Methylphenidate, Dexamfetamine, Atomoxetine, Lisdexamphetamine and Guanfacine
Shared care guideline for the treatment of Attention Deficit Hyperactivity Disorder in children, young people and adults

Please note: Although some of these products are not licensed in adults – NICE recommends them as treatment in adults

Introduction

NICE recommendations[1]
NG87

Medication choice – children aged 5 years and over and young people

1.7.7 Offer methylphenidate (either short or long acting) as the first line pharmacological treatment for children aged 5 years and over and young people with ADHD. **[2018]**

1.7.8 Consider switching to lisdexamfetamine for children aged 5 years and over and young people who have had a 6-week trial of methylphenidate at an adequate dose and not derived enough benefit in terms of reduced ADHD symptoms and associated impairment. **[2018]**

1.7.9 Consider dexamfetamine for children aged 5 years and over and young people whose ADHD symptoms are responding to lisdexamfetamine but who cannot tolerate the longer effect profile. **[2018]**

1.7.10 Offer atomoxetine or guanfacine to children aged 5 years and over and young people if:

- they cannot tolerate methylphenidate or lisdexamfetamine **or**
- their symptoms have not responded to separate 6-week trials of lisdexamfetamine and methylphenidate, having considered alternative preparations and adequate doses. **[2018]**

Medication choice – adults

1.7.11 Offer lisdexamfetamine or methylphenidate[as first-line pharmacological treatment for adults with ADHD. **[2018]**

1.7.12 Consider switching to lisdexamfetamine for adults who have had a 6-week trial of methylphenidate at an adequate dose but have not derived enough benefit in terms of reduced ADHD symptoms and associated impairment. **[2018]**

1.7.13 Consider switching to methylphenidate for adults who have had a 6-week trial of lisdexamfetamine at an adequate dose but have not derived enough benefit in terms of reduced ADHD symptoms and associated impairment. **[2018]**

1.7.14 Consider dexamfetamine for adults whose ADHD symptoms are responding to lisdexamfetamine but who cannot tolerate the longer effect profile. **[2018]**

1.7.15 Offer atomoxetine to adults if:

- they cannot tolerate lisdexamfetamine or methylphenidate **or**
- their symptoms have not responded to separate 6-week trials of lisdexamfetamine and methylphenidate, having considered alternative preparations and adequate doses. **[2018]**

Further medication choices

1.7.16 Obtain a second opinion or refer to a tertiary service if ADHD symptoms in a child aged 5 years or over, a young person or adult are unresponsive to one or more stimulants and one non-stimulant. **[2018]**

1.7.17 Do not offer any of the following medication for ADHD without advice from a tertiary ADHD service:

- guanfacine for adults
- clonidine for children with ADHD and sleep disturbance, rages or tics
- atypical antipsychotics in addition to stimulants for people with ADHD and coexisting pervasive aggression, rages or irritability

Currently only atomoxetine and Concerta XL are licensed for treatment of adults with ADHD Concerta XL is only licensed if it was started before the age of 18. Prescribing of Concerta XL for the first time after the age of 18 or any other stimulant, is ‘‘of-label’’. Lisdexamphetamine is now also licensed in adults including initiation

Background

Treatment aims in Attention Deficit Hyperactivity Disorder (ADHD) are to reduce hyperactive behaviour, detect and treat any co-existing disorders, promote academic and social learning, improve emotional adjustment and self esteem, and to relieve family distress.

Hyperactivity is considered a disorder if it interferes with social functions, learning or development. Early treatment of ADHD has been shown to be beneficial in order to avoid long term adverse effects on the child’s development.

The core symptoms of ADHD are:

- Inattention (difficulty in concentration).
- Hyperactivity (disorganised, excessive levels of activity).
- Impulsive behaviour.

For diagnosis of ADHD the following symptoms arise:-

- Have their onset before the age of seven years.
- Have persisted for at least six months.
- Impairment present in more than one setting e.g. at home, at school, socially.
- Have caused significant functional impairment.
- Are not purely accounted for by other mental disorders: pervasive developmental disorder, schizophrenia, other psychotic disorders.

It is believed that the prevalence of severe combined ADHD in the school age population is 1.5%, and the less severe form is 3-5%.

