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Guidelines for the diagnosis and management of osteoporosis in Poland. Update 2022

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Abstract

Guidelines to provide an update of the previously published Polish recommendations for the management of women and men with osteoporosis have been developed in line with advances in medical knowledge, evidence-based data, and new concepts in diagnostic and therapeutic strategies. A Working Group of experts from the Multidisciplinary Osteoporosis Forum and from the National Institute of Geriatrics, Rheumatology, and Rehabilitation in Warsaw performed a thorough comprehensive review of current relevant publications in the field (including all age groups of people and management of secondary osteoporosis), and they evaluated epidemiological data on osteoporosis in Poland and the existing standards of care and costs. A voting panel of all co-authors assessed and discussed the quality of evidence to formulate 29 specific recommendations and voted independently the strength of each recommendation. This updated practice guidance highlights a new algorithm of the diagnostic and therapeutic procedures for individuals at high and very high fracture risk and presents a spectrum of general management and the use of medication including anabolic therapy. Furthermore, the paper discusses the strategy of primary and secondary fracture prevention, detection of fragility fractures in the population, and points to vital elements for improving management of osteoporosis in Poland. (*Endokrynol Pol* 2023; 74 (1): 5–15)

Key words: osteoporosis; diagnosis; fracture risk; treatment

Introduction

This review aims to revise and update the currently applicable diagnostic and therapeutic recommendations for women and men with suspected osteoporosis, with and without fractures [1, 2]. The urgent need to update the current recommendations is due to the emergence of new concepts in the strategies for the diagnosis and treatment of osteoporosis. The updates are therefore related to the guidelines that differentiate the diagnostic and intervention thresholds, the definition of which now makes the therapy dependent not on

the diagnosis of osteoporosis itself, but on the risk of fractures. Therefore, in the diagnostic and therapeutic procedures, the grading of fracture risk (low, high, and very high) should now be taken into account, especially the high and very high risk of fractures that require an immediate therapeutic response. In particular, anabolic drugs (teriparatide and romosozumab, currently approved in the European Union) are indicated as the first-line therapy for effective bone tissue reconstruction in subjects with a very high fracture risk. Then, the administration of resorption inhibitors is recommended as part of a sequential therapy [3–5].



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An updated pharmacotherapy algorithm has been presented, taking into account the attempts to define therapeutic goals (T2T, *treat to target*) [6], the methods of monitoring, the criteria for treatment failure, risk of fractures, the principles for temporary treatment discontinuation (drug holiday), drug changes, and sequential treatment [3–5, 7–9]. An attempt has also been undertaken to raise the issue of osteoporosis in children and adolescents in our guidelines [10, 11].

Another important argument concerns the alarming epidemiological data on osteoporosis in Poland, especially the data on the very small number of patients treated (a treatment gap). This situation creates an urgent need to revise and improve the existing standards of care, with consideration of the actual conditions of health insurance and the organization of the health-care service in Poland.

According to the data, published in 2019 by the International Osteoporosis Foundation (IOF) Expert Group [12], 1,985,000 adults in Poland suffered from osteoporosis, including 80% of women. According to the estimates of the National Health Fund (NHF) [13], it was 2,120,000 people, including 80% of women. At the same time, both reports indicated that the percentage of people receiving an adequate pharmacological treatment had been very small, i.e. about 6% of all the patients according to the NHF report [13] and 17% of women eligible for treatment, according to IOF data [12]. Following those reports, (2017–2019) from 126,000 [13] to 206,000 [12] low-energy fractures are annually recorded in Poland, with the mortality rate in the first year after hip fracture being approximately 30% [13], which is an unacceptable index.

Methods

A group of experts (specialists in rheumatology, orthopaedics and traumatology, internal medicine, geriatrics, endocrinology, rehabilitation, nephrology, diabetology, oncology, paediatrics, biochemistry, imaging techniques, and patient representatives) from the Multidisciplinary Osteoporosis Forum and from the National Institute of Geriatrics, Rheumatology, and Rehabilitation in Warsaw, performed a thorough analysis of English-language publications in the MEDLINE, COCHRANE, and SCOPUS databases, seeking reports on the diagnostics, prevention, and therapeutic procedures of osteoporosis, published from the beginning of 2017 to August 2022, to find an input enabling revision of the previous recommendations [1].

The Guidelines were established by a voting panel, comprising all the co-authors, which was preceded by an intensive exchange of e-mail messages, telephone discussions, and written comments. Conclusions

and recommendations were systematically graded, according to the available evidence, and simultaneously, the panel assessed and voted, using a 1–10 (10 = the strongest) point scale, the strength of each recommendation in the Polish conditions [expressed in brackets as mean values \pm standard deviation (SD)]. The presented guidelines were finally submitted to a review and approved by national consultants in the fields of orthopaedics and traumatology, geriatrics, endocrinology, internal medicine, medical rehabilitation, family medicine, rheumatology, paediatrics, and public health.

Management strategy

The overall strategy is to effectively coordinate comprehensive prevention, diagnosis and treatment activities, including the expansion of tasks for primary care physicians, family doctors, duties for hospitals and fracture clinics, and to define the scope of responsibilities for specialist centres, including osteoporosis clinics (Fig. 1). We assume the following 2 basic stages of the management.

