporosis, including risks associated with failure to receive 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.

⁵ Wright NC, Chen L, Saag KG, Brown CJ, Shikany JM, Curtis JR. Racial Disparities Exist in Outcomes After Major Fragility Fractures. *J Am Geriatr Soc.* 2020 Aug;68(8):1803-1810. doi: 10.1111/jgs.16455. Epub 2020 Apr 26. PMID: 32337717; PMCID: PMC7935465.

⁶ *Am Geriatr Soc.* 2020 Apr 26. doi: 10.1111/jgs.16455.

⁷ Milliman Research Report.

⁸ [POV+in+Bone+Health+Report+NOF+7.29.pdf \(squarespace.com\)](#)

BHOF report findings revealed that regardless of their treatment status, patients view osteoporosis as a serious concern that may threaten their ability to maintain functional independence.

- Osteoporotic fractures discourage patients from engaging in healthy exercise behaviors likely to improve and/or maintain health and independence. 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.
- Over 22% of untreated individuals with a history of a previous fracture reported that they discontinued treatment due to side effects and remain untreated.
- Survey responses also revealed that health care providers, particularly fragmented care, plays a role in the post-fracture care gap. Individuals reporting a fracture history were about half as likely to have been offered osteoporosis treatment as those in whom osteoporosis was diagnosed solely through DXA or other primary prevention service.

FLS programs are uniquely suited to ensure that patients at high risk of a future fracture are identified and can receive the standard of care to address their long- and short-term future fracture risk. 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 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 to ensure that patients wishing to discontinue treatment due to side effects are offered alternative therapeutic options. FLS programs also reach out to other clinicians 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.

The first Fracture Liaison Services were 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%).

Despite international recognition of FLS as the “gold standard” for post-fracture follow-up,⁹ these services are not widely available in the U.S. FLS requires proactive provider implementation of an infrastructure to identify osteoporotic fracture patients and ensure follow-up to and through an effective treatment plan. BHOF has reached out to practices and facilities operating or wishing to implement FLS and found that resistance to FLS start-up (and threats to continuing operation of existing programs) is not only common but that it is overwhelmingly due to uncertainties on how to bill Medicare and fears that an FLS program will not be self-sustaining.

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 require reliance on additional funding sources. Those interviews underscored the substantial, uncompensated time and resources required to ensure that osteoporotic fracture patients receive appropriate follow-up. FLS programs agreed that services are concentrated over a 45-day time period that starts with an initial FLS visit. Subsequent follow-up services are usually brief and are reimbursed using existing codes. It is important to note that although FLS care addresses a chronic condition (osteoporosis), services are not delivered on a relatively consistent basis or over a long period of time as would be expected for chronic care management services. The goal of care is to ascertain and address future fracture risk, assess whether there are any secondary causes of bone fragility, develop a treatment plan, and ascertain patient tolerance of and adherence to treatment. Unlike care addressing, for example, chronic cardiovascular conditions, there are no mechanisms or biomarkers to periodically assess response to treatment. Ongoing monthly patient assessment visits are not incorporated into a care plan and are rarely needed.

FLS programs describe their patient population as individuals with a known or suspected fragility fracture within the previous 6 months (patients are usually seen within 3 months but the initial visit may be delayed if the patient remains in a rehabilitation facility for an extended period of time.) FLS programs describe their services as:

⁹ 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.

- 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 primary care provider, coordination with patient's relevant specialists (including orthopedic surgeon, geriatrician, physical rehabilitation, hematologist, oncologist, endocrinologist, psychiatrist, etc.)
- Coordination and communication with ancillary providers (including physical therapy, occupational therapy)
- Ordering and reviewing imaging studies and laboratory tests as necessary to diagnosis osteoporosis and/or other condition contributing to bone fragility
- Shared decision making in creation of treatment plan, including development of pharmacological plan, updating current drugs and prescriptions
- Follow up that incorporates the patient's short-term goals and tasks that must be performed to attain short-term goals for reducing risk of future fractures.

The list of services and encounters below details the time and resources FLS programs report as required to deliver the care outlined above, and the coding and payment gaps impeding reimbursement for those services.

- Physician/Qualified Health Practitioner (QHP) time:
 - prior to initial encounter (non-face-to-face): 20 minutes (often unreimbursed)
 - Clinicians often perform services in advance of the patient visit, and the time cannot be included in evaluation and management services unless it is within 3 days of the direct encounter.
 - Chronic care management codes are generally inappropriate 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 initial visit if the patient has not yet been diagnosed with osteoporosis. The single chronic condition description within the code appears to preclude use of the code for osteoporosis care.
 - Transition care management codes require an inpatient transition, limiting potential utility to hip fracture patients. Unfortunately,

these patients are rarely able to receive FLS care within the 14-day timeframe following their inpatient stay.

- 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) are reluctant to bill for high-level E&M services for each FLS patient, despite meeting or exceeding face-to-face time requirements due to fears that it will subject them to scrutiny and delay or deny payment.

- 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 generally inappropriate 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 because the single chronic condition description within the code appears to preclude use of the code for 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 (when performed): 26 minutes
 - Evaluation and management codes are sufficient

- 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

The consensus “White Paper” (Attachment 4) outlines a pragmatic approach to encourage FLS program adoption that CMS could implement with the creation of “G” codes. CMS has used this approach to improve care for substance use disorder and pain management and proposes to implement new sets of “G” codes for “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 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 needed 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 our proposed FLS coding mechanism 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 on a monthly basis) and (b) describe FLS services over the 45-day day period from the initial visit through treatment planning and follow-up.

We understand that CMS has, thus far, declined to create a coding mechanism specific to FLS care. BHOFF and ASBMR have been key drivers in encouraging FLS implementation and supporting clinicians and practices interested in offering this “gold standard” in 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 likely bear. Existing FLS programs without external funding must rely on Medicare payments to remain viable; inadequate reimbursement has forced some programs to consider 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.

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 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 2023 and 2024, with an intent to implement sufficient coding mechanisms in a future rulemaking cycle.

BHOFF and ASBMR generally support CMS’ proposal to implement sets of “G” codes for “Services Addressing Health-Related Social Needs.” Although the sets of services are analogous to those performed within an FLS program, the requirements associated with the codes all but rule out their use in addressing disparities in osteoporosis care.

BHOF and ASBMR appreciate the Administration's focus on reducing the health disparities and inequities individuals with food, housing, and transportation insecurity, or unreliable access to public utilities have long experienced. We support CMS' implementation of coding and payment mechanisms to reimburse clinicians and auxiliary personnel for the time required to help patients navigate the healthcare system and access the resources they need to receive timely and effective medical care. Similarly, we applaud CMS for recognizing that the system does not always work to ensure that ALL patients (a) are aware of the diagnostic and treatment services they might need; (b) can locate and access the right practitioners for their condition; and (c) have a treatment plan that takes their personal circumstances into account. The services required to bridge the gap between what a patient might independently recognize they need, and the medical care required to give them the best chance for a positive outcome are not only valuable but are crucial to building/maintaining an equitable health care system. BHOF and ASBMR, therefore, support finalization of the proposed G Code sets.

Many of the services described in the Community Health Integration (CHI) code set are valuable to fracture patients regardless of the presence of any social determinants of health (SDOHs), and these patients certainly face substantial hurdles impeding diagnoses and treatment for underlying osteoporosis. Of particular relevance to FLS care are those related to coordinating care, 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. Unfortunately, even fracture patients with SDOH who might benefit from CHI services to obtain appropriate follow-up care are unlikely to be referred for, or qualify for, these services.

