Review proposal of technology appraisals for treatment and prevention of osteoporosis (TA160, TA161, TA204, TA464, TA791, TA991)

Summary of TAs to be considered for review

A summary of the TAs to be considered for review is listed in Table 1.

Table 1: TAs to be considered for review

TA number	Title	Recommendation	Year of publication
TA160	Raloxifene for the primary prevention of osteoporotic fragility fractures in postmenopausal women	• NB: many recommendations replaced by TA464	2008
TA161	Raloxifene and teriparatide for the secondary prevention of osteoporotic fragility fractures in postmenopausal women	• Raloxifene is recommended as an alternative treatment option for the secondary prevention of osteoporotic fragility fractures in postmenopausal women (risk factors expressed in a table using age, T-score and clinical risk factors) • Teriparatide is recommended as an alternative treatment option for the secondary prevention of osteoporotic fragility fractures in postmenopausal women (risk factors expressed as combinations of age, T-score and number of fractures)	2008
TA204	Denosumab for the prevention of osteoporotic fractures in postmenopausal women	• Denosumab is recommended as a treatment option for the primary prevention of osteoporotic fragility fractures only in postmenopausal women at increased risk of fractures (risk factors expressed in a table using age, T-score and clinical risk factors) • Denosumab is recommended as a treatment option for the secondary prevention of osteoporotic fragility fractures only in postmenopausal women at increased risk of fractures who	2010

		are unable to comply with the special instructions for administering alendronate and either risedronate or etidronate, or have an intolerance of, or a contraindication to, those treatments.	
TA464	Bisphosphonates for treating osteoporosis	• Oral bisphosphonates (alendronic acid, ibandronic acid and risedronate sodium) and intravenous bisphosphonates (ibandronic acid and zoledronic acid) are recommended, within their marketing authorisations, as options for treating osteoporosis in adults (risk factors as described in 2019 osteoporosis guideline update and NICE's quality standard on osteoporosis)	2017
TA791	Romosozumab for treating severe osteoporosis	• Romosozumab is recommended 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)	2022
TA991	Abaloparatide for treating osteoporosis after menopause	• Abaloparatide is recommended as an option for treating osteoporosis after menopause in women, trans men and non-binary people, only if they have a very high risk of fracture (defined by National Osteoporosis Guideline Group (NOGG) clinical guideline for the prevention and treatment of osteoporosis)	2024

Rationale for change

1. The NICE Centre for Guidelines is currently conducting an update of NICE clinical guideline 146 (CG146) Osteoporosis: assessing the risk of fragility fracture. This update will be delivered in 2 parts, the first part covering

assessment for fragility fracture risk, methods of risk assessment, identifying vertebral fractures, treatment criteria and repeat risk assessment (timing and methods) for people not receiving treatment. This part of the update is currently being consulted on alongside this surveillance review, starting 13th January 2026.

2. The second part of the update of CG146 will cover treatment (pharmacological, exercise and calcium and vitamin D), monitoring of treatment and treatment pauses. The draft recommendations for risk assessment in part 1 of the updated CG146 are inconsistent with the methods of risk assessment that were used as treatment thresholds in the technology appraisals listed above. In addition, the risk assessment criteria within the wording of each TA are representative of the time at which they were appraised and are therefore not consistent with each other, or updated clinical practice, and require updating. This inconsistency in intervention thresholds for pharmacological treatments needs to be resolved so that NICE can produce useful and usable recommendations in line with the CG146 update.

Review proposal

A review of all guidance relating to medicines in osteoporosis should be planned into the appraisal work programme. The review will be conducted through the multiple technology appraisal (MTA) process.

Proposed process summary

A summary of the proposed process is below:

3. This draft surveillance review proposal will be used to summarise the process for updating the guidance and for stakeholders to provide feedback on the decision to review current TA guidance. NICE will consult on this proposal alongside the guideline consultation. The consultation period will be 28 days, and consultation will be open to consultees and commentators, as specified in the stakeholder list.

4. Alongside consultation of part 1 of the CG146 update, NICE will provide a draft scope for consultation for the technologies listed above in the MTA process, consistent with updated risk assessment criteria from the guideline update.

5. Appraisal of these treatments will follow NICE Medicines Evaluation's standard MTA process, with minor changes to the process outlined below to ensure consistency with the guideline production.

6. NICE intends to update the guidance through an evaluation, publishing new guidance to replace the existing guidance covering all relevant pharmacological interventions (section 8.2.17 of the manual). The MTA process would therefore create a single updated piece of guidance including all pharmacological interventions with updated recommendations.

7. Further work in part 2 of the guideline update will incorporate and contextualise pharmacological management recommendations from the outcomes of this MTA process into CG146 update, as well as recommendations for exercise, calcium and vitamin D supplementation and monitoring of treatment and treatment pauses.

