

### Guidance for GPs on common off-label use of psychotropic medication

In the UK no medicine can be marketed for human use without a Product Licence (PL) granted by the Licensing Authority (Medicines & Healthcare products Regulatory Authority—MHRA). The PL specifies the indications for which a product may be used and also the dose, route of administration etc. Licensing arrangements are determined by the Medicines Act 1968 and implemented through the MHRA. The summary of product characteristics (SPC) outlines the circumstances for use for which the product is licensed.

Off label use can be defined as Medicines used outside the terms of the Product Licence e.g. unlicensed indication, dose, route.

Below is a list of licensed medicines that are commonly used in psychiatry for indications that are not listed in the SPC, making their use off-label.

Some of the products listed below are **Amber** on the Barnsley Area Formulary ([www.barnsleyformulary.nhs.uk](http://www.barnsleyformulary.nhs.uk)) and therefore are subject to Shared Care. However the **Shared Care Agreements do not cover off –label indications but the monitoring requirements and professional responsibilities within the appropriate documents should be followed when prescribing and asking a GP colleague to prescribe**

**\*\* Some medication with a red asterisk are to be initiated and monitored by a specialist experienced in the management of child and adolescent mental health and neurodevelopmental disorders.\*\***

**CAHMS Only** – unlicensed/off-label medication not described below with a **red asterisk** requires completion of the off-license/off-label form and possibly a clinical query form. Patients, families and/or carers should be informed about the off-label or unlicensed nature of the prescribing and sign a consent form (**Appendix 1** – page 7).

Group of drugs	Indication	Licensed/unlicensed/ off label use description	Supporting Evidence
<b>Benzodiazepines:</b> <ul style="list-style-type: none"> <li>Benzodiazepines (unspecified)</li> </ul>	-Rapid Tranquilisation -Akathisia -Acute mania -Acute Psychosis	Off-Label	<ul style="list-style-type: none"> <li>Maudsley (Lorazepam, Clonazepam)</li> <li>Bazire</li> <li>NICE guidelines NG10 Violence and aggression: the short –term management and violent and physically threatening behaviour in mental health, health and community settings</li> </ul>
<b>Beta Blocker:</b> <ul style="list-style-type: none"> <li>Propranolol</li> </ul>	-Akathisia	Off-Label	<ul style="list-style-type: none"> <li>Maudsley</li> </ul>

<b>Alpha2-adrenoreceptor Agonist:</b> <ul style="list-style-type: none"> <li>Guanfacine*</li> </ul>	<ol style="list-style-type: none"> <li>Tics &amp; Tourette's syndrome</li> <li>ADHD</li> <li>PTSD</li> </ol>	<ol style="list-style-type: none"> <li>Off-Label</li> <li>Off-Label in ages 5 and under</li> <li>Off-Label</li> </ol>	<ol style="list-style-type: none"> <li>Recommended first line treatments if medicines are necessary in Maudsley. Listed in BMJ best practice algorithm <a href="https://bestpractice.bmj.com/topics/en-gb/970/treatment-algorithm#referencePop79">https://bestpractice.bmj.com/topics/en-gb/970/treatment-algorithm#referencePop79</a></li> <li>NICE NG85</li> <li>Maudsley</li> </ol>
<b>Antihypertensive:</b> <ul style="list-style-type: none"> <li>Clonidine*</li> </ul>	<ol style="list-style-type: none"> <li>Tics &amp; Tourette's syndrome</li> <li>ADHD</li> <li>PTSD</li> </ol>	Off-Label	<ol style="list-style-type: none"> <li>Recommended first line treatments if medicines are necessary in Maudsley. Listed in BMJ best practice algorithm <a href="https://bestpractice.bmj.com/topics/en-gb/970/treatment-algorithm#referencePop79">https://bestpractice.bmj.com/topics/en-gb/970/treatment-algorithm#referencePop79</a></li> <li>Recommended 3<sup>rd</sup> line</li> <li>Maudsley</li> </ol>
<b>Anxiolytics:</b> <ul style="list-style-type: none"> <li>Benzodiazepines</li> </ul>	-Behavioural symptoms of dementia	Off-Label	<ol style="list-style-type: none"> <li>Maudsley</li> </ol>
<b>Antipsychotics:</b> <ul style="list-style-type: none"> <li>Antipsychotics (unspecified)</li> </ul>	<ul style="list-style-type: none"> <li>-Anxiety</li> <li>-Personality disorders</li> <li>-Behavioural disorders in learning disabilities</li> <li>-Augmentation of treatment of depression</li> <li>-Psychotic depression</li> <li>-Acute Psychosis</li> </ul>	Off-Label	<ol style="list-style-type: none"> <li>Bazire</li> <li>Maudsley</li> </ol>
<ul style="list-style-type: none"> <li>Quetiapine*</li> </ul>	<ol style="list-style-type: none"> <li>Acute Mania/Prophylaxis from 12yr+</li> <li>Bipolar Depression</li> <li>Schizophrenia 12yr+</li> <li>PTSD</li> </ol>	<ol style="list-style-type: none"> <li>Off Label</li> <li>Off-Label</li> <li>Off-Label</li> <li>Off-Label</li> </ol>	<ol style="list-style-type: none"> <li>Maudsley</li> <li>Maudsley, NICE CG185</li> <li>NICE CG135, BNFc</li> <li>Maudsley</li> </ol>
<ul style="list-style-type: none"> <li>Olanzapine*</li> </ul>	<ol style="list-style-type: none"> <li>Acute Mania/Prophylaxis from 12-17yrs</li> <li>Bipolar Depression</li> <li>Schizophrenia 12-17yrs</li> </ol>	<ol style="list-style-type: none"> <li>Off-Label</li> <li>Off-Label</li> <li>Off-Label</li> </ol>	<ol style="list-style-type: none"> <li>Maudsley, BNFc</li> <li>Maudsley, NICE CG185, can combine Fluoxetine</li> <li>BNFc</li> </ol>

