NICE National Institute for Health and Care Excellence

Putting NICE guidance into practice

Resource impact report:
Romosozumab for treating severe osteoporosis (TA791)

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Summary

NICE has recommended romosozumab as an option for treating severe osteoporosis in people after menopause who are at high risk of fracture. See the full recommendation wording in section 1.

We estimate that:

- around 12,500 people after menopause who have had a major osteoporotic fracture in the last 13-24 months (prevalent population) who have severe osteoporosis and are at high risk of fracture are eligible for treatment with romosozumab in year 2022/23.
- a further 12,500 people after menopause who have had a major osteoporotic fracture in the last 12 months (incident population) who have severe osteoporosis and are at high risk of fracture are eligible for treatment with romosozumab each year from 2022/23 onwards.
- In 2022/23, around 1,250 people in the prevalent population and a further 1,250 people in the incident population will receive treatment with romosozumab, based on an uptake of 10%. In 2026/27 it is expected that around 6,260 people will receive treatment with romosozumab once uptake has reached 50% as shown in table 1.

Table 1 Estimated number of people in England receiving treatment with romosozumab each year

	2022/23	2023/24	2024/25	2025/26	2026/27
Uptake %	10	20	30	40	50
People receiving treatment with romosozumab (prevalent population)	1,252	0	0	0	0
People receiving treatment with romosozumab (incident population)	1,252	2,504	3,756	5,009	6,261
Total number of people receiving treatment with romosozumab	**2,504**	**2,504**	**3,756**	**5,009**	**6,261**

The recommended treatment dose is 210 mg romosozumab (administered as two subcutaneous injections of 105 mg each) once monthly for 12 months.

This report is supported by a local resource impact template because the list price of romosozumab has a discount that is commercial in confidence. The discounted price of romosozumab can be put into the template and other variables may be amended.

This technology is commissioned by integrated care systems and clinical commissioning groups. Providers are NHS hospital trusts.

1 Romosozumab

1.1 NICE has recommended romosozumab within its marketing authorisation, as an option for treating severe osteoporosis in people after menopause who are at high risk of fracture, only if:

- they have had a major osteoporotic fracture (spine, hip, forearm or humerus fracture) within 24 months (so are at imminent risk of another fracture) and

- the company provides romosozumab according to the commercial arrangement.

This recommendation is not intended to affect treatment with romosozumab that was started in the NHS before this guidance was published. People having treatment outside this recommendation may continue without change to the funding arrangements in place for them before this guidance was published, until they and their NHS clinician consider it appropriate to stop.

1.2 Osteoporosis is a progressive skeletal disorder. It is characterised by low bone mass and deterioration of the structure of bone tissue leading to an increase in bone fragility and risk of fracture.

1.3 Romosozumab is a unique osteoporosis therapy that stimulates bone formation and decreases bone resorption. Most people at high risk of fracture have bisphosphonates as their first treatment but these do not provide optimal fracture risk reduction within 12 months, instead reaching optimal reduction by 36 months, therefore romosozumab will meet a high unmet need for people who are at high risk of fracture.

1.4 Current treatments for people with severe osteoporosis after menopause include bisphosphonates, such as alendronic acid, and other types of medicines, such as denosumab or teriparatide.

2 Resource impact of the guidance

2.1 We estimate that:

- around 12,500 people after menopause who have had a major osteoporotic fracture in the last 13-24 months (prevalent population) who have severe osteoporosis and are at high risk of fracture are eligible for treatment with romosozumab in year 2022/23.
- a further 12,500 people after menopause who have had a major osteoporotic fracture in the last 12 months (incident population) who have severe osteoporosis and are at high risk of fracture are eligible for treatment with romosozumab each year from 2022/23 onwards.
- In 2022/23, around 1,250 people in the prevalent population and a further 1,250 people in the incident population will receive treatment with romosozumab, based on an uptake of 10%. In 2026/27 it is expected that around 6,260 people will receive treatment with romosozumab once uptake has reached 50% as shown in table 2.

Table 2 Estimated number of people in England receiving treatment with romosozumab each year using NICE assumptions

	2022/23	2023/24	2024/25	2025/26	2026/27
Uptake %	10	20	30	40	50
People receiving treatment with romosozumab (prevalent population)	1,252	0	0	0	0
People receiving treatment with romosozumab (incident population)	1,252	2,504	3,756	5,009	6,261
Total number of people receiving treatment with romosozumab	**2,504**	**2,504**	**3,756**	**5,009**	**6,261**

2.2 This report is supported by a local resource impact template because the list price of romosozumab has a discount that is commercial in confidence. The discounted price of romosozumab can be put into the template and other variables may be amended. This technology is commissioned by integrated care systems and clinical commissioning groups. Providers are NHS hospital trusts.

Savings and benefits

2.3 Evidence suggests that romosozumab followed by alendronic acid is more effective at reducing the risk of fractures than alendronic acid alone.

2.4 Users can calculate savings from potential fractures avoided by inputting the percentage for the incidence of hip fractures, vertebral fractures and other fractures when receiving treatment with romosozumab and comparator drugs.