- System-wide failures to identify fracture patients requiring osteoporosis follow-up is the key impediment to appropriate post-fracture follow-up. It impedes care for patients regardless of socio-economic status.
- The initiating visit requirements will preclude use of these services in ensuring that osteoporotic fracture patients get the follow-up care they need.
 - CMS noted that the initiating visit is a requirement for CHI services eligibility and articulated its belief that "certain types of E/M visits, such as inpatient/observation visits, ED visits, and SNF visits would not typically serve as CHI initiating visits."
 - We are concerned that this beneficiary-focused coding and payment proposal failed to consider osteoporotic fracture patients, many of whom will have SDOH-related needs that could interfere with both their recovery from the acute episode and their access to information and follow-up care needed to address bone fragility, fall risk, and other factors increasing the likelihood of a subsequent fracture.

- We urge CMS to leverage existing post-fracture follow-up initiatives, including FLS programs, to ensure that the requirements associated with the proposed sets of G codes do not preclude access for osteoporotic fracture patients.
 - AGS CoCare[®]: Ortho is a Geriatrics-Orthopedics Co-Management model in which geriatrics professionals, or specially trained geriatrics co-managers (e.g., hospitalists) work with orthopedic surgeons to coordinate and improve the perioperative care of older adults with hip fractures.
 - The inpatient observation visit(s) within this model are well-suited to serve as initiating visits for geriatric practitioners interested in incorporating CHI (as well as PIN) services into their practices or as referral points to other clinicians.
 - The American Orthopaedic Association (AOA) has operated the Own the Bone quality improvement program since 2009, with the objective of improving post-fracture bone health care coordination, evaluation, and treatment.
 - The program has been utilized to assist hospitals and physician practice groups to offer FLS care to their fracture treatment patients.
 - The G code requirements rely on assumptions that orthopedic surgery professionals are not positioned to offer patients continuing, holistic care. The fact that approximately 300 practices and facilities have participated in Own the Bone indicates that these practices can and will incorporate services associated with the fracture but extending beyond the acute episode, including FLS.
 - The AOA experience has also demonstrated that the lack of reimbursement for FLS care continues to be a significant barrier to the widespread adoption of post-fracture bone health management by orthopedic departments and practices, to the detriment of fragility fracture patients.

BHOF and ASBMR also generally support implementation of codes for SDOH Risk Assessment and Principal Illness Navigation, despite our expectation that these codes will not move the needle on ensuring that fracture patients receive the standard of care to prevent a future osteoporotic fracture. It is particularly disappointing that the Principal Illness Navigation codes are proposed to exclude their use in addressing post-fracture patient care needs. 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. 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.
- We expect that a small subset of hip fracture patients may be referred for and receive PIN services and hope that those services would focus beyond fracture recovery to include osteoporosis treatment and management.

BHOF and ASBMR recognize that the incentives and disincentives within the Quality Payment Program have not and cannot make a meaningful difference in reducing the osteoporosis care gap. We are disappointed that CMS' proposed changes are likely to widen the gap between the standard of care and Medicare beneficiaries' experience.

BHOF and ASBMR appreciate that CMS continues its efforts to improve the Quality Payment Program (QPP) and make it less burdensome for clinicians. We continue to believe that the QPP can be a valuable tool enabling CMS to evaluate progress in secondary prevention of osteoporotic fractures. Throughout the years since its implementation, however, it has not, and almost certainly cannot, provide sufficient incentives/disincentives to encourage clinicians to provide under-reimbursed secondary fracture prevention services within the primary care setting the Agency appears to rely on for post-fracture follow-up. We are, however, concerned that QPP refinements appear to intentionally exclude reference to osteoporosis-related services or incentivize treatment standards that conflict with the prevailing standard of care and evolving science on disease mechanisms and therapeutic impacts. Although we are convinced that the only way to ensure patients receive post-fracture services is to reduce care fragmentation by paying providers for FLS care, **the combination of inadequate FLS payment plus quality measures that discourage osteoporosis diagnosis and steer prescribers away from FDA-approved osteoporosis medications trivializes this chronic condition and could widen the care gap in post-fracture follow up.**

- A. CMS proposed a new "Focusing on Women's Health" MIPS Value Pathway (MVP) with quality measures the Agency describes as "providing a meaningful and comprehensive assessment of the clinical care for clinicians who specialize in women's health." Two of the eighteen measures are osteoporosis related:
- Q472: "Appropriate Use of DXA Scans in Women Under 65 Years Who Do Not Meet the Risk Factor Profile for Osteoporotic Fracture"
 - CMS states that this measure "ensures women receive an order for a dual-energy x ray absorptiometry (DXA) scan if they exhibit select risk factors for osteoporotic fracture."

- This statement appears to be incorrect. The measure is designed to assess whether a patient under 65 receiving a DXA scan has documented risk factors. It cannot, therefore, ensure that those with risk factors receive appropriate testing.
 - The effect of this measure is more likely to discourage DXA use since providers face a documentation burden for each DXA provided to a woman under age 65.
- UREQA8: Vitamin D level: Effective Control of Low Bone Mass/Osteopenia and Osteoporosis: Therapeutic Level Of 25 OH Vitamin D Level Achieved:
 - This appears to be a new, CMS-created quality measure that is described as ensuring effective control of osteopenia and osteoporosis. It implies a Medicare scientific judgment that osteoporosis treatment success is based on Vitamin D level.
 - We are concerned that the measure promotes a standard of care that does not align with current scientific understanding of Vitamin D and its use in treating osteoporosis.
 - Clinical guidelines recommend that clinicians select treatments for high-risk patients based on the specific patient’s future fracture risk and other patient-specific factors.
 - The measure applies only to clinicians treating osteoporosis in women and will almost certainly delay and could preclude patient access to FDA-approved treatments appropriate and necessary to reduce future fracture risk. Clinicians treating men for osteoporosis would, assumedly, base their treatment decisions on the standard of care within clinical guidelines.

B. CMS proposes consolidating the previously finalized Promoting Wellness and Optimizing Chronic Disease Management MVPs into a single consolidated primary care MVP titled “Value in Primary Care MVP.”

- As part of the consolidation to a single measure, the Agency proposed removing 5 measures, including **Q039: Screening for Osteoporosis for Women Aged 65-85 Years of Age**.
 - The measure removal was proposed “to align with the clinical concepts of preventive care, quality chronic disease management, and alignment with the Adult Universal Foundation measures.”

Conclusion

BHOF and ASBMR appreciate the opportunity to submit their comments to the 2024 Proposed Rule. We are disappointed that CMS declined to prioritize post-fracture services to prevent subsequent osteoporotic fractures with sufficient coding and payment mechanisms to facilitate

the viability of FLS programs in delivering the standard of care to Medicare beneficiaries.

Once again, we respectfully request that the final rule acknowledge the deficit in osteoporotic fracture follow-up care experienced by nearly 2 million Medicare beneficiaries, acknowledge the utility of FLS care in addressing those deficits, and articulate whether, when, and how the Medicare program will ensure that FLS providers have, and are aware of, a set of appropriate coding mechanisms to obtain reimbursement for the time and resources required to deliver quality care. If you have any questions please contact Claire Gill, CEO, Bone Health and Osteoporosis Foundation cgill@bonehealthandosteoporosis.org or Doug Fesler, Executive Director, American Society for Bone and Mineral Research at dfesler@asbmr.org.

