





Chapter 6. Endocrine

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Key

	Red drug see GMMMG RAG list <i>Click on the symbols to access this list</i>
	Amber drug see GMMMG RAG list <i>Click on the symbols to access this list</i>
	Green drug see GMMMG RAG list <i>Click on the symbols to access this list</i>
U	If a medicine is unlicensed this should be highlighted in the template as follows Drug name U
	Not Recommended
OTC	Over the Counter
Order of Drug Choice	Where there is no preferred 1 st line agent provided, the drug choice appears in alphabetical order.

BNF chapter	6	Endocrine
Section	6.1	Drugs used in Diabetes
Subsection	6.1.1	Insulin
Subsection	6.1.1.1	Short-acting insulin
Soluble insulin		
Additional notes		
<ul style="list-style-type: none"> Patients starting on insulin should receive an insulin passport; See the adult patient's passport to safer insulin use (NPSA). A passport should be provided by the prescriber initiating treatment The NPSA issued an alert in June 2010 for the safer administration of insulin. All patients starting on insulin must inform the DVLA and also their motor vehicle insurance company. Insulins are available in a variety of vial, cartridge and pre-loaded pen presentations. Not all cartridges fit all pens. NICE NG17: Type 1 diabetes in adults: diagnosis and management NICE NG28: Type 2 diabetes in adults: management NICE NG19: Diabetic foot problems: prevention and management 		
First choice	Actrapid® (Novo Nordisk) <ul style="list-style-type: none"> 10ml vial 	
Alternatives	Humulin S® (Lilly) <ul style="list-style-type: none"> 3ml cartridge (via Autopen® Classic or HumaPen®) 10ml vial Insuman® Rapid (Sanofi-Aventis) <ul style="list-style-type: none"> 3ml cartridge (via ClikSTAR® or Autopen® 24) 	
Rapid acting insulin analogues		
First choice	Apidra® (Sanofi-Aventis) <ul style="list-style-type: none"> 3ml cartridge (via ClikSTAR® or Autopen® 24) 3ml prefilled disposable pen 10ml vial Insulin lispro Sanofi▼ (Sanofi) <ul style="list-style-type: none"> 3ml cartridge (via JuniorSTAR®, Tactipen®, AllStar® and AllStar PRO® pens) 3ml prefilled disposable pen 10ml vial 	
Alternatives	NovoRapid® (Novo Nordisk) <ul style="list-style-type: none"> 3ml cartridge (via NovoPen® devices) 3ml prefilled disposable pen, 10ml vial 1.6ml PumpCart (for infusion pumps) 	

Subsection 6.1.1.2 Intermediate and long acting insulin		
Additional notes		
<ul style="list-style-type: none"> Any decision to commence an insulin analogue needs to be balanced carefully against the lack of long term safety data and increased prescribing costs (see NPC document 'Key Therapeutic Topics' for full information). The NICE guideline on type 2 diabetes; NICE NG28: Type 2 diabetes in adults: management recommends that, when insulin therapy is necessary, human NPH (isophane) insulin (e.g. Insulatard®, Humulin I® or Insuman® Basal) is the preferred option. Long-acting insulin analogues have a role in some patients, and can be considered for those who fall into specific categories e.g. those who require assistance from a carer or healthcare professional to administer their insulin injections, or those with problematic hypoglycaemia. However, for most people with type 2 diabetes, long-acting insulin analogues offer no significant advantage over human NPH insulin and are much more expensive. 		
Intermediate Acting Insulin (Isophane)		
First choice	Insuman® Basal (Sanofi-Aventis) <ul style="list-style-type: none"> 3ml cartridge (via <i>ClikSTAR®</i> or <i>Autopen®</i> 24 devices) 3ml prefilled disposable pen – <i>SoloSTAR®</i> 5ml vial 	NICE NG28: Type 2 diabetes in adults: management
Alternatives	Insulatard® (Novo Nordisk) <ul style="list-style-type: none"> 3ml cartridge (via <i>NovoPen®</i> 5 device) 3ml prefilled disposable pen - <i>InnoLet®</i> 10ml vial Humulin I® (Lilly) <ul style="list-style-type: none"> 3ml cartridge (via <i>HumaPen® Luxura</i> device) 3ml prefilled disposable pen – <i>KwikPen®</i> 10ml vial 	
Long Acting Insulin Analogues		
First choice	Abasaglar®▼ (Insulin Glargine, Eli Lilly) <ul style="list-style-type: none"> 3ml cartridge (via <i>HumaPen Savvio®</i>) 3ml prefilled disposable pen (via <i>KwikPen®</i>) 	GM NTS: Insulin Glargine Biosimilars for T1DM and T2DM NICE NG28: Type 2 diabetes in adults: management
Alternatives	Levemir® (Insulin Detemir, Novo Nordisk) <ul style="list-style-type: none"> 3ml cartridges (via <i>NovoPen®</i> 4 device) 3ml prefilled disposable pen - <i>FlexPen®</i> or <i>Innolet®</i> (only for patients with manual dexterity problems) 	
Biphasic Insulin		
First choice	Soluble/Isophane Mixtures Humulin M3® (Lilly) <ul style="list-style-type: none"> 3ml cartridge (via <i>HumaPen® Luxura</i> device) 3ml prefilled disposable - <i>KwikPen®</i> 10ml vial 	