Responsibilities of the specialist initiating treatment

Summary

- Confirm diagnosis of ADHD following full assessment
- Initiation of patient on methylphenidate, atomoxetine, dexamfetamine lisdexamfetamine or guanfacine
- Ensure baseline BP, height, weight plus any other relevant investigations have been undertaken. With respect to patients starting on atomoxetine, a thorough cardiovascular assessment should be undertaken to assess any presence of cardiac disease. Before prescribing atomoxetine, the patient's cardiovascular status, including blood pressure and heart rate should be measured and recorded appropriately.
- Continue to prescribe methylphenidate or atomoxetine dexamfetamine lisdexamfetamine or guanfacine for 3 months
- Communicate with the GP regarding all aspects of patient care and to inform the GP (in writing) if and when the patient is suitable for shared care, asking if GP is willing to participate in shared care
- Explain shared care to the patient and gain acceptance from them
- Review the patient every six months or sooner if indicated or requested by the GP
- Monitor height, weight, blood pressure and relevant blood tests at each six monthly review
- Report adverse effects to the MHRA and GP
- To inform the GP if patient misses repeated follow up appointments

Baseline Tests

Height, weight, blood pressure and heart rate (where appropriate). Also consider ECG where medication can alter QTC

Routine Tests

Height, weight, blood pressure and six monthly review. For patients taking atomoxetine, cardiovascular status should be regularly monitored during treatment, with blood pressure and pulse recorded appropriately after every dose adjustment and at least every 6 months to detect potentially clinically important increases.

Parameter	Frequency of monitoring	Action
Full Blood Count		Only perform if patient looks pale and suffering recurrent infection **or** easy bruising
Blood Pressure and pulse	6 monthly	Monitor whilst taking medication to ensure within published range.
Growth Development/ Weight	6 monthly	If adversely affected consideration should be given to dose reduction or interrupting therapy in those on long-term treatment.

General Practitioner responsibilities

Acceptance of Responsibility by the Primary Care Clinician

It is optional for GPs to participate in taking on responsibility for shared care for the patient. GPs will take on shared care only if they are willing and able.

- To reply to the request for shared care as soon as possible.
- To prescribe and adjust the dose as recommended by the specialist.
- To ensure there are no interactions with any other medications initiated in primary care.
- To refer back to the specialist where appropriate. For example:
  - Patient or general practitioner is **not** comfortable to continue with the existing regime due to either change in condition or drug side effects.
  - Advice in respect of concordance.
- Discontinue the drug as directed by the specialist if required
- To identify adverse events if the patient presents with any signs and liaise with the hospital specialist where necessary.

To report adverse events to the specialist and where appropriate the Commission on Human Medicines/MHRA (Yellow card scheme).

Clinical Particulars

Lisdexamfetamine Elvanse®▼ and Guanfacine (Intuniv®)▼ *are black triangle drugs so all adverse reactions should be reported to the MHRA via the yellow card system*

The information given below is not exhaustive and merely is a guide with salient information about methylphenidate, atomoxetine dexamfetamine, lisdexamfetamine *and Guanfacine* preparations. When in doubt, please refer to an up to date copy of the Specific Product Characteristics[2,3,4,7], the British National Formulary[5] or The Maudsley Prescribing Guidelines.[6]

BNF therapeutic class	4.4 CNS stimulants and drugs used for attention deficit hyperactivity disorder
Dosage and Administration	**Atomoxetine** **Products Available:- Strattera®** CHILD 6–18 years, body-weight over 70 kg, initially 40 mg daily for 7 days, increased according to response; usual maintenance 80 mg daily, but may be increased to max. 120 mg daily [unlicensed] under the direction of a specialist; CHILD over 6 years, body-weight under 70 kg, initially 500 micrograms/kg daily for 7 days, increased according to response; usual maintenance 1.2 mg/kg daily. Total daily dose may be given *either* as a single dose in the morning *or* in 2 divided doses with last dose no later than early evening ADULT Dosage information for adults is the same as above. The usual maintenance dose is 80mg to 100mg. **Methylphenidate** **Products Available:- Xenidate® Matoride®** Ritalin®, Concerta XL® , Medikinet ® or Equasym XL® The MR brand of choice in Barnsley for new patients is **Xenidate®** XL tablets. Existing patients can remain on **Matoride®** XL tablets. Matoride® XL is available in 18mg, 36mg and 54mg tablets. Xenidate® XL is available in 18mg, 27mg, 36mg and 54mg tablets. Child 4–6 years 2.5 mg twice daily increased if necessary at weekly intervals by 2.5 mg daily to max. 1.4 mg/kg daily in divided doses; discontinue if no response after 1 month, suspend treatment every 1–2

