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Royal Osteoporosis Society
Better bone health for everybody

APPG ON OSTEOPOROSIS AND BONE HEALTH

EQUAL ACCESS TO STRONG BONES: ADDRESSING THE TREATMENT GAP IN OSTEOPOROSIS

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Foreword from the Co-Chairs

Osteoporosis is one of the most urgent threats to living well in later life. Half of women over 50, and a fifth of men will suffer a fracture due to osteoporosis. Many fractures are preventable. A timely diagnosis and a treatment plan can prevent fractures. The cost of these medicines can be as little as £1 per month. But there is an enormous treatment gap with two-thirds of people who need anti-osteoporosis medications are missing out on them - around 90,000 people every year.

The All-Party Parliamentary Group on Osteoporosis and Bone Health launched this review to investigate the how the accessibility of osteoporosis medicines contributes to this treatment gap. Our evidence shows how a chaotic patchwork of drug prescribing rules is leading to inequity and inefficiency. While people living in more affluent areas can receive their medication from a GP, others are forced to endure lengthy waits for a referral to a specialist to get the same drug, or find that the treatment is not even available in their region. Our research found that if you lived in a more affluent area, you were more likely to have a range of medicines available to treat osteoporosis compared to if you lived in a more deprived area.

The consequences for Government, Integrated Care Boards (ICBs) and Health Boards are stark. The already enormous economic and societal burden of fractures is growing. Fractures caused by osteoporosis are the fourth worst cause of disability and premature death in the UK. Hip fractures (the end result of untreated osteoporosis) are the second biggest cause of unplanned admissions to hospital and cost £2 billion per year. And osteoporotic fractures among people of working age directly cost employers more than £130 million ever year through sickness absences.

This is solutions-focussed review. The needless barriers to identification, treatment and management of osteoporosis outlined in this report are sobering. But, the constructive recommendations, many of which are based on pockets of existing good practice, show a way through. And this report comes at vital time. The commitment from the Secretary of State for Health and Social Care to roll out Fracture Liaison Services nationally provides a rare opportunity. With universal early diagnosis services alongside equal access to bone strengthening medicine we can transform the lives of millions of people with osteoporosis across the UK, save the NHS and social care vast sums of money, and help our economy grow.


Sonia Kumar MP


Lord Black of Brentwood

Executive Summary

The scale of the 'treatment gap' in osteoporosis is impossible to overstate: 66% of people who should be on treatment are currently not on treatment. The result is over 550,000 fragility fractures every year in the UK at a £4.5 billion cost to the NHS. In the face of these costs, restricting or denying people access to medicines makes no clinical or economic sense.

In this Review, we have investigated the experience of accessing medicines for people living with osteoporosis, the variation across local drug formularies, and other barriers. We identified significant inequities and systemic challenges in the accessibility and delivery of osteoporosis medicines across the UK. These disparities exacerbate the treatment gap, which leads to tens of thousands of preventable fractures, widespread and avoidable disability, as well as thousands of premature deaths every year.

Key Findings

The Treatment Gap

Despite the existence of a range of osteoporosis treatments that are both clinically- and cost-effective, treatment rates are low and 69% of people with osteoporosis have experienced problems accessing medication, especially due to lack of expertise in primary care. Moreover, only 31% of patients start treatment within four months of diagnosis, and just 14% remain on treatment after a year. Many patients face significant barriers to adhering to prescribed regimens due to lack of understanding of benefits, side effects and poor communication with healthcare professionals.

Inconsistencies in Access

A postcode lottery currently determines whether people get access to osteoporosis medicines - with local formularies operating widely inconsistent policies for individual medicines. In some regions, treatments can be freely prescribed by GPs, in others they are completely unavailable, while in others, people are denied timely access to treatment and must wait for a specialist referral. Shared care protocols, intended to provide patients with safe, convenient and seamless care, are inconsistently applied, contributing to delays and inequities in treatment.

Health Inequalities

Disparity of access to medicines disproportionately affects people living in areas of deprivation for whom barriers to accessing healthcare are already pronounced. Studies show that prescribing rates of the most common osteoporosis treatments are lower in these areas compared to more affluent areas.

Delays and Systemic Barriers

Referrals for medicines that are classified as requiring a specialist lead to longer wait times for people who are at risk of fractures.

Gaps in Clinical Expertise and Leadership

Heavy reliance on hard-pressed non-specialist GPs means that people do not receive the support they need to make good treatment decisions. Without funding in primary care for effective management and follow-up, osteoporosis remains low priority. Across healthcare, lack of clinical ownership of osteoporosis has created a leadership vacuum that allows poor provision to continue unchallenged.

This Review underscores the critical need for systemic reforms to address the inequities and inefficiencies in osteoporosis treatment. A unified approach, involving a clear patient pathway, harmonized formularies and strengthened clinical leadership, is essential to close the treatment gap and improve outcomes for patients. By implementing these recommendations, policymakers can mitigate the devastating health and economic impacts of untreated osteoporosis, ensuring quality care for everyone, regardless of their postcode.

