

NICE TA 292 – Aripiprazole for treating moderate to severe manic episodes in adolescents with bipolar I disorder

<p>1</p>	<p>Summary of NICE TA 292</p> <p>Aripiprazole is recommended as an option for treating moderate to severe manic episodes in adolescents with bipolar I disorder, within its marketing authorisation, that is, up to 12 weeks of treatment for moderate to severe manic episodes in bipolar I disorder in adolescents aged 13 and older. It also has a UK marketing authorisation for the treatment of moderate to severe manic episodes in bipolar I disorder in adults, and for the prevention of a new manic episode in adults who experienced predominantly manic episodes which responded to aripiprazole treatment.</p> <p>NICE states there are no studies directly comparing aripiprazole with other antipsychotics in the treatment of bipolar I disorder in the adolescent population. However it is noted that no other antipsychotics are currently licensed for these patients. NICE also noted that there is currently no long-term safety data for aripiprazole.</p> <p>Aripiprazole offers a licensed antipsychotic treatment option for adolescent patients for this indication. NICE confirms that no single antipsychotic drug is considered to be more clinically effective. However, there is wide variation in the individual response. Aripiprazole, by adding to range of prescribing options may allow some individuals to respond who may not have responded well to the other existing unlicensed prescribing options.</p> <p>NICE confirmed that expert clinical opinion suggested that in UK clinical practice Aripiprazole is a routinely prescribed antipsychotic drug for this indication and was prescribed off-label to this population prior to licence extension in Jan 2013. The position in NI indicates that it has been prescribed where side effects of other front line treatments have been problematic.</p> <p>It is important for adolescents with acute manic episodes to have a range of treatment options available. This is in order to individualise treatment and to minimise adverse treatment effects, as adolescents are often less tolerant of adverse reactions than adults, leading to problems with adherence to medication.</p>
	<p>Number of people in Northern Ireland expected to take up service/therapy (new cases per year)</p> <p>Prevalence of Bi-polar I disorder is within 0.3% to 1.5% range. It is estimated between 300 to 1,500 individuals have this condition in N. Ireland. However, only a proportion (unknown) would be prescribed this specific medication per year as TA</p>

	<p>292 relates specifically to adolescents, which is a subset of the group above. Based on the NICE costing template, it is estimated that approximately 27 adolescents will require access to aripiprazole each year.</p> <p>Expert clinical opinion obtained by NICE suggests that there may be an increase of between 15% to 25% in the prescribing of aripiprazole for this indication. This equates to around 7 patients per annum.</p>
3	Costs
3.1	<p>Drug cost per patient per annum</p> <p>Aripiprazole is available as 5mg, 10mg, 15mg and 30mg tablets, 10mg and 15mg orodispersible tablets and as an oral solution 1mg/ml. For those who respond to aripiprazole, the cost of a 12 week course of treatment at the recommended dose of 10mg daily (following 2 days at 2mg and 2 days at 5mg) is £303.21. Costs will be greater if the oral solution is the preferred formulation, estimated to cost £608, at dose of 10mg daily for 12 weeks (based on October 2013 electronic Drug Tariff).</p> <p>The NICE costing statement advises that the maximum the predicted increase in prescribing is 25% (approximately an additional 7 people in NI) with an average of 1.5 mania episodes per annum (average cost of £426 per person per year). This equates to an estimated annual increase in cost of £2982.</p>
3.2	<p>In year costs</p> <p>The in year costs are likely to be less than £1250 (calculated on a part year effect if implemented for the 5 months remaining of the 2013/14 financial year)</p>
3.3	<p>Infrastructure Costs per annum</p> <p>No additional costs are anticipated.</p>
3.4	<p>Cost savings and how these will be secured</p> <p>This drug will be placed among the potential pharmacological treatments available to CAMHs services – prescribing of other existing drugs could potentially decrease. However NICE expect a 25% increase in use of aripiprazole for patients with this condition and it is likely therefore that medication costs will increase and no savings are expected.</p>
3.5	<p>Recurrent overall cost</p> <p>The costing statement advises that there may be an increase in use of aripiprazole of 25%. Given the small number of individuals applicable for this treatment and assuming the maximum caseload for N. Ireland, the estimated annual additional costs are expected to be less than £3000. (The estimated additional cost for</p>

	<p>England and Wales is £85,000)</p> <p>As per the TA and the summary of product characteristics, the treatment duration should be the minimum necessary for symptom control and must not exceed 12 weeks. The TA assumes a 12 week course of aripiprazole treatment; it is incumbent for prescribers to ensure treatment is then reviewed as per the NICE guidance. It is therefore suggested that the prescribing responsibility of aripiprazole for this indication should lie with a hospital consultant or a specialist.</p>
4	<p>Expected implementation period</p> <p>There are no expected barriers to implementation.</p>
5	<p>Commissioning arrangements</p> <p>No additional commissioning arrangements are anticipated. However it is envisaged that aripiprazole for this indication is not suitable for GP prescribing and will be a consultant only prescription. This drug may need to be adjudicated for red/amber status and shared care guidelines may be required if prescribing in primary care. Primary and secondary care will be notified of the place of this drug in therapy following consideration of the shared care arrangements.</p>
6	<p>Monitoring arrangements</p> <p>For this indication and population, it is suggested that aripiprazole should only be initiated and prescribed by a healthcare professional specialising in child and adolescent psychiatry and is not suitable for GP prescribing. The treatment duration should be the minimum necessary for symptom control and must not exceed 12 weeks as per the marketing authorisation. Thereafter, prescribing will be unlicensed and discontinuation of treatment will be the responsibility of the prescriber. During antipsychotic treatment, improvement in the patient's clinical condition may take several days to some weeks. Patients should be closely monitored by the initiating prescriber during this period. Clinical trials in children and adolescents showed that extrapyramidal side effects may be more prevalent in this group. For further information reported with aripiprazole see the summary of product characteristics.</p> <p>As this TA relates to a specific age group and a specific indication in adolescents monitoring carried out routinely in primary care will not accommodate this in terms of age and indication. Consequently, it will be monitored through the HSCB prescribing monitoring system only in an overview of the overall usage of aripiprazole. Health Care Trusts are expected to audit and ensure treatment is in line with NICE guidance.</p>
7	<p>DHSSPS Legislative/Policy Caveats</p> <p>This advice does not override or replace the individual responsibility of health professionals to make appropriate decisions in the circumstances of their individual</p>

<p>patients, in consultation with the patient and/or guardian or carer. This would, for example, include situations where individual patients have other conditions or complications that need to be taken into account in determining whether the NICE guidance is fully appropriate in their case.</p>
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