	years to assess condition Child 6–18 years Initially 5 mg 1–2 times daily, increased if necessary at weekly intervals by 5–10 mg daily; usual max. 60 mg daily in divided doses but may be increased to 2.1 mg/kg daily (max. 90 mg daily) under the direction of a specialist; discontinue if no response after 1 month, review treatment every 1–2 years to assess condition **ADULT over 18 years ,** 5 mg 2–3 times daily increased if necessary at weekly intervals according to response, max. 100 mg daily in 2–3 divided doses; the dose should be individually adjusted, based on response and tolerability and in some cases doses above 100mg may be required. *Evening dose* If effect wears off in evening (with rebound hyperactivity) a dose at bedtime may be appropriate (establish need with trial bedtime dose) *Note* Treatment may be started using a modified-release preparation **Methylphenidate modified release preparations** Modified-release preparations should be given as a single dose in the morning. They may be useful in the following situations: Secondary school children where problems of safety and compliance are important. Other children who are difficult to maintain on immediate release tablets. Modified-release preparations may increase adherence and be preferred if there is concern about misuse or drug diversion. **Dexamfetamine** **Products Available:- Dexedrine®** CHILD 3-5years, 2.5mg daily and increase if necessary by 2.5mg daily at weekly intervals CHILD 6–18 years, initially 5–10 mg daily, increased if necessary at weekly intervals by 5 mg daily, usual max. 1 mg/kg (up to 20 mg) daily (40 mg daily has been required in some children) ADULT over 18 year, initially 5mg twice daily, increased at intervals according to response; maximum 60mg daily *Note* Maintenance dose given in 2–4 divided doses *Evening dose* If effect wears off in evening (with rebound hyperactivity) a dose at bedtime may be appropriate (establish need with trial bedtime dose) **Lisdexamfetamine** **Products Available:- Elvanse®▼Elvanse Adult®▼** ADULT over 18 years and CHILD 6–18 years, initially 30 mg once daily in the morning, increased if necessary at weekly intervals by 20 mg; max. 70 mg daily (discontinue if response insufficient after 1 month) **Guanfacine** **Products Available:- Intuniv®▼** For all patients, the recommended starting dose is 1 mg of guanfacine, taken orally once a day. The dose may be adjusted in increments of not more than 1mg per week. Dose should be individualised according to the patient's response and tolerability, age and weight. The recommended maintenance dose range is 0.05-0.12 mg/kg/day. If using guanfacine for extended periods (over 12 months) usefulness of guanfacine should be assessed every 3 months for the first year and then at least yearly. Consider trial periods off medication to assess the patient's functioning without pharmacotherapy, preferably during times of school holidays.
Cautions and Contraindications	**Atomoxetine** • cardiovascular disease including hypertension and tachycardia; structural cardiac

abnormalities; monitor growth in children; QT interval prolongation (avoid concomitant administration of drugs that prolong QT interval);
- psychosis or mania;
- history of seizures;
- aggressive behaviour, hostility, or emotional lability;
- susceptibility to angle-closure glaucoma;
- Hepatic disorders following rare reports of hepatic disorders, patients and carers should be advised of the risk and be told how to recognise symptoms; prompt medical attention should be sought in case of abdominal pain, unexplained nausea, malaise, darkening of the urine, or jaundice
- Suicidal ideation following reports of suicidal thoughts and behaviour, patients and their carers should be informed about the risk and told to report clinical worsening, suicidal thoughts or behaviour, irritability, agitation, or depression

Methylphenidate
- Children under four years of age.
- Anxiety and/or overt agitation/psychosis/suicidal ideation.
- Tourette's Syndrome: Methylphenidate can be used after the risks have been discussed with the family.
- Glaucoma
- Thyrotoxicosis
- History of drug and alcohol misuse
- Hypertension
- Cardiac arrhythmia
- Epilepsy (particularly poorly controlled epilepsy. Children with well-controlled epilepsy can be considered for careful introduction of Methylphenidate or consider dexamfetamine)
- Pregnancy /breast feeding, unless absolutely essential – females of child-bearing potential (i.e. post-menarche) should not use methylphenidate unless clearly necessary
- Certain hereditary metabolic disorders (see SPC)
- Chronic abuse of methylphenidate may produce tolerance and dependence (resulting in abnormal behaviour and psychosis).