Summary of Recommendations

Supporting Quality Care

1. Once the new NICE osteoporosis guideline is published in 2025:
    - Integrated Care Systems (ICSs) must agree how it can be implemented across primary and secondary care in a coordinated manner within 6 months of release.
    - National governments must provide enough resource to fund implementation in primary care through mechanisms such as the Quality and Outcomes Framework (QOF) in England. (QOF is a system that rewards GP practices for providing high-quality care based on specific health outcomes).
2. NHS England should develop an osteoporosis/bone health workstream in the Getting-It-Right-First-Time programme to support implementation of osteoporosis guidance and best practice within ICSs.
3. NHS bodies should consider embedding into the patient pathway the referral of patients with osteoporosis to a medication support programme (such as that offered by the ROS).

Inconsistencies across formularies

4. NHS England must ensure that those ICSs yet to develop a unified drug formulary must do so by July 2025 to reduce the current postcode lottery and improve access to osteoporosis treatments.
5. NHS Wales should combine formularies under a national formulary in line with the 'One Wales' approach.

Access to individual medicines

6. ICS and Health Boards should issue guidance for healthcare professionals in primary care on the appropriate referral pathways for patients with osteoporosis to improve timely access to medicines.
7. ICS and Health Boards should ensure that all NICE or SMC (Scotland)-approved medicines for osteoporosis are included in local formularies to ensure that patients can access the most suitable medicine.
8. A review of the impact of formulary classification decisions on the rates of patients on treatment must be conducted by the Clinical Director for MSK supported by new Regional Osteoporosis and Fracture Prevention leads in each ICS or Health Board (see Effective clinical leadership).

Shared Care Protocols

9. NHSE and NHS Scotland should consult upon and publish national shared care protocol templates for injectable osteoporosis medicines suitable for administration in the community to reduce inconsistencies between regions and promote equitable access to osteoporosis medicines.

Delays to treatment

10. ICSs should reassess local decisions on the availability of osteoporosis treatments to ensure timely access to medicine, reduce the reliance on lengthy specialist referrals and increase the range of medicines available to primary care clinicians.

Raising the priority of osteoporosis

11. QOF indicators (England and Northern Ireland) must be updated to include ongoing management, and funding must be increased to reflect this change and to ensure that GP surgeries receive appropriate support, resources and remuneration to deliver the best care for their patients. New indicators must address identification of people at high risk of fracture, rates of people at risk who are on treatment, adherence to prescribed medicines and ongoing review and monitoring. Suitably high thresholds should be set to encourage proactive interest in patients with osteoporosis.

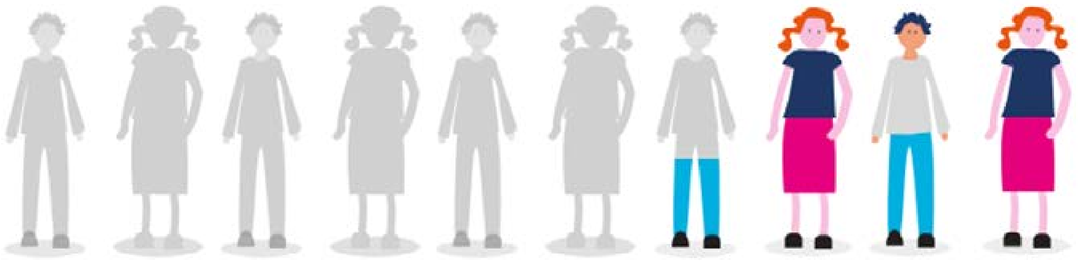
Effective clinical leadership

12. Regional Osteoporosis and Fracture Prevention Leads (in every ICS, Health Board and Health and Social Care Trust) should be appointed to provide clinical leadership for osteoporosis, to coordinate osteoporosis provision and improve access to medicines.

Introduction

Osteoporosis is known as a 'silent condition' because its progression is often invisible until someone breaks a bone. Considerable efforts are being made across the health service to identify people both before and after their first fracture – such as the UK Government's commitment to a roll-out of Fracture Liaison Services (FLS) which identify, assess and treat people who have had a fragility fracture.

Once identified, people have the opportunity to halt or slow the progression of the disease by taking medicine and making changes to their diet, lifestyle and habits to improve their bone health. Good progress has been made to produce a range of osteoporosis medicines that are both clinically – and cost-effective. However, for a number of reasons, despite the existence of effective treatments, treatment rates are low and have been falling for some time.[1–5] This is known as the **'treatment gap'**.



66% of people in the UK at high risk of fragility fractures are not on treatment [6]

Osteoporosis Medicines

Once diagnosed, someone with osteoporosis faces the prospect of lifelong management of their condition, including taking medicine for many years. Around 80% of calls to the ROS Helpline relate to medicines.[7] People need support to understand the choices of treatment available to them, practical issues around taking different drug treatments, side-effects, risks and benefits. The range of medicines fall into two main categories:

1. **Medicines that slow down or stop bone loss known as anti-resorptive drugs.** This includes the most prescribed treatment, oral bisphosphonates. These are taken as tablets and are the first-line treatment for most people diagnosed with osteoporosis. They can be prescribed by all GPs. The instructions for taking these medicines are slightly more complicated than for other medicines, so patients often find it difficult to take them correctly. Some side effects are common, while other, more serious longer-term side effects can happen but are extremely rare. Sadly, these drugs have been subject to significant scaremongering and misinformation in the media and amongst some medical professionals, as well as in online and offline communities of people living with the condition.[8] There are also medicines in this group that are administered as injections (usually in a primary or secondary care clinic, occasionally self-administered at home) or as an intravenous treatment in a healthcare setting.

