Effective Shared Care Agreement (ESCA)

Methylphenidate (from age 6 years)

ESCA: For the treatment of Attention-Deficit/Hyperactivity Disorder (ADHD) as part of a comprehensive treatment programme.

Please refer to the methylphenidate formulary entry for commissioning arrangements which vary across BSSE – click here

AREAS OF RESPONSIBILITY FOR THE SHARING OF CARE

This shared care agreement outlines suggested ways in which the responsibilities for managing the prescribing of Methylphenidate in Attention-Deficit/Hyperactivity Disorder (ADHD) as part of a comprehensive treatment programme can be shared between the specialist and general practitioner (GP). You are **invited** to participate however, if you do not feel competent to undertake this role, then you are under no obligation to do so. In such an event, the total clinical responsibility for the patient for the diagnosed condition remains with the specialist.

Sharing of care assumes communication between the specialist, GP and patient. The intention to share care will be explained to the patient by the specialist initiating treatment. It is important that patients are consulted about treatment and are in agreement with it. Patients with Attention-Deficit/Hyperactivity Disorder (ADHD) are usually under regular specialist follow-up, which provides an opportunity to discuss drug therapy.

The doctor who prescribes the medication legally assumes clinical responsibility for the drug and the consequences of its use.

RESPONSIBILITIES and ROLES

Specialist responsibilities
1. Patients who are being transferred to adult services need to be reviewed by the specialist adult teams as per the trust internal governance process and to confirm that the current treatment is suitable and in line with the BSSE APC formulary
2. Specialist assessment and confirmation of the diagnosis of attention deficit/hyperactivity disorder
3. Discuss the potential benefits, treatment side effects, and possible drug interactions with the patient.
4. Ask the GP whether he or she is willing to participate in shared care before initiating therapy so that appropriate follow on prescribing arrangements can be made
5. Do baseline monitoring prior to initiation of this agent: • weight, blood pressure, pulse and essential medical history, cardiovascular examination and ECG where indicated. • full mental health and social assessment, full history and physical examination, family history of cardiac disease and an ECG if there is past medical and/or family history of cardiac or cerebrovascular problems. • risk assessment for substance misuse and potential for drug diversion.
6. Initiate treatment and stabilise dose of methylphenidate. If using modified release preparation, please prescribe by BRAND name
7. Methylphenidate is a Schedule 2 Controlled Drug (CD, therefore should be prescribed in line with the Misuse of Drug Regulations.). Prescription requirements for prescribing CDs should therefore be observed, maximum of 30 day per prescription.
8. Advise the patient on the importance of good adherence with the prescribed medication. Check adherence at each clinic appointment
9. Review the patient's condition and response to treatment every 6 months. Advise patients, families/ carers to report any side effects and/ or concerns. At 6 monthly reviews (unless otherwise indicated): • Monitor efficacy of long term treatment and consider whether benefit can be gained from continued treatment. • Monitor height, weight, appetite, heart rate and BP and any psychiatric symptoms • Request any further investigations that are clinically indicated such as ECG, blood investigations • Assess progress with regards to psychological, behavioural, educational and occupational needs • Assess ongoing need for medication • Assess any side effects • Consider the potential for drug diversion and potential for misuse
10. Reassume prescribing responsibilities if a woman becomes or wishes to become pregnant.
11. A written summary to be sent promptly to the GP i.e. within 10 working days of a hospital outpatient review or inpatient stay
12. Advise the GP what to do when defined parameters are altered, and when (if at all) an emergency referral should be made back to the specialist service.
13. Advise GP on the management of side effects and raise awareness at which point these will be reviewed and/ or managed by the specialist.
14. Advise the GP when to stop treatment and on management of discontinuation if necessary.
15. Report serious adverse events to the MHRA via Yellow Card Scheme https://yellowcard.mhra.gov.uk
16. Ensure clear backup arrangements exist for GPs, for advice and support (please complete contact details in appendix 1)

General Practitioner responsibilities
1. Reply to the request for shared care as soon as practicable i.e. within 10 working days
2. Ensure: • Patient/ family are clear who will be responsible for monitoring and what this will entail. • Patient/ family are aware of any significant adverse effects/ events, which should be urgently reported and who these should be reported to. (GP/ specialist)
3. Prescribe methylphenidate at the dose recommended. If using modified release preparation, please prescribe by BRAND name.
4. Adjust the dose as advised by the specialist.
5. Methylphenidate is a Schedule 2 Controlled Drug (CD, therefore should be prescribed in line with the Misuse of Drug Regulations.). Prescription requirements for prescribing CDs should therefore be observed, maximum of 30 day per prescription.
6. In the patient's notes, using the appropriate Read Code listed below, denote that the patient is receiving treatment under a shared care agreement

