

L *bendrosios praktikos* *Lietuvos gydytojas*

Practical Interpretation of the Order on Treatment of Osteoporosis with Compensated Drugs: Answers to Frequently Asked Questions on Diagnosis and Treatment of Osteoporosis



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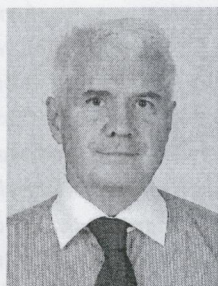
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Summary

Osteoporosis is a disease characterized by low bone mass and microarchitectural deterioration of bone tissue, leading to enhanced bone fragility and a consequent increase in fracture risk. The main goal of treatment for osteoporosis is to prevent fractures. As a result of fractures, people lose their independence and become dependent on those around them. In Lithuania, osteoporosis is diagnosed and treated in accordance with the Order on treatment of osteoporosis with compensated drugs, effective since 2014. Over five years of application of this order in daily clinical practice, physicians have encountered a number of questions, which we summarize and provide answers in this article.

Key words: osteoporosis, bone mineral density, DXA scan, bone fractures.

DIAGNOSTICS OF OSTEOPOROSIS AND OSTEOPOROTIC FRACTURES

1. Which fracture is osteoporotic? "Major" and "minor" fractures.

1.1. An **osteoporotic fracture** is a fracture of a certain localization arising from low-energy trauma (e.g., falling from a standing height) or spontaneously and not associated with a malignant or other pathological process in the bone.

1.2. **"Major" osteoporotic fractures** include fractures of the spine, three or more ribs, pelvis, humerus, hip and tibia.

1.3. **"Minor" osteoporotic fractures** include fractures of the sternum, 1–2 ribs, shoulder and forearm.

1.4. Osteoporotic fractures do not include skull, face, hand, ankle and foot fractures.

2. What is the localization of radiological examination to be performed when an osteoporotic fracture is suspected?

2.1. Radiological examination of the **affected area** should be performed without delay if an osteoporotic fracture is suspected.

2.2. For all patients with suspected osteoporosis **anterior and lateral radiographs of the thoracic and lumbar spine should be performed**, since vertebral fractures in these areas can occur spontaneously and can be asymptomatic.

3. When should a repeated radiological examination of the spine be performed?

3.1. Repeated radiographs of the spine are performed:

- If a new vertebral fracture is suspected.
- Deciding whether to continue treatment or before deciding to stop treatment for osteoporosis. If a new vertebral fracture is detected, the start of treatment will be considered as the date of confirmation of this fracture and treatment may be continued for another five years.

4. What is a new osteoporotic fracture (when deciding to start treatment for osteoporosis)?

4.1. Radiologically confirmed osteoporotic fracture for which a person is admitted immediately after the fracture.

4.2. Radiologically confirmed fracture previously not considered as osteoporotic (e.g., circumstances of trauma were not described or/and assessed and/or for which treatment of osteoporosis has not been initiated).

4.3. Osteoporotic vertebral fracture, which was not present in previous radiograms. Such a fracture is often described by the radiologist as "old".

5. How should osteoporotic fractures be documented?

5.1. Fractures and their external causes of accidental injury should be described in medical documents and recorded in statistical forms.

5.2. Radiologically confirmed fractures should be coded using ICD-10-AM codes for localization (S code) and external cause of accidental injury (W code).

5.3. If the fracture occurred spontaneously, W code is not applied, but it must be described in the medical documents.

6. When is osteoporosis with fracture diagnosed?

6.1. Osteoporosis with fracture is diagnosed when it is determined that a radiologically confirmed osteoporotic fracture is not associated with a malignant or other pathological process in the bone. Diagnosis of osteoporosis with pathological fracture and ICD-10-AM code should be recorded in medical documents and statistical form.

6.2. The date of diagnosis of osteoporosis with fracture does not necessarily coincide with the date of diagnosis of fracture.