Very truly yours,

Alliance for Women's Health and Prevention
American Association of Clinical Endocrinology
American Association of Hip and Knee Surgeons
American Association of Orthopaedic Surgeons
American Society for Bone and Mineral Research
American Society of Endocrine PAs
American Academy of Physician Associates
American Orthopaedic Association
Bone Health and Osteoporosis Foundation
Cancer Fashionista
Caregiver Action Network
Celiac Disease Foundation
Geisinger Health System
Global Healthy Living Foundation
HealthyWomen
Hebrew Senior Life
International Osteoporosis Foundation
National Caucus and Center for Black Aging
National Council on Aging
National Menopause Foundation
National Spine Health Foundation
Orthopaedic Trauma Association
Tigerlily Foundation
TOUCH, The Black Breast Cancer Alliance

BHOF, ASBMR, et al., Comments to 2023 PFS Proposed Rule Summary Points

Post-fracture osteoporosis care services are high value.

- Hip, vertebral, and other fragility fractures that lead to institutionalization and death are **not** a natural consequence of aging.
- Death rates among women over age 65 with hip fractures are higher than those facing breast cancer.
- In a recent study, 23% of opioid-naïve hip fracture patients became chronic opioid users after surgery.ⁱ
- 1.8 million Medicare beneficiaries suffered approximately 2.1 million osteoporotic fractures in 2016.ⁱⁱ
- Medicare paid over \$57 billion for osteoporotic fractures in 2018.ⁱⁱⁱ
- Unless CMS acts to increase secondary prevention service utilization, the number of osteoporotic fractures is projected to increase by 68% and cost Medicare over \$95 billion by 2040.
- ***Preventing between 5% and 20% of subsequent fractures could have saved between \$272 million and \$1.1 billion for the Medicare FFS program.***

Severe underutilization of post-fracture osteoporosis diagnosis, treatment planning, care coordination and follow-up drive inequities for the predominantly female osteoporosis population and disproportionately poor outcomes for Black women and other underserved communities.

- Heart attack and fractures are both acute, sentinel events within a chronic condition.
- 70% of heart attack patients are male; approximately 70% of osteoporotic fracture patients are female.
- 30% of hip fracture patients and 19% of patients with **any** osteoporotic fracture die within 12 months
- Virtually all heart attack patients receive diagnostic services and treatment; 91% of osteoporotic fracture patients **do not** receive diagnostic services and 80% **do not** receive osteoporosis treatment to reduce their future fracture risk.
- 95% of Black osteoporotic fracture patients **do not** receive any osteoporosis follow-up care.
- Black patients are 30% less likely to receive post-fracture physical therapy.
- Black patients are 2.3 times more likely to suffer destitution, debility and death in the year following vertebral fracture.
- Follow-up in patients receiving treatment is crucial since a significant proportion of patients discontinue treatment due to side effects, costs, or other factors. These patients remain at risk of a future fracture.

Care coordination through evidence-based Fracture Liaison Service (FLS) interventions improves access to the standard of care and reduces future fractures (and their associated costs).

- FLS programs are a collaborative care coordination intervention with services analogous to those in Medicare's SUD and proposed chronic pain management bundles.
- FLS starts with identifying fracture patients for post-acute follow-up, moves through clinician collection of medical history, evaluation and management services, diagnostic testing, assessment of fracture risk and fall risk, coordination of ancillary services (e.g., PT and OT), treatment planning and necessary follow-up.
- The first FLS was started in the early 2000s. A 2018 meta-analysis of FLS impact identified a total of 159 publications including 74 controlled studies and found that FLS patients 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, higher rates of BMD testing, higher rates of treatment initiation, and greater adherence.

- FLS is recognized internationally as the “gold standard” for secondary prevention of osteoporotic fractures.^{iv v vi vii viii}

Coding and payment mechanisms are needed to facilitate coordinated post-fracture care (fracture liaison service).

- Just as CMS’ efforts to leverage the QPP to address the opioid use crisis were insufficient in encouraging clinicians to incorporate substance use disorder (SUD) treatment or pain management coordination into their practices, the QPP incentives/disincentives have not been, and likely will never be, sufficient to close the care gap in osteoporosis.
- BHOF and ASBMR together with 17 leading organizations in the bone health community presented a pragmatic, actionable coding and payment solution that would recognize and address the significant barriers in initiating and maintaining FLS.
- Like the services associated with chronic pain management, **FLS providers work within the scope of their license** in coordination and collaboration with other providers (as needed) to ensure that each patient receives the set of services they need.
- As with chronic pain management, there are currently no existing CPT code(s) that specifically or sufficiently describe the work of the clinician who performs comprehensive, holistic post-fracture follow-up for secondary prevention of fragility fractures.
- The primary reason cited by clinicians for not providing post-fracture care is concern that an FLS program would not be self-sustaining due to inadequate/uncertain reimbursement.
- A set of “G” codes for FLS, similar to those for SUD, chronic care management, and chronic pain management, are needed to reduce the disparities and inequities that osteoporosis care gaps exact on women, including the disproportionately catastrophic impact on the health and lives of Black women and other underserved populations.

ⁱ Hereford, et al., Prevalence of Chronic Opioid Use in the Elderly After Hip Fracture Surgery, [Prevalence of Chronic Opioid Use in the Elderly After Hip Fracture Surgery - The Journal of Arthroplasty \(arthroplastyjournal.org\)](#) (Feb 2022).

ⁱⁱ 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)

ⁱⁱⁱ 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.

^{iv} 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.

^v Javaid MK, Kyer C, Mitchell PJ, et al. Effective secondary fracture prevention: implementation of a global benchmarking of clinical quality using the IOF capture the fracture(r) best practice framework tool. *Osteoporos Int*. 2015;26(11):2573–2578.

Mitchell PJ. Best practices in secondary fracture prevention: fracture liaison services. *Curr Osteoporos Rep*. 2013;11(1):52–60.

^{vii} Akesson K, Marsh D, Mitchell PJ, et al. Capture the fracture: a best practice framework and global campaign to break the fragility fracture cycle. *Osteoporos Int*. 2013;24(8):2135–2152.

^{viii} Marsh D, Akesson K, Beaton DE, et al. Coordinator-based systems for secondary prevention in fragility fracture patients. *Osteoporos Int*. 2011;22(7):2051–2065.

Submitted electronically

September 6, 2022

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

CMS-1770-P -- Medicare and Medicaid Programs; CY 2023 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicare and Medicaid Provider Enrollment Policies, Including for Skilled Nursing Facilities; Conditions of Payment for Suppliers of Durable Medicaid Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS); and Implementing Requirements for Manufacturers of Certain Single-Dose Container or Single-Use Package Drugs To Provide Refunds With Respect to Discarded Amounts

Dear Administrator Brooks-Lasure:

The Bone Health and Osteoporosis Foundation (BHOFF) and the American Society for Bone and Mineral Research (ASBMR) are joined by the undersigned leading national bone health, women's health, health equity, and aging patient advocacy organizations in submitting our comments to the Centers for Medicare & Medicaid Services'¹ (CMS') proposed rule updating Medicare payment and refining policies under the Physician Fee Schedule (PFS) for the 2023 calendar year (the Proposed Rule). Together, we urge CMS to address the health inequities and care disparities impacting the lives of women within the Medicare program due to the significant care gap in secondary prevention of osteoporotic fractures. Specifically, we ask that CMS implement sufficient coding and payment mechanisms to facilitate provider adoption of the proven, internationally-accepted Fracture Liaison Service (FLS) paradigm for post-fracture care coordination, treatment planning and follow-up.