	<p>Insuman® Comb 25 (Sanofi-Aventis)</p> <ul style="list-style-type: none"> • 3ml cartridge (via <i>ClikSTAR®</i> or <i>Autopen® 24</i> devices) • 3ml prefilled disposable pen - <i>SoloSTAR®</i> • 5ml vial <p>Insuman® Comb 15 (Sanofi-Aventis)</p> <ul style="list-style-type: none"> • 3ml cartridge (via <i>ClikSTAR®</i> or <i>Autopen® 24</i> devices) <p>Insuman® Comb 50 (Sanofi-Aventis)</p> <ul style="list-style-type: none"> • 3ml cartridge (via <i>ClikSTAR®</i> or <i>Autopen® 24</i> devices) 	
Alternatives	<p>Intermediate Acting Analogue Mixtures</p> <p>NovoMix® 30 (Novo Nordisk)</p> <ul style="list-style-type: none"> • 3ml cartridge (via <i>NovoPen® 4</i> device) • 3ml prefilled disposable pen - <i>FlexPen®</i> <p>Humalog® Mix25 (Lilly)</p> <ul style="list-style-type: none"> • 3ml cartridge (via <i>HumaPen® Luxura</i> device) • 3ml prefilled disposable pen - <i>KwikPen®</i> • 10ml vial <p>Humalog® Mix50 (Lilly)</p> <ul style="list-style-type: none"> • 3ml cartridge (via <i>HumaPen® Luxura</i> device) • 3ml disposable prefilled pen - <i>KwikPen®</i> 	
<p>Additional notes</p> <ul style="list-style-type: none"> • Biphasic analogue insulin (Novomix, Humalog Mix) do not offer any advantage over conventional human biphasic insulin in terms of efficacy, long term outcomes or safety but they cost considerably more. 		
Subsection	6.1.1.2 Animal insulins	
Bovine and Porcine Insulin		
<p>Additional notes</p> <ul style="list-style-type: none"> • Some long-standing type 1 diabetic patients may be on animal insulin. These are made by the company Wockhardt and come in 10ml vials or 3ml Cartridges that fit into the <i>Autopen Classic®</i> which is available on prescription • Patients need not be transferred to human insulin unless clinical need dictates • Human insulin and analogues should be used in preference to animal insulin 		
Subsection	6.1.1.3 Hypodermic equipment	
<p>Lancets, needles, syringes and accessories are listed under Hypodermic Equipment in Part 1XA of the Drug Tariff.</p>		
Lancets		
<p>Additional notes</p> <ul style="list-style-type: none"> • There are many different lancets available. Prescribing of lancets should be based on the compatibility of the device the patient has. • Finger-pricking devices are not prescribable on the NHS 		