6.3. The diagnosis of osteoporosis with fracture is made regardless of the value of T or Z score.

CLINICAL CASES

*78-year-old woman slipped on ice and experienced a fracture of her left hip. Traumatologist diagnosed the fracture (S72 W00), but neither traumatologist nor family doctor diagnosed osteoporosis. Six years later, patient was consulted by rheumatologist who considered the previous fracture as osteoporotic, performed X-ray of the left hip (old fracture), radiographs of the spine (no fractures), and excluded other diseases. Since osteoporosis with fracture has never been diagnosed, hip fracture experienced six years ago was considered as newly diagnosed and the following diagnosis was made: **Postmenopausal osteoporosis with pathological fracture, pelvic region and thigh (M80.05)**. Treatment for osteoporosis was initiated. Patient was referred for BMD test in order to monitor the efficacy of the treatment. Regardless of the value of BMD T score, osteoporosis treatment with compensated drugs will be continued for five years.*

*75-year-old woman was consulted by a family doctor for low back pain. Radiographs of the thoracic and lumbar spine were performed, Th10 vertebral fracture was found, which the radiologist assessed as "old". Family doctor excluded other diseases, considered the vertebral fracture as osteoporotic and made the diagnosis: **Postmenopausal osteoporosis with pathological fracture, other sites (M80.08)**. BMD test in order to monitor the efficacy of the treatment was performed, the "worst" result of all the sites examined, was the T score of the lumbar spine (L1-L4) -2.4. Because there is a "major" fracture, regardless of the fact that T score is at the level of osteopenia (-2.4), osteoporosis treatment with compensated drugs will be continued for five years.*

37-year-old man slipped on a wet shower floor and experienced a fracture of his right forearm. Consulted by traumatologist, fracture confirmed by X-ray. Has been suffering from multiple sclerosis for five years, taking prednisolone 10 mg tablets daily for almost two years. Lumbar spine and hip BMD measurements were performed. Because the man is younger than age 50 years, Z but not T score should be evaluated. Z score of all the sites examined was the lowest in the lumbar spine -3.0. **Diagnosis: Drug-induced osteoporosis with pathological fracture, forearm (M80.43).** Treatment with compensated drugs cannot be prescribed because osteoporotic fracture is "minor" and the criterion for administration of treatment is T score. Family doctor decided to perform X-ray of thoracic and lumbar spine and found Th8 and Th9 vertebral fractures. **Diagnosis changed to: Drug-induced osteoporosis with pathological fracture, multiple sites (M80.40).** As vertebral fractures are classified as "major," osteoporosis treatment with compensated drugs has been started and will be continued for five years, regardless of the BMD findings.

7. When is osteoporosis without fracture diagnosed?

7.1. Osteoporosis without fracture is diagnosed if two or more clinical fracture risk factors and at least one fall-risk factor are identified, plus T score is -2.5 or less. Diagnosis of osteoporosis without pathological fracture and ICD-10-AM code should be recorded in the medical documents and statistical forms.

7.2. Since diagnostic criterion for osteoporosis without fracture is T score, this disease can only be diagnosed in postmenopausal women and in men over 50 years of age.

8. What are ICD-10-AM codes allowing administration of osteoporosis treatment with compensated drugs?

8.1. To be eligible for osteoporosis treatment according to the Order, one of the following diagnoses should be confirmed:

- **Postmenopausal osteoporosis:** ICD-10-AM codes M80.0 (postmenopausal osteoporosis with pathological fracture) or M81.0 (postmenopausal osteoporosis).
- **Male osteoporosis:** ICD-10-AM codes M80.5 (idiopathic osteoporosis with pathological fracture) or M81.5 (idiopathic osteoporosis).
- **Drug-induced osteoporosis** (due to long-term systemic glucocorticoid use or androgen deprivation treatment for prostate cancer): ICD-10-AM codes M80.4 (drug-induced osteoporosis with pathological fracture) or M81.4 (drug-induced osteoporosis).

None of drugs for osteoporosis treatment have other approved indications.

8.2. When osteoporosis without fracture is diagnosed, the fourth digit of the ICD-10-AM code will always be 0: M81.00 (postmenopausal osteoporosis, multiple sites), M81.50 (idiopathic osteoporosis, multiple sites), M81.40 (drug-induced osteoporosis, multiple sites).