The BHOFF 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.

The 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. Our membership comprises basic research scientists and clinical investigators in bone and mineral metabolism and related fields, along with physicians and other healthcare practitioners.

¹ 87 FR 45860 (July 29, 2022).

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.

Osteoporosis is, as CMS noted in the Proposed Rule, “an important public health issue requiring attention as it can lead to co-morbidities and decreased quality of life.”² Care gaps in osteoporosis offer a significant opportunity for CMS to improve health equity. Our organizations are committed to addressing the health crisis in the screening, detection, diagnosis, and treatment of osteoporosis. Over the past year, we have:

- Developed a consensus “White Paper” (<https://www.bonehealthpolicyinstitute.org/newsroom/2022/8/15/proposal-for-fls-reimbursement-mechanism-through-the-centers-for-medicare-amp-medicaid-services-cms>) outlining the significant care gaps in bone health that disproportionately impact women as they age, and identifying a pragmatic, actionable plan to reduce osteoporotic fractures by leveraging the Fracture Liaison Service (FLS) model in US health systems.
 - This White Paper has been endorsed by 17 bone health stakeholders, including specialty societies in orthopedics, endocrinology, and geriatrics.
- Identified an episode-based payment mechanism that, if implemented in the Medicare program, would encourage adoption of FLS programs and ensure that individuals with osteoporosis are diagnosed and receive the care needed to reduce their future fracture risk.
- Maintained discussions between CMS and bone health experts on the impact of secondary fracture prevention failures and the utility of FLS in closing the osteoporosis care gap.

Our comments focus primarily on CMS’ Request for Information on health equities and underutilized services (the RFI). We provide a brief contextual background outlining the ever-growing cost of preventable osteoporotic fractures to our health system and the lives of Medicare beneficiaries and underscoring the importance of osteoporotic fracture prevention. FLS payment mechanisms align with the issues identified and priorities articulated in CMS’ Proposed Rule:

- Underutilization of osteoporosis diagnostic testing and treatment drive health inequities and disparities that disproportionately prevent women from remaining independent and in their homes as they age.
 - The high financial cost and patient burden of osteoporotic fractures is more likely to be catastrophic in underserved populations and can be mitigated.
 - FLS care coordination effectively addresses the under-utilization of osteoporosis diagnostic testing (dual-energy x-ray absorptiometry (DXA) and treatments in patients at highest risk of poor health outcomes.

² Id.

- Global period structures are a key contributor to the osteoporosis care gap as orthopedic surgeons treating an acute fracture are not compensated for the time and services required to address the underlying chronic condition of osteoporosis.

Post-fracture services to detect and address bone fragility due to osteoporosis are “high value” health services.

CMS’ RFI seeks stakeholder input to identify “high value” health services that are underutilized and impact health equity within the Medicare program. CMS describes high value services as those “services that provide the best possible health outcomes at the lowest possible cost” or seek “to improve health, avoid harms, and eliminate wasteful practices.”³

Osteoporosis is a chronic condition that disproportionately impacts women as they age. The National Institutes of Health (NIH) defines 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).”⁴ 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.⁵

- Medicare beneficiaries suffered approximately 2.1 million osteoporotic fractures in 2016.⁶
- The total annual cost for osteoporotic fractures among Medicare beneficiaries was \$57 billion in 2018.⁷
- Medical costs for Medicare beneficiaries in the 12-month period following a new osteoporotic fracture were more than double the costs incurred for the same beneficiary in the 12-month period prior to the fracture.
- ***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.***

³ Id.

⁴ Lems WF, Dreinhöfer KE, Bischoff-Ferrari H, et al. EULAR/EFORT recommendations for management of patients older than 50 years with a fragility fracture and prevention of subsequent fractures. *Ann Rheum Dis* 2017;76(5):802–10. NIH, Osteoporosis Overview, Osteoporosis Overview | NIH Osteoporosis and Related Bone Diseases National Resource Center.

⁵ Looker AC, Frenk SM. Percentage of Adults Aged 65 and Over With Osteoporosis or Low Bone Mass at the Femur Neck or Lumbar Spine: United States, 2005–2010. Centers for Disease Control and Prevention. https://www.cdc.gov/nchs/data/hestat/osteoporsis/osteoporosis2005_2010.pdf. Published 2015.

⁶ 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)

⁷ 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.

The National Committee for Quality Assurance (NCQA) recently (February 2020) reiterated 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.⁸ (NCQA, 2020).

The 2021 Update to the Milliman report (2016 claims data) confirmed the catastrophic impact that health inequities in osteoporotic fractures exact on Medicare beneficiaries:

- 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.⁹

In addition to the high costs to the health care system and Medicare beneficiaries, osteoporotic fractures have been identified as a key underlying condition for which high-dose opioids are prescribed. In the proposed 2022 Medicare Physician Schedule rule, CMS cited a 2019 study¹⁰ indicating that osteoporosis was one of the common conditions among dually eligible beneficiaries using “high dose” opioids to treat pain between 2006 through 2015. A recent study found that twenty-three percent of opioid-naïve hip fracture patients became chronic users after surgery.¹¹

It is important to note that osteoporosis is generally considered a “silent disease” because **there are typically no symptoms until a bone is broken or one or more vertebrae collapse**. Osteoporotic fractures, not the underlying disease, drive patient need for high dose opioids. The best approach to reducing that opioid use is to prioritize efforts that promote care coordination and management approaches to osteoporotic fracture prevention.

⁸ NCQA, Proposed New Measure for HEDIS®1 MY 2020 Osteoporosis Screening in Older Women (OSW), 20200212_09_Osteo.pdf (ncqa.org)

⁹ Milliman Report (2021 Update).

¹⁰ <https://www.macpac.gov/wp-content/uploads/2020/06/Chapter-1-Integrating-Care-for-Dually-Eligible-Beneficiaries-Background-and-Context.pdf>.

¹¹ Hereford, et al., Prevalence of Chronic Opioid Use in the Elderly After Hip Fracture Surgery, [Prevalence of Chronic Opioid Use in the Elderly After Hip Fracture Surgery - The Journal of Arthroplasty \(arthroplastyjournal.org\)](https://arthroplastyjournal.org) (Feb 2022).

Underutilization of osteoporosis diagnostic testing and treatment drive health inequities and disparities that disproportionately prevent women from remaining independent and in their homes as they age.

Unlike many other high-cost, debilitating conditions, outcomes in osteoporosis can be significantly improved through effective screening, osteoporosis diagnosis and fracture risk assessment, and treatment planning and follow-up services to ensure that patients receive appropriate therapeutic and lifestyle modification interventions, including prescription medications. 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. This means that for many Medicare beneficiaries, the first sign of osteoporosis is an osteoporotic fracture event. Unfortunately, failures in primary prevention are compounded by inadequate post-fracture follow-up that could prevent a future, potentially catastrophic osteoporotic fracture.

- The table on the following page delineates the real-world failures in secondary prevention, particularly in light of the diagnostic and treatment tools that are available and within the standard of care.
- 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.¹²
- 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 by 2040.¹³
- 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.
 - 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 their fracture.¹⁴

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.” Orthopedists treat the fractures and discharge patients for rehabilitation. Primary care physicians, even when informed of a fracture, may not see the patient in the near-term or be comfortable determining a treatment plan tailored to the patient’s future fracture risk. The table below compares access to the standard of care in osteoporotic fracture patients with

¹² Id.