First stage

All the persons with a suspected increase of fracture risk should be recommended to screening, to individually assess and grade the risk as follows: a) very high, b) high, c) medium, or d) low, which will provide a baseline input to plan further management. Identification of existing fracture risk factors, with an initial fracture risk assessment, remain the tasks of GPs and nurses, but, depending on specific needs, this may also apply to other physicians, including orthopaedists-traumatologists, geriatricians, medical rehabilitation specialists, and other health professionals, e.g. hospital coordinators, physiotherapists, etc.

Assuming a suspicion of osteoporosis in a patient should be followed by his/her medical history, physical examination with a particular emphasis on body height, muscle strength, fall risk plus selected functional tests, as well as an assessment of 10-year fracture risk, using the fracture risk assessment (FRAX) tool for the Polish population (FRAX-PL) in the age group appropriate for the calculator (in the nearest future it will probably become an extended FRAX [9]). At this stage (stage 1), no bone mineral density (BMD) measurement is required (<http://www.shef.ac.uk/FRAX/tool.aspx?country=40>), while detailed diagnostics and the choice of therapy are within the scope of duties of an osteoporotic specialist (stage 2).

Figure 2 presents the criteria for fracture risk stratification, adopted for the Polish population, based on the solutions proposed by the IOF [3] and the publica-

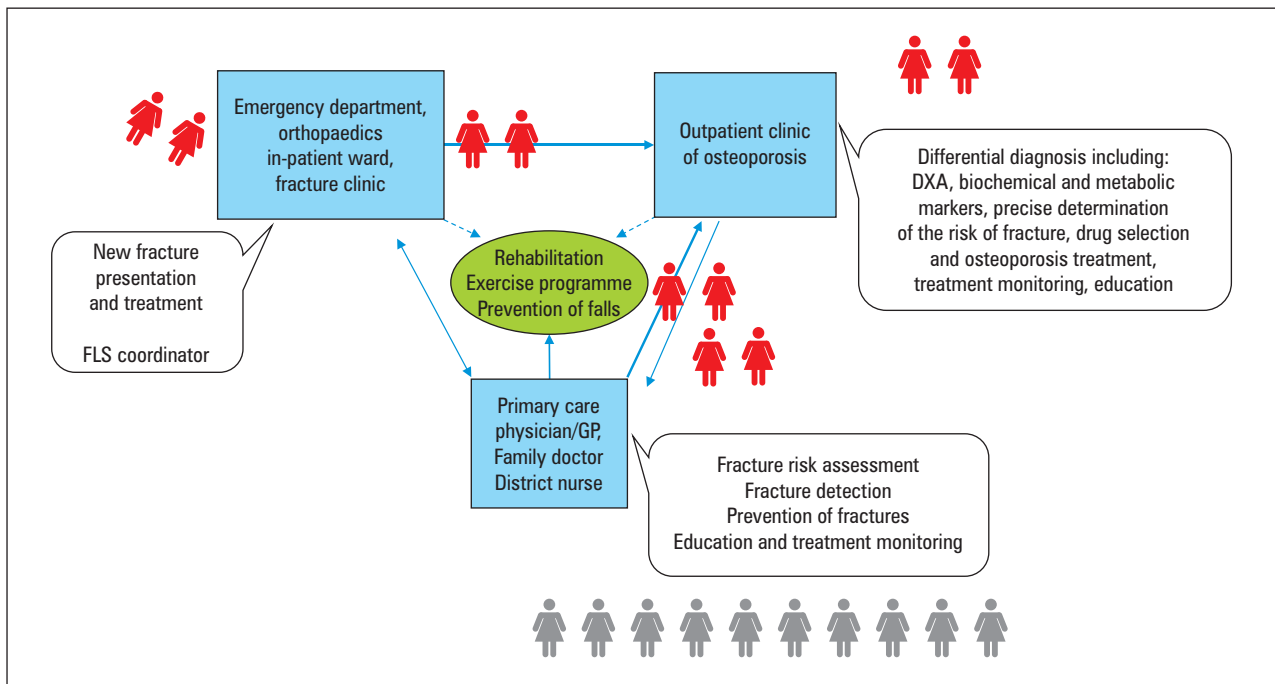


Figure 1. Management of osteoporosis — coordination of care; FLS — Fracture Liaison Service

| VERY HIGH RISK | HIGH RISK | MEDIUM / LOW RISK |
|--|--|--|
| <p>At least one of the following applies:</p> <p>Newly-diagnosed major osteoporotic fracture (MOF) within past 12 months and T-score ≤ -1.0</p> <p>or</p> <p>Multiple major fractures (≥ 2)</p> <p>or</p> <p>Fractures while medication used for other reasons is harmful to bone, e.g: glucocorticosteroids, aromatase inhibitors or others</p> <p>and/or</p> <p>Very low T-score < -3.0</p> <p>and/or</p> <p>FRAX $> 15\%$ for MOF or $> 4.5\%$ for hip</p> | <p>At least one of the following applies:</p> <p>Major osteoporotic fracture in the last 2 years</p> <p>and/or</p> <p>T-score ≤ -2.5</p> <p>and/or</p> <p>FRAX 10 to 15% for MOF or 3 to 4,5% for hip</p> | <p>If present:</p> <p>Age > 50 or postmenopausal</p> <p>No fracture</p> <p>and</p> <p>T-score > -2.5</p> <p>and/or</p> <p>FRAX: 5 to $< 10\%$ for MOF medium RF, FRAX: $< 5\%$ for MOF low RF</p> |