Dexamfetamine
- cardiovascular disease including moderate to severe hypertension, structural cardiac abnormalities, advanced arteriosclerosis,
- hyperexcitability or agitated states,
- hyperthyroidism,
- history of drug or alcohol abuse
- anorexia;
- psychosis or bipolar disorder; monitor for aggressive behaviour or hostility during initial treatment;
- history of epilepsy (discontinue if convulsions occur);
- tics and Tourette syndrome (use with caution)—discontinue if tics occur; monitor growth in children (see also below);
- susceptibility to angle-closure glaucoma;
- avoid abrupt withdrawal; data on safety and efficacy of long-term use not complete;

Lisdexamfetamine

As dexamfetamine (above)

Guanfacine

Bradycardia (risk of torsade de pointes); heart block (risk of torsade de pointes); history of cardiovascular disease; history of QT-interval prolongation; hypokalaemia (risk of torsade de pointes)

Pregnancy and Lactation

Atomoxetine

Pregnancy no information available; avoid unless potential benefit outweighs risk

	Breast-feeding avoid—present in milk in *animal* studies **Methylphenidate** Pregnancy limited experience—avoid unless potential benefit outweighs risk; toxicity in *animal* studies Breast-feeding no information available—avoid **Dexamfetamine** Pregnancy avoid (retrospective evidence of uncertain significance suggesting possible embryotoxicity) Breast-feeding significant amount in milk—avoid **Lisdexamfetamine** Pregnancy manufacturer advises use only if potential benefit outweighs risk Breast-feeding manufacturer advises avoid—present in human milk
Adverse Drug Reactions	**Atomoxetine** Anorexia, dry mouth, nausea, vomiting, abdominal pain, constipation, dyspepsia, flatulence; palpitation, tachycardia, increased blood pressure, postural hypotension, hot flushes; sleep disturbance, dizziness, headache, fatigue, lethargy, depression, psychotic or manic symptoms, aggression, hostility, emotional lability, drowsiness, anxiety, irritability, tremor, rigors; urinary retention, enuresis, prostatitis, sexual dysfunction, menstrual disturbances; mydriasis, conjunctivitis; dermatitis, pruritus, rash, sweating, weight changes; *less commonly* suicidal ideation (see Suicidal Ideation, above), cold extremities; *very rarely* hepatic disorders (see Hepatic Disorders, above), seizures, angle-closure glaucoma, and Raynaud's phenomenon **Methylphenidate** Insomnia, decreased appetite, stomach-ache and headache, the latter three usually mild and transient. Insomnia may be controlled by altering the dosage times. There is little evidence to suggest that long term treatment suppresses height and weight gain. Other side effects include those of drowsiness, dizziness, dyskinesia, abdominal pain, nausea/vomiting, dry mouth, tachycardia, palpitations, arrhythmias, Changes in BP and heart rate, rash, pruritus, urticaria, fever, arthralgia, hair loss, very rarely leucopenia, thrombocytopenia, anaemia and other – moderately reduced weight gain and slight growth retardation **Dexamfetamine** Insomnia, restlessness, irritability and excitability, night terrors, euphoria, tremor, dizziness, aggression, paranoia, anxiety, confusion, depression, fatigue, headache; seizures (see also Cautions); dependence and tolerance, psychosis; anorexia, gastro-intestinal symptoms, growth restriction in children (see also under Cautions); dry mouth, sweating, tachycardia (and anginal pain), palpitation, myocardial infarction, hypertension, hypotension; impotence; visual disturbances; alopecia, rash; cardiomyopathy reported with chronic use; cardiovascular collapse; cerebral vasculitis; central stimulants have provoked choreoathetoid movements and dyskinesia, tics and Tourette syndrome in predisposed individuals (see also Cautions above); *very rarely* angle-closure glaucoma **Lisdexamfetamine** nausea, decreased appetite, vomiting, diarrhoea, dry mouth, abdominal cramps, dyspnoea, sleep disturbances, tics, aggression, headache, dizziness, drowsiness, mydriasis, labile mood, weight loss, pyrexia, malaise, growth restriction in children (see also under Cautions and notes above); *less commonly* anorexia, tachycardia, palpitation, hypertension, logorrhoea, anxiety, paranoia, restlessness, depression, dysphoria, dermatillomania, mania, hallucination, sweating, tremor, visual disturbances, sexual dysfunction, rash; *very rarely* angle-closure glaucoma; *also reported* cardiomyopathy, euphoria, seizures (see also Cautions), central stimulants have provoked choreoathetoid movements and dyskinesia, and Tourette syndrome in predisposed individuals **Guanfacine** Abdominal pain; anxiety; bradycardia; constipation; decreased appetite; depression; diarrhoea; dizziness; dry mouth; enuresis;headache; hypotension; irritability; malaise; mood lability;nausea; rash; sleep