¹³ Id.

¹⁴ Yusuf A, et al. Presented at: ASBMR annual meeting. October 9-12, 2015; Seattle, WA. Abstract MO0350.

care received by myocardial infarction (heart attack) patients. Heart attack and fractures are both acute, sentinel events within a chronic condition. Both have established care pathways to mitigate the risk of poor health outcomes. The vast majority of the predominantly-male heart attack population receive the standard of care. The clear majority of the primarily-female osteoporotic fracture patient population remain at high risk of a future fracture due to failures in adequate follow-up to treat and manage their osteoporosis.

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

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

Primary and secondary prevention failures are not only costly; they drive significant health inequities and disparities. The burden of osteoporotic fractures falls disproportionately on women, who make up approximately 70.5% of osteoporotic fracture patients. This is in direct contrast to the majority-male AMI patient population. It is also important to note that although Black men and women are generally less likely to suffer from osteoporosis and sustain a fragility fracture than White women and men, they are more likely to die from an osteoporotic fracture than their White counterparts. Black women tend to have higher bone mineral density throughout their life and a lower prevalence of osteoporosis overall. However, they face health disparities and other issues that put them at high risk for developing and suffering complications from this disease:

- Compared to white women, Black women with postmenopausal osteoporosis experience worse outcomes after sustaining hip and several other types of fractures.¹⁵
- Black women are more likely to have lupus¹⁶ or sickle cell anemia¹⁷ - both of which are linked with a higher osteoporosis risk.
- The Black community is less likely to get screened¹⁸ for osteoporosis depending on age, and therefore more likely to go undiagnosed.
- Up to 75% of Black Americans are lactose-intolerant. This can prevent them from consuming dairy products—an excellent source of bone-strengthening calcium and Vitamin D. In fact, Black women's calcium intake is 50% less than the Recommended Dietary Allowance.
- Black women are less likely to receive medication to treat osteoporosis and prevent fractures.
- A recent study found that Black patients were at greater risk for delayed surgery following a hip fracture.
- Women in the Black community also tend to have less awareness about osteoporosis than white women,¹⁹ which can delay prevention and treatment.
- The Milliman report found that Black patients suffering an osteoporotic fracture in 2016 had worse outcomes, including:
 - higher mortality (22% die within 12 months and 35.4% die within 2-3 years post-fracture)
 - just 5% of Black osteoporotic fracture patients receive any follow-up care to address their underlying bone fragility
 - Black patients were 30% less likely to receive post-fracture physical therapy
 - Black patients have a 2.3 times higher risk of destitution, debility and death in the year following vertebral fracture.^{20 21}

¹⁵ Wright NC, Chen L, Saag KG, Brown CJ, Shikany JM, Curtis JR. Racial Disparities Exist in Outcomes After Major Fragility Fractures. *J Am Geriatr Soc.* 2020 Aug;68(8):1803-1810. doi: 10.1111/jgs.16455. Epub 2020 Apr 26. PMID: 32337717; PMCID: PMC7935465.

¹⁶ [African Americans and Lupus.pdf](#)

¹⁷ [Sickle Cell Disease - Hematology.org](#)

¹⁸ Gillespie CW, Morin PE. Trends and Disparities in Osteoporosis Screening Among Women in the United States, 2008-2014. *Am J Med.* 2017 Mar;130(3):306-316. doi: 10.1016/j.amjmed.2016.10.018. Epub 2016 Nov 21. PMID: 27884649.

¹⁹ [10 Things to Know About Racial Differences in Bone Health - American Bone Health](#)

²⁰ *Am Geriatr Soc.* 2020 Apr 26. doi: 10.1111/jgs.16455.

²¹ Milliman Research Report.

The persistent divergence between real-world treatment experience and the standard of care in post-fracture osteoporosis care underscores the complex care fragmentation as patients move from acute episode to rehabilitative care and community-based primary care. This “Bermuda triangle” has impeded osteoporosis diagnosis, treatment planning, and long-term chronic care management.

A July 2019 BHOF 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 ([POV+in+Bone+Health+Report+NOF+7.29.pdf \(squarespace.com\)](#)). This report was derived from a 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. The BHOF survey augments the Milliman report findings to underscore the complexities associated with secondary prevention of osteoporotic fractures. It also highlights the need for patient-centered care that includes timely intervention from a bone health clinician, 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.

Notable findings from the BHOF report include:

- 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:
 - o Have been less active than previously due to fracture risk concerns; and
 - o 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 50), remain untreated.
- Over 22% of untreated individuals with a history of a previous fracture reported that they discontinued treatment due to side effects.
- 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 post-fracture osteoporosis care gap. The likelihood of having not been offered treatment in individuals with a fracture history was nearly double that of those with osteoporosis diagnosed through DXA or other primary prevention service (24.1% and 13.3%, respectively).

FLS programs are uniquely suited to bridge gaps due to care fragmentation and ensure that patients receive the standard of care to address their long- and short-term future fracture risk. Quality measure reporting, including the evolving set of Merit-based Incentive Payment System (MIPS) Value Pathways (MVPs) quality measures may be a reasonable mechanism for evaluating progress in secondary prevention of osteoporotic fractures. It has not, and almost certainly cannot, however, provide sufficient incentives/disincentives to drive high quality secondary fracture prevention in the primary care settings the Medicare program has historically relied upon. The Quality Payment Program is, similarly, not designed to spur creation of new FLS sites or sustain existing programs.

HHS can address the osteoporosis care gap by implementing a payment mechanism that captures the resources required to deliver high-quality care within an FLS

The sets of incentives and/or disincentives within the Physician Fee Schedule, including the Quality Payment Program, have been ineffective in ensuring that fragility fracture patients receive any level of medical care for their underlying bone fragility. Encouraging communication from acute to primary care has not closed the care gap in secondary prevention of fragility fractures, and efforts to date have failed to ensure that bone fragility follow-up is performed and/or that osteoporosis treatment is prescribed. This is neither unusual nor surprising – CMS’ efforts to leverage the QPP to address the opioid use crisis were an important but insufficient step toward encouraging clinicians to incorporate substance use disorder (SUD) treatment or pain management coordination into their practices. CMS acknowledged the need for a more comprehensive approach and implemented sets of “G” codes to increase provider adoption of coordinated, collaborative approaches to SUD treatment. The proposed pain management “G” codes further underscore CMS’ commitment to ensuring that Medicare beneficiaries have access to the standard of care.

Osteoporosis and substance use disorders are both subject to significant under-diagnosis and under-treatment, and both drive health inequities. Based on CMS data, however, osteoporotic fractures impact a greater number of Medicare beneficiaries than opioid use disorder (6.6% versus 2.8%) and exact a disproportionate and inequitable toll on the health and lives of women as they age. CMS’ urgency in addressing the pain management and SUD treatment needs of Medicare beneficiaries through coding and payment mechanisms was a necessary step to improve access to the standard of care. We urge the Agency to act with similar urgency to ensure that the primarily-female patients with unaddressed osteoporosis receive the standard of care in reducing their risk of a catastrophic osteoporotic fracture.