2. **Medicines that stimulate bone formation known as anabolic drugs.** These treatments may be offered to people who are identified to be at high risk of further fracture (in accordance with NICE recommendations). They are typically self-administered as injections.

NICE has produced a range of guidance on the anti-osteoporosis drugs available, including how and when to use them.9–12 However, as noted in their 2018 report, only 31% of people had started treatment within four months of fracture and only 14% were still on treatment after twelve months.[13,14]

Drug Formularies

The British National Formulary (BNF) lists drugs that have been approved for use in the UK and provides treatment guidance.[i] Local formularies include a smaller selection of medicines to simplify prescribing. They are designed to set standards for best practice and promote high quality, evidence-based prescribing. It should reduce variation in the level of treatment provided to patients and rationalise the range of medicines used in standard practice, preventing the use of ineffective or overly expensive drugs.

In England, each Integrated Care System (ICS) should have its own formulary following a process to combine Clinical Commissioning Group (CCG) formularies. Similarly, each Health Board (in Wales and Scotland) or Health and Social Care Trust (Northern Ireland) has its own formulary and makes its own commissioning decisions around which medicines should be prescribed, under what circumstances, and in which setting it should be delivered (i.e. primary care or secondary care). Some medicines for example may be prescribed initially by a clinician at a hospital clinic but ongoing management taken over by the GP, while other medicines may only be available in secondary care settings. This varies by postcode.

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[i] Important treatment guidelines are also provided by other bodies such as National Institute for Health and Care Excellence (NICE) in England and the Scottish Medicines Consortium in Scotland.

Purpose of this Review

During our 2022 Inquiry into Primary Care we heard about difficulties people were having in accessing[ii] osteoporosis medicines and inconsistencies between neighbouring areas.[15] Therefore we decided to undertake a review of access to medicines to get a clearer picture of the problem across the UK, to identify barriers and find solutions.

What we did

- We conducted a survey of 365 people with osteoporosis through the ROS Helpline to ask them about their experience accessing medicines.
- We conducted a review of the 88 local formularies across the UK to understand the varying national picture of access to osteoporosis medicines.
- In November 2024 we held an oral evidence session in Parliament where we heard from: Janice McKinley, who has osteoporosis; Dr Chris Ellis, a GP and co-president of the Primary Care Rheumatology and Musculoskeletal Medicine Society; Louise Statham, Senior Lecturer in Clinical Pharmacy at Sunderland University and Honorary Metabolic Bone Specialist Pharmacist, Newcastle hospitals; PhD student Ashley Hawarden and Professor Zoe Paskins, Professor of Rheumatology and Honorary consultant rheumatologist – both from Keele University.

The lived experience

We know from our previous Inquiry into Primary Care and the oral evidence to this Review that the issue of sticking to a medicine regimen ('adherence') is a particular challenge in osteoporosis care.[16] Osteoporosis medicines are preventative, so people cannot 'feel' any benefit from taking them and if they miss a dose they will not notice any adverse effect, unlike other medicines.

The quality of the clinical encounter between a clinician (often a GP) and patient around the risks, side effects and benefits of osteoporosis treatment is critical. People will need to revisit this conversation several times over many years in order to stay on such long-term treatment, as their health, needs and circumstances change. It is difficult for people with busy lives to maintain focus on the devastating fractures they are aiming to avoid by taking their medicine.

We know that 25% of people never even start their medicine due to lack of awareness of the benefits and fear of side effects. Of those who take medicine initially, studies show that up to 86% will have stopped within a year.[13,16–18]

What we found

Our survey of people with osteoporosis found that:

- 69% of patients have experienced problems with accessing drug treatments. These problems included drug shortages and confusion among clinicians as to whether they were allowed to prescribe it.

> *"I have been taking strontium ranelate…for some years now but the drug has come off production…I have a severe kyphosis [forward rounding of the upper back] affecting my lungs and digestion and severe spinal collapse. I feel I should be prescribed romosozumab as I feel more confident in the [that] drug. The spinal pain I am suffering is unbearable."*

[ii] By *access* to medication, we mean people being able to get medicine that is right for them at the time they need it.

“My GP ignored the diagnosis in early stages and no treatment was given. Ultimately, I took charge of the management of my condition privately. Thereafter [I was prescribed] Denosumab, and scans were carried out. By this time I have lost over 4 inches in height and I’m struggling with exaggerated Kyphosis.”

“I had a consultation with a specialist who recommended two possible drugs for the serious osteoporosis in my spine & hips. I was told that one, given by injection, was only available privately for £10,000….However, the [ROS] said I could get the drug on the NHS. I now have to wait another month before I can get a phone appointment with the consultant to sort this discrepancy and decide which drug I should be taking.”