<ul style="list-style-type: none"> <li>• Aripiprazole*</li> </ul>	<ol style="list-style-type: none"> <li>1. Moderate-Severe Mania in Bipolar 1</li> <li>2. Prophylaxis Bipolar</li> <li>3. Schizophrenia</li> <li>4. Tics &amp; Tourette's Syndrome</li> <li>5. Severe aggression/irritability/SIB/disruptive behaviour in Autism ages 6-17yrs</li> <li>6. Aripiprazole for hyperprolactinaemia (adults)</li> </ol>	<ol style="list-style-type: none"> <li>1. Licenced from 13yrs up to 12 weeks, Off-Label under 13yrs or beyond 12 weeks</li> <li>2. Off-Label</li> <li>3. Licensed from 15yrs if Risperidone not tolerated/no response, Off-Label under 15yrs or if Risperidone not trialled</li> <li>4. Off-Label</li> <li>5. Off-Label</li> <li>6. Off-Label</li> </ol>	<ol style="list-style-type: none"> <li>1. Maudsley, NICE TA292</li> <li>2. Maudsley</li> <li>3. NICE TA213, BNFC</li> <li>4. Second line, Maudsley</li> <li>5. Maudsley</li> <li>6. Maudsley</li> </ol>
<ul style="list-style-type: none"> <li>• Risperidone*</li> </ul>	<ol style="list-style-type: none"> <li>1. Aggression in Conduct Disorder</li> <li>2. Short-term Treatment of Severe aggression/irritability/SIB/disruptive behaviour in Autism age 5yr+</li> <li>3. Tic &amp; Tourette's Syndrome</li> <li>4. Psychosis 12yr+</li> <li>5. Acute Mania in Bipolar/Prophylaxis 12yr+</li> <li>6. PTSD</li> <li>7. Risperidone for continuation treatment in bi-polar disorder (adults)</li> <li>8. Risperidone for psychosis and behavioural management/augmentation in developmental disorders, also augmentation for severe agitation in OCD/anxiety in under 18s</li> </ol>	<ol style="list-style-type: none"> <li>1. Licensed for 6 weeks treatment in 5yr+, Off-Label if treatment more than 6 weeks</li> <li>2. Off-Label, BNFC does not specify length of treatment but advises to stop if no response after 6 weeks use</li> <li>3. Off-Label</li> <li>4. Off-Label</li> <li>5. Off-Label</li> <li>6. Off-Label</li> <li>7. Off-Label</li> <li>8. Off-Label</li> </ol>	<ol style="list-style-type: none"> <li>1. NICE QS59, Maudsley, Bazire, BNFC</li> <li>2. Maudsley, BNFC</li> <li>3. Second line in Maudsley, BNFC</li> <li>4. Maudsley, BNFC</li> <li>5. Maudsley, BNFC</li> <li>6. Maudsley</li> <li>7. Maudsley, Bazire</li> </ol>
<p><b>Antimuscarinics:</b></p> <ul style="list-style-type: none"> <li>• Hyoscine Hydrobromide</li> <li>• Trihexylphenidyl</li> </ul>	<p>-Hyoscine tablets and patches for the treatment of clozapine induced hypersalivation</p> <p>-Trihexylphenidyl for the treatment of clozapine induced hypersalivation</p>	<p>Off-Label</p>	<p>o Maudsley</p>