We have identified several logistic and reimbursement (coding/payment) hurdles that can be addressed through coding and payment mechanisms acknowledging and encouraging FLS interventions, including:

- Acute hip fractures are reimbursed through bundled payments with 90-day global periods (discussed in greater detail below).
- Existing structures for treatment and follow-up in acute care settings approach fractures as an injury rather than as a sentinel event indicative of underlying bone fragility.
- Multiple care settings for patients (inpatient/outpatient, rehabilitation hospitals, skilled nursing facilities) 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 – these models may actually discourage evidence-based secondary prevention of osteoporotic fractures.
- The limited sets of quality reporting mechanisms do not sufficiently incentivize the standard of care. In addition, many patients, particularly those in underserved populations, do not have an ongoing care relationship with a primary care provider
- Many patients are lost to follow-up due to care received within a rehabilitation hospital or other facility in the immediate post-acute period; patients in underserved communities are particularly vulnerable to fragmented care and may not have an identifiable primary care clinician.
- Provider-assumed risk and quality reporting periods do not fully encompass the time period for heightened risk for a repeat fracture.

FLS programs can be described as coordinated care interventions headed by an FLS coordinator (a physician, 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 planning, follow-up, 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.

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. Since the first Fracture Liaison Services in the early 2000s, multiple studies have been conducted to confirm the utility of these fracture care models. 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%).

Leading US health systems, including Geisinger and Kaiser Permanente, and specialty societies 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 Geriatric Society (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 Orthopaedic Association (AOA) has operated the Own the Bone quality improvement program since 2009, with the objective of improving post-fracture bone health care coordination, evaluation, and treatment.
 - o During this time, almost 300 hospitals and physician practice groups have utilized the program to structure and implement a post-fracture, or fracture liaison service (FLS), at their institutions.
 - o The AOA experience has demonstrated that the lack of reimbursement for FLS care continues to be a significant barrier to the widespread adoption of post-fracture bone health management by orthopaedic departments and practices, to the detriment of fragility fracture patients.

Kaiser and Geisinger are, however, “closed” health systems. Their assessment of cost-effectiveness favors preventive care efforts that have potential to avoid future costs. Unfortunately, existing Medicare payment mechanisms and policies – in fee-for-service as well as Medicare Advantage, take a year-to-year approach to costs incurred or avoided that impedes adoption of FLS. 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. The key issue for CMS as steward of the Medicare program, however, is that a systemic failure to ensure beneficiary access to the standard of care disproportionately and inequitably burdens the primarily female osteoporosis patient population.

The attached “White Paper” outlines a pragmatic approach to encourage FLS program adoption that HHS could implement with the creation of “G” codes. CMS has used this approach to improve care for opioid use disorder and proposes to implement new “G” codes for pain management services. 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 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. It also identifies a set of FLS quality measures that FLS programs, CMS, and other payers could use for program evaluation and improvement.

FLS programs are analogous to the sets of services within the G codes for SUD treatment and Chronic Pain Management and Treatment (CPM) Bundles – providers act 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. FLS programs are specifically designed to address underutilization of high-value services that are not adequately captured within the existing set of reimbursement codes. Like the services associated with chronic pain management:

- There is currently no existing CPT code that specifically describes the work of the clinician who performs comprehensive, holistic post-fracture follow-up for secondary prevention of fragility fractures.
- The resources required to furnish FLS are not appropriately recognized under current coding and payment mechanisms.
- E/M codes, chronic care management codes, and transition care management codes and values do not appropriately reflect time involved in furnishing FLS to beneficiaries suffering an initial osteoporotic fracture.
- CMS has authority under section 1848 of the Act to establish codes and payment amounts to reflect the relative value of the resources involved in furnishing care to Medicare beneficiaries.
- Creating separate coding and payment for FLS will enable CMS to track beneficiary access to evidence-based post-fracture care.
- FLS services have been demonstrated to prevent or reduce the need for acute services, such as those due to subsequent osteoporotic fractures (including emergency room visits, inpatient stays, surgery, and pain management).
- FLS have the potential to reduce the disparities and health inequities that osteoporosis care gaps exact on women, including the disproportionately catastrophic impact on the health and lives of Black women and other underserved populations.

CMS' proposed code descriptor for the chronic pain management bundle details a set of services that are similar to those within the "G" codes we propose for FLS. CMS proposes:

HCPCS code GYYY1: *Chronic pain management and treatment, monthly bundle including, diagnosis; assessment and monitoring; administration of a validated pain rating scale or tool; the development, implementation, revision, and maintenance of a person-centered care plan that includes strengths, goals, clinical needs, and desired outcomes;*

HCPCS code GYYY2: *Each additional 15 minutes of chronic pain management and treatment by a physician or other qualified health care professional, per calendar month (List separately in addition to code for GYYY1). (When using GYYY2, 15 minutes must be met or exceeded.)*

The set of services within our proposed FLS bundle are more resource-intensive, and we have proposed that this code would (a) be billable once per beneficiary per fracture episode (rather than on a monthly basis) and (b) describe FLS services over the 45-day day period from the initial visit through treatment planning and follow-up. Although payment on a monthly basis could be implemented, we believe that a 45-day care episode is more consistent with the FLS model; E/M codes are sufficient to describe the services provided in subsequent follow-up visits. We propose:

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 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*

The attached PowerPoint slides outline BHOE and ASBMR's methodology for valuing the FLS set of services, as well as our proposed payment for these services based upon interviews with FLS programs. Those interviews underscored the substantial, uncompensated time and resources required to ensure that osteoporotic fracture patients receive appropriate follow-up:

- Physician/QHP time:
 - o prior to initial encounter (non-face-to-face): 20 minutes
 - o initial face-to-face encounter: 53 minutes (either in person or via telehealth)
 - o 45-day-period-subsequent-to-initial-encounter period (non-face-to-face): 96 minutes
 - o 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.
- Clinical/Administrative 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

FLS is recognized internationally and has been identified as the gold standard for responding to the ever-increasing financial and personal costs of preventable osteoporotic fractures.

The osteoporosis care gap is not unique to the US. 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. Other nations have increasingly recognized that their aging populations make maintaining the status quo in osteoporotic fracture prevention financially unsustainable.²² It is also unnecessary given the availability of reliable tools to detect, diagnose, and treat osteoporosis and a proven coordinated, collaborative care model – Fracture Liaison Service (FLS) - that is recognized internationally as the “gold standard” for secondary prevention of osteoporotic fractures.^{23 24 25 26 27}

Although we have found wide differences in service provision and uptake, all 29 European countries surveyed face an enormous osteoporosis and fragility fracture burden, with a substantial impact on current and future healthcare budgets. In aggregate, the economic burden of incident and prior fragility fractures was estimated at close to €57 billion in 2019, with an estimated 248,487 causally related deaths that year. As the number of women and men aged 75 years or more is expected to increase by more than 29% and 42% respectively between 2019 and 2034, the annual number of

²² Willers, C., Norton, N., Harvey, N.C. *et al.* Osteoporosis in Europe: a compendium of country-specific reports. *Arch Osteoporos* **17**, 23 (2022). <https://doi.org/10.1007/s11657-021-00969-8>.

²³ 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.

²⁴ Javaid MK, Kyer C, Mitchell PJ, et al. Effective secondary fracture prevention: implementation of a global benchmarking of clinical quality using the IOF capture the fracture(r) best practice framework tool. *Osteoporos Int.* 2015;26(11):2573–2578.

Mitchell PJ. Best practices in secondary fracture prevention: fracture liaison services. *Curr Osteoporos Rep.* 2013;11(1):52–60.