8.3. When diagnosing osteoporosis with fracture, the fourth digit of the ICD-10-AM code is selected depending on the site of the fracture: 0 (multiple sites), 1 (shoulder region), 2 (upper arm), 3 (forearm), 5 (pelvic region and thigh), 6 (lower leg) or 8 (other sites).

9. How does the diagnosis of osteoporosis and its code change during the cause of the disease and treatment?

9.1. **If osteoporosis is diagnosed,** it is a **lifelong diagnosis**, regardless of the fact that T score after treatment becomes greater than -2.5. An improvement in BMD indicates the efficacy of treatment but not recovery from osteoporosis.

9.2. If a new osteoporotic fracture is diagnosed, for osteoporosis with fracture the fourth digit of the ICD-10-AM code, indicating the site of the fracture, may change (or, in case of osteoporosis without fracture, the diagnosis may change from M81 to M80). Each new fracture must be radiologically confirmed and described in medical documents, either indicating the external cause of accidental injury or describing that the fracture occurred spontaneously.

CLINICAL CASE

80-year-old woman experienced a hip fracture when slipping on ice. The fracture was confirmed radiologically, other diseases excluded, and diagnosis made: Postmenopausal osteoporosis with pathological fracture, pelvic region and thigh (M80.05). A year later, X-ray of the thoracic and lumbar spine was performed due to low back pain, and Th10 vertebral fracture which was not present in previous radiograms was found. Spontaneous vertebral fracture was considered as a new osteoporotic fracture; in the diagnosis of osteoporosis with fracture the fourth digit was changed to indicate the location of both fractures experienced: Postmenopausal osteoporosis with pathological fracture, multiple sites (M80.08).

Osteoporosis treatment with compensated drugs should be administered at the time of diagnosis of a hip fracture (for five years), and after confirmation of additional spontaneous vertebral fracture should be extended for five years calculating from the date of diagnosis of the vertebral fracture.

9.3. According to the Order, a priority in the treatment of osteoporosis is given to osteoporosis with fracture. Each new confirmed fracture allows starting a new episode of treatment.

9.4. **If treatment for osteoporosis with fracture (M80) was effective** and no new osteoporotic fractures occurred within five years and thereafter, person should be observed, at least once every two years fracture risk and fall-risk factors should be evaluated and BMD measured. If two or more clinical fracture risk factors (one of which is previous osteoporotic fracture) and at least one fall-risk factor are identified plus T score is less than -2.5, osteoporosis without fracture is diagnosed and treatment with compensated drugs is administered under code M81 (diagnosis is changed from M80 to M81). If a new fracture occurs during treatment, a new treatment episode under code M80 is initiated.

9.5. **If treatment for osteoporosis without fracture (M81) was ineffective** and person experienced a new osteoporotic fracture during treatment (while using a drug for osteoporosis for at least 1 year), osteoporosis with fracture is diagnosed (i.e., diagnosis is changed from M81 to M80). Because of an osteoporotic fracture during treatment, a new treatment episode under code M80 should be initiated immediately.

CLINICAL CASE

Two vertebral fractures were radiologically confirmed in a 72-year-old woman. After exclusion of other diseases the following diagnosis was made: Postmenopausal osteoporosis with pathological fracture, other sites (M80.08). BMD T score -2.8. Treatment with bisphosphonates for five years, no new fractures, BMD stable, 3% increase in lumbar spine, no change in hip, T score -2.7. It was decided to take a break from treatment. After two years (patient now is 79-year-old) risk factors (previous vertebral fractures, postmenopausal woman), fall-risk factors (impaired vision and hearing) were evaluated, BMD examination was performed: T score -2.9, no new fractures were found in thoracic and lumbar spine radiographs. Diagnosis: Postmenopausal osteoporosis, multiple sites (M81.00), a new treatment episode under code M81 was initiated, bisphosphonates administered. Used bisphosphonates neatly, but after two years (patient now is 81-year-old) slipped in the kitchen and experienced a hip fracture, which was considered as osteoporotic. In previous diagnosis of osteoporosis with fracture the fourth digit was changed to indicate the location of both fractures experienced: Postmenopausal osteoporosis, multiple sites (M80.00) and a new treatment episode under code M80 was initiated. Because of fracture during treatment, treatment is

considered as ineffective and the bisphosphonate is switched to denosumab.