<p><b>Antidepressants:</b></p> <ul style="list-style-type: none"> <li>• Antidepressants (unspecified) for use in Adults</li> <li>• Sertraline*</li> <li>• Fluoxetine*</li> <li>• Citalopram*</li> </ul>	<p>-Behavioural symptoms of dementia -Anxiety -Generic fluoxetine liquid and capsules for under 18's -Sertraline for depression, anxiety and OCD in under 18s</p> <p>1. OCD from 6yr+ 2. Major depression 12yr+ 3. Moderate to severe anxiety 4. Panic disorder/PTSD</p> <p>1. Major depression 8yr+ 2. Bipolar depression 3. Moderate to severe anxiety 4. OCD from 8yr+ 5. Repetitive behaviours in ASD</p> <p>1. Major depression 12yr+ 2. Moderate to severe anxiety 3. Panic disorder/PTSD 4. OCD</p>	<p>Off-Label</p> <p>1. Licensed 2. Licensed, but Off-Label between ages 5-11yrs 3. Off-Label 4. Off-Label</p> <p>1. Licensed, but Off-Label between ages 5-7yrs 2. Off-Label 3. Off-Label 4. Off-Label 5. Off-Label</p> <p>1. Licensed, but Off-Label between 5-11yrs 2. Off-Label 3. Off-Label 4. Off-Label from 8yrs</p> <p>Off-Label</p>	<p>○ Maudsley ○ Bazire (SSRIs &amp; venlafaxine) ○ BNF</p> <p>1. NICE CG31 2. Second line in NICE NG134 3. Maudsley 4. Maudsley</p> <p>1. First line in NICE NG134 2. NICE CG185 combine with Olanzapine 3. Maudsley 4. NICE CG31 5. Maudsley, lower doses indicated, start at 2.5mg/d</p> <p>1. Second line in NICE NG134 2. Maudsley 3. NICE CG31 4. Maudsley</p> <p>○ Maudsley ○ BNF (bipolar disorder) ○ NICE</p> <p>○ BNF (bipolar disorder) ○ Maudsley ○ Bazire ○ NICE Guidelines CG185 – assessment and management bipolar in adults and children in primary and secondary care</p>
<p><b>Anticonvulsants:</b></p> <ul style="list-style-type: none"> <li>• Sodium Valproate</li> <li>• Carbamazepine</li> </ul>	<p>-Carbamazepine and sodium valproate for treatment of aggression -Sodium valproate for prophylaxis and treatment of bipolar disorder -Carbamazepine and Sodium Valproate in BPSD</p>	<p>Off-Label</p>	<p>○ Maudsley ○ BNF (bipolar disorder) ○ NICE</p>
<p><b>Anti-manic Drugs:</b></p> <ul style="list-style-type: none"> <li>• Depakote (semi-sodium valproate)</li> </ul>	<p>-Long term treatment/prophylaxis in bipolar disorder -Acute Psychosis</p>	<p>Off-Label</p>	<p>○ BNF (bipolar disorder) ○ Maudsley ○ Bazire ○ NICE Guidelines CG185 – assessment and management bipolar in adults and children in primary and secondary care</p>

<p><b>Non-benzodiazepine Hypnotics/Sedatives:</b></p> <ul style="list-style-type: none"> <li>Melatonin*</li> </ul>	<p>-Insomnia</p>	<p>-Circadin brand Off-Label use          -Slenyto prolonged release tablets Licensed in children aged 2-17 with ASD and / or Smith-Magenis syndrome, where sleep hygiene measures have been insufficient          -1mg/1ml oral solution special, state “special” and add brand name on prescription e.g. Kidmel / Neomel – Unlicensed products          -Licensed 1mg/1ml oral solution (ColonisPharma) is not suitable for children</p>	<ul style="list-style-type: none"> <li>Shared care guidelines</li> <li>NICE Evidence summary [ESUOM2] Jan13</li> <li>BAP Guidelines  <a href="https://www.bap.org.uk/pdfs/BAP_Guidelines-Sleep.pdf">https://www.bap.org.uk/pdfs/BAP_Guidelines-Sleep.pdf</a></li> <li>Maudsley</li> <li>BNFfC</li> </ul>
<p><b>Centrally Acting Sympathomimetic:</b></p> <ul style="list-style-type: none"> <li>Atomoxetine*</li> <li>Methylphenidate*</li> </ul>	<p>-Stimulants          -ADHD (from age 5)</p>	<p>-Licensed from age 6          -Off-Label for age 5          -Doses above 100mg daily are not licensed          -May prescribe up to 120mg/day under specialist</p>	<p>Maudsley          NICE Guidelines CG72 ADHD – Diagnosis and management of ADHD in children, young people and adults          NICE NG87 – use in age 5          BNfC</p>
	<p>-ADHD (from age 5)</p>	<p><u>Methylphenidate</u>          -Doses up to 60mg/day (54mg/day for XL) are Licensed          -XL form Licensed from age 6          -Off-Label at age 5          -Higher doses 2.1mg/kg/day or 90mg/day (108mg/day for XL) under specialist are Off-Label</p>	<p>NICE NG87 – use in age 5          Shared care guideline available          Significant data for efficacy and safety          BNfC</p>
<p><b>Substance Misuse:</b></p> <ul style="list-style-type: none"> <li>Naltrexone</li> </ul>	<p>-Relapse prevention in alcohol dependence</p>	<p>Off-Label</p>	<ul style="list-style-type: none"> <li>Maudsley</li> <li>NICE guidelines CG115 Alcohol-use disorders; diagnosis, assessment and management of harmful drinking &amp; alcohol dependence</li> </ul>

