

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Health Technology Appraisal

Aripiprazole for the treatment of schizophrenia in people aged 15-17

Draft scope

Draft remit/appraisal objective

To appraise the clinical and cost-effectiveness of aripiprazole within its licensed indication for the treatment of schizophrenia in people aged 15-17 years.

Background

Schizophrenia is a major psychiatric disorder, or cluster of disorders, characterised by psychotic symptoms that alter a person's perception, thought, affect, and behaviour. The symptoms of schizophrenia are usually divided into 'positive' symptoms (such as hallucinations, delusions, thought disorders) and 'negative' symptoms (such as lack of motivation, self-neglect, social withdrawal).

Typically there is a prodromal period characterised by early signs of deterioration in personal functioning, including memory and concentration problems, unusual behaviour and ideas, social withdrawal and apathy. An acute episode marked by hallucinations, delusions, thought disorders can follow the prodromal period. After resolution of the acute episode, symptoms can diminish or disappear for some people (after pharmacological and psychological treatment) and 'negative' symptoms may remain. This period can last for years, and might be interrupted by recurrent acute episodes, which may need pharmacological treatment.

Although the pathophysiology of schizophrenia is unclear, increased dopamine activity in the mesolimbic pathway of the brain has been consistently found in people with schizophrenia. Additional factors that may contribute to the onset of schizophrenia include genetic (hereditary) factors, social processes (for example social isolation, bereavement, financial difficulties), neurobiological and psychological factors. People with schizophrenia have a lower average life expectancy than people without the condition mainly due to the increased physical health problems and the higher rate of suicide attributable to schizophrenia. Currently no definitive test for schizophrenia exists. The diagnosis of schizophrenia is based on a comprehensive assessment of history, symptoms and signs.

Schizophrenia is rare below the age of 13 years, but onset of a psychotic episode becomes progressively more likely with increasing age. The lifetime incidence is 1%. Of these, 12-33% may show some signs of the illness before the age of 18 years, more commonly boys than girls.

The management of schizophrenia in children usually includes pharmacological together with psychosocial/ psychological interventions. Pharmacological treatment mainly consists of antipsychotic drugs which are categorised into typical and atypical antipsychotic agents.

A number of atypical antipsychotic drugs (for example risperidone, quetiapine, olanzapine, and amisulpride) can be offered. Clozapine may also be offered to children unresponsive to, or intolerant of, conventional antipsychotic drugs. The 'BNF for Children' states that the most commonly used atypical antipsychotics for children are risperidone and olanzapine.

The technology

Aripiprazole (Abilify, Bristol-Myers Squibb and Otsuka Pharmaceuticals) is a piperazine atypical antipsychotic that acts as partial agonist of dopamine D2 and serotonin 5HT1a receptors and as an antagonist of serotonin 5HT2a receptors. Aripiprazole is administered orally.

Aripiprazole holds UK marketing authorisation for the treatment of schizophrenia in adults and adolescents 15 years and older.

Intervention(s)	Aripiprazole
Population(s)	People with schizophrenia, aged 15-17 years.
Comparators	<ul style="list-style-type: none"> • risperidone • quetiapine • olanzapine • amisulpride • clozapine

Outcomes	<p>The outcome measures to be considered include:</p> <ul style="list-style-type: none"> • treatment response (such as time to relapse, remission of symptoms) • positive symptoms (such as hallucinations, delusions, thought disorders) • negative symptoms (such as lack of motivation, self-neglect, social withdrawal) • recurrence of psychosis • mortality • adverse effects of treatment (such as weight gain, effects on endocrine system, extrapyramidal symptoms, depression and/or suicidal ideation) • 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>
Other considerations	<p>Guidance will only be issued in accordance with the marketing authorisation.</p> <p>If evidence allows, the appraisal will seek to identify subgroups of individuals for whom the technology is particularly clinically and cost-effective.</p>
Related NICE recommendations	<p>Related Technology Appraisals:</p> <p>Technology Appraisal No. 59, April 2003. Guidance on the use of electroconvulsive therapy. Review date: to be confirmed</p> <p>Related Guidelines:</p> <p>Clinical guideline No 82, March 2009. Core interventions in the treatment and management of schizophrenia in primary and secondary care (update). Review date: to be confirmed</p>

Questions for consultation

Have the most appropriate comparators for the treatment of schizophrenia in children and young people aged 15-17 been included in the scope? Are the comparators listed routinely used in clinical practice?

Have the most appropriate comparators been included?

Views from consultees and commentators would be appreciated on the size of the patient population (People with schizophrenia, aged 15-17 years)?

Have the most appropriate outcomes for the treatment of schizophrenia in children and young people aged 15-17 been included in the scope? Should social functioning (such as educational outcomes) be included as an outcome?

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

Are there any issues that require special attention in light of the duty to have due regard to the need to eliminate unlawful discrimination and promote equality?

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/aboutnice/howwework/devnicetech/technologyappraisalprocessguides/technology_appraisal_process_guides.jsp)