Needles

First choice

4mm 31G needles

Additional notes

- First choice should usually be a 4mm needle to reduce injection pain

Do Not Prescribe

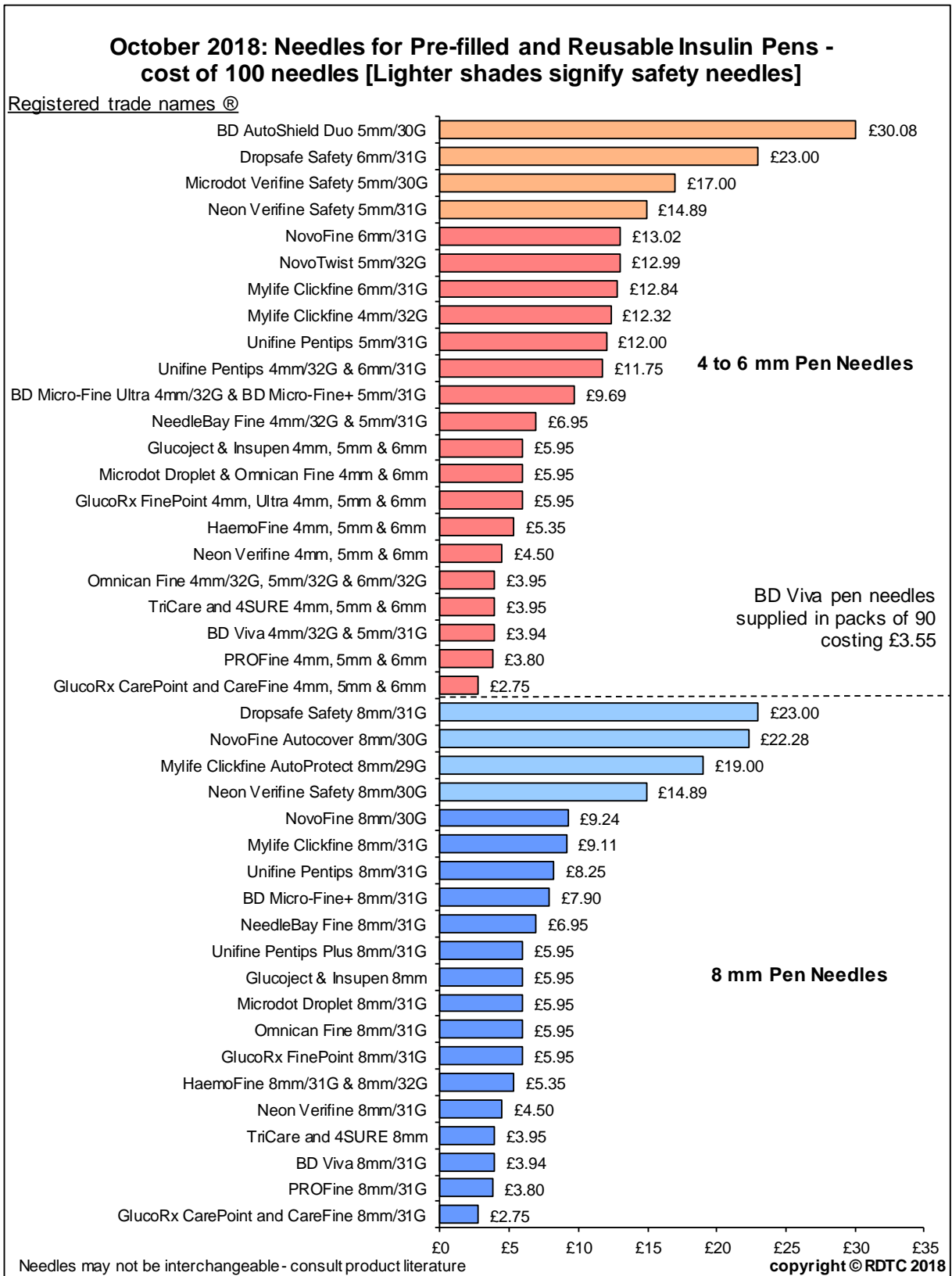
Pen needles 8 mm, 10 mm or 12 mm in length