As in our previous Inquiry into Primary Care, we heard how people who were unable to take their medicine due to side effects encountered both a lack of expertise among primary care professionals and an unwillingness to prescribe alternative treatments. Some people were put off taking their medicine due to scaremongering and misinformation about serious but rare side effects. This is resulting in people remaining off-treatment and at risk of fracture.

“Neither my GP or consultant acknowledge the situation regarding the side effects I experienced taking alendronic acid. The situation now is I have stopped taking the medication and informed them.”

“I feel that once a drug treatment has been given then other options are not discussed.”

“When I was diagnosed with osteoporosis…the doctor seemed uninterested and not very knowledgeable about the questions I asked. She just said I should take one particular drug, gave no alternatives and seemed very pushed for time, as they usually are. I read a lot about it online which unfortunately put me off taking drugs.”

- *23% of these felt that they had problems in being prescribed the best drug treatments for them.*

“I have been excluded from the decision-making process [for] the treatment of my osteoporosis. I am unable to tolerate the oral medications due to side effects and have not been offered the annual IV infusion despite having ongoing issues with fractures.”

- *35% had experienced problems trying to discuss medicines with healthcare professionals.*

“[After contacting the ROS Helpline] I have been able to discuss the suggestion of alternative infusion rather than alendronic acid which is causing major side effects.”

Supporting quality care

Janice McKinley, who lives with osteoporosis, gave oral evidence to the APPG Review and highlighted how she needed to know what to expect next and what options were open to her as a patient.

“The GP was dismissive because he didn’t know what to do. There is no pathway or guidance, no obvious secondary care, referral or treatment pathway for newly diagnosed osteoporosis patients.” Janice McKinley

We heard from several people who gave oral evidence about the need for improvement in shared decision making about osteoporosis medicines. People with osteoporosis need expert advice around practical regimens for taking medicine, information regarding risks and benefits and advice around side-effects. This is a long-standing issue that the Group has raised through previous inquiries but positive action remains outstanding.[15] Qualitative research studies, including examples highlighted by Dr Hawarden, report that patients have insufficient information to make informed shared decisions about osteoporosis medicine. Members of Keele University’s Research User Group who were having difficulty taking oral bisphosphonates also reported being unaware other treatment options were available. [15]

Dr Ellis also highlighted how currently, in the absence of an up-to-date single osteoporosis guideline (a unified NICE guideline is under development), GPs are expected to navigate a large amount of conflicting clinical guidance on medicines and management during short consultations. He described the IT hoops that GPs face during consultations to assess a patient’s fracture risk and make the right clinical decisions regarding next steps (entering patient information into external risk checking tools, re-entering results back into the GP IT system, navigating the extensive clinical guidance, making a referral for a scan or specialist care or checking the formulary for prescribing guidance).

A new unified osteoporosis guideline is under development currently which is expected to bring together fracture risk assessment, treatments, repeat risk assessment, treatment monitoring and the information and support needs of people with osteoporosis.[19]

Our recommendations

1. Once the new NICE osteoporosis guideline is published in 2025:
    - ICSs must agree how it can be implemented across primary and secondary care in a coordinated manner within 6 months of release.
    - National governments must provide enough resource to fund implementation in primary care through mechanisms such as the Quality and Outcomes Framework in England.
2. NHS England should develop an osteoporosis/bone health workstream in the Getting It Right First Time programme to support implementation of osteoporosis guidance and best practice within ICSs.
3. NHS bodies should consider embedding into the patient pathway, the referral of patients with osteoporosis to a medication support programme (such as that offered by the ROS).

Inconsistencies across formularies

There is no consistent approach between local formularies in their classification of osteoporosis treatments – most use some sort of traffic light approach but the number of possible classifications varied from 4 to up to 16 classifications.

For the purposes of this analysis we simplified the systems (see Fig. 1)

Fig.1: Simplified formulary classification system

Green	Medicine can be prescribed by a GP (according to clinical guidelines) without referral to a specialist
Amber	Referral to a specialist is needed for a GP to prescribe, further monitoring by a specialist may also be required, including a Shared Care Agreement
Red	Medicine can be prescribed in secondary care only
Non-formulary	Medicine either not included on the formulary or designated 'non-formulary' which means that special dispensation may be required to prescribe.

Our analysis of the drug formularies found widespread inconsistency across the UK, and even within individual ICSs in England, regarding which medicines can be prescribed and who can prescribe them. In some areas treatments are prescribed without restrictions by GPs, in other areas, the same medicines are only available to patients if prescribed by secondary care clinicians, and in other areas they are not available at all. This inequity of access to treatments results in lower prescription rates and exacerbates the treatment gap.

We found **evidence of good practice** such as:

- areas where alternatives to bisphosphonates such as Denosumab are routinely prescribed in Primary Care.
- Northern Ireland has created a single national formulary reducing unwarranted variation in prescribing. In Scotland, the East Region Formulary provides a consistent approach across wide regions, whilst a single national formulary is in development.[20]

We also found that the process of combining formularies under an ICS remains incomplete. There are currently 64 formularies across 42 ICSs. A third of ICSs (14/42) still have two to five formularies operating within the region.

Our recommendations

4. NHS England must ensure that those ICSs yet to develop a unified drug formulary must do so by July 2025 to reduce the current postcode lottery and improve access to osteoporosis treatments.
5. NHS Wales should combine formularies under a national formulary in line with the 'One Wales' approach.