Proposed changes to the MTA process

MTA scoping process

8. Scoping for the MTA will be carried out in line with the methods and processes outlined in section 2 of the NICE technology appraisals manual.

9. Section 2.2.3 recognises that the relevant use of the technologies will normally depend on the marketing authorisation for each technology. There are no proposed changes to this, however there may also be additional consideration to align definitions of risk assessment as outlined by the guideline, that shapes the clinical treatment pathway. Positioning of individual treatments within the updated definitions of risk assessment will be considered as part of the scoping workshop, taking into account stakeholder views.

10. Section 2.2.8 and 2.3.1 notes that all technologies must meet the eligibility criteria for selection in the NICE-wide topic prioritisation process. Please note that this topic has been identified as a strategic priority as part of the Whole Lifecycle Approach work programme outlined in the NHS 10-year plan.

11. Section 2.4 outlines how stakeholders are identified, please note that NICE will align the stakeholders for the MTA with the stakeholders for the CG146 guideline update, alongside relevant manufacturers of the treatments above.

12. Section 2.5 outlines the consultation process on the draft scope. Please note that the consultation will align with the CG146 guideline update timing, starting from 13th January and consulting for 6 weeks.

MTA appraisal process

13. The appraisal process will follow our standard MTA process using sections 3-7 of the NICE technology appraisals manual. Key changes to the process are to include greater involvement from guideline committee members and teams across NICE, to support consistency across related guidance and reflect work already undertaken within the disease area.

14. Section 5.1.3 notes that NICE charges companies for technology appraisals. However, as part of the Whole Lifecycle Approach work programme, there will be no charges for companies who are invited to participate in this MTA review.

15. In line with section 5.2.1, it is not possible to set absolute timelines for all stages of the evaluation, however the estimated time of the end of the MTA evaluation will be by the end of the 2026/27 business year.

16. To promote consistency between the MTA and guideline, NICE guideline developers may support the external assessment group (EAG) and NICE medicines evaluation team when considering approaches to addressing the decision problem following scoping (in section 5.6.2). NICE Guideline developers will also have the opportunity to quality assure the EAG's economic model for efficient knowledge-sharing from guideline development and comment on whether it is likely that the model could support future guideline development.

17. In line with section 5.8.14, a subgroup of guideline committee members will be invited to participate in the public session of technology appraisal meetings. In addition, these guideline committee members will also be able to attend the private session (part 2) of the technology appraisal meeting. This is to ensure

that technology appraisal recommendations align with guideline recommendations, and that guidance is clear for end users to understand. Guideline committee members will be given access to the same information as technology appraisal committee members; confidentiality will be strictly preserved.

18. Evidence that may be relevant to the MTA that has been identified or generated elsewhere in the development of the CG146 guideline update will be made available by NICE to the external assessment group.

19. If applicable, the technology appraisal and guideline committees will work collaboratively to ensure recommendations in multi-comparator decision spaces not only follow the manual considerations of recommendation wording (see section 6.4.2 - 6.4.5 of the manual), but also give clarity for implementation in clinical practice to meet user needs whilst providing value for money.

Questions for consultation

Is the proposed process for reviewing and updating the TAs appropriate to achieve useful and usable guidance?

Is the proposed process sufficiently clear? Are further details of the proposed process required by stakeholders?

Should NICE consider adapting other elements of the proposed process to achieve more useful and usable guidance?

Do you have any other comments on the proposed process for updating the TAs within the MTA process?

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that the proposal may need changing in order to meet these aims. In particular, please tell us if the proposed remit and scope:

- could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which the treatments are licensed;

- could lead to recommendations that have a different impact on people protected by the equality legislation than on the wider population, e.g. by making it more difficult in practice for a specific group to access the technology;

- could have any adverse impact on people with a particular disability or disabilities.

Please tell us what evidence should be obtained to enable the committee to identify and consider such impacts.

Equality issues

Please note that previous technology appraisals have highlighted equality issues for consideration:

- TA991 noted that the marketing authorisation for abaloparatide is for the 'treatment of osteoporosis in postmenopausal women', a person can have osteoporosis after menopause and not identify as a woman. Gender reassignment is a protected characteristic under the Equality Act 2010.

- TA791 also noted that there that there may be some people who have been through the menopause but do not identify as a woman. It also highlighted inequality based on fracture risk associated with socioeconomic status and highlighted that rare types of osteoporosis may need consideration.

Proposal/decision paper sign off

Jacoline Bouvy – Programme Director, Technology Appraisals and Highly Specialised Technologies

Lorna Dunning – Associate Director, Technology Appraisals and Highly Specialised Technologies

08/01/2026

Contributors to this paper

Principal Technical Adviser: Adam Brooke

Technical Analyst: Giacomo de Guisa

Technical Adviser: Claire Hawksworth