GP Prescribing System	Read Code	Description		GP Prescribing System	Read Code	Description
EMIS and Vision	8BM5.00	Shared care prescribing		SystmOne	XaB58	Shared care

7. Monitor patient's response to treatment; make dosage adjustments if agreed with specialist
8. Report to and seek advice from the specialist or clinical nurse specialist on any aspect of patient care that is of concern to the GP, patient or carer and may affect treatment
9. Refer back to specialist if condition deteriorates
10. For women of child bearing age, refer prescribing responsibilities back to specialist immediately if patient becomes, or wishes to become, pregnant.
11. Report serious adverse events to specialist and MHRA via the Yellow Card Scheme https://yellowcard.mhra.gov.uk
12. Stop treatment on advice of specialist

Patient's role
1. Report to the specialist, clinical nurse specialist or GP if he or she does not have a clear understanding of the treatment
2. Attend regularly for required blood tests and annual health checks.
3. Share any concerns in relation to treatment with Methylphenidate with the specialist, clinical nurse specialist or GP
4. Report any adverse effects to the specialist or GP whilst taking Methylphenidate
5. Attend regular outpatient appointments with the specialist
6. Inform the specialist, clinical nurse specialist or GP if she becomes or wishes to become pregnant.

Please enter Specialist contact details and patient specific information in Appendix 1

SUPPORTING INFORMATION

Agent + Form	Medikinet Tablets	Equasym XL modified-release capsules	Medikinet XL modified-release capsules	Concerta XL prolonged-release tablets	Xenidate XL	Xaggitin XL
Strength and cost*	5 mg = £3.03 (30) 10 mg = £5.49 (30) 20 mg = £10.92 (30)	10mg = £25.00 (30) 20mg =£30.00 (30) 30mg = £35.00 (30)	5mg = £24.04 (30) 10mg = £24.04 (30) 20mg = £28.86 (30) 30mg = £33.66 (30) 50mg = £62.52 (30)	18mg = £31.19 (30) 27mg = £36.81 (30) 36mg = £42.45 (30) 54mg = £73.62 (30)	18mg=£15.57 (30) 27mg=£18.39 (30) 36mg =£21.21 (30) 54mg =£36.79 (30)	18mg=£15.58 (30) 27mg=£18.40 (30) 36mg =£21.22 (30) 54mg =£36.80 (30)
Indication	Attention-Deficit/Hyperactivity Disorder (ADHD) • Methylphenidate is indicated as part of a comprehensive treatment programme for Attention Deficit Hyperactivity Disorder (ADHD in children aged 6 years of age and over when remedial measures alone prove insufficient. • Treatment must be under the supervision of a specialist in childhood behavioural disorders. • Diagnosis should be made according to DSM-5 criteria or the guidelines in ICD-10 and should be based on a complete history and evaluation of the patient. Diagnosis cannot be made solely on the presence of one or more symptoms. • The specific aetiology of this syndrome is unknown, and there is no single diagnostic test. Adequate diagnosis requires the use of medical and specialised psychological, educational, and social resources. • A comprehensive treatment programme typically includes psychological, educational and social measures as well as pharmacotherapy and is aimed at stabilising children with a behavioural syndrome characterised by symptoms which may include chronic history of short attention span, distractibility, emotional lability, impulsivity, moderate to severe hyperactivity, minor neurological signs and abnormal EEG. Learning may or may not be impaired. • Methylphenidate treatment is not indicated in all children with ADHD and the decision to use the drug must be based on a very thorough assessment of the severity and chronicity of the child's symptoms in relation to the child's age. Appropriate educational placement is essential, and psychosocial intervention is generally necessary. Where remedial measures alone prove insufficient, the decision to prescribe a stimulant must be based on rigorous assessment of the severity of the child's symptoms. The use of methylphenidate should always be used in this way according to the licensed indication and according to prescribing / diagnostic guidelines.					
	Careful dose titration is necessary at the start of treatment with methylphenidate Dose titration should be started at the lowest possible dose. This is normally achieved using an immediate release formulation taken in divided doses.					

