Protocol for prescribing asenapine tablets (Sycrest®)
(Version 2 – June 2017)

1. Key Points

1.1 Asenapine is only licensed / indicated for the treatment of moderate to severe manic episodes associated with bipolar disorder in adults over 18.

1.2 Asenapine is not indicated for schizophrenia or prophylaxis of mania.

1.3 Asenapine is only approved for Trust use under the following conditions:

- The drug may only be newly prescribed by doctors of associate specialist grade or above and who have completed an individual named-patient request form (appendix 1). Other grades may not initiate therapy or adjust dose without direct instruction from their consultant or associate specialist.

- It is used third-line after at least two other licensed mood stabilizers have failed. (This may include failures documented following a previous admission).

- It is used for the treatment of the manic episode only. The drug is not to be used as prophylactic / maintenance therapy.

- It has been discussed with and made clear to the patient / their carers that the drug will only be prescribed for the manic episode and not for prophylaxis.

- The initiating consultant / associate specialist agrees to submit anonymised efficacy data, if requested, for inclusion in any national or local evaluation approved for Trust participation.

1.4 Asenapine is a sublingual tablet that is administered twice a day and can cause a number of local side-effects in the mouth (see section 2.2 below).

1.5 Administration is relatively complex (see section 4. below) and patients who are unlikely to comply with the method of administration should not be prescribed the drug.

1.6 Asenapine is very expensive when compared to generic antipsychotics also used to treat acute mania.

1.7 GPs have been instructed by their clinical commissioning groups not to prescribe asenapine so any patient under the care of a community team must get all their supplies prescribed on FP10 or via the hospital pharmacy.

If you require this document in an alternative format, ie easy read, large text, audio, Braille or a community language please contact the Pharmacy Team on 01243 623349 (Text Relay calls welcome)
2. Prescribing and Side-effects

2.1 Recommended Dose Scheme:

Monotherapy: Initially 10mg twice daily reduced to 5mg twice daily depending on response.

Combination therapy: Initially 5mg twice daily, increased if necessary to 10mg twice daily depending on response.

2.2 Side effects: (Refer to Summary of Product Characteristics for full list).

- Very common side effects include: Anxiety and somnolence
- Common side effects include:
  
  Increased appetite, weight gain, sedation, extrapyramidal effects, dizziness, oral hypoaesthesia, abnormal taste, fatigue, elevated alanine aminotransferase.

2.3 Other Dosing Recommendations / Considerations.

- The elderly: Asenapine should be used with care in the elderly. Limited data on efficacy in patients 65 years of age and older are available.
- Children & Adolescents: The product is not licensed for use in patients less than 18 years of age.
- Renal impairment: No dosage adjustment needed in mild to moderate impairment. Use with caution if eGFR is less than 15mL/minute/1.73m² as there is no experience of its use in this group of people.
- Hepatic impairment: No dosage adjustment needed in mild impairment. Use with caution in moderate impairment. Avoid in severe impairment.

4. Administration – these instructions must be followed carefully

4.1 The tablet should not be removed from the blister until just before taking it.
4.2 Dry hands must be used when touching the tablet. The tablet should not be pushed through the tablet pack and the pack should not be cut or torn. Instead, the coloured tab should be peeled back and the tablet gently removed. The tablet must not be crushed.
4.3 To ensure optimal absorption, the sublingual tablet should be placed under the tongue and allowed to dissolve completely. Dissolution usually occurs within seconds.
4.4 Asenapine sublingual tablets must not be chewed or swallowed.
4.5 Eating and drinking should be avoided for 10 minutes after administration.
4.6 When used in combination with other medication, asenapine should be taken last.
4.7 Treatment with asenapine is not advised in patients who are unable to comply with this method of administration, as the bioavailability of asenapine reduces to only 2% if the tablet is swallowed.

5. Cost Comparison of Oral Antipsychotics used for Acute Mania

<table>
<thead>
<tr>
<th>Preparation</th>
<th>Dose</th>
<th>Cost per day / per week</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>(NHS Drug Tariff – June 2017).</td>
</tr>
<tr>
<td>Asenapine (Sycrest™)</td>
<td>10mg BD</td>
<td>£3.42 / £23.94</td>
</tr>
<tr>
<td>Aripiprazole</td>
<td>15mg OD</td>
<td>£0.05 / £0.35</td>
</tr>
<tr>
<td>Olanzapine</td>
<td>15mg OD</td>
<td>£0.05 / £0.35</td>
</tr>
<tr>
<td>Quetiapine</td>
<td>600mg OD</td>
<td>£0.10 / £0.70</td>
</tr>
</tbody>
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Next review: June 2019
Appendix 1.

Asenapine (Sycrest®) - Named Patient Request Form (v2)

Patient's Initials  DoB  Gender

CIS Number

Consultant Name

Before this request can be approved the following criteria must be met and confirmed. (Please initial boxes to confirm).

1. Asenapine is being used in accordance with its Product Licence for the treatment of moderate to severe manic episode associated with bipolar disorder.

2. It is being used after at least two other mood stabilizers have failed. (This may include failures documented following a previous episode).

3. Planned use is for the treatment of the manic episode only. The drug will not be continued as prophylactic / maintenance therapy.

4. It has been discussed with and made clear to the patient / their carers that the drug will only be prescribed for the manic episode and not for prophylaxis.

5. I am aware that prescribing of asenapine cannot be transferred to the patient's GP and must remain with Trust teams.

6. In prescribing asenapine I agree to provide anonymised efficacy data if requested.

Initiating Consultant / Associate Specialist:

<table>
<thead>
<tr>
<th>Signature</th>
<th>Name</th>
<th>Date</th>
</tr>
</thead>
</table>

Completed form to be submitted (scan/email) to:
Jed Hewitt, Chief Pharmacist – Governance & Professional Practice
Woodside, Hellingly.

jed.hewitt@sussexpartnership.nhs.uk  June 2017