NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Deutetrabenazine for treating tardive dyskinesia ID6550

Draft scope

Draft remit/evaluation objective

To appraise the clinical and cost effectiveness of Deutetrabenazine within its marketing authorisation for treating tardive dyskinesia.

Background

Tardive dyskinesia is an involuntary neurological movement disorder. It is often caused by the use of dopamine receptor-blocking agents, such as antipsychotics and some antiemetics, such as metoclopramide.[1] Risk factors for tardive dyskinesia include older age and previous movement disorders.
. There is often a delay between taking a medication and developing tardive dyskinesia. Tardive dyskinesia is characterised by involuntary muscle movements such as stereotypic, repetitive movements, choreic, dance like jerking movements and slow athetoid or dystonic, involuntary muscle spasms. It can affect different areas of the body including affecting the face, mouth, lips, torso and limbs.[1]

Tardive dyskinesia is thought to affect 25% of people who have had long term treatment with antipsychotic medication globally.[2]

There is currently no established standard care for tardive dyskinesia. In some cases withdrawal or dose reduction of the causative medication can be considered, but this may not be appropriate if doing so could worsen the underlying condition. Tetrabenazine, a vesicular monoamine transporter type 2 (VMAT2) inhibitor, is licensed in the UK for the treatment of moderate to severe tardive dyskinesia. Benzodiazepines, amantadine, botulinum toxin, and deep brain stimulation may also be considered as treatment options. [3]

The technology

Deutetrabenazine (Austedo, Teva pharmaceuticals) does not currently have a marketing authorisation in the UK for tardive dyskinesia. It has been studied in phase 3 randomised double blind clinical trials in adults with tardive dyskinesia compared with placebo.

Intervention(s)	Deutetrabenazine
Population(s)	Adults with tardive dyskinesia
Comparators	Established clinical management without deutetrabenazine, including but not limited to: • tetrabenazine, for people with moderate to severe tardive dyskinesia
Outcomes	The outcome measures to be considered include: • change in abnormal involuntary movement scale (AIMS) score • clinical global impression of change (CGI) score • adverse effects of treatment • health-related quality of life.
Economic analysis	The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year. 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. Costs will be considered from an NHS and Personal Social Services perspective. The availability of any commercial arrangements for the intervention, comparator and subsequent treatment technologies will be taken into account.
Other considerations	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.
Related NICE recommendations	None

Questions for consultation

How many people would be expected to be considered for treatment with deutetrabenazine in clinical practice in England?

Which treatments would be considered to be established clinical practice in the NHS for tardive dyskinesia?

Are benzodiazepines used to treat tardive dyskinesia in the NHS? If so, are any specific benzodiazepines preferred?

Is amantadine used to treat tardive dyskinesia in the NHS?

Is botulinum toxin used to treat tardive dyskinesia in the NHS?

Is deep brain stimulation used to treat tardive dyskinesia in the NHS?

Should benzodiazepines, amantadine, botulinum toxin or deep brain stimulation be considered as appropriate comparators?

Where do you consider deutetrabenazine will fit into the existing care pathway for tardive dyskinesia?

Please select from the following, will deutetrabenazine be:
A. Prescribed in primary care with routine follow-up in primary care
B. Prescribed in secondary care with routine follow-up in primary care
C. Prescribed in secondary care with routine follow-up in secondary care
D. Other (please give details):
For comparators and subsequent treatments, please detail if the setting for prescribing and routine follow-up differs from the intervention.

Would deutetrabenazine be a candidate for managed access?

Are the outcomes listed appropriate?

Do you consider that the use of deutetrabenazine can result in any potential 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 committee to take account of these benefits.

Do you consider deutetrabenazine 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)?

Please indicate if any of the treatments in the scope are used in NHS practice differently than advised in their Summary of Product Characteristics. For example, if the dose or dosing schedule for a treatment is different in clinical practice. If so, please indicate the reasons for different usage of the treatment(s) in NHS practice. If stakeholders consider this a relevant issue, please provide references for data on the efficacy of any treatments in the pathway used differently than advised in the Summary of Product Characteristics.

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 deutetrabenazine 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.

NICE intends to evaluate this technology through its Single Technology Appraisal process. (Information on NICE's health technology evaluation processes is available at https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-technology-appraisal-guidance/changes-to-health-technology-evaluation).

References

1. BMJ Best Practice (2025) Tardive dyskinesia. Accessed May 2025.

2. Carbon M, Hsieh CH, Kane JM, Correll CU. Tardive Dyskinesia Prevalence in the Period of Second-Generation Antipsychotic Use: A Meta-Analysis. J Clin Psychiatry. 2017 Mar;78(3):e264-e278. doi: 10.4088/JCP.16r10832. PMID: 28146614.

3. Savitt D, Jankovic J. Tardive syndromes. J Neurol Sci. 2018 Jun 15;389:35-42. doi: 10.1016/j.jns.2018.02.005. Epub 2018 Feb 5. PMID: 29506749.