Figure 2. Modified criteria to determine the fracture risk in women and men > 50 years of age for the Polish population. FRAX — fracture risk assessment tool; MOF — major osteoporotic fracture; RF — risk of fracture

tion of experts representing the American Association of Clinical Endocrinologists [4]. Despite the lack of sufficient data, we have decided to adopt similar criteria for women and men. An important task, both in the field of primary health care and specialist care, is the identification of persons with low-energy fractures at major locations, such as proximal femur (hip fractures), vertebrae, proximal humerus, distal radial bone, and pelvis

fractures [7, 14]. Every previous low-energy fracture in the hip or other major location, both in primary and secondary osteoporosis, highly increases the risk of subsequent fractures and is an absolute indication for in-depth diagnostics, followed by rapid implementation of comprehensive — orthopaedic, pharmacological, and analgesic treatment plus dietary indications, rehabilitation, and the efforts to eliminate of any modifiable

factors of fracture risk [1, 5, 7]. After the patient's surgical treatment, it is the duty of the orthopaedists/traumatologists, who provide assistance in cases classified as low-energy fractures, to implement a pharmacological treatment and/or refer the patient to a specialised centre for the diagnosis and treatment of osteoporosis.

The procedure should be carried out with participation of a hospital coordinator in accordance with the principles of Fracture Liaison Service (FLS) (Fig. 1) [15].

A low-energy fracture is a fracture in a major location (a low-energy fracture may also occur in other locations) that occurs despite a disproportionately low inducing force, e.g. when falling from the height of one's own body or a spontaneous fracture (pathological fractures and atypical femoral fractures should be excluded here) [1, 2, 7].

Second stage

The initiation of diagnostics and the implementation of osteoporosis treatment, especially in the case of low-energy fractures, should be carried out by a primary care physician or, when fresh injuries happen, immediately after surgical treatment of fractures. As stated in our previous recommendations [1, 2], it is

basically a specialist stage, carried out at osteoporosis clinics, including a differential diagnosis (searching for secondary osteoporosis, other bone diseases, comorbidities), detailed determination of all fracture risk factors, and an assessment of fracture risk for the next 10 years (FRAX BMD), taking into account, if possible, the currently modernised and extended versions of FRAX [9], and the programming of an effective pharmacological treatment based on determined fracture risk [3, 4]), the results of DXA densitometry (dual energy X-ray absorptiometry), serum vitamin D [25 (OH) D] concentration, along with the assessment of the calcium balance and — if possible — the levels of bone turnover markers [1, 7]. Regarding the choice of a medicinal agent, the following factors should be taken into account: the established risk of fractures, registration indications, possible contraindications, comorbidities, reimbursement options, and patient preferences [1, 2, 7]. It is also important to establish an adjuvant treatment, prevent falls, implement a rehabilitation programme, reduce or eliminate modifiable risk factors for fractures, apply calcium and vitamin D supplementation, adjust diet, and employ treatment monitoring measures [1, 7] (see Tab. 1, Fig. 3).

Table 1. Drugs used in the treatment of osteoporosis

| Drug | Doses and forms | Dosage | Postmenopausal osteoporosis | | | Osteoporosis in men | GIO |
|----------------------------|---|--|-----------------------------|-----|---------------|---------------------|-----|
| | | | Reduction of fracture risk | | | | |
| | | | Spine | Hip | Non-vertebral | | |
| Alendronate | Tablet 70 mg | 1 tablet/week <i>p.o.</i> | Yes | Yes | Yes | Yes | Yes |
| Risedronate | Tablet 35 mg | 1 tablet/week <i>p.o.</i> | Yes | Yes | Yes | Yes | Yes |
| Ibandronate | Tablet 150 mg | 1 tablet/month | Yes | No | No | No | No |
| | Ampoule 3 mg/3 mL | 1 ampoule every 3 months <i>i.v.</i> | Yes | No | No | No | No |
| Zoledronic acid | Solution for injection 5 mg/100 mL | 1 ampoule as an <i>i.v.</i> infusion | Yes | Yes | Yes | Yes | Yes |
| Denosumab | Pre-filled syringe 60 mg/1 mL | 1 ampoule every 6 months <i>s.c.</i> | Yes | Yes | Yes | Yes | Yes |
| Raloxifene | Tablet 60 mg | 1 tablet/day <i>p.o.</i> | Yes | No | No | No | No |
| Teriparatide* | Solution for injection 20 µg/80 µL — pen 3 mL | 1 injection/day <i>s.c.</i> | Yes | No | Yes | Yes | Yes |
| Abaloparatide** | Solution for injection 80 µg/dose — pen | 1 injection/day <i>s.c.</i> | Yes | No | Yes | No | No |
| HRT [‡] | Tablet <i>p.o.</i> or subcutaneously | | Yes | Yes | Yes | No | No |
| Romozosumab # [§] | Pre-filled syringe 105 mg of romozosumab in 1.17 mL solution (90 mg/mL) | Dose 210 mg in 2 injections <i>s.c.</i> 105 mg each 1 time per month | Yes | Yes | Yes | No | No |

GIO — glucocorticoid-induced osteoporosis; HRT — hormonal replacement therapy; *s.c.* — subcutaneously; *i.v.* — intravenously; *unavailable in Poland;

**not allowed in Poland; #approved in European Union (EU) in 2019 — no refund; [‡]HRT is currently not recommended for the treatment of postmenopausal osteoporosis;

[§]reduction of non-vertebral and hip fractures demonstrated in sequential treatment (see sections 17 and 17A)