<table>
<tr><td></td><td>disturbance; somnolence; vomiting; weight increase</td></tr>
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<u>Atomoxetine</u>
Amiodarone increased risk of ventricular arrhythmias when atomoxetine given with amiodarone. Antidepressants possible increased risk of convulsions when atomoxetine given with antidepressants and increased risk of ventricular arrhythmias when atomoxetine given with tricyclics. Metabolism of atomoxetine reduced when given with fluoxetine and paroxetine. Antipsychotics increased risk of ventricular arrhythmias when atomoxetine given with antipsychotics that prolong the QT interval
Buproprion

<u>Methylphenidate</u> may inhibit the metabolism of coumarin anti-coagulants, some anti-convulsants (e.g. phenobarbitone, phenytoin, primidone), tricyclic anti-depressants, and phenylbutazone-the dosage of these drugs may have to be reduced. Methylphenidate should be used in caution with patients receiving MAOI’s (should never be used at the same time as, or within 14 days of), as there is a risk of hypertensive crisis. Methylphenidate can affect the metabolism of Warfarin and coumarin anticoagulants (may increase INR), can antagonize the hypotensive action of adrenergic neurone blockers and guanethidine. Cardiac arrhythmias may occur when used with amphetamines, tricyclic antidepressants or volatile liquid. Serious adverse events have been reported when used with Clonidine (the cause has not been established). Therefore avoid concomitant use of Clonidine or other centrally acting alpha-2-agonists.Stimulant effect of Methylphenidate is inhibited by chlorpromazine, haloperidol and lithium. Urinary excretion of Methylphenidate is affected by urinary alkinisers (decreased) and acidifiers (increased). Disulfiram may inhibit metabolism and excretion of Methylphenidate. Alcohol should be avoided as it may exacerbate the adverse CNS side-effects of Methylphenidate. The CNS stimulation effects of Methylphenidate can be additive when used with other chemicals and medications used to stimulate the CNS, such as caffeine (in coffee tea and cola drinks and pseudoephedrine (in cold and cough preparations).

<u>Dexamfetamine</u>
Chlorpromazine- dexamfetamine possibly antagonises antipsychotic effects of chlorpromazine
Other Antipsychotics - hypertensive effect of dexamfetamine antagonised by antipsychotics

<u>Lisdexamfetamine</u>

As dexamphetamine (above)

<u>Guanfacine</u>
The pharmacodynamic effect of guanfacine can have an additive effect when taken with other products known to cause
sedation (eg CNSdepressants such as hypnotics, antidepressants or alcohol),
hypotension (eg antihypertensives) or
QT prolongation (eg. Antipsychotics)

CYP3A4/5 inhibitors and inducers, plasma concentrations of guanfacine may be elevated or lowered, potentially affecting the efficacy and safety of guanfacine. Guanfacine can increase plasma concentrations of concomitantly administered medicinal products that are metabolised via CYP3A4/5
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Communication

Specialist to GP
The specialist will inform the GP when they have initiated methylphenidate, atomoxetine dexamfetamine lisdexamfetamine or guanfacine After the 3 month initiation period, the specialist will write to the GP to request they take over prescribing and where possible give an indication as to the expected length of treatment. The Specialist will also send a Shared care request form to support the GP in undertaking shared care. (Appendix A)
GP to specialist
If the GP has concerns over the prescribing of methylphenidate, atomoxetine dexamfetamine lisdexamphetamine, or guanfacine they will contact the specialist as soon as possible.