9.6. It is acceptable to use a combination of few diagnoses of osteoporosis – for example, the same woman is diagnosed both postmenopausal (M81.00) and glucocorticoid-induced osteoporosis (M81.40), or the same man has both idiopathic (M81.50) and androgen therapy due to prostate cancer induced osteoporosis (M81.40).

For administration of osteoporosis treatment one diagnosis (one indication) has to be selected.

9.7. If the combination of few diagnoses of osteoporosis (e.g. M81.00 and M81.40) also includes code M82 (osteoporosis in diseases classified elsewhere), it should be noted that none of compensated drugs has an approved indication for the treatment of osteoporosis in diseases classified elsewhere (M82). In such a case, a diagnosis for which osteoporosis drug has an approved indication should be selected.

MEASUREMENT OF BONE MINERAL DENSITY (BMD)

10. What is bone mass and BMD?

10.1. Bone mass is the amount of bone mineral (hydroxyapatite) in bone tissue, measured in grams. BMD is the bone mass divided by the scanned area.

10.2. BMD, measured in grams per square centimetre (g/cm^2), is the only quantitative marker that gives an objective and accurate estimation of bone mass.

11. What techniques are used to measure BMD?

11.1. BMD is measured by dual-energy X-ray absorptiometry (DXA).

11.2. According to the Order DXA is the only method to assess BMD. If the BMD measurement was performed by another method (e.g. ultrasound, computed tomography), the assessment of BMD by DXA is required to initiate, change or continue osteoporosis treatment with compensated drugs and/or to evaluate its efficacy.

12. What skeletal sites are being examined?

12.1. All patients should undergo measurements at **lumbar spine** (L1-L4) and **one hip** (left or right), with evaluation of **total lumbar spine** (from at least two vertebrae), **total hip** and **femoral neck T and/or Z scores**.

12.2. The forearm (of non-dominant hand) should be examined only when lumbar spine or hip BMD assessment is not possible; T and/or Z scores are evaluated at the distal third radius.

13. How are BMD T and Z scores evaluated?

13.1. After determining the subject's BMD (g/cm^2) by DXA, the result is compared to a standard normal and two values, so called T and Z scores, are calculated.

13.2. **T score** is the subject's BMD deviation, expressed in the number of standard deviations from the maximum mean BMD of young healthy subjects of the same gender.

13.3. **Z score** is the subject's BMD deviation expressed in the number of standard deviations from the mean BMD of the same age and gender.

13.4. **T score is a diagnostic criterion for osteoporosis in postmenopausal women and men over 50 years of age.** Normal bone mass: T score +1 to -1; osteopenia: T score from -1 to -2.5; osteoporosis: T score -2.5 or less.

13.5. **Z score is used to evaluate BMD in children, in females prior to menopause and in males under age 50.** Z-score of -2.0 or lower is defined as below the expected range for age – decreased bone mass; and a Z-score above -2.0 is within the expected range for age – normal bone mass.

13.6. If DXA is performed in few skeletal sites, **BMD deviation from the site with the lowest T and/or Z score should be used to draw the conclusion:** the "worst" result – T and/or Z score of either total lumbar spine (calculated from at least two vertebrae), or total hip, or femoral neck, or distal third radius should be selected (e.g., combination of diagnoses "osteopenia in the spine" and "osteoporosis in the hip" cannot be used).

13.7. In case of osteoporotic fracture, which is not caused by a malignant or other pathological process in the bone, diagnosis of osteoporosis is made regardless of BMD T and/or Z score.

14. When should an initial BMD measurement be performed?

14.1. Having identified at least two clinical fracture risk factors and at least one fall-risk factor.

14.2. When a "minor" osteoporotic fracture is diagnosed.

14.3. When a "major" osteoporotic fracture is diagnosed, BMD measurement is not required to confirm the diagnosis, but is recommended to monitor treatment efficacy.