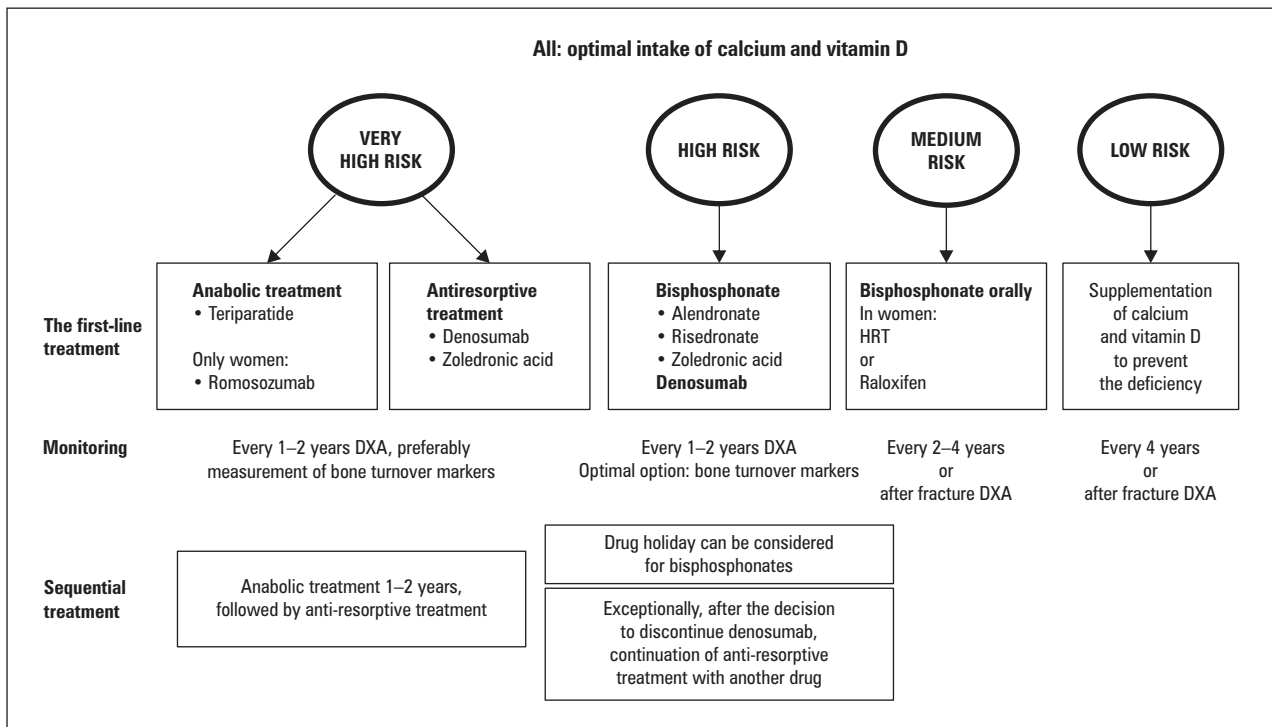


Figure 3. A proposed treatment algorithm for suspected postmenopausal osteoporosis in women and for osteoporosis in men, aged > 50 years. HRT — hormonal replacement therapy; DXA — dual-energy X-ray absorptiometry

In individuals of both sexes, aged ≥ 50 years and without low-energy fractures, a comprehensive treatment, including pharmacotherapy, should be undertaken when the probability of major fractures is $\geq 10\%$ in a 10-year perspective or $\geq 3\%$ for hip fracture and/or DXA measurement of the T-score ≤ -2.5 SD for the hip or for the lumbar vertebrae. The average risk (from 5% to $< 10\%$) is an indication for further medical verification and a possible treatment. In patients with a low risk of fractures (the fracture risk, according to FRAX $PL \leq 5\%$), preventive measures are recommended [1].

The management of secondary osteoporosis and the management of osteoporosis in children and adolescents are presented in detailed recommendations.

Patients with low-energy fractures should be classified into groups with a very high or high risk of fractures [3–5] (Fig. 2). In such cases, it is necessary to undergo pharmacological treatment in parallel with an orthopaedic intervention, followed by rehabilitation. Both European and American experts [3, 4] currently point out to the need for identification of patients with a very high fracture risk, as the first target group for anabolic (teriparatide, romosozumab) therapy, followed by a sequential administration of antiresorptive medications (see Fig. 3, Tab. 1). It is advisable to perform DXA examination and obtain an in-depth diagnosis to either exclude or confirm secondary osteoporosis.

During medication, it is necessary to systematically control its effectiveness and safety and periodically verify the current as well as emerging fracture risk factors [7, 16]. The follow-up of treatment continuation (adherence to therapy etc.), the assessment of its effectiveness, and a decision to interrupt treatment (drug holiday) [8] or change the drug will depend on periodic densitometric controls, including — optimally — the assessment of bone markers and radiological examination, e.g. when the patient's body height becomes an issue, i.e. if it decreases by more than 4 cm [1, 7].

The diagnosis of primary osteoporosis should be based on:

- World Health Organization (WHO) densitometric criteria [17] for postmenopausal women (which has also been adopted for elderly men): BMD measurement using DXA technique, T-score ≤ -2.5 SD at the femoral neck or in an alternative location — lumbar spine [International Classification of Diseases, 10th Revision (ICD-10) — M81];
- the occurrence of a low-energy fracture in postmenopausal women and in men over 50 years of age in major locations and T-score ≤ -1.0 [1, 14]. It should be noted that, in certain cases, BMD does not confirm clinical osteoporosis (ICD10 — M80);
- the above criteria do not exclude the diagnosis of osteoporosis in younger people with risk factors based on other criteria, including Z-score < -2.0 ,

interpreted as: BMD below the expected value for sex and age [7, 11].