	Medikinet Tablets	Equasym XL modified-release capsules	Medikinet XL modified-release capsules	Concerta XL prolonged-release tablets	Xenidate XL	Xaggitin XL
Dose	The recommended starting daily dose is 5 mg once daily or twice daily (e.g. at breakfast and lunch), increasing if necessary by weekly increments of 5-10 mg in the daily dose according to tolerability and degree of efficacy observed. The total daily dose should be administered in divided doses			The recommended starting dose of methylphenidate prolonged-release tablets for patients who are not currently taking methylphenidate, or for patients who are on stimulants other than methylphenidate, is 18 mg once daily.		
		Methylphenidate XL 10 mg once daily may be used in place of immediate release methylphenidate hydrochloride 5 mg twice daily from the beginning of treatment where the treating physician considers that twice daily dosing is appropriate from the outset and twice daily treatment administration is impracticable.				
Maximum daily dosage	60mg.	60 mg	60 mg.	54mg.	54 mg	54 mg
Patients New to Methylphenidate				Clinical experience with methylphenidate XL/prolonged-release tablets is limited in these patients. Methylphenidate XL/prolonged-release tablets may not be indicated in all children with ADHD syndrome.		

*Prices are correct at the time of writing

	Medikinet Tablets	Equasym XL modified-release capsules	Medikinet XL modified-release capsules	Concerta XL prolonged-release tablets	Xenidate XL	Xaggitin XL
Patients Currently Using Methylphenidate (immediate-release)		Patients established on an immediate release methylphenidate hydrochloride formulation may be switched to the milligram equivalent daily dose of Methylphenidate XL		The recommended dose of methylphenidate XL/prolonged-release tablets for patients who are currently taking methylphenidate three times daily at doses of 15 to 45 mg/day is provided in Table 1. Dosing recommendations are based on current dose regimen and clinical judgement		
				TABLE 1 Recommended Dose Conversion from Other Methylphenidate Hydrochloride Regimens, where available, to modified release preparations:		

			<table><tr><th>Previous Methylphenidate Hydrochloride Daily Dose</th><th>Recommended modified release preparations dose</th></tr><tr><td>5 mg Methylphenidate three times daily</td><td>18 mg once daily</td></tr><tr><td>10 mg Methylphenidate three times daily</td><td>36 mg once daily</td></tr><tr><td>15 mg Methylphenidate three times daily</td><td>54 mg once daily</td></tr></table> If improvement is not observed after appropriate dosage adjustment over a one-month period, the drug should be discontinued
Renal Impairment **Hepatic impairment**	**There is no experience with the use of methylphenidate in patients with renal or hepatic insufficiency. Caution should be exercised in these patients.**		
Contraindications	**Refer to individual product SPC**		
Cautions	**Refer to individual product SPC**		

<table>
<tr><td rowspan="4">Cautions</td><td rowspan="2">Use in adults</td><td>Medikinet Tablets</td><td>Equasym XL modified-release capsules</td><td>Medikinet XL modified-release capsules</td><td>Concerta XL prolonged-release tablets</td><td>Xenidate XL</td><td>Xaggitin XL</td></tr>
<tr><td colspan="2">Methylphenidate is not licensed for use in adults with ADHD. Safety and efficacy have not yet been established in this age group.</td><td>Continuation of methylphenidate therapy

Adult patients who have shown clear benefit from treatment with Medikinet XL in childhood and/or adolescence may continue treatment with Medikinet XL into adulthood, initially at the same daily dose (mg/day). Whether or not a dose adjustment depending on efficacy and tolerability is necessary or possible must be reviewed regularly.

Adults new to Medikinet XL

Any treatment with methylphenidate requires individual dose titration against efficacy and tolerability because individual response may vary substantially. Initiation of treatment in adults who are new to Medikinet XL therefore requires careful dose titration. Dose titration should be started at the lowest possible dose.

The recommended starting dose is 10 mg daily, which may be increased if necessary by weekly increments of 10 mg in the daily dose according to tolerability and degree of efficacy observed. The total daily dose should be given in two divided doses in the morning and at midday.

The aim of individual titration should be to find the lowest daily dose that achieves satisfactory symptom control.

Compared to children and adolescents, adult patients may require a higher daily dose, based on the patient's body weight.