15. When should repeat BMD measurement be performed?

15.1 BMD measurement should be repeated:

- One year after the start of treatment for osteoporosis to evaluate the efficacy of the drug given to treat osteoporosis (measurement is recommended, to be decided by the treating physician).
- Three years after the start of treatment for osteoporosis, deciding on the need to extend treatment for another two years (not mandatory in case of a "major" osteoporotic fracture, unless aiming to evaluate the efficacy of the drug given to treat osteoporosis).

- Before deciding to stop treatment for osteoporosis.

- Every two years, if BMD does not match the level of osteoporosis, but osteopenia has been diagnosed and there are at least two clinical fracture risk factors and at least one fall-risk factor.

- At least once every two years after stopping treatment with osteoporosis.

- After discontinuation of denosumab treatment, it is recommended to measure BMD annually.

- In case of suspected rapid bone turnover induced by diseases and/or drugs that adversely affect bone turnover, it is recommended to measure BMD annually or even every six months. Decision on timing of the repeated measurement is taken by the treating physician.

16. What are the requirements for repeat BMD measurement?

16.1. To be able to compare results of the repeat BMD measurement with the initial or previous one:

- The measurement must be performed with the **same DXA device** (preferably by the same technologist); if repeat measurement is performed with a different device, T or Z scores can be evaluated, but comparison between two measurements and calculation of BMD change are not possible.

- Only the **same skeletal sites** can be compared, e.g. BMD results of lumbar spine and hip, left and right hip, four vertebrae evaluated in the initial examination and three or two vertebrae in a repeated measurement, cannot be compared to each other.

- The areas of the scanned sites to be compared should be equal (if different, evaluate if examination was performed properly, results were analysed correctly and if new artefacts such as fractures, degenerative changes etc. appeared).

CLINICAL CASE

If there are less evaluable vertebrae in the repeat BMD examination of the lumbar spine than in the initial test (e.g. L3 vertebra fractured), to be able to compare results of both examinations, the same vertebrae should be excluded from analysis of the first and repeat BMD measurements (in this case L3 vertebra). This can be done by DXA technologist, but not by the treating physician.

17. How is the change in BMD calculated?

17.1. Change in BMD (g/cm²) should be considered not T or Z scores!

17.2. Change in BMD (percentage) is being calcu-

lated using formula: $(b-a)/a \times 100$, where **a** is BMD (g/cm²) of the first evaluation, and **b** is BMD (g/cm²) of the repeat measurement.

CLINICAL CASES

75-year-old woman with diagnosis: Postmenopausal osteoporosis, multiple sites (M81.00); comparison of initial BMD and BMD after three years of treatment.

Initial lumbar spine BMD (**a**) – 0.867 g/cm²

Repeat lumbar spine BMD (**b**) – 0.832 g/cm²

Difference (**b-a**) – (-0.035) g/cm²

Calculation of percentage change in BMD using formula $(b-a)/a \times 100$: $(-0.035/0.867) \times 100 = -4.03$

Conclusion: BMD reduced by 4.0%.

72-year-old woman with diagnosis: Postmenopausal osteoporosis, multiple sites (M81.00), comparison of initial BMD and BMD after three years of treatment.

Initial lumbar spine BMD (**a**) – 0.832 g/cm²

Repeat lumbar spine BMD (**b**) – 0.867 g/cm²

Difference (**b-a**) – 0.035 g/cm²

Calculation of percentage change in BMD using the formula $(b-a)/a \times 100$: $(0.035/0.832) \times 100 = 4.21$

Conclusion: BMD increased by 4.2%

18. What BMD change is clinically significant?

18.1. Decrease in lumbar spine BMD by 5% (g/cm²) and more, and in the hip or femoral neck by 4% and more, compared to initial BMD of the same area measured by the same DXA device, is considered clinically significant.

19. How do BMD findings result in administration of osteoporosis treatment with compensated drugs?

19.1. If a person has experienced a “major” osteoporotic fracture, diagnosis of osteoporosis is made regardless of BMD results. BMD measurement is not required but only recommended to evaluate dynamics of BMD changes and/or treatment efficacy. Osteoporosis treatment with compensated drugs is administered for five years, regardless of the value of T and/or Z score.

19.2. If a person has experienced a “minor” osteoporotic fracture, BMD measurement is mandatory to decide if osteoporosis treatment with compensated drugs can be initiated and administered for 3 years and then continued of for another two years. Only T score is evaluated and must be -2.5 or less.