It should be noted that the identification of high or very high risk of fractures, based on FRAX, both in its current version and its extended version in the future [9, 18], indicates the presence of osteoporosis and is a premise for therapeutic intervention. Nevertheless, the current international recommendations [4, 7] still recognise the measurement of BMD by DXA (operational definition of osteoporosis) as the gold standard and the occurrence of low-energy fractures as the diagnostic criteria [5, 7, 14, 19].

Guidelines

1. Low-energy hip fracture in women and men over 50 years of age, as well as any low-energy fracture in other major locations (after excluding other causes), qualify a patient to at least a high-risk group and are an indication for the implementation of comprehensive treatment (orthopaedic, pharmacological, analgesic, rehabilitation, etc). It should be simultaneously considered as the criterion for the diagnosis of clinical osteoporosis [strength: 9.4 ± 0.7 SD].
2. The qualification of a patient with a fracture or fractures to a group with a very high fracture risk is done by a physician, when at least one of the following criteria is met: multiple low-energy fractures in major locations, low-energy fracture in < 1 year in a person with a T-score ≤ -1.0 , FRAX PL for major fractures > 15% or for hip > 4.5%, and DXA BMD T-score < -3.0. On the other hand, an individual assessment requires such criteria as a high risk of falls and possible negative influence of some medications on the quality of bone tissue [8.5 ± 0.7].
3. In persons of both sexes over 50 years of age without fractures, the identification of a high risk of fractures within 10 years (FRAX PL > 10% for major fractures, 3–4.5% for hip) is an indication for the implementation of a comprehensive treatment and for more accurate diagnostics, including BMD measurement with DXA in hip and vertebrae L1–L4. T-score ≤ -2.5 (regardless of the risk value, according to FRAX) is the basis for the diagnosis of osteoporosis and the implementation of treatment [8.0 ± 1.4].
4. In persons of both sexes over 50 years of age without fractures, the average risk, according to a FRAX PL of 5–10% for major fractures, is an indication for further diagnostics, including DXA BMD measurement (as above) and, depending on the assessment, treatment implementation or only prophylactic measures — as in low-risk groups (FRAX < 5%). In all cases, it is advisable to either reduce or eliminate modifiable risk factors for fractures. [8.3 ± 1.2].
5. We recommend that, immediately after surgical or conservative treatment of a low-energy fracture, the orthopaedic surgeon initiates either oral or parenteral pharmacotherapy and refers the patient to a competent osteoporosis therapy centre and to rehabilitation to reduce the risk of further fractures. We recommend the implementation of comprehensive orthogeriatric care for all elderly people [9.6 ± 0.6].
 - 5A. To improve the care of patients, we recommend appointing health professionals (nurses, physiotherapists, dedicated coordinators) in orthopaedic clinics and fracture treatment departments to act as coordinators to identify patients with low-energy fractures for the purpose of education, and to recognise fracture risk factors and refer them to a competent osteoporosis therapy centre [8.7 ± 1.4].
 - 5B. In order to improve the diagnostic and therapeutic process, we recommend that, if possible, orthopaedic departments should have at their disposal a DXA densitometer for diagnostics after a fracture and for selection of further therapy [6.0 ± 1.4].
6. The tasks of the primary care physician and/or family medicine physician (and, depending on the competence, of other physicians as well, e.g. geriatricians, rehabilitation specialists) (stage I) include the following:
 - an identification of patients at risk of fracture or with fracture history, a preliminary assessment of the fracture risk with FRAX and, in accordance with this assessment, referral of patients to an outpatient osteoporosis clinic;
 - elimination or reduction of modifiable fracture risk factors and, depending on the competence, initiation of pharmacological treatment (stage II);
 - in persons without fractures and/or with low fracture risk, the primary care physician's tasks include mainly preventive and educational measures.
 When making a diagnostic and therapeutic decision, one should take into account the results of the medical examination (including the obligatory measurement of body height and weight) and the history of fractures, falls, comorbidities, medications, and fracture risk calculated by FRAX PL [8.2 ± 0.6].
7. The routine tasks of a primary care physician or a family physician should include continuation and supervision of the treatment established by the osteoporosis clinic and by other specialists, monitoring of adherence to treatment, verification of possible adverse drug reactions, possible elimination of existing and new fracture risk factors, and cooperation with hospital FLS teams [8.4 ± 0.5].