Criterion 1 (see RAG list)


Pen needles costing in excess of £6 per 100

Criterion 2 (see RAG list)

See cost comparison chart below




Needle clipping device		
First choice	BD Safe-Clip[®]	Should be given to all patients who do not have a sharps bin
Alternatives	Sharpsguard[®] 1 litre & 5 litre sharps bin Sharpsafe[®] 1 litre sharps bin	5 litre sharps bins are suitable for regular users of injectables, e.g. insulin & insulin pumps.
Subsection	6.1.2 Anti Diabetic drugs	
Subsection	6.1.2.1 Sulphonylureas	
First choice	Gliclazide Immediate release tablets 40mg, 80mg Glimepiride Tablets 1mg, 2mg, 4mg	
Do Not Prescribe	Chlorpropamide Tablets Gliclazide MR Modified release tablets (e.g. Diamicon [®] MR)	<u>Criterion 1 (see RAG list)</u> <u>Criterion 2 (see RAG list)</u>
Subsection	6.1.2.2. Biguanides	
First choice	Metformin Tablets 500mg, 850mg	
Alternatives	Metformin modified release Tablets 500mg, 750mg, 1g	
Additional notes		
<ul style="list-style-type: none"> Metformin modified release should only be used where the standard metformin tablets have been tried and are not tolerated due to GI problems. Any new prescription of the SR preparation should be reviewed soon after initiation (recommend checking HbA_{1c} after 3 months and assess patient for adherence to treatment / adverse effects), discontinue if not tolerated or ineffective. Metformin can be used in pregnancy under specialist supervision see NICE NG3: Diabetes in pregnancy Liquid formulations of metformin are available, however prescribers should note these are significantly more expensive, and should assess the requirement for a liquid preparation on an individual patient basis. In line with NICE PH38: Type 2 diabetes: prevention in people at high risk, metformin can be used to reduce the risk or delay the onset of T2DM in adult, overweight patients with impaired glucose tolerance and/or increased HbA_{1c} who are: <ul style="list-style-type: none"> at high risk of developing overt T2DM and still progressing towards T2DM despite implementation of intensive lifestyle change for 3-6 months 		

Subsection	6.1.2.3. Other antidiabetic drugs	
Thiazolidinediones (Glitazones)		
First choice	Pioglitazone Tablets 15mg, 30mg, 45mg	NICE NG28: Type 2 diabetes in adults: management NICE NG49: Non-alcoholic fatty liver disease (NAFLD): assessment and management MHRA DSU: Pioglitazone bladder cancer, Aug 2011 MHRA DSU: Pioglitazone cardiovascular safety, Jan 2011
Dipeptidylpeptidase-4 inhibitors (Gliptins)		
First choice	Alogliptin Tablets 6.25mg, 12.5mg, 25mg tablets	 NICE NG28 MHRA DSU: DPP4 inhibitors: risk of acute pancreatitis (Sept 2012)
Alternatives	Saxagliptin Tablets 5mg Sitagliptin Tablets 25mg, 50mg, 100mg Linagliptin Tablets 5mg	
Gliptin plus metformin		Only to be prescribed if genuine issue with adherence to therapy
First choice	Alogliptin plus metformin Tablets 12.5mg plus metformin 1000mg	
Alternatives	Saxagliptin plus metformin Tablets 2.5mg plus metformin 850mg / 1g Sitagliptin plus metformin Tablets 50mg plus metformin 1g Linagliptin plus metformin Tablets 2.5mg plus metformin 850mg/1g	Linagliptin is an alternative for patients with renal impairment (CrCl <50ml/min, eGFR <59ml/min)
Additional notes		
MHRA DSU: Gliptins: Risk of pancreatitis, Sept 2012 Acute pancreatitis associated with gliptins has been reported. Inform patients of the symptoms of acute pancreatitis. If pancreatitis is suspected, the DPP-4 inhibitor should be discontinued.		
<ul style="list-style-type: none"> • Only continue DPP-4 inhibitor therapy if the person has had a beneficial metabolic response (a reduction of at least 0.5 percentage points in HbA1c in 6 months) –as per NICE CG87. • Monotherapy: Saxagliptin, Sitagliptin and Linagliptin – only if metformin contra-indicated or not tolerated. Alogliptin is not licensed for monotherapy. • Renal impairment: <ul style="list-style-type: none"> ○ Alogliptin: Dose reduced to half of the recommended dose (12.5mg once daily) in moderate 		