Access to individual medicines

The NHS Constitution in England states that "You have the right to drugs and treatments that have been recommended by NICE for use in the NHS, if your doctor says they are clinically appropriate for you."[21]

In this analysis we have focused on two anti-resorptive medicines that have been approved by NICE (and equivalents in devolved nations) for eligible patients - ibandronate tablets (one of the bisphosphonate family of medicines, the majority of which GPs can prescribe freely) and denosumab injections.

Ibandronate

Ibandronate is an anti-resorptive medicine taken as a tablet once a month, making it a good option if adherence to treatment is problematic. It is usually considered when someone has tried other bisphosphonates and they have not been suitable.

Denosumab

The drug, denosumab (Prolia®) is an anti-resorptive drug that is administered as a six-monthly injection. It is normally an option for people who have already tried more common drug treatments and they have not been suitable (due to side effects etc.). As it is only administered every six months, it can be helpful to support people to adhere to their treatment plan. However, the benefit from denosumab reverses rapidly if treatment is stopped, putting the patient at high risk of fracture. If someone needs to come off treatment, alternative osteoporosis medicine is required with careful monitoring during the transition.

What we found

These charts illustrate the current inequity of access to denosumab and ibandronate depending on where someone lives.

Ibandronate

In Fig. 2 we see an illustration of the inconsistency of the availability of ibandronate tablets for people with osteoporosis despite it being an approved medicine. Figures in England are proportionate to the 64 formularies in place.

- At 53% (34) of sites in England, 57% (4) in Wales and 35.7% (5) in Scotland, ibandronate tablets can be prescribed by a GP without referring to a specialist.
- At 28% (18) of sites in England and 43% (3) in Wales, referral to a specialist is required.
- In Northern Ireland ibandronate is not recommended, as other drug treatments are prioritised. This is also the case in 50% (7) of NHS Health Boards in Scotland.

ROS analysis found that prescription rates for ibandronate tablets for women 50 and over were 70% higher in ICSs where they are classified as 'green' on the formulary compared to ICSs where they are classified as 'amber' or 'red'. This disparity means that 1 million women in England, who could be eligible for Ibandronate, live in areas where a GP cannot prescribe it, which means they face additional barriers and delays to treatment.

Fig. 2: Access to ibandronate tablets (150mg)

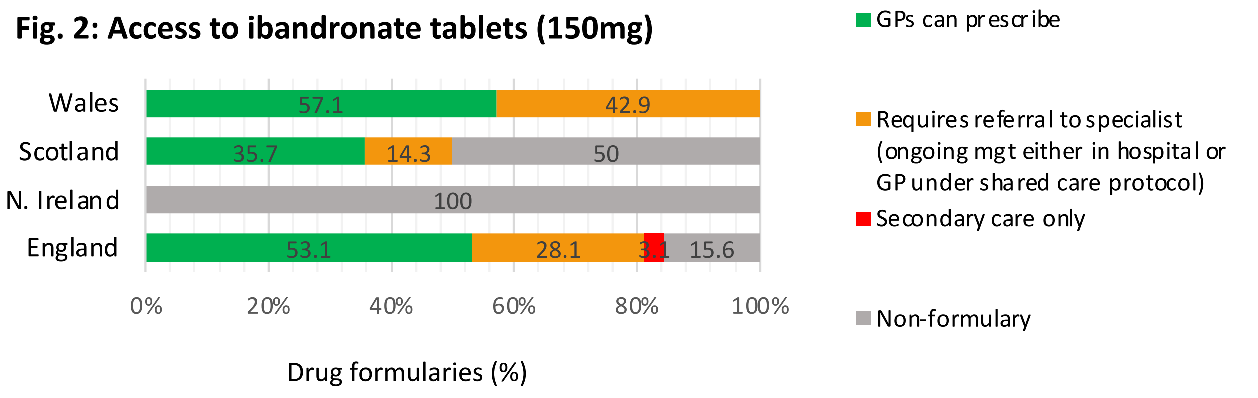
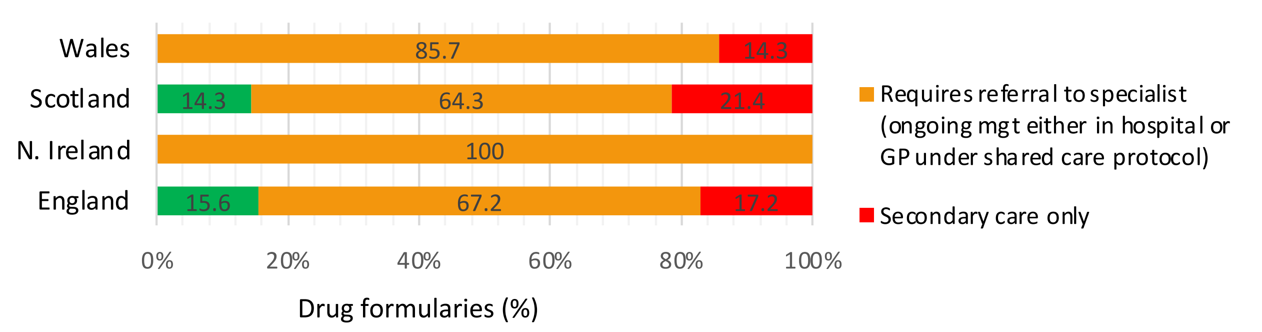


Fig.3: Access to denosumab



Denosumab

Similarly, fig. 3 demonstrates the inequity of access to denosumab. Taking England as an example:

- At 15.6% (10) of sites, a GP can prescribe denosumab without referring to a specialist.
- At 67% (43) of sites a GP must first refer to a specialist or consultant (with further protocols such as shared care agreements also required in some areas) before a prescription can be made.
- At 17% (11) of sites denosumab can only be prescribed by a specialist in secondary care.