19.3. If a person has not experienced an osteoporotic fracture, BMD examination shall be performed when at least two clinical fracture risk factors and at least one fall-risk factor is identified. The result of BMD measurement determines if osteoporosis treatment with compensated drugs can be initiated and adminis-

tered for 3 years and then continued of for another two years. Only T score is evaluated and must -2.5 or less.

TREATMENT OF OSTEOPOROSIS

20. How is medication for osteoporosis treatment selected?

20.1. In compliance with the Order, treatment for osteoporosis should be selected according to the approved drug indications, mode of action, contraindications for use, ability of the patient to use the drug properly and according to the following drug administration rules:

- First-line drugs – oral bisphosphonates;
- Second-line drugs – injectable bisphosphonates and denosumab;
- Third-line drugs – teriparatide.

21. Can a family doctor administer osteoporosis treatment without advice of specialist?

21.1 Treatment for osteoporosis can be initiated and continued by family doctor as well as by specialist physician within the scope of their professional qualifications. The exception is only for third-line drugs, i.e. treatment with third-line drug can be administered by a consilium of specialist physicians and then continued only by a specialist physician.

22. What date is considered to be the start of treatment (episode of treatment) for osteoporosis?

22.1. The onset of treatment (episode of treatment) for osteoporosis is the date when a person begins to take anti-osteoporosis medication (does not necessarily coincide with the date when diagnosis of osteoporosis with or without fracture is made).

23. What date is considered to be the end of treatment (episode of treatment) for osteoporosis?

23.1. The end of treatment (episode of treatment) for osteoporosis is the date when according to the summary of product characteristics the next dose of drug should be given to continue treatment.

24. What is the duration of treatment episode for osteoporosis with fracture?

24.1. If osteoporosis treatment with compensated drugs is administered for **osteoporosis with a “major” fracture**, duration of the treatment episode is five years. If a new “major” osteoporotic fracture occurs during treatment, a new five-year treatment episode is initiated, which start date is considered to be the date of confirmation of the new fracture. If a “minor” osteoporotic fracture, in case of which indication for osteoporosis treatment depends on T score, occurs during treatment, the fracture that allows longer duration of treatment (or its continuation) should be selected.

24.2. If osteoporosis treatment with compensated drugs is administered for **osteoporosis with a “mi-**

nor fracture and T score -2.5 or less, the duration of treatment episode is up to five years. Initially treatment is administered for three years and then is continued for another two years if T score remains below -2.5 . If T score after three years of treatment is greater than -2.5 but decreases to -2.5 or less at some time point between three and five years after the start of the previous treatment episode (e.g. after four years), treatment may be extended for another two years. If T score decreases to -2.5 or less after five years or more and no new osteoporotic fractures are diagnosed, **osteoporosis without fracture** is diagnosed and treatment is administered under code M81 (diagnosis is changed from M80 to M81).

24.3. It is important to emphasize that osteoporosis with fracture is treated with compensated drugs for up to five years after the most recent fracture. Regardless of whether the treatment with compensated drugs for osteoporosis with a "major" or "minor" fracture was administered, treatment efficacy is evaluated after five years of treatment. This means that for both "major" and "minor" fractures, diagnosis code M80 is used for prescribing compensated drugs for at least five years.

CLINICAL CASES

78-year-old woman slipped on ice and experienced a fracture of her left hip. The fracture was confirmed radiologically, other diseases were excluded, and the following diagnosis was made: Postmenopausal osteoporosis with pathological fracture, pelvic region and thigh (M80.05). Because of the "major" fracture, treatment for osteoporosis was promptly initiated and BMD examination was recommended in order to monitor the efficacy of the treatment. The patient did not come for BMD examination. Three years later, she consulted a rheumatologist and asked if she could stop treatment for osteoporosis. Rheumatologist confirmed that treatment should be continued for another two years, but to find out if there are no new fractures performed thoracic and lumbar spine radiographs in which fractures of Th9 and Th10 vertebrae were detected. Although radiologist described these fractures as "old", they were considered as newly diagnosed because they were not present in radiographs made three years ago. The fourth digit in the diagnosis is changed to indicate the location of all fractures experienced: Postmenopausal osteoporosis with pathological fracture, multiple sites (M80.00). A new treatment episode is started, which will be continued for another five years; previously administered drug is switched to another one due to inefficiency, manifesting by vertebral fractures.

