REFERENCE NUMBER:

PRESCRIBING GUIDANCE FOR THE USE OF ARIPIPRAZOLE IN MODERATE TO SEVERE MANIC EPISODES IN ADOLESCENTS WITH BIPOLAR I DISORDER

AREA: Mental Health

NAME OF RESPONSIBLE COMMITTEE / INDIVIDUAL: Medicines Management Group

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Medicines Management/Pharmacy

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PREScribing guidance for the USE of Aripiprazole in moderate to severe manic episodes in adolescents with bipolar I disorder

1.0 Introduction

1.1 Under the Pan-Dorset Formulary traffic light system, aripiprazole has been classified as red for the treatment of Bipolar 1 Disorder in adolescents. This Prescribing Guidance has been prepared to support the prescribing of aripiprazole. It is intended to apply to adolescents 13 years and older and should be initiated by a Consultant in Child and Adolescent Psychiatry as part of a comprehensive treatment programme.

1.2 Prescribing responsibility must not be transferred to GPs. It must remain with the Trust.

1.2 NICE Technology Appraisal 292 recommends:

‘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).’

1.3 Under the marketing authorisation for aripiprazole in this age group, the maximum recommended treatment period is up to 12 weeks.

1.4 Clinicians should review the patients regularly with a view to stopping treatment at 12 weeks.

1.4 Children should be involved in decisions about taking medicines and encouraged to take responsibility for using them correctly. The degree of such involvement will depend on the child’s age, understanding, and personal circumstances.

2. Dosing Instructions

2.1 The summary of product characteristics states that the recommended dosage for aripiprazole is 10mg per day administered once daily without regard to meals.

- Initiate at 2mg (using aripiprazole oral solution 1mg/ml) for 2 days,
- Dose titrated to 5mg for 2 additional days to reach the recommended daily dose of 10mg.

2.2 The summary of product characteristics notes that enhanced efficacy at doses higher than a daily dose of 10mg has not been demonstrated and that a daily dose of 30mg is associated with a substantially higher incidence of significant undesirable effects. It states that doses higher than 10mg/day should therefore only be used in exceptional cases and with close clinical monitoring.

2.3 Aripiprazole is available in 5 mg, 10 mg, 15 mg and 30 mg tablets, as 10 mg and 15 mg orodispersible tablets, and as an oral solution (1 mg/ml). The oral forms are
bioequivalent. Peak plasma concentration occurs in 3-5 hours. The half life of aripiprazole is approximately 75 hours (31-146). Aripiprazole is the major active component.

3. Side-effects

3.1 Somnolence (23.0%), extrapyramidal disorder (18.4%), akathisia (16.0%) fatigue (11.8%) upper abdominal pain increased heart rate increased weight increased appetite muscle twitching dyskinesia. The following undesirable effects had a possible dose–response relationship: extrapyramidal disorder

3.2 For full details of adverse reactions and contraindications, see the summary of product characteristics

4.0 References

- NICE TA 292 Aripiprazole for treating moderate to severe manic episodes in adolescents with bipolar I disorder. Technology appraisals, TA292 - Issued: July 2013