ROS analysis found that prescription rates for denosumab were 3.5 times higher in ICSs where it is classified as 'green' on the formulary compared to ICSs where it is classified as 'amber' or 'red'[iii]. The impact of this inconsistency is that 1.25 million women in England, who could be eligible for this treatment, face additional delays and barriers to accessing denosumab due to the ICS region in which they live.

Romosozumab

Further to our findings, other research suggests that there is a similar pattern of inconsistency for the relatively new medicine, romosozumab. This medicine became available on the NHS in 2021. It is both anabolic and anti-resorptive and effective at increasing BMD and reducing fracture risk in post-menopausal women.[22-24] An analysis of prescribing of this medicine suggested that over 1.4 million eligible women over the age of 50 in the UK did not have access to romosozumab (as of December 2023).[25] The proportion of NHS sites with at least one prescription varied from nearly 60% in Wales to over 88% in England. The research suggests that even where romosozumab is being prescribed, the treatment numbers are far below the population (conservatively estimated) believed to be eligible in accordance with NICE resources.

Our recommendations

6. ICS and Health Boards should issue guidance for healthcare professionals in primary care on the appropriate referral pathways for patients with osteoporosis to improve timely access to medicines.
7. ICS and Health Boards should ensure that all NICE or SMC (Scotland)-approved medicines for osteoporosis are included in local formularies to ensure that patients can access the most suitable medicine.
8. A review of the impact of formulary classification decisions on the rates of patients on treatment must be conducted by the National Clinical Director for MSK supported by new Regional Osteoporosis and Fracture Prevention leads in each ICS or Health Board (see Effective clinical leadership).

Shared Care Protocols

Shared Care is where a specialist consultant and GP agree to share the management of a patient. In this case, a consultant will first prescribe a medicine (such as denosumab injections), after which the GP will prescribe and, in some cases, administer it. The GP will also monitor the patient within specified parameters in line with the shared care agreement, with support from secondary care. Clinical pharmacist Louise Statham told this Review about how often shared care agreements around denosumab (injectable treatment) cannot be reached and how this was being exacerbated by GP collective action. GP practices are under no obligation to agree. They often decline shared care arrangements due to capacity issues (e.g. someone trained and available to administer the injection, capacity to monitor blood results). Dr. Ellis, GP, told this Review that shared care for injectables depended very much on the relationship between primary and secondary care services which varies by area.

Shared care protocols also vary by ICS, Health Board or NHS Trust. There is evidence of good practice in Wales and Northern Ireland, where template shared care protocols for denosumab have been made available centrally by their NHS agency.[26] Neither NHS England or NHS Scotland have a centrally produced template shared care protocols for any osteoporosis medicines.

Impact on health inequalities

People with osteoporosis living in areas of deprivation have higher levels of need, they are:

- more likely to have low bone density and are at 25% higher risk of fragility fractures than people of higher socio-economic status.[27,28]
- more likely to experience a hip fracture and more likely to die as a result; they also spend longer in hospital recovering and are more likely to need to be readmitted after discharge.[29,30]

Despite higher levels of need there is evidence of the *inverse care law* whereby the people who most need healthcare are, perversely, the least likely to receive it.[31] Prescribing of bisphosphonates for example, and denosumab in particular, has increased markedly in affluent areas compared to areas of deprivation.[32] People living in deprived areas are not being given access to medicines for reasons that are unclear. They also have fewer economic and social resources to access healthcare services.[32,33] ROS analysis of drug formularies found that areas where a GP can prescribe denosumab without additional referral are focussed in the least deprived ICSs in the country. Eight of the nine ICSs where it is classified as 'green' are among the least deprived ICSs in England. Whilst only one of the most deprived half of ICSs classifies the medicine as 'green'. A person with osteoporosis is therefore much more likely to face additional delays and barriers to being prescribed denosumab if they live in a deprived area.

GP practices and community pharmacies are the best point of access to healthcare for these neediest groups. Louise Statham, clinical pharmacist, told this Review however, that where there is no shared care arrangement in place for denosumab and GPs cannot prescribe it, patients must travel to hospital for two to four appointments every six months (see Fig.4). Similarly, access to zoledronic acid is impacted if hospitals cannot order blood tests locally through phlebotomy hubs and patients are forced to travel to hospital on a regular basis. This disproportionately impacts people living in areas of deprivation who face barriers including:

- the cost of parking and fuel.
- a greater reliance on inadequate or unsuitable public transport.
- a greater reliance on other people to take them to appointments.
- more difficulty getting time off work for appointments due to insecure, temporary or low paid employment.