Immediate advice and support

Contact Details	Telephone No	Fax No	Email
Child and Adolescent Psychiatrists Dr Niloufar Mirhaghani	01226 644829	01226 433194	niloufar.mirhaghani@swyt.nhs.uk
Child & Adolescent Unit ADHD Specialist Nurse	01226 644829	01226 433194	Jo.Newing@swyt.nhs.uk
Dr Ovidiu Sandica Consultant child and adolescent Psychiatrist	01226 644829	01226 433194	Ovidiu.sandica@swyt.nhs.uk
Dr Lourence Lewis-Hanna Consultant child and adolescent Psychiatrist	01226 644829	01226 433194	Lourence.lewis-hanna@swyt.nhs.uk
Dr Aly Middleton, Specialty Doctor	01226 644829	01226 433194	Aly.middleton@swyt.nhs.uk
Adult ADHD Prof. Marios Adamou	01924 328102		Marios.**Adamou**@swyt.nhs.uk
Barnsley Hospital Foundation Trust Medicines Information	01226 432857	01226 434431	GilllianSmith2@nhs.net
Lead Pharmacist SWYPFT Barnsley BDU Sarah Hudson	01226 644339		Sarah.hudson@swyt.nhs.uk
Chris Lawson, Head of Medicines Optimisation, Barnsley CCG	01226 433798		Chris.lawson@nhs.net

References

1. NICE Clinical Guideline NG87. Attention deficit hyperactivity disorder. Available at: https://www.nice.org.uk/guidance/ng87 Accessed 31.10.18
2. Summary of Product Characteristics. Accessed from www.medicines.org.uk Accessed 31.10.18
3. British National Formulary, BNF accessed online www.medicinescomplete.com Accessed 31.10.18

Further Resources

- Hyperactivity Children's Support Group
  Sally Bunday, 71 Whyke Lane, Chichester, West Sussex, PO19 2LD, BA13 4DL Helpline: 01243 551313
- Training and publications for health and education professionals: www.devdis.com/index.html
- Information for parents and professionals: www.attention.com
- Addis website is http://www.addiss.co.uk (good info site for parents)
- The Milton Keynes group now have a website, http://www.mkadhd.org.uk
- The royal college of psychiatrists website with info on aspects of C& A mental health including ADHD http://www.rcpsych.ac.uk/mentalhealthinformation/childrenandyoungpeople.aspx

- ADHD alliance info http://www.adhdalliance.org.uk

Appendix A – Shared Care request form (Amber) ADHD

- Specialist to complete when requesting GP to enter a shared care arrangement.
- GP to return signed copy of form.
- Both parties should retain a signed copy of the form in the patient's record.

From (**Specialist**): _____ **To** (**GP**): _____

Patient details

Name: _____ ID Number: _____

Address: _____ DOB: _____

Diagnosed condition: _____

Amber Drug details

Drug name: _____ Dose: _____

Date of initiation: _____ Length of treatment: _____

The patient will be reviewed by the Consultant on: _____

The patient should be reviewed by the GP by: _____

Monitoring

The following monitoring should be undertaken by the GP:

Parameter	Date next test due	Frequency

Communication

Consultant
Telephone number: _____ Fax number:_____

Email address: _____

Specialist Nurse
Telephone number: _____ Fax number: _____

Email address: _____

Confirmation of acceptance of shared care

Specialist (Doctor/Nurse) name: _____

Specialist (Doctor/Nurse) signature: _____ Date: _____

I, Dr ……., can confirm I :

☐ accept the request to participate in shared care for the patient named above.

☐ reject the request to participate in shared care for the patient named above. The reason for this being ……..

GP signature: _____ Date: _____

To save resources you have been sent appendix A of the shared care document. The full document (methylphenidate, dexamfetamine, atomoxetine, lisdexamphetamine and guanfacine for the treatment of ADHD in children, young people and adults, *date approved February 2019)* can be accessed on the Barnsley BEST website at the following link:
http://best.barnsleyccg.nhs.uk/clinical-support/medicines/shared-care-guidelines/

Or via the Barnsley Area Formulary www.barnsleyformulary.nhs.uk