The maximum daily dose is based on the patient's body weight and must not exceed 1 mg/kg body weight. Regardless of body weight, a maximum daily dose of 80 mg methylphenidate hydrochloride should not be exceeded because limited experience with daily doses greater than 80 mg is available from clinical studies.</td><td colspan="2">In adolescents whose symptoms persist into adulthood and who have shown clear benefit from treatment, it may be appropriate to continue treatment into adulthood. However, start of treatment with methylphenidate prolonged-release tablets in adults is not appropriate</td><td>Safety and efficacy have not been established for the initiation of treatment in adults or the routine continuation of treatment beyond 18 years of age. If treatment withdrawal has not been successful when an adolescent has reached 18 years of age continued treatment into adulthood may be necessary. The need for further treatment of these adults should be reviewed regularly and undertaken annually.</td></tr>
<tr><td colspan="7">Patients who are being transferred to adult services need to be reviewed by the specialist adult teams as per the trust internal governance process and to confirm that the current treatment is suitable and in line with the BSSE APC formulary</td></tr>
<tr><td colspan="2">Medikinet Tablets</td><td>Equasym XL modified-release capsules</td><td>Medikinet XL modified-release capsules</td><td>Concerta XL prolonged-release tablets</td><td>Xenidate XL</td><td>Xaggitin XL</td></tr>
<tr><td colspan="3"></td><td>Because the methylphenidate XL tablet is nondeformable and does not appreciably change in shape in the gastrointestinal (GI) tract, it should not ordinarily be administered to patients with pre-existing severe GI narrowing (pathologic or iatrogenic) or in patients with dysphagia or significant difficulty in swallowing tablets. There have been rare reports of obstructive symptoms in patients with known strictures in association with the ingestion of</td><td></td><td></td></tr>
</table>

			drugs in nondeformable prolonged-release formulations.	
	The tablets should be swallowed whole or divided into halves with the aid of liquids, either with meals or after meals.	The capsules may be swallowed whole with the aid of liquids, or alternatively, the capsule may be opened and the capsule contents sprinkled onto a small amount (tablespoon) of **applesauce (EquasymXL & Medikinet XL) or yoghurt (Medikinet)** and given immediately, and not stored for future use. Drinking some fluids, e.g. water, should follow the intake of the sprinkles with applesauce. The capsules and the capsule contents must not be crushed or chewed.	Due to the prolonged-release design of the tablet, methylphenidate XL should only be used in patients who are able to swallow the tablet whole. Patients should be informed that methylphenidate XL must be swallowed whole with sufficient liquid. Tablets must not be chewed, divided, or crushed	
Side Effects	**Refer to individual product SPC**			

<table>
<tr><td>Monitoring</td><td colspan="3">Treatment must be initiated under the supervision of a specialist in childhood and/or adolescent behavioural disorders
Patients should be monitored for the risk of diversion, misuse and abuse of methylphenidate</td></tr>
<tr><td>Pre-treatment screening:</td><td colspan="3">Prior to prescribing, it is necessary to conduct a baseline evaluation of a patient's cardiovascular status including blood pressure and heart rate. A comprehensive history should document concomitant medications, past and present co-morbid medical and psychiatric disorders or symptoms, family history of sudden cardiac/unexplained death and accurate recording of pre-treatment height and weight on a growth chart</td></tr>
<tr><td>Ongoing monitoring:</td><td colspan="3">Growth, psychiatric and cardiovascular status should be continuously monitored.
• Blood pressure and pulse should be recorded on a centile chart at each adjustment of dose and then at least every 6 months;
• Height, weight and appetite should be recorded at least 6 monthly with maintenance of a growth chart;
• Weight should be recorded 3 monthly in patients aged under 10 years;
• Development of de novo or worsening of pre-existing psychiatric disorders should be monitored at every adjustment of dose and then at least every 6 months and at every visit.
<table>
<tr><th>Parameter</th><th>By Specialist</th><th>By GP</th></tr>
<tr><td>Height and weight</td><td>Baseline and @6 months (or before discharge) including keeping a growth chart</td><td>6 monthly after discharge from specialist.</td></tr>
<tr><td>Appetite</td><td>Baseline and @6 months (or before discharge)</td><td>6 monthly after discharge from specialist.</td></tr>
<tr><td>Heart rate and BP</td><td>Baseline and @6 months (or before discharge) and before and after each dose change</td><td>6 monthly after discharge from specialist.</td></tr>
<tr><td>Psychiatric assessments</td><td>Baseline and @6 months (or before discharge)</td><td>6 monthly after discharge from specialist.</td></tr>
<tr><td>Risk of diversion or abuse</td><td>Baseline and @6 months (or before discharge)</td><td>6 monthly after discharge from specialist.</td></tr>
</table></td></tr>
<tr><td>Long-term (more than 12 months) use in children and adolescents</td><td colspan="3">• The safety and efficacy of long-term use of methylphenidate has not been systematically evaluated in controlled trials.
• Methylphenidate treatment should not and need not, be indefinite. Methylphenidate treatment is usually discontinued during or after puberty.
• The physician who elects to use methylphenidate for extended periods (over 12 months) in children and adolescents with ADHD should periodically re-evaluate the long-term usefulness of the medicinal product for the individual patient with trial periods off medication to assess the patient's functioning without pharmacotherapy.
• It is recommended that methylphenidate is de-challenged at least once yearly to assess the child's condition (preferable during times of school holidays). Improvement may be sustained when the medicinal product is either temporarily or permanently discontinued.</td></tr>
<tr><td>Dose reduction and discontinuation</td><td colspan="3">Treatment must be stopped if the symptoms do not improve after appropriate dosage adjustment over a one-month period. If paradoxical aggravation of symptoms or other serious adverse events occur, the dosage should be reduced or discontinued.</td></tr>
<tr><td>Drug Interactions</td><td colspan="3">Refer to individual product SPC</td></tr>
</table>