- 7A. An initial assessment of persons aged > 50 years, in terms of fracture risk, based on the FRAX BMI algorithm (without BMD) for the Polish population and/or the identification of previous low-energy fractures, can and should be performed by all health professionals (physiotherapists, nurses, medical caregivers, rescuers, etc.) [7.3 ± 1.4].
8. We recommend that the task of specialists, providing the diagnosis and treatment of osteoporosis (stage II) is to verify previous fractures, both clinically and based on X-ray or vertebral fracture assessment (VFA), to identify all the existing risk factors for fractures and qualify the patient for a risk group to obtain the final diagnosis (i.e. primary, secondary osteoporosis, osteomalacia, or other metabolic bone disease), and — based on a differential diagnosis, densitometry, the assessment of calcium-phosphate metabolism indicators, including daily urinary calcium excretion and serum 25(OH)D concentration, if possible — bone turnover markers — in order to establish a comprehensive therapy together with the patient (9.2 ± 1.0).
- 8A. A special task of a specialist in the treatment of osteoporosis (stage II) in patients with a very high risk of fractures and without contraindications should be to consider the option of a first-line treatment with anabolic agents (if available) or to choose an alternative therapy [8.6 ± 1.3].
 - 8B. We recommend that specialists treating patients in stage II are responsible for the determination of appropriate monitoring measures (BMD measurement, optimally, determination of bone turnover markers etc), and, if necessary, discontinuation or change of the therapy [8.7 ± 1.0].
9. DXA densitometry remains the gold standard in the diagnostics of osteoporosis. The WHO provides the following densitometric criteria for the diagnosis of osteoporosis, based on the measurement of BMD by the DXA technique of the femoral neck (or lumbar vertebrae) in postmenopausal women. [T-score is expressed as the number of SD from the reference point, which is the peak bone mass]:
- T-score > -1 SD — normal value,
 - T-score from -1 to -2.5 SD — osteopaenia,
 - T-score ≤ -2.5 SD — osteoporosis,
 - T-score ≤ -2.5 SD and osteoporotic fracture — advanced osteoporosis.
- Similar criteria have been adopted also for men over 50 years of age [9.9 ± 0.2].
- 9A. In younger people (< 40 years of age), the Z-score should be taken into account in densitometry-based diagnostics. A Z-score < -2.0 should be defined as “below the expected BMD value for gender and age”. In young adults, idiopathic osteoporosis is rather rare, while secondary osteoporosis, being more frequently observed, requires an in-depth differential diagnosis, followed by a final diagnosis of the disease. The assessment of fracture risk factors (FRAX is not carried out in persons < 40 years of age) and the choice of treatment should be made by a specialist physician in cooperation with the patient [9.0 ± 1.0].
 - 9B. The diagnosis of osteoporosis in children and adolescents may always be established, provided that vertebral fractures are identified, i.e. the presence of at least one vertebral compression fracture, confirmed by radiographs, in the absence of any other underlying disease or an evident injury of this area. Otherwise, the diagnosis is obtained on the basis of the following 2 concomitant criteria: 1) clinically significant fractures in the peripheral skeleton and 2) significantly decreased BMD in a routine DXA scan, i.e. Z-score < -2.0. Clinically significant fractures are defined as follows: 2 or more low-energy fractures of the long bones sustained up to 10 years of age, and ≥ 3 fractures resulting from minimal trauma at any age before the age of 19 years [7.9 ± 1.0].
 - 9C. The diagnosis of osteoporosis in children is based on the history of fragility fractures, clinical manifestations, and phenotype assessment, followed by a differential diagnosis towards secondary osteoporosis and iatrogenic causes. The measurement of areal BMD/BMC (bone mineral content) by DXA is routinely performed in 2 standard locations: lumbar anteroposterior (AP) spine (vertebrae L1–L4) and the total body/whole skeleton (TBLH, total body less head) [7.8 ± 1.5].
 - 9D. The management of paediatric osteoporosis should focus on the prevention of skeletal fragility and the targeted treatment of an underlying chronic disease, to minimise the risk of subsequent low-energy fractures, alleviate the rate of bone loss, and increase BMD. Although no approved drugs for paediatric osteoporosis are listed in Poland, cyclic intravenous bisphosphonate therapies are accepted in children and adolescents under exceptional circumstances. At specialised care facilities, the current treatments include the off-label use of zoledronic acid and pamidronic acid. A systematic calcium intake is mandatory, and effective vitamin D supplementation should be continued throughout the treatment period (8.0 ± 1.5).
10. A pathological acceleration of bone metabolism is an independent risk factor for fractures; however, it may also be an indicator of neoplastic bone disease. To assess bone metabolism, collagen type I crosslinked C-telopeptide (CTX), a resorp-

tion marker, is used plus the N-terminal propeptide of type I procollagen (P1NP), a bone formation marker. A standard-compliant measurement of bone turnover markers (BTMs) in the blood is an important element in monitoring the effectiveness of osteoporosis therapy and planning a drug holiday [7.0 ± 1.1].