- renal impairment. In patients with severe renal impairment one-quarter of the recommended dose (6.25mg once daily) should be administered.
- Linagliptin: No dose adjustment required.
 - Saxagliptin: Dose reduced to 2.5mg for use in moderate to severe renal impairment; caution in patients with severe renal impairment due to very limited experience of use in this group of patients.
 - Sitagliptin: Dose is 50mg per day for use in moderate renal impairment and 25mg per day for use in severe renal impairment.
- There are no head-to-head trial data to support the use of any gliptin over another in relation to patients who may fast during Ramadan.

GLP-1 receptor mimetics (glucagon-like peptide-1)

First choice DAILY preparation	Liraglutide (Victoza®) Disposable pen 0.6mg, 1.2mg	 NICE NG28: Type 2 diabetes in adults: management
Alternative DAILY preparation	Lixisenatide (Lyxumia®) Disposable pen 10mcg, 20mcg	
First choice WEEKLY preparation	Dulaglutide (Trulicity®) ▼ Disposable pen 0.75mg and 1.5mg	
Alternative WEEKLY preparation	Exenatide (Bydureon®) Disposable pen 2mg	

Additional notes

- GLP-1 mimetics should only be considered as third-line therapy in accordance with [NICE NG28](#)
- GLP-1 mimetics should only be continued if reduction of at least 1% point in HbA_{1c} AND a weight loss of at least 3% of initial body weight at 6 months
- For individuals with type 2 diabetes and established cardiovascular disease, GLP-1 receptor agonist therapies with proven cardiovascular benefit (currently liraglutide) should be considered


Sodium glucose cotransporter-2 (SGLT-2) inhibitor

<p>Canagliflozin (Invokana®) Tablets 100mg, 300mg</p> <p>Dapagliflozin (Forxiga®) Tablets 5mg, 10mg</p> <p>Empagliflozin (Jardiance®) ▼ Tablets 10mg, 25mg</p>	<p>NICE TA390: Canagliflozin, dapagliflozin and empagliflozin as monotherapies for treating type 2 diabetes</p> <p>NICE TA315: Canagliflozin in combination therapy for treating type 2 diabetes.</p> <p>NICE TA288: Dapagliflozin in combination therapy for treating type 2 diabetes</p> <p>NICE TA336: Empagliflozin in combination therapy for treating type 2 diabetes</p> <p>NICE TA418: Dapagliflozin in triple therapy for treating type 2 diabetes</p> <p>MHRA DSU: SGLT2 inhibitors: updated advice on the risk of diabetic ketoacidosis, April 2016</p> <p>MHRA DSU: Updated advice on increased risk of lower limb amputation (mainly toes), March 2017</p>
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Additional notes

- In individuals with type 2 diabetes and established cardiovascular disease, SGLT2 inhibitors with proven cardiovascular benefit (currently empagliflozin and canagliflozin) should be considered

