

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Evaluation

Xanomeline tartrate–trospium chloride for treating schizophrenia ID6716

Draft scope

Draft remit/evaluation objective

To appraise the clinical and cost effectiveness of xanomeline tartrate–trospium chloride within its marketing authorisation for treating schizophrenia.

Background

Schizophrenia is a long-term mental health condition that causes a range of psychological symptoms, including hallucinations, delusions, disrupted speech and thoughts (associated with hallucinations or delusions), social withdrawal, demotivation and self-neglect. Symptoms of schizophrenia typically peak around age 20 to 25 years for males and 25 to 30 years for females¹. Children and young people can also be affected but this is very rare.² People with schizophrenia have a higher risk of death than the general population due to greater incidence of physical illnesses (such as cardiovascular disease and cancers), accidents and suicide.¹

Estimates of incidence of schizophrenia varies. Globally, schizophrenia is estimated to affect around 23.6 million people.¹ In England, 0.4% of adults have a psychotic disorder, which includes schizophrenia.³ Men are at higher risk of schizophrenia than women, with a risk ratio of 1.4:1.¹

First-line treatment involves the use of non-clozapine antipsychotic medication such as aripiprazole, amisulpride, haloperidol, lurasidone, olanzapine, risperidone, or chlorpromazine. For longer-term maintenance treatments, long-acting injectable antipsychotics, such as aripiprazole, haloperidol decanoate and paliperidone, may be used.^{Error! Bookmark not defined.} If the first antipsychotic is not effective, people with schizophrenia can switch to an alternative non-clozapine antipsychotic at second-line treatment. NICE technology appraisal [213](#) recommends aripiprazole as an option for people aged 15 to 17 years if the condition does not respond to risperidone, or if it is not tolerated or contraindicated.

NICE clinical guideline [CG178](#) recommends that people who have not had an adequate response to two different antipsychotics, despite the sequential use of adequate doses (and adherence), can have the antipsychotic clozapine at third-line.

Psychosocial interventions such as cognitive behavioural therapy for psychosis (CBTp) and family interventions are recommended throughout treatment and management of the condition.^{Error! Bookmark not defined.}

The technology

Xanomeline tartrate–trospium chloride (KarXT, Bristol Myers Squibb) does not currently have a marketing authorisation in the UK. It has been studied in phase 3 randomised control trials in adults with schizophrenia who were hospitalised with an acute exacerbation or relapse of psychosis.

Intervention(s)	Xanomeline tartrate–trospium chloride
Population(s)	People with schizophrenia
Subgroups	None
Comparators	<ul style="list-style-type: none"> • Non-clozapine antipsychotics (aripiprazole, amisulpride, haloperidol, lurasidone, olanzapine, risperidone, and chlorpromazine) • Clozapine • Long-acting injectable antipsychotics (aripiprazole, haloperidol decanoate and paliperidone)
Outcomes	<p>The outcome measures to be considered include:</p> <ul style="list-style-type: none"> • symptom severity (general, positive and negative symptoms) • adverse effects of treatment • health-related quality of life.
Economic analysis	<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> <p>The availability and cost of biosimilar and generic products should be taken into account.</p>
Other considerations	<p>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.</p>
Related NICE recommendations	<p>Related technology appraisals:</p> <p>Aripiprazole for the treatment of schizophrenia in people aged 15 to 17 years (2011) NICE technology appraisal guidance 213</p> <p>Guidance on the use of electroconvulsive therapy (2003, updated 2009) NICE technology appraisal guidance 59</p> <p>Related NICE guidelines:</p>

	<p>Psychosis and schizophrenia in adults: prevention and management (2014) NICE clinical guideline CG178. Last reviewed July 2025</p> <p>Psychosis and schizophrenia in children and young people: recognition and management (2013, updated 2016) NICE clinical guideline CG155. Last reviewed September 2024</p> <p>Related HealthTech guidance:</p> <p>Digital health technologies to help manage symptoms of psychosis and prevent relapse in adults and young people: early value assessment (2024) NICE HealthTech guidance 713</p> <p>KardiaMobile 6L for measuring cardiac QT interval in adults having antipsychotic medication: early value assessment (2023) NICE HealthTech guidance 694</p> <p>Transcranial magnetic stimulation for auditory hallucinations (2020) NICE HealthTech guidance 555</p> <p>Related quality standards:</p> <p>Bipolar disorder, psychosis and schizophrenia in children and young people (2015) NICE quality standard 102</p> <p>Psychosis and schizophrenia in adults (2015) NICE quality standard 80</p>
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Questions for consultation

Where do you consider xanomeline tartrate–trospium chloride will fit into the existing care pathway for schizophrenia?

Please select from the following, will xanomeline tartrate–trospium chloride 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 xanomeline tartrate–trospium chloride be a candidate for managed access?

Do you consider that the use of xanomeline tartrate–trospium chloride 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.

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 xanomeline tartrate–trospium chloride 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

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- 1 British Medical Journal Best Practice – Schizophrenia. Available: [Schizophrenia - Symptoms, diagnosis and treatment | BMJ Best Practice](#). Accessed: 15/04/26
 - 2 Driver, D.I., Thomas, S., Gogtay, N. and Rapoport, J.L. (2020) Childhood-Onset Schizophrenia and Early-onset Schizophrenia Spectrum Disorders: An Update. *Child Adolescent Psychiatry Clinics of North America* 29(1), 71-90.
 - 3 Brown, A., Liubertiene, G., Morris, S., Timpe, A., McManus, S., Kirkbride, J., Morgan, C., Morgan, Z., Tromans, S., Brugha, T., (2025) Adult Psychiatric Morbidity Survey: Survey of Mental Health and Wellbeing, England, 2023/4. Available: [Chapter 12: Psychotic Disorder - NHS England Digital](#). Accessed: 15/04/26
 - 4 British Medical Journal Best Practice – Schizophrenia treatment algorithm. Available: [Schizophrenia - Treatment algorithm | BMJ Best Practice](#). Accessed: 16/04/26