75-year-old woman has a radiographically confirmed Th10 vertebral osteoporotic fracture. Diagno-

sis: Postmenopausal osteoporosis with pathological fracture, other sites (M80.08). BMD test to monitor treatment efficacy was performed, the "worst" result of all sites examined was lumbar spine (L1-L4) T score -2.9 . Osteoporosis treatment with compensated drugs was administered, which, because of the "major" fracture, is expected to be continued for five years. After four years of treatment patient experienced an osteoporotic fracture of forearm. Diagnosis was changed to: Postmenopausal osteoporosis with pathological fracture, multiple sites (M80.00). As the new fracture is "minor", further tactics of osteoporosis treatment with compensated drugs depend on T score: if T score is less than -2.5 , a new three-year treatment episode is initiated, and if T score is greater than -2.5 , treatment is continued according to the episode of the "major" fracture.

37-year-old man with five-year history of multiple sclerosis, taking prednisolone 10 mg tablets daily for two years has confirmed osteoporotic Th8 and Th9 vertebral fractures. Lumbar spine and hip BMD examination was performed. As the man is younger than age 50 years, Z score was evaluated and was the lowest in the lumbar spine of all the sites examined -3.0 . Diagnosis: Drug-induced osteoporosis with pathological fracture, other sites (M80.48). Because vertebral fractures are classified as "major", osteoporosis treatment with compensated drugs will be continued for five years regardless of BMD findings. Two years later, while slipping on a wet shower floor, the patient experienced fracture of his right forearm, a new "minor" osteoporotic fracture was confirmed. Diagnosis was changed to: Drug-induced osteoporosis with pathological fracture, multiple sites (M80.40). In this case, a new treatment episode with compensated drugs cannot be initiated, as treatment for "minor" fractures is determined by T score and the patient is younger than age 50 years and is therefore assessed for Z score. A five-year episode of treatment for a "major" fracture is continued switching to another drug as a new osteoporotic fracture indicates that previous treatment was ineffective.

25. What is the duration of treatment episode for osteoporosis without fracture?

25.1. If treatment with compensated drugs is administered for **osteoporosis without fracture**, when there are two or more clinical fracture risk factors, at least one fall-risk factor, and T score -2.5 or less, duration of the treatment episode is up to five years. Initially treatment is administered for three years and then is continued for another two years if T score remains -2.5 or less. If T score after three years of treatment is greater than -2.5 but decreases to -2.5 or less at some

time point between three and five years after the start of the previous treatment episode (e.g. after four years), treatment may be extended for another two years. If T score decreases to -2.5 or less after five years or more, a new treatment episode for up to five years is initiated. If an osteoporotic fracture is diagnosed during treatment, a new five-year treatment episode for osteoporosis with fracture is immediately initiated.

26. What are the criteria for treatment efficacy (discontinuation)?

26.1 Treatment is considered effective and can be discontinued if during five years of treatment no new osteoporotic fractures occurred, BMD stabilized and total L1-L4 vertebrae (from at least two vertebrae), total hip and femoral neck T scores are greater than -2.5.

27. What if after five years BMD has not stabilized, and T score is -2.5 or less?

27.1. If after five years of treatment, BMD has not stabilized and T score remains -2.5 or less, fracture and fall risk is reassessed and treatment is continued for another two years.

27.2. If the patient took a break from treatment, frac-

ture and fall risk shall be reassessed, BMD examination shall be performed and if T score is -2.5 or less, a new treatment episode for up to five years shall be initiated.

27.3. It is desirable for BMD to increase significantly or remain stable. If clinically significant BMD reduction is detected – 5% (g/cm²) reduction at lumbar spine and/or 4% (g/cm²) at hip when compared to initial BMD (g/cm²), measured at the same sites with the same DXA device, ongoing drug for osteoporosis treatment should be changed.

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