References

1. NICE NG87 Attention deficit hyperactivity disorder: diagnosis and management
2. SPC Ritalin tablet, Medikinet Tablets, Equasym XL modified-release capsules, Medikinet XL modified-release capsules, Concerta XL prolonged-release tablets, Matoride XL Prolonged-release Tablets and Xenidate XL, Delmosart Prolonged-release Tablets, Xaggitin XL available
3. BNF for Children Online

Monitoring Parameters- Maintenance therapy

If the patient returns to the specialist services within a 6 month period, the monitoring should be continued within the specialist services. For treatment periods greater than 6 month continued monitoring can be agreed with the GP service as appropriate.

Methylphenidate

Parameter	By Specialist	By GP
Height and weight	Baseline and @6 months (or before discharge) including keeping a growth chart	6 monthly after discharge from specialist.
Appetite	Baseline and @6 months (or before discharge)	6 monthly after discharge from specialist.
Heart rate and BP	Baseline and @6 months (or before discharge) and before and after each dose change	6 monthly after discharge from specialist.
Psychiatric assessments	Baseline and @6 months (or before discharge)	6 monthly after discharge from specialist.
Risk of diversion or abuse	Baseline and @6 months (or before discharge)	6 monthly after discharge from specialist.

Please note:

Children/adolescents who are not growing or gaining height and weight as expected may need to have their treatment interrupted. This should involve discussions with the specialist

Medication profile

Medication to be TRANSFERRED TO GP PRESCRIBING		
Drug name and form (NB Brand name prescribing essential)	**Dose and frequency**	**Commence on:**

BACK-UP ADVICE AND SUPPORT

Contact details	Telephone No.	Bleep:	Fax:	Email address:
Specialist:				
Specialist nurse				

Appendix 1:

Effective Shared Care Agreement (ESCA)
Methylphenidate (from age 6 years)

For the treatment of attention deficit hyperactivity disorder

Please refer to BSSE APC formulary website for complete document.

Agent	Tick	Dose		Agent	Tick	Dose
Medikinet Tablets				**Concerta XL prolonged-release tablets**		
Medikinet XL modified-release capsules				**Xenidate XL**		
Equasym XL modified-release capsules				**Xaggitin XL**		

BACK-UP ADVICE AND SUPPORT (To be completed by Specialist team)

Trust	Contact details	Telephone No.	Email address:
	Consultant:-		
	Specialist Nurse		

Patient's name	Date of birth	Sex	Home Address	Hospital Number
				NHS Number

Transitioning patients Patients who are being transferred to adult services need to be reviewed by the specialist adult teams as per the trust internal governance process and to confirm that the current treatment is suitable and in line with the BSSE APC formulary	Adult service consultant to tick and sign please

Hospital Specialist/Consultant
Name (please print)_____Signature_____Date_____

To be completed by the General Practitioner:

I agree to participate in this shared care agreement for the treatment of the below named patient with Methylphenidate in Attention-Deficit/Hyperactivity Disorder (ADHD) as part of a comprehensive treatment programme

General Practitioner
Name (please print)_____Signature _____Date_____

Please keep a copy of this agreement for your own records and forward the original to the above named Consultant.

In the patient's notes, using the appropriate Read Code listed below, denote that the patient is receiving treatment under a shared care agreement.

GP Prescribing System	Read Code	Description		GP Prescribing System	Read Code	Description
EMIS and Vision	8BM5.00	Shared care prescribing		SystmOne	XaB58	Shared care