

Patient/carer organisation statement template

Thank you for agreeing to give us your views on the technology and the way it should be used in the NHS.

Patients and patient advocates can provide a unique perspective on the technology, which is not typically available from the published literature.

To help you give your views, we have provided a template. The questions are there as prompts to guide you. You do not have to answer every question. Please do not exceed the 8-page limit.

About you

Your name: [REDACTED]

Name of your organisation: National Osteoporosis Society

Are you (tick all that apply):

- a patient with the condition for which NICE is considering this technology?
- a carer of a patient with the condition for which NICE is considering this technology?
- ✓ an employee of a patient organisation that represents patients with the condition for which NICE is considering the technology? If so, give your position in the organisation where appropriate (e.g. policy officer, trustee, member, etc)

Medical Policy Officer

- other? (please specify)

What do patients and/or carers consider to be the advantages and disadvantages of the technology for the condition?

1. Advantages

(a) Please list the specific aspect(s) of the condition that you expect the technology to help with. For each aspect you list please describe, if possible, what difference you expect the technology to make.

We expect denosumab to reduce the fracture risk in post-menopausal women with osteoporosis (the patient group defined in the scope of the technology appraisal).

(b) Please list any short-term and/or long-term benefits that patients expect to gain from using the technology. These might include the effect of the technology on:

- the course and/or outcome of the condition
- physical symptoms
- pain
- level of disability
- mental health
- quality of life (lifestyle, work, social functioning etc.)
- other quality of life issues not listed above
- other people (for example family, friends, employers)
- other issues not listed above.

The long-term benefit of fracture risk reduction could have significant impact on the patient quality of life. Reducing a person's risk of fracture could help increase confidence levels in performing activities of daily living, exercise and improving general well-being.

Administering denosumab via a 6-monthly injection (in either primary care or via self administration) is a convenient treatment method which will not impinge on daily life.

We are aware that there are significant issues in compliance with current oral osteoporosis treatments. With low compliance of osteoporosis medication there is an increased risk of fracture. The delivery of denosumab via a 6 monthly injection will assist patients in complying with their medication.

Introducing denosumab to the existing treatments for osteoporosis will provide more options for both patients and clinicians when deciding on the most appropriate treatment regime for the individual.

What do patients and/or carers consider to be the advantages and disadvantages of the technology for the condition? (continued)

2. Disadvantages

Please list any problems with or concerns you have about the technology.

Disadvantages might include:

- aspects of the condition that the technology cannot help with or might make worse.
- difficulties in taking or using the technology
- side effects (please describe which side effects patients might be willing to accept or tolerate and which would be difficult to accept or tolerate)
- impact on others (for example family, friends, employers)
- financial impact on the patient and/or their family (for example cost of travel needed to access the technology, or the cost of paying a carer).

Administering denosumab via a 6-monthly injection could also be seen as a disadvantage to some patients who aren't comfortable with needles.

There is a potential increase in infection risk associated with injection and also with denosumab itself.

As with any new treatment approach there may be concerns about long term risks which are as yet unknown.

3. Are there differences in opinion between patients about the usefulness or otherwise of this technology? If so, please describe them.

As highlighted by its inclusion in both advantages and disadvantages the route of administration via injection can be viewed differently.

4. Are there any groups of patients who might benefit **more** from the technology than others? Are there any groups of patients who might benefit **less** from the technology than others?

Groups of patients who might benefit more:

Patients who contraindicated for current bisphosphonate therapies (patients with renal impairment, gastrointestinal problems)

Patients who are unable to comply with current bisphosphonate treatment protocols, specifically an inability to remain upright for 30min (patients with vertebral fracture, patients with disabilities)

Patients with memory problems who have difficulty in remembering daily/weekly medications.

Comparing the technology with alternative available treatments or technologies

NICE is interested in your views on how the technology compares with existing treatments for this condition in the UK.

(i) Please list any current standard practice (alternatives if any) used in the UK.

Existing medications used to treat osteoporosis are alendronate, risedronate, ibandronate, etidronate, strontium ranelate, raloxifene, teriparatide, zoledronate, HRT, calcitonin, calcitriol.

Alendronate, risedronate, etidronate, strontium ranelate, raloxifene and teriparatide have been assessed by NICE and therefore can be considered as standard practice.

(ii) If you think that the new technology has any **advantages** for patients over other current standard practice, please describe them. Advantages might include:

- improvement in the condition overall
- improvement in certain aspects of the condition
- ease of use (for example tablets rather than injection)
- where the technology has to be used (for example at home rather than in hospital)
- side effects (please describe nature and number of problems, frequency, duration, severity etc.)

Denosumab provides considerable improvements over the strict regimes associated with oral bisphosphonate (taking on an empty stomach, 30mins – 1h before food, drink or other medication, remaining upright for 30mins)

Oral bisphosphonates are commonly associated with gastrointestinal side effects which can lead to discontinuation of the medication. Being able to administer an osteoporosis treatment via injection and avoiding these side effects will be a significant advantage.

Bisphosphonates have long-term effects on the skeleton and remain in the body after treatment is stopped. The different mode of action denosumab has means that its effects are reversible i.e. if a patient stops treatment the drug is cleared from the body. This would be an advantage for those patients who have concerns about the persistence of bisphosphonates in the skeleton.

(iii) If you think that the new technology has any **disadvantages** for patients compared with current standard practice, please describe them. Disadvantages might include:

- worsening of the condition overall
- worsening of specific aspects of the condition
- difficulty in use (for example injection rather than tablets)
- where the technology has to be used (for example in hospital rather than at home)
- side effects (for example nature or number of problems, how often, for how long, how severe).

No specific disadvantages compared with standard practice.

Appendix I – Patient/carer organisation statement template

Research evidence on patient or carer views of the technology

If you are familiar with the evidence base for the technology, please comment on whether patients' experience of using the technology as part of their routine NHS care reflects that observed under clinical trial conditions.

We are not aware of any patients using denosumab

Are there any adverse effects that were not apparent in the clinical trials but have come to light since, during routine NHS care?

Not applicable

Are you aware of any research carried out on patient or carer views of the condition or existing treatments that is relevant to an appraisal of this technology? If yes, please provide references to the relevant studies.

No

Availability of this technology to patients in the NHS

What key differences, if any, would it make to patients and/or carers if this technology was made available on the NHS?

It would provide more treatment options for patients with osteoporosis. More importantly a treatment with a new method of delivery and mode of action that would be suitable for patients who currently have difficulties with bisphosphonate treatment.

What implications would it have for patients and/or carers if the technology was **not** made available to patients on the NHS?

If denosumab was not made available on the NHS it would mean that patients who are unable to take current bisphosphonate treatments would be left with fewer options for their treatment.

Are there groups of patients that have difficulties using the technology?

Patients who are uncomfortable with receiving medication via injection.

Other Issues

Please include here any other issues you would like the Appraisal Committee to consider when appraising this technology.

None