[iii] In some areas zoledronate is prescribed in secondary care as an alternative to denosumab but reliable data on zoledronate prescription is not publicly available

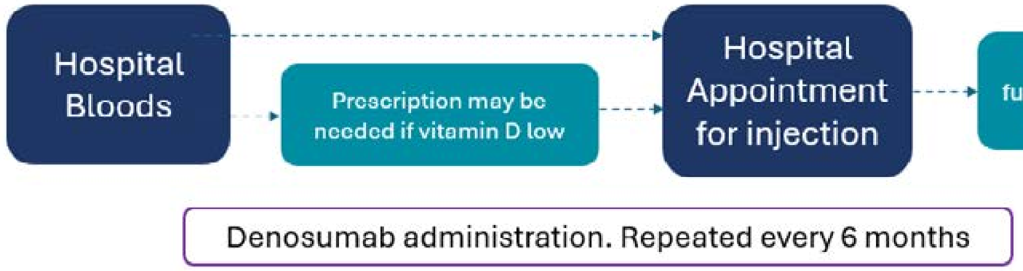


Fig. 4: Required appointments for denosumab administration in hospital

Louise Statham explained to the APPG how opportunities for people to access medicines in the community through district nurses were being lost due to overstretched services. She also explained how patients could have intravenous zoledronic acid either at home or in a GP clinic – but that this was highly variable and had been done in some areas, but not others.

Our recommendation

9. NHSE and NHS Scotland should consult upon and publish national shared care protocol templates34 for injectable osteoporosis medicines suitable for administration in the community to reduce inconsistencies between regions and promote equitable access to osteoporosis medicines. [34]

Delays to treatment

In areas where the formulary classification is amber or red people with osteoporosis will experience delays in accessing treatment. For example, someone in Brighton currently can access denosumab through their GP, while someone in neighbouring Eastbourne has to wait for a specialist appointment to access the medicine.

In England, the NHS constitution states that patients should wait no longer than 18 weeks from GP referral to receiving treatment, however as of September 2024, 41.5% of patients are waiting longer.[35] Delays are very clinically significant – particularly for denosumab injections if no follow-on treatment is provided because a pause in treatment puts people at very high risk of spinal fractures. Similarly, delayed access to medicines for someone who has just had a fracture is unwise because they are at heightened risk of breaking another bone imminently – 23% of second fractures happen within 12 months of the first (in women over 50).[36]

Our recommendation

10. ICSs should reassess local decisions on the availability of osteoporosis treatments) to ensure timely access to medicine, reduce the reliance on lengthy specialist referrals and increase the range of medicines available to primary care clinicians.

Facilitators of access to medicine

Proactive multidisciplinary medication review and follow-up

Dr Hawarden described how his research had found that only half of primary care practitioners reported routinely arranging a medication follow-up when prescribing osteoporosis medicines. He also highlighted that these are often part of a general medication review rather than osteoporosis specific.[37] This means that osteoporosis medicines may receive less than a few minutes of a ten-minute medication review, due to the fact that increasing numbers of people have two or more long term conditions. This will be most significant for people living in deprived areas where multimorbidity rates are significantly higher.[38,39]

All of those who gave oral evidence to this Review agreed that to deliver better access to medicine, general practices need support from health professionals other than doctors to review, follow-up and monitor people's adherence to treatment and the suitability of treatment for each individual. The experts agreed that practice pharmacists are well placed as they have the necessary knowledge and skills to undertake medication reviews and are able to ensure access to medicines that suit the patient.[37]

Raising the priority of osteoporosis

As we have heard in every previous APPG inquiry, the issue of the low prioritisation of osteoporosis was described by all of those who gave evidence. This low priority is reflected in the service provided to patients, particularly in primary care.

In their oral evidence to this Review, Ashley Hawarden and Professor Zoe Paskins from Keele University and Dr. Chris Ellis, GP, all pointed to the importance of providing sufficient resource to deliver the necessary clinical work through mechanisms such as the Quality and Outcomes Framework (QOF)[iv] in England or the Investment and Impact Fund (IIF) (a component of the NHS England's Primary Care Network Directed Enhanced Service). They highlighted how currently under QOF there are no 'ongoing management' indicators for osteoporosis unlike other common conditions such as mental health, hypertension and COPD. Currently, practices only need to maintain a register of patients with osteoporosis, with no threshold. As long as a practice has one person on the register, they receive the funding.

Professor Paskins went on to explain how primary care practitioners from across the UK have reported in quantitative and qualitative research that the current QOF means that any management of osteoporosis is 'essentially unfunded work'.[37,40] The expert speakers explained that sufficient financial resources are needed for effective identification of people at risk of fracture, regular follow-up and a significant increase in the numbers of people on treatment.