Other antidiabetic agents (no class)		
First choice	Repaglinide Tablets 500micrograms, 1mg, 2mg	
Alternatives	Nateglinide Tablets 60mg, 120mg, 180mg	
Additional notes		
<ul style="list-style-type: none"> Nateglinide only licensed for use in combination with metformin. Cautioned in moderate hepatic impairment. <p>Repaglinide can be given as monotherapy or in combination with metformin. It should be avoided in patients >75 years old and in patients with severe liver disease.</p>		
Subsection	6.1.3 Diabetic ketoacidosis	
<p>Refer to national diabetic ketoacidosis guidance for management of this condition: The Management of Diabetic acidosis (full report)</p>		
Subsection	6.1.4 Treatment of hypoglycaemia	
First choice	Patients will normally be able to recognise and self-treat hypoglycaemia themselves with fast acting carbohydrate – e.g. 2 teaspoons of sugar, small glass of fruit juice, Coca-Cola® or Lucozade® Energy Original or 4 glucose tablets. This would be followed by the next meal if due or a snack e.g. sandwich, fruit or biscuits.	
Alternatives	<p>GlucoGel® Oral gel tube (containing 10g of glucose in each 23g weight tube) Pack Size: box of 3 tubes</p> <p>GlucaGen® Hypokit Injection: 1mg NB: Family members can be taught to inject GlucaGen® in emergencies where the patient becomes unconscious during a hypoglycaemic event.</p>	<p>Only to be used in specific circumstances as most patients will be able to take oral sugar</p> <p>If the patient is unconscious or experiencing frequent hypoglycaemic episodes (this may be an option first-line)</p>
Subsection	6.1.5 Treatment of diabetic nephropathy and neuropathy	
Diabetic neuropathy		
This section of the formulary should be used in conjunction with chapter 4 section 4.7.3 (Neuropathic pain)		
First choice	<p>Amitriptyline U Tablets 10mg, 25mg, 50mg</p> <p>Duloxetine Capsules 60mg</p>	<p>GMMMG neuropathic pain guideline</p> <p>NICE CG173: Neuropathic pain in adults: pharmacological management in non-specialist settings</p>

Alternatives	<p>Gabapentin Capsules 100mg, 300mg, 400mg</p> <p>Nortriptyline U Tablets 10mg, 25mg</p> <p>Pregabalin Capsules 25mg, 50mg, 75mg, 100mg, 150mg, 200mg, 225mg, 300mg</p> <p>Capsaicin cream 0.075%</p>	<p>MHRA DSU: Gabapentin (Neurontin): risk of severe respiratory depression, Oct 2017</p> <p>Nortriptyline is useful if the patient gains benefit with amitriptyline but experiences side/adverse effects.</p> <p>Pregabalin should be prescribed as twice daily dosing to improve patient adherence, reduce overall treatment cost and is as efficacious as thrice-daily.</p>
Subsection	6.1.6 Diagnostic and monitoring devices for diabetes mellitus	
Blood monitoring		
<p>Each CCG will have their own agreed choice of blood glucose testing meters and corresponding test strips, due to local procurement arrangements.</p> <p>GMMMG recommendation on FreeStyle Libre Flash Glucose Monitoring System</p> <p>DVLA current guidance states there must be appropriate blood glucose monitoring for patients receiving insulin therapy. This has been defined by the Secretary of State’s Honorary Medical Advisory Panel on Driving and Diabetes as no more than 2 hours before the start of the first journey and every 2 hours while driving. DVLA also provides advice for testing for blood glucose for patients receiving medication with a higher risk of causing hypoglycaemia.</p>		
Urinalysis – Glucose		
	Diastix®	
Urinalysis – Ketones		
	Ketostix® N.B. Tests for ketones by patients are rarely required unless they become unwell.	
Alternatives	All other test strips should only be used in clinics for proteinuria / microalbuminuria and renal screening.	
Chapter	6 Endocrine	
Section	6.2 Thyroid and antithyroid drugs	
Subsection	6.2.1 Thyroid hormones	
First choice	Levothyroxine Tablets 25 microgram, 50 microgram, 100 microgram	
Grey drugs	Liothyronine	 following specialist initiation