11. An important role in the diagnosis and treatment is held by an assessment of the patient's general health condition, especially his/her locomotor system and muscle condition (frailty, sarcopaenia, myopathy, a risk of falls), usually based on the measurement of muscle mass, walking speed, handgrip strength, and the get-up-and-go test [9.4 ± 0.8].
12. The diagnosis and treatment of osteoporosis in men after the age of 50 years does not differ significantly from the procedure in postmenopausal women. The history of a single fall and, especially of multiple falls, correlates in men but not in women, with a significant increase in the risk of major osteoporotic fractures, regardless of FRAX (with or without BMD). Testosterone administration to men with a deficiency of this hormone improves BMD and general performance, but it has not been proven to reduce the risk of fractures. Some of the drugs approved for the treatment of postmenopausal osteoporosis have not been approved for the treatment of osteoporosis in men (e.g. ibandronate, raloxifene) [8.8 ± 0.9].
13. Pharmacological treatment is part of a comprehensive therapy which includes the following: patient's education, the elimination of modifiable risk factors for fractures, diet optimisation, calcium and vitamin D supplementation, a rehabilitation programme, and implementation of a treatment monitoring protocol [9.4 ± 0.8].
 - 13A. The goal of treatment is to reduce the risk of fractures. A pharmacological treatment should be carried out in all persons of both sexes, aged 50+, with low-energy fractures and in persons with a very high, high, and medium risk of fractures. The choice of the first-line therapy (stage II) with the highest anti-fracture efficacy for an individual patient should be made by a specialist physician in cooperation with the patient, taking into account the appropriate stratification of the risk of fractures, BMD measurement values, biochemical tests, drug approval, possible contraindications for the treatment, and the costs of medication [9.0 ± 0.6].
 - 13B. In patients with a very high risk of fractures and without contraindications, it is recommended that the option of the first-line treatment with an anabolic agent (if available — teriparatide or romosozumab, etc.) be considered, followed by a sequential therapy with bone resorption inhibitors or the possible choice of an alternative therapy (e.g. zoledronic acid or denosumab) [8.7 ± 0.8].
14. Oral bisphosphonates are the longest and most frequently used anti-resorptive drugs in the first-line therapy, with proven anti-fracture effects in the vertebrae, the proximal femoral bone (hip), and other extra-vertebral locations. Intravenous bisphosphonates are most often used in patients with contraindications to the administration of oral medications or with specific indications, e.g. after a recent hip fracture (zoledronic acid). The efficacy of bisphosphonate treatment depends on the prior administration and maintenance of optimal serum 25 (OH) D levels and on a correct calcium/phosphate balance [9.1 ± 1.2].
 - 14A. It is advisable to regularly monitor the therapy [annual BMD measurements in the same location and with the same DXA device. Within 3–6 months from the start of the treatment, the assessment of therapy effectiveness may also include the measurement (if available) of bone markers *vs.* their baseline values]. After 3 years of intravenous bisphosphonate therapy and 5 years of oral bisphosphonate intake, the effectiveness and safety of the treatment should be reviewed. If a significant improvement is achieved (T-score > -2.5 , no new fractures), a treatment interruption (drug holiday) may be considered and, in other cases, a drug change [8.7 ± 1.7].
 - 14B. A failure of the treatment with bisphosphonates in therapeutic doses is defined as the occurrence of a new fracture after 12 months of the treatment or a decrease in BMD after 12 months of the treatment from its baseline value by more than the least significant change (4.4% for vertebrae, 5.2% for the femoral neck) measured with the same device and at the same place [8.8 ± 1.2].
15. Denosumab can be administered to women and men with osteoporosis, both as a first-line and second-line therapy after other treatment programmes, especially in the case of oral drug intolerance, as well as in sequential therapy, i.e. after an anabolic agent. Denosumab demonstrates proven anti-fracture effects in vertebral, non-vertebral, and hip sites. Similarly to bisphosphonates, the condition for optimal effectiveness is the compensation of calcium/phosphate metabolism and the achievement of a serum 25 (OH) D concentration within the reference range. There are no contraindications for the administration of denosumab to patients with renal failure [9.0 ± 1.0].

- 15A. Due to the high efficacy of treatment and the systematic increase in BMD during the therapy, vitamin D levels should be adjusted prior to the administration of denosumab, followed by the monitoring and measuring of serum calcium levels to prevent hypocalcaemia. The treatment with denosumab should not be interrupted. If denosumab treatment is discontinued (for any reason), the optimal time point to start the oral bisphosphonate administration or infusion with zoledronate is 6 months after the last denosumab dose [8.7 ± 1.1]
16. Teriparatide [recombinant human parathyroid hormone (PTH) 1-34] or abaloparatide (modified peptide 1-34 similar to PTH — not approved in Europe) drugs with an anabolic effect are recommended in the treatment of osteoporosis in women and men at a very high risk of fractures and in advanced osteoporosis with fractures if other drugs have failed. Teriparatide is also approved for the treatment of glucocorticoid-induced osteoporosis. Teriparatide reduces the risk of vertebral and non-vertebral fractures (it does not reduce the risk of hip fractures). The maximum duration of treatment is 24 months once in a lifetime. Before the treatment onset, it is advisable to control the serum levels of calcium, alkaline phosphatase, PTH, and vitamin 25 (OH) D [8.7 ± 1.2].
 - 16A. The second-line administration of teriparatide after an anti-resorptive medication may be associated with a temporary stimulation of bone turnover, which requires a periodic continuation of the treatment with an anti-resorptive drug together with the teriparatide. A discontinuation of the teriparatide therapy reduces BMD within a year, although fracture reduction is maintained for 1–2 years. The use of bisphosphonates or denosumab after teriparatide (a sequential therapy) protects against bone resorption and may increase BMD [7.7 ± 1.1].
 17. Romosozumab is an anabolic biological drug indicated for the treatment of postmenopausal osteoporosis. It reveals a proven antifracture effect in the spine and in sequential treatment in hip and other non-vertebral locations. Romosozumab is specifically used as the first-line therapy for patients with very high risk of fractures. The drug is not currently (2022) approved for the treatment of osteoporosis in men [8.7 ± 1.0].
 - 17A. Due to its high antifracture efficacy, romosozumab can be used in patients previously treated with bisphosphonates, especially in those who have suffered from fractures during the therapy, although the duration of the previous treatment may adversely affect its effectiveness. After one year of the treatment with romosozumab, a continuation of the treatment with an anti-resorptive drug (denosumab, bisphosphonates) is indicated. Romosozumab should not be used in patients at risk of cardiovascular diseases [8.5 ± 1.0].
 18. Hormone replacement therapy (HRT) in postmenopausal women is mainly used to treat the symptoms of postmenopausal syndrome; at the same time, it can prevent the development of osteoporosis. The principle is to use the lowest necessary doses and within the shortest possible time. The administration of conjugated oestrogens, with or without medroxyprogesterone, has been shown to inhibit bone resorption, reduce the risk of vertebral fractures, hip fractures, and other non-vertebral fractures, and improve the overall performance of patients. HRT is currently not recommended for the treatment of osteoporosis [8.0 ± 0.8].
 19. Selective oestrogen receptor modulators (SERMs) demonstrate an anti-resorptive effect, reduce the risk of vertebral fractures, and reduce the risk of oestrogen-dependent breast cancer. Therefore, they can be used in the prevention of breast cancer in women with postmenopausal osteoporosis. Due to the severity of “hot flushes”, raloxifene should be administered after the menopausal symptoms have subsided [7.5 ± 2.0].
 20. Regarding the prevention and treatment of osteoporosis, an important role is played by a proper diet, the optimization of calcium intake (approx. 800–1200 mg/day in diet and supplements), protein (1.2 g/kg bw/day), potassium (approx. 3500 mg/day), and magnesium (> 300 mg/day). A proper supply of vitamin D is the basis of the prophylaxis and an essential component of the osteoporosis treatment. The normalisation of serum 25 (OH) D levels and a correct balance of the calcium/phosphate metabolism determine the effectiveness of the pharmacotherapy of primary and secondary osteoporosis [9.0 ± 1.0].
 21. The management of secondary osteoporosis requires an effective treatment of the primary disease and/or an elimination of other causes that may lead to bone tissue deterioration and an increased fracture risk. An individualized course of treatment is recommended. Particular attention should be paid to patients at risk of fractures in the course of neoplastic diseases. In most cases, there is a need for a comprehensive therapy, aimed at reducing the risk of fractures [9.2 ± 1.4].
 22. Glucocorticoid-induced osteoporosis (GIO) is a common, iatrogenic, secondary osteoporosis. It is recommended that all the patients receive-