²⁶ Akesson K, Marsh D, Mitchell PJ, et al. Capture the fracture: a best practice framework and global campaign to break the fragility fracture cycle. *Osteoporos Int.* 2013;24(8):2135–2152.

²⁷ Marsh D, Akesson K, Beaton DE, et al. Coordinator-based systems for secondary prevention in fragility fracture patients. *Osteoporos Int.* 2011;22(7):2051–2065.

osteoporotic fractures will rise considerably. It is expected to increase by approximately +24.8% in that time period, reaching 5.34 million annual fragility fractures.”²⁸

The survey results highlighted the need for action. Paddy Kenny, Ireland’s Joint National Clinical Lead for the National Clinical Programme for Trauma and Orthopaedic Surgery (NCPTOS) said “[t]he publication and findings of the facilities survey demonstrates the need for the implementation of FLS nationally as a matter of urgency. FLS has been proven internationally to be effective clinically and economically for the management of secondary fracture prevention. This service will result in reduced hospital admissions. The program fully supports the establishment of the FLS Database which will be publishing its preliminary report and recommendations later this year.”

A June 2022 review article outlines osteoporosis care gaps and FLS program adoption efforts in response to those gaps throughout Europe, noting 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.

Medicare’s global period structures are a key contributor to the osteoporosis care gap as orthopedic surgeons treating an acute fracture are not compensated for the time and services required to address the underlying chronic condition of osteoporosis

FLS services are a chronic care intervention triggered by an acute episode. As outlined above, although the FLS model has been demonstrated to improve osteoporosis diagnosis and treatment, and a decrease in morbidity in osteoporotic fracture patients, the existing coding and payment framework fails to sufficiently reimburse providers for the set of services rendered within an FLS program. This has resulted in limited adoption of these services in new programs to serve Medicare beneficiaries and resource constraints impeding optimal performance for existing FLS programs. Moreover, the orthopedic surgery practices treating fractures are constrained from performing additional services due to applicable “global periods” and their limitations on post-fracture services for which payment can be made.

The need for these additional services is *not* related to the acuity or complexity of the acute fracture. Rather, it is based on the characteristics of the patient (age, medication history, family history) and

²⁸ [Scope-2021 | International Osteoporosis Foundation](#)

nature of the injury causing the fracture (fall from standing height vs high-trauma injury). We urge CMS to ensure that orthopedic surgery practices interested in incorporating osteoporosis-related care coordination and collaborative care services are reimbursed for that care by:

- identifying or creating a payment code that orthopedic surgery practices could report when coordinating their care with that of an FLS program to which they refer patients
- ensuring that any FLS-specific payment code is reportable by an orthopedic surgery practice treating the acute episode, and payable regardless of the applicable global period for that acute episode

Conclusion

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.

The undersigned appreciate the opportunity to provide comments on the Proposed Rule and are hopeful that CMS will act with urgency to ensure that the primarily-female osteoporotic fracture population has access to the services required to avoid a future, and potentially catastrophic, osteoporotic fracture.

If you have any questions please contact Doug Fesler, Executive Director, American Society for Bone and Mineral Research at 202-367-2341 or dfesler@asbmr.org, or Claire Gill, CEO, National Osteoporosis Foundation at 703.647.2025 or claire.gill@nof.org.

Very truly yours,

Claire Gill, CEO
Bone Health and Osteoporosis Foundation

Doug Fesler, Executive Director
American Society for Bone and Mineral Research

Joined by (in alphabetical order):

Alliance for Aging Research

American Academy of PAs

American Association of Clinical Endocrinology

Health Equity and Osteoporosis

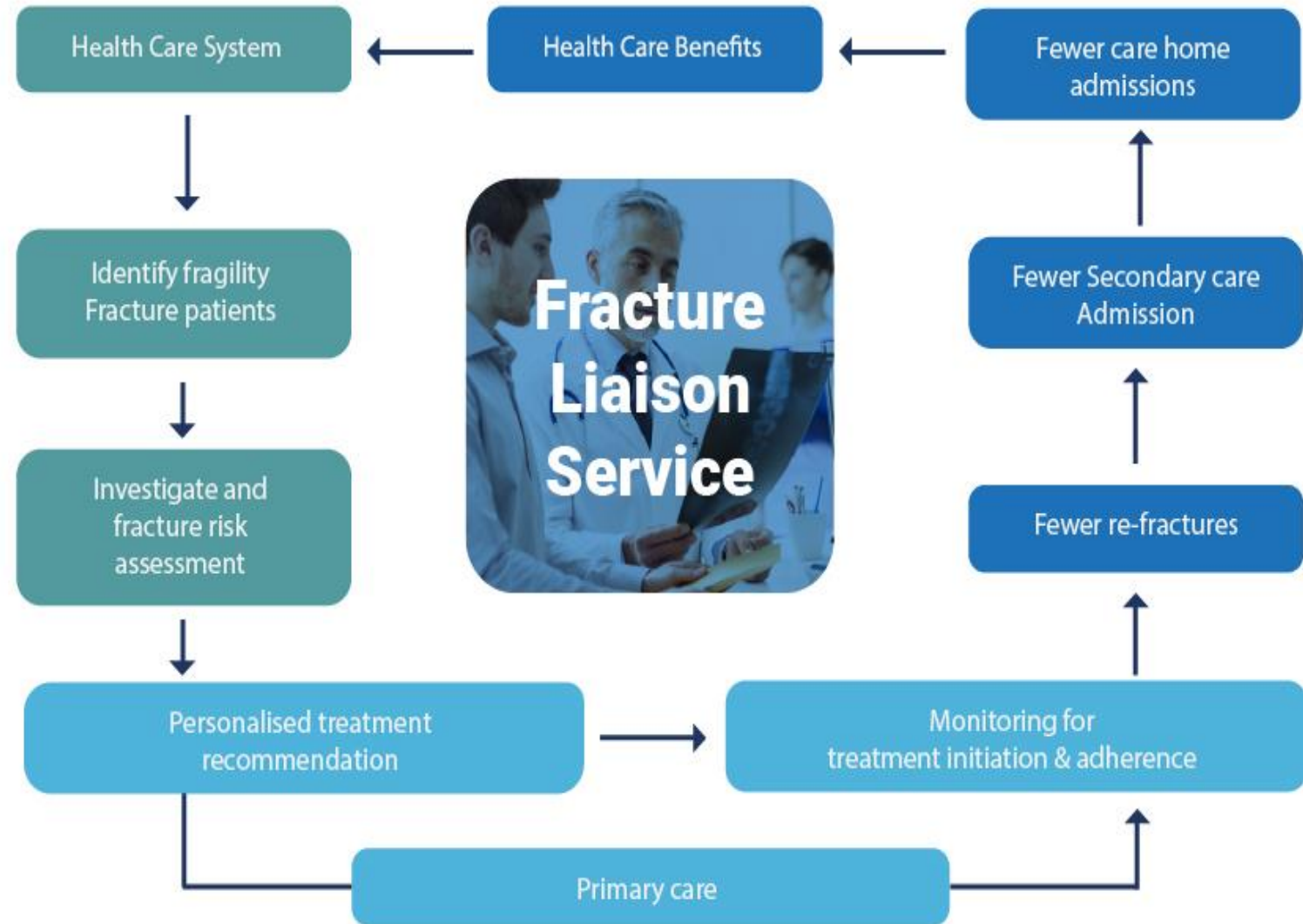
American Association of Hip and Knee Surgeons
American Association of Nurse Practitioners
American Association of Orthopaedic Surgeons
American Bone Health
American Orthopaedic Association, Own the Bone Program
American Society of Endocrine PAs
American Society of Osteoporosis Providers
Black Women's Health Imperative
Cancer Fashionista
Caregiver Action Network
Carrie's TOUCH
Geisinger Health System
Global Healthy Living Foundation
HealthyWomen
International Society for Clinical Densitometry
Marcus Institute for Aging Research and Hebrew Rehabilitation Center, Hebrew SeniorLife, Affiliated with Harvard Medical School
National Association of Nurse Practitioners in Women's Health
National Menopause Foundation
National Spine Health Foundation
North American Spine Society
Orthopaedic Trauma Association
Society for Women's Health Research
The Endocrine Society
U. S. Bone and Joint Initiative
Washington University in St. Louis, Division of Bone and Mineral Diseases, Bone Health Program

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)**

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.