**The Maudsley Prescribing guidelines in Psychiatry** aim to provide clinicians with practically useful advice on the prescribing of psychotropic agents in commonly encountered clinical situations. It is based on a combination of literature review, clinical experience and expert contribution. It is widely considered a key reference source in psychiatry

**Psychotropic drug directory 2016** provides for professional prescribing clinicians a source of rapidly accessible information, advice and references on psychiatric drugs and to act as an aide memoire. With over 10,000 key references are included for rapid identification of key papers. Steve Bazire the author is a well-respected pharmacist within Mental Health Pharmacy

**REFERENCES:**

1. Maudsley – The Maudsley Prescribing Guidelines in Psychiatry 12<sup>th</sup> edition 2015 by David Taylor, Carol Paton, Shitij Kapur April
2. Bazire – Psychotropic drug directory 2016 by Stephen Bazire
3. NICE guidelines - <https://www.nice.org.uk/>
4. BAP guidelines - <https://www.bap.org.uk/guidelines>
5. BNF - <https://bnf.nice.org.uk/>
6. BNFc - <https://bnfc.nice.org.uk/>

**This guideline was ratified by the Area Prescribing Committee on 11<sup>th</sup> December 2019 and is due for review in December 2021.**

**APPENDIX 1**

**Child and Adolescent Mental Health Service Medication Consent Form.** *Tick each box when you agree with the statement. (\* delete as appropriate)*

Patient name: ..... NHS Number.....

Recommended medication: ..... to treat.....*[diagnosis]*

Allergies or sensitivities .....

**The law presumes people age 16 and 17 have the capacity to consent to (agree to) being prescribed medication. Some children under the age of 16 may have competence to agree to treatment themselves and the prescriber is able to assess this.**

- This form is completed by the young person because they have been assessed as being competent or having the capacity to agree to medication.
- This form is completed by the parent/ carer (within the scope of parental responsibility) as the young person does not have the capacity or competence to consent to medication.

I confirm that:

- The prescriber has explained the likely benefits and possible side effects of using the medication and the option of not using it; and I have understood the explanation.
- I have been given a patient medication leaflet for the above medication, which covers side effects.
- I had enough time to consider my decision and to ask questions. I am aware that additional information is available on-line <https://www.choiceandmedication.org/swyp/> and in leaflet form and this may be utilised at any time.
- I will inform the prescriber if I change my mind and withdraw my consent.
- I understand that this medication is being prescribed *within its license / outside its licensed indication / as an unlicensed medicine\**. The prescriber has explained what this means.
- We have also discussed that the following factors can affect mental health:
  - o Lifestyle choices (exercise, healthy diet, sleep hygiene etc.)
  - o The impact of substances, smoking, alcohol
  - o Contraceptive advice if relevant (some medications may be a risk to unborn babies)
- The prescriber has discussed other possible treatment options.
- I consent to the above medication being prescribed on behalf of the named patient above*  
*Young person/ parent / carer / guardian\**

Sign: \_\_\_\_\_ *[Print name]* \_\_\_\_\_ *[Date]* \_\_\_\_\_

*Doctor / Non-medical prescriber\**

Sign: \_\_\_\_\_ *[Print name]* \_\_\_\_\_ *[Date]* \_\_\_\_\_

- Scan form and any prescription/s and upload onto SystemOne. Provide original copy of consent form to young person/ parent/ carer/ guardian.