2.5 There is an unmet need for people with very high fracture risk for whom current drugs are not suitable, or for those at particularly high risk of vertebral or hip fractures.

2.6 Romosozumab has both anabolic and anti-resorptive properties and is the first new treatment option for osteoporosis in several years.

3 Implications for commissioners and providers

3.1 Romosozumab is commissioned by integrated care systems and clinical commissioning groups. Providers are NHS hospital trusts.

4 How we estimated the resource impact

The population

4.1 There are around 11,043,600 postmenopausal people (50 years and older) in England (Office for National Statistics).

4.2 Of these, the Fragility fractures in Europe: burden, management and opportunities study estimated around 22% have osteoporosis.

4.3 The number of people after menopause with osteoporosis who have had a major osteoporotic fracture in the last 13-24 months was derived from clinical expert opinion. This was based on an annual figure of 2,000 fractures per 500,000 population, clinical experts estimated around 70% of these people are postmenopausal and a further 50% have severe osteoporosis. Applying this to the total population of England equates to approximately 78,800 people. Of these, clinical experts estimated 15%-20% (midpoint 17.5%) of people are at high risk of fracture and are assumed to have severe osteoporosis.

4.4 The cardiovascular risk factors and incidence of cardiovascular events in postmenopausal women at high risk of fracture study estimated around 9.2% would have a history of myocardial infarction or stroke. These people cannot receive romosozumab in accordance with contraindications listed in the summary of product characteristics.

4.5 This equates to approximately 12,500 people eligible for romosozumab in 2022/23 who have had a major osteoporotic fracture in the last 13-24 months ('prevalent population'). The same assumptions are used to estimate that in each year there will be approximately 12,500 people who have had a major osteoporotic fracture in the last 12 months and become eligible for romosozumab ('incident population'). From 2023/24 it is assumed that people will start treatment up to 12 months after their fracture and not between 13 and 24 months after their fracture.

4.6 Table 3 shows the number of people eligible for treatment with romosozumab.

Table 3 Number of people eligible for treatment in England

Population	Proportion of previous row (%)	Number of people
Total population		56,286,961
Number of postmenopausal people (50 years and older)[1]	19.62%	11,043,600
People after menopause with osteoporosis (Defined as BMD T-score ≤-2.5)[2]	21.80%	2,407,500
People after menopause with osteoporosis who have had a major osteoporotic fracture in the last 13-24 months[3]	3.3%	78,800
People after menopause with severe osteoporosis who have had a major osteoporotic fracture in the last 13-24 months and are at high risk of fracture[3]	17.5%	13,790
People after menopause with severe osteoporosis who have had a major osteoporotic fracture in the last 13-24 months at high risk of fracture with no history of MI or stroke (prevalent population)[4]	**91%**	**12,520**
People after menopause with osteoporosis who have had a major osteoporotic fracture in the last 12 months[3]	3.3%	78,800
People after menopause with severe osteoporosis who have had a major osteoporotic fracture in the last 12 months and are at high risk of fracture[3]	17.5%	13,790
People after menopause with severe osteoporosis who have had a major osteoporotic fracture in the last 12 months at high risk of fracture with no history of MI or stroke (incident population)[4]	**91%**	**12,520**

[1] Office for National Statistics

[2] Fragility fractures in Europe: burden, management and opportunities

[3] Clinical expert opinion

[4] The cardiovascular risk factors and incidence of cardiovascular events in postmenopausal women at high risk of fracture

Assumptions

4.7 The resource impact template assumes that:

- Current treatments for people with severe osteoporosis after menopause include bisphosphonates, such as alendronic acid, and other types of medicines, such as denosumab or teriparatide.
- Romosozumab is given as monthly 210 mg subcutaneous injections (administered as two injections of 105 mg each), for one year, followed by anti-resorptive maintenance therapy.
- The persistence on alendronic acid after romosozumab is likely to be higher than alendronic acid alone as people having romosozumab would likely be more motivated to continue with treatment. The cost of the subsequent anti-resorptive treatment is not included in the resource impact template because there is minimal resource impact expected due to the low cost of alendronic acid; only the change in practice in the year of receiving romosozumab treatment is included.
- A homecare service for delivery of stock will be provided for romosozumab.
- Administration costs in clinic for denosumab and zoledronic acid are based on the 2021/22 National Tariff Payment System.
- The costs for fractures and rehabilitation are based on the 2019/20 national cost collection data, users also have the option to include any other costs associated with a fracture.
- Clinical expert opinion suggests market share of romosozumab will increase each year until 2026/27 when it reaches 50% of the eligible population.
- Clinical experts estimate 60% of denosumab is prescribed in secondary care and 40% in primary care.
- Where comparator drugs alendronic acid, teriparatide and denosumab are prescribed in primary care, no administration costs are applied.

- In each year, postmenopausal people with severe osteoporosis who have had a major osteoporotic fracture are assumed to be newly eligible and have not previously been prescribed romosozumab following a previous fracture.

About this resource impact report

This resource impact report accompanies the NICE guidance on romosozumab for treating severe osteoporosis and should be read with it. See terms and conditions on the NICE website.