Proper resourcing of good clinical practice (in line with NICE guidelines) is needed for GP practices that reflects the health and social care costs of osteoporosis:

- Osteoporosis and fragility fractures cost £4.6 billion in health and social care costs every year.[41]
- Fractures caused by osteoporosis are the fourth worst cause of disability and premature death in the UK.[42]
- Hip fractures (the end result of untreated osteoporosis) are the second biggest cause of unplanned admissions to hospital and cost £2 billion per year.[41]

Despite the huge financial burden of osteoporosis and fragility fractures, practices currently receive significantly more funding for managing other chronic conditions with comparable prevalence such as diabetes. Last year GP practices received three QOF points or £622.58 for the vital task of identifying and maintaining a register of people with osteoporosis. Diabetes management, by way of contrast, provided up to £14,000 per practice. This funding disparity gives low priority to osteoporosis in relation to other conditions and results in a lack of proactive management of people at risk of devastating fractures.

Failing to invest in identification and management of osteoporosis keeps the number of people at risk of fracture and who are not on treatment high. 50% of hip fracture patients had a previous fracture which could have flagged them as at risk, yet around 66% of people who should be on treatment are not.[6,43] Current policies allow the number of fractures to escalate unchecked as the population ages, posing an increasingly critical public health crisis.

Our recommendation

11. QOF indicators (England and Northern Ireland) must be updated to include ongoing management, and funding must be increased to reflect this change and motivate behavioural change among GP practices. New indicators must address identification of people at high risk of fracture, rates of people at risk who are on treatment, adherence to prescribed medicines and ongoing review and monitoring. Suitably high thresholds should be set to encourage proactive interest in patients with osteoporosis.

> *"The [problems around] integration between primary and secondary care isn't unique to osteoporosis. But what is unique to osteoporosis is the fact that it's not owned by any one specialty [in MSK]. That makes problems with consistency, the postcode lottery, communication and pathways much worse."*
>
> Professor Zoe Paskins, Honorary Consultant Rheumatologist and Professor of Rheumatology, Keele University.

Effective clinical leadership

As in previous Inquiries, we heard about the importance of clinical leadership for establishing clear pathways for patients through services and clearly defined roles for all healthcare professionals. As osteoporosis does not fall under one specialty, but stretches across several, this 'ownership vacuum' has made room for failures of integration between secondary and primary care such as unwillingness to agree shared care protocols. Effective local clinical leadership can remove roadblocks to agreement thereby facilitating equitable access to medicines.

In the oral evidence, we heard evidence of problems with the integration of primary and secondary care services, including a lack of clarity in roles between Fracture Liaison Services and general practices meaning that some patients received counselling around medication twice, while others receive none at all.[44] Over a third of primary care practitioners reported in a UK survey reported being unaware if their area was served by a Fracture Liaison Service.[37] Integration was also being hampered by deficits in communication by secondary care services such as not coding fractures as 'fragility' or "low trauma" for the benefit of general practice colleagues or not communicating about the inpatient treatment of osteoporosis patients. This leads to more work for primary care colleagues and missed opportunities for osteoporosis management. Effective clinical leadership would galvanise efforts to achieve true collaboration and resolve practical barriers to integration.

Our recommendation

12. Regional Osteoporosis and Fracture Prevention Leads (in every ICS, Health Board and Health and Social Care Trust) should be appointed to provide clinical leadership for osteoporosis, to coordinate osteoporosis provision and improve access to medicine.

[iv] QOF no longer operates in Scotland and the similar QAIF system no longer operates in Wales. There are iterations of the system in England and Northern Ireland.

Conclusion

Our Review of access to medicines has found a postcode lottery that is letting down people with osteoporosis and their clinicians.

Despite being approved by NICE (or its equivalent in Scotland and Northern Ireland), under some drug formulary policies across the UK, clinicians are not able to prescribe medications for patients who need them and are eligible for them. Similarly, variations in formulary classification of osteoporosis medicines means some people can access them through primary care and avoid delays, while others have to wait for up to 18 weeks to access treatment via a secondary care clinician. The scale of the 'treatment gap' in osteoporosis is a growing emergency, which will spiral further as the population continues to age: 66% of people who should be on treatment are currently not on treatment, the result is over 550,000 fragility fractures every year in the UK at a £4.5 billion cost to the NHS.It's clear that, quite apart from the lives needlessly ruined, our recovering NHS will not be able to keep pace with the growing volume of patients pushed to crisis point. The cost to health and social care services, as well as the economy and public services more widely, is clearly both unmanageable and indefensible.

Lack of access to medicines is currently compounded by a lack of knowledge and expertise amongst GPs which we have described in our previous APPG report on primary care. GPs need to share the task of increasing treatment rates with pharmacist colleagues who are well placed as they have the necessary knowledge and skills to undertake medication reviews and ensure that patients can access the medicines that suit them.. Beyond this, new clinical leadership for osteoporosis must be created at regional level (under the National Clinical Director for Musculoskeletal conditions) to bring people together, remove barriers to access, allow for more effective integration of primary and secondary care under shared care agreements, and adopt the Best MSK Health clinical pathways which has been developed but currently gathers dust in the absence of political will.

We call on the UK and devolved governments to take action to establish clinical leadership in every region in the field of osteoporosis. Leadership is required to drive change and to reduce the treatment gap. People with osteoporosis have a right to access the medicines they need. Improving access will prevent thousands of broken bones and transform the lives of hundreds of thousands of people with osteoporosis in the UK.

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