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.

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

Payment to assess, treat osteoporosis separated from all mechanisms (payment, quality, costs) for acute fracture episode.

Initial 45-day episode for FLS assessment, treatment planning, care coordination, treatment initiation, and initial follow-up

Enable flexibility to incorporate telemedicine as appropriate.

Acute fracture care provider can perform FLS services or receive transition payment for “warm” hand-off and transition to FLS.

Incrementally higher payment for complex patients requiring more time to assess, diagnose, communicate treatment plan, follow-up

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.

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.

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

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

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.

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

September 2021





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 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 for 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 Fracture Liaison Service (FLS) framework 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' 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 (154,000 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 50), 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.
 - o 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 mc
- 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.

References

AGS CoCare, <https://www.americangeriatrics.org/programs/ags-cocarer-ortho>

ASBMR Secondary Fracture Prevention Initiative Coalition,
<https://www.secondaryfractures.org/about-coalition>

Balasubramanian A, et al. Presented at: ASBMR annual meeting; October 16-18, 2016; Atlanta, GA. Abstract FR0233.

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. doi:10.1007/s00198-018-4732-1

Camacho PM, et al., American Association of Clinical Endocrinologists/American College of Endocrinology Clinical Practice Guidelines for the Diagnosis and Treatment of Postmenopausal Osteoporosis—2020 Update, *Endocrine Practice*, Volume 26, Supplement 1, 2020,
<https://doi.org/10.4158/GL-2020-0524SUPPL>

Chaudhry SI, et al., National trends in recurrent AMI hospitalizations 1 year after acute myocardial infarction in Medicare beneficiaries: 1999-2010." *J Am Heart Assoc* 2014; 3 e001197.

Conley, R.B., Adib, G., et al., (2020), Secondary Fracture Prevention: Consensus Clinical Recommendations from a Multistakeholder Coalition. *J Bone Miner Res*, 35: 36-52. <https://doi.org/10.1002/jbmr.3877>

Dunn P, Webb D, Oleginski TP. Geisinger high-risk osteoporosis clinic (HiROC): 2013-2015 FLS performance analysis. *Osteoporos Int* 2018;29:451–7.

Eastell R, Rosen CJ, Black DM, Cheung AM, Murad MH, Shoback D. Pharmacological Management of Osteoporosis in Postmenopausal Women: An Endocrine Society* Clinical Practice Guideline. *J Clin Endocrinol Metab*. 2019 May 1;104(5):1595-1622. doi: 10.1210/jc.2019-00221. PMID: 30907953.

Eisman JA, Bogoch ER, Dell R, et al. Making the first fracture the last fracture: ASBMR task force report on secondary fracture prevention. *J Bone Miner Res* 2012;27(10):2039–46. September 16, 2019 25

Faridi KF, et al. Timing of First Postdischarge Follow-up and Medication Adherence After Acute Myocardial Infarction. *JAMA Cardiol* 2016;1 147-155.

Greenspan SL, Singer A, Vujevich K, et al. Implementing a fracture liaison service open model of care utilizing a cloud-based tool. *Osteoporos Int* 2018;29:953–60.

JAMA . 2001 Feb 14;285(6):785-95.doi: 10.1001/jama.285.6.785.

Javaid MK, Sami A, Lems W, Mitchell P, Thomas T, Singer A, Speerin R, Fujita M, Pierroz DD, Akesson K, Halbout P, Ferrari S, Cooper C. A patient-level key performance indicator set to measure the effectiveness of fracture liaison services and guide quality improvement: a position paper of the IOF Capture the Fracture Working Group, National Osteoporosis Foundation and Fragility Fracture Network. *Osteoporos Int*. 2020 Jul;31(7):1193-1204. doi: 10.1007/s00198-020-05377-1. Epub 2020 Apr 8. PMID: 32266437; PMCID: PMC7280347.

Lems WF, Dreinhöfer KE, Bischoff-Ferrari H, et al. EULAR/EFORT recommendations for management of patients older than 50 years with a fragility fracture and prevention of subsequent fractures. *Ann Rheum Dis* 2017;76(5):802–10.

NIH, Osteoporosis Overview, [Osteoporosis Overview | NIH Osteoporosis and Related Bone Diseases National Resource Center](#).

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.

Looker AC, Frenk SM. Percentage of Adults Aged 65 and Over With Osteoporosis or Low Bone Mass at the Femur Neck or Lumbar Spine: United States, 2005–2010. Centers for Disease Control and Prevention.

https://www.cdc.gov/nchs/data/hestat/osteoporsis/osteoporosis2005_2010.pdf. Published 2015.

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 \(squarespace.com\)](#)

NCQA, Proposed New Measure for HEDIS®1 MY 2020 Osteoporosis Screening in Older Women (OSW), [20200212_09_Osteo.pdf \(ncqa.org\)](#)

Olenginski TP, Maloney-Saxon G, Matzko CK, Kirchner HL, Bengier A, Newman ED. High-risk osteoporosis clinic (HiROC): improving osteoporosis and postfracture care with an organized, programmatic approach. *Osteoporos Int* 2015;26:801–10.

Shoback D, Rosen C, Black DM, Cheung AM, Murad MH, Eastell R, Pharmacological Management of Osteoporosis in Postmenopausal Women: An Endocrine Society Guideline Update, *The Journal of Clinical Endocrinology & Metabolism*, Volume 105, Issue 3, March 2020, Pages 587–594, <https://doi.org/10.1210/clinem/dgaa048>

Scholten DJ 2nd, Bray JK, Wang KY, Lake AF, Emory CL. Implementation of a fracture liaison service and its effects on osteoporosis treatment adherence and secondary fracture at a tertiary care academic health system. *Arch Osteoporos*. 2020 May 28;15(1):80. doi: 10.1007/s11657-020-00736-1. PMID: 32468516.

Wu C-H, Tu S-T, Chang Y-F, et al. Fracture liaison services improve outcomes of patients with osteoporosis-related fractures: a systematic literature review and meta-analysis. *Bone* 2018;111:92–100.

Wu C-H, Chen C-H, Chen P-H, et al. Identifying characteristics of an effective fracture liaison service: systematic literature review. *Osteoporos Int* 2018;1–25.

Wu C-H, Kao I-J, Hung W-C, et al. Economic impact and cost-effectiveness of fracture liaison services: a systematic review of the literature. *Osteoporos Int* 2018;1–16.

Yusuf A, et al. Presented at: ASBMR annual meeting. October 9-12, 2015; Seattle, WA. Abstract MO0350.

FLS 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
(Avg 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