

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Appraisal

Tanezumab for treating moderate to severe chronic pain caused by osteoarthritis

Draft scope

**Draft remit/appraisal objective**

To appraise the clinical and cost effectiveness of tanezumab within its marketing authorisation for treating moderate to severe chronic pain caused by osteoarthritis.

**Background**

Pain that persists past normal healing time when associated with injury, and pain that lasts or recurs for more than 3 to 6 months is often defined as chronic.<sup>1</sup> Pain can be categorised according to different dimensions, including by its duration (chronic or acute) and severity (e.g. mild, moderate or severe).

Osteoarthritis is a condition in which the joints of the body become damaged, stop moving freely and become painful. Osteoarthritis most commonly affects the knee, followed by the hip and hand or wrist joints, but can affect any joint in the body. Pain is the main symptom of osteoarthritis, but joints can also feel stiff and become swollen.<sup>2</sup> Osteoarthritis has a negative impact on daily activities, quality of life and health outcomes.

The musculoskeletal calculator from Versus Arthritis estimates that in 2012 there were around 4.1 million people aged over 45 years in England with osteoarthritis of the knee and around 2.5 million with osteoarthritis of the hip. Of these, around 6.1% and 3.2% had severe disease of the knee and hip, respectively.<sup>4</sup> Nearly three quarters of people with osteoarthritis report some form of constant pain, with 1 in 8 describing their pain as often unbearable.<sup>3</sup>

The aim of treatment is to reduce pain and improve function and quality of life. A range of pharmacological (analgesics such as non-steroidal anti-inflammatory drugs [NSAIDs]), non-pharmacological (for example manual therapy, devices, electrotherapy) and surgical interventions can be used to manage pain but these interventions are not used consistently.

The NICE guideline for [osteoarthritis: care and management](#) currently recommends:

- paracetamol and/or topical NSAIDs as a first-line treatment option
- the addition of opioid analgesics if paracetamol or topical NSAIDs is not effective
- oral NSAID/COX-2 inhibitor instead of or in addition to first-line treatment if paracetamol and/or topical NSAIDs are ineffective
- other treatments such as intra-articular corticosteroid injections for moderate to severe pain and topical capsaicin.

### The technology

Tanezumab (brand name unknown, Pfizer) is a humanized monoclonal antibody directed against nerve growth factor (NGF), a modulator of nociceptor function, with potential analgesic activity. It is administered subcutaneously.

Tanezumab does not currently have a marketing authorisation for treating moderate to severe chronic pain caused by osteoarthritis. It has been studied in a clinical trial compared with oral NSAIDs in adults with osteoarthritis of the hip or knee who are on a stable dose of NSAIDs and have a history of insufficient pain relief from paracetamol and tramadol or opioid treatments.

<b>Intervention</b>	Tanezumab
<b>Population</b>	Adults with osteoarthritis
<b>Comparators</b>	Established clinical management without tanezumab (including but not limited to paracetamol, NSAIDs/COX-2 inhibitors, opioids, topical capsaicin and intra-articular corticosteroid injections)
<b>Outcomes</b>	<p>The outcome measures to be considered include:</p> <ul style="list-style-type: none"> <li>• changes in symptoms such as pain and functioning</li> <li>• disease progression such as joint replacement, fracture or osteonecrosis</li> <li>• Use of rescue medications</li> <li>• adverse effects of treatment</li> <li>• health-related quality of life.</li> </ul>
<b>Economic analysis</b>	<p>The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year.</p> <p>The reference case stipulates that the time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared.</p> <p>Costs will be considered from an NHS and Personal Social Services perspective.</p>
<b>Other considerations</b>	Guidance will only be issued in accordance with the marketing authorisation. Where the wording of the therapeutic indication does not include specific treatment combinations, guidance will be issued only in the context of the evidence that has underpinned the marketing authorisation granted by the regulator.
<b>Related NICE recommendations and NICE Pathways</b>	<p><b>Related Guidelines</b></p> <p><a href="#">‘Osteoarthritis: care and management’</a> (2014). NICE clinical guideline 177. Update in progress</p>

	<p><b>Guidelines in development</b></p> <p>'<a href="#">Osteoarthritis: care and management (update)</a>'. Publication expected August 2021.</p> <p><b>Related NICE Pathways:</b></p> <p>Osteoarthritis (2019) NICE pathway</p> <p><a href="http://pathways.nice.org.uk/osteoarthritis">http://pathways.nice.org.uk/osteoarthritis</a></p>
<p><b>Related National Policy</b></p>	<p>The NHS Long Term Plan, 2019. <a href="#">NHS Long Term Plan</a></p> <p>NHS England (2018/2019) <a href="#">NHS manual for prescribed specialist services (2018/2019)</a>. Chapter 3 Adult highly specialised pain management services</p> <p>Department of Health and Social Care, NHS Outcomes Framework 2016-2017: Domain 2.</p> <p><a href="https://www.gov.uk/government/publications/nhs-outcomes-framework-2016-to-2017">https://www.gov.uk/government/publications/nhs-outcomes-framework-2016-to-2017</a></p>

### Questions for consultation

Have all relevant comparators for tanezumab been included in the scope? Which treatments are considered to be established clinical practice in the NHS for pain from osteoarthritis?

Are the outcomes listed appropriate?

Are there any subgroups of people in whom tanezumab is expected to be more clinically effective and cost effective or other groups that should be examined separately?

Where do you consider tanezumab will fit into the existing NICE pathway, <http://pathways.nice.org.uk/osteoarthritis>?

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 proposed remit and scope 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 tanezumab will be 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.

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Do you consider tanezumab to be innovative in its potential to make a significant and substantial impact on health-related benefits and how it might improve the way that current need is met (is this a 'step-change' in the management of the condition)?

Do you consider that the use of tanezumab can result in any potential significant and substantial health-related benefits that are unlikely to be included in the QALY calculation?

Please identify the nature of the data which you understand to be available to enable the Appraisal Committee to take account of these benefits.

To help NICE prioritise topics for additional adoption support, do you consider that there will be any barriers to adoption of this technology into practice? If yes, please describe briefly.

NICE intends to appraise this technology through its Single Technology Appraisal (STA) Process. We welcome comments on the appropriateness of appraising this topic through this process. (Information on the Institute's Technology Appraisal processes is available at <http://www.nice.org.uk/article/pmg19/chapter/1-Introduction>).

### References

- 1 Treede R-D, Rief W, Barke A, Aziz Q, Bennett MI, Benoliel R, et al. (2015). A classification of chronic pain for ICD-11. *Pain* 156(6):1003.
- 2 Versus Arthritis. State of Musculoskeletal Health 2019 report. Available from: <https://www.versusarthritis.org/about-arthritis/data-and-statistics/state-of-musculoskeletal-health-2019/> Accessed June 2020
- 3 Conaghan PG, Porcheret M, Kingsbury SR, Gammon A, Soni A, Hurley M, et al. (2015). Impact and therapy of osteoarthritis: the Arthritis Care OA Nation 2012 survey. *Clin Rheumatol*; 34(9):1581-8.
- 4 Versus Arthritis. Musculoskeletal Calculator. 2018. Available from: <https://www.versusarthritis.org/policy/resources-for-policy-makers/musculoskeletal-calculator/download-full-msk-calculator-datasets/> Accessed June 2020.