Items which are listed as Grey are deemed not suitable for routine prescribing but may be suitable for a defined patient population	<p>Only for individuals who, in exceptional circumstances, have an on-going need for liothyronine as confirmed by a consultant NHS endocrinologist.</p> <p>Liothyronine</p> <p>Hypothyroid crisis and short-term use post-thyroid surgery only</p>	<p>Criterion 2 (see RAG list)</p> <p>R for new patients only</p> <p>Criterion 2 (see RAG list)</p>
Do Not Prescribe	<p>Liothyronine combination products</p> <p>e.g. Armour Thyroid</p> <p>For oral administration</p>	Criterion 2 (see RAG list)
<p>Additional notes</p> <ul style="list-style-type: none"> Micrograms should not be abbreviated 		
Subsection	6.2.2 Antithyroid hormones	
First choice	<p>Carbimazole</p> <p>Tablets 5mg, 20mg</p>	
Alternatives	<p>Propylthiouracil</p> <p>Tablets 50mg</p>	<p>Gn</p> <p>Prescribing to remain with specialist care until stable.</p> <p>FDA: Propylthiouracil induced liver failure, April 2010</p>

Chapter	6	Endocrine
Section	6.3	Corticosteroids
Subsection	6.3.1	Replacement therapy
First choice	Fludrocortisone acetate Tablets (scored) 100 micrograms	
Additional notes		
<ul style="list-style-type: none"> When prescribing fludrocortisone do not abbreviate micrograms. 		
Subsection	6.3.2.	Glucocorticoid therapy
First choice	Prednisolone (NOT enteric coated) Tablets 1mg, 5mg, 25mg Hydrocortisone Tablets 10mg, 20mg Injection (as sodium phosphate) 100mg in 1ml Injection (as sodium succinate) 100mg Dexamethasone Tablets 500 microgram, 2mg Injection (as sodium phosphate) 4mg/ml Oral solution SF 2mg/5ml	
Alternatives	Betamethasone Injection 4mg in 1ml Soluble tablets 500 microgram Methylprednisolone Injection (as sodium succinate) 40mg, 125mg, 500mg, 1g, 2g (Solu-Medrone) Depot Injection (as acetate – aqueous suspension) 40mg/ml (Depo-Medrone) Tablets 100mg	
<p style="text-align: right;">MHRA DSU: Methylprednisolone injectable medicine containing lactose (Solu-Medrone 40 mg): do not use in patients with cows' milk allergy, Oct 2017</p>		
Additional notes		
<ul style="list-style-type: none"> Steroid cards should be issued to all patients who are prescribed steroids for longer than 3 weeks. 		
Do Not Prescribe	Prednisolone enteric coated tablets Prednisone MR tablets (e.g. Lodotra®)	<u>Criterion 2 (see RAG list)</u> <u>Criterion 2 (see RAG list)</u>

Chapter	6	Endocrine
Section	6.4	Sex hormones
Subsection	6.4.1.	Female sex hormones and their modulators
Subsection	6.4.1.1.	Oestrogens and HRT
<p>Additional notes</p> <p>The MHRA provides information on risks and benefits of HRT: MHRA DSU: Hormone Replacement Therapy, March 2007</p> <p>NICE NG23: Menopause: diagnosis and management</p> <p>Some low dose preparations only provide relief from menopausal symptoms.</p> <p>Other preparations offer relief from menopausal symptoms plus osteoporosis prophylaxis – check BNF.</p>		
<p>Sequential combined therapy – for women with a uterus</p>		
Options	<p>Elleste Duet® Tablets 1mg, 2mg Estradiol 1mg / 2mg plus Estradiol 1mg / 2mg + norethisterone 1mg</p> <p>Femoston® Tablets 1mg, 2mg Estradiol 1mg / 2 mg Plus Estradiol 1 mg/2 mg + dydrogesterone 10 mg</p> <p>Evorel Sequi® Patches Estradiol 50 micrograms plus Estradiol 50 micrograms + norethisterone acetate 170 micrograms</p>	<p>Patches should be reserved for use in patients with diabetes, liver disease or severe side effects</p>
<p>Continuous combined therapy – for women with a uterus</p>		
First choice	<p>Premique® low dose Tablets conjugated oestrogen 300micrograms + medroxyprogesterone acetate 1.5mg</p>	

<p>Alternatives</p>	<p>Kliovance® Tablets Estradiol 1mg + norethisterone acetate 500micrograms</p> <p>Kliofem® Tablets Estradiol 2mg + norethisterone acetate