ing prednisone (or its equivalent) for more than 3 months at a daily dose of more than 2.5 mg should be assessed for the risk of fracture and be submitted to prophylactics or therapy. In patients over 50 years of age, receiving 5 mg of prednisone daily for more than 3 months and with risk factors for fractures, a preventive bisphosphonate administration should be considered. In persons over 65 years of age, even in the absence of other risk factors for fractures, such a procedure should be implemented. GIO may be the cause of very high risk of fractures [9.4 ± 0.5].

- 22A. In persons over 50 years of age and with GIO with very high risk of fractures, the use of teriparatide (if available) should be considered as the first-line therapy. Alternatively, and in patients with high or medium fracture risk, denosumab or bisphosphonates may be used, or in postmenopausal women, raloxifene may be administered. A fracture is always an indication for treatment. There are general principles of how to reduce the risk of fractures, such as limiting the supply of glucocorticoids to a necessary and clinically effective minimum, the balance of the calcium metabolism, and an optimal vitamin D supply. The pharmacological treatment of GIO should be continued as long as there is an increased risk of fractures (the treatment of women at childbearing age, adolescents, and children is described in the detailed comments) [8.7 ± 1.4].
23. The risk of fractures is increased in diabetic patients. In patients with type 1 diabetes, first BMD measurement should be performed about 5 years after the diagnosis of the disease is obtained and repeated every 2–5 years, depending on the results. In type 2 diabetes, the risk of fractures may not correspond to BMD values [8.5 ± 0.9].
 - 23A. The FRAX tool is not suitable for assessing the fracture risk in younger patients with type 1 diabetes; it is more useful in older patients with type 2 diabetes, but the calculated fracture risk in these patients may be underestimated [7.3 ± 0.3].
 24. Osteoporosis in endocrinopathies: diseases of the pituitary gland, the thyroid gland, the parathyroid adrenal cortex and hypogonadism, require, first of all, specialised treatment of the underlying disease, although this does not exclude the need for symptomatic treatment, aimed at the protection of the skeletal system [9.0 ± 1.0].
 25. The management of patients with chronic kidney disease (CKD), including those on dialysis, due to the complex nature of calcium/phosphate metabolism disorders and the diversification of the forms of

bone changes in individual types of renal osteodystrophy, requires extensive biochemical diagnostics and, in some cases, bone biopsy with a histomorphometric evaluation. It is advisable that patients with CKD in 3–5D stage are diagnosed and treated at specialised centres [8.7 ± 1.2].

26. There is a distinctive group of persons at risk of osteoporosis, including patients with chronic gastrointestinal diseases, patients after bariatric surgery, anorexics, persons on extreme vegan diets, etc. An important role in maintaining normal absorption processes and for proper calcium and phosphate metabolism control is also played by the normal microbiome. In these cases, gastroenterological treatment often should be combined with psychological support [7.7 ± 1.6].
27. Osteoporosis associated with pregnancy and lactation (PLO) is rare and characterised by the occurrence of low-energy fractures, often of the vertebral bodies in advanced pregnancy or, more frequently, in the early postpartum period. Its diagnosis requires a specialized differential approach. Most patients are generally found to have classic fracture risk factors and vitamin D deficiency. No standards of pharmacotherapy have yet been established [7.5 ± 1.4].
28. An important and indispensable component of patient care at all stages of osteoporosis treatment is comprehensive rehabilitation and prevention of falls [9.4 ± 0.7].
29. Fracture prevention applies to all people, including those with a low fracture risk (FRAX < 5%). Every person is advised to adhere to a healthy, active lifestyle, eliminate smoking and alcohol abuse, follow a proper diet, and limit the use of medicinal agents that may increase the risk of fractures [9.7 ± 0.4].

The authors' individual comments on the recommendations, together with full references, are included in the journal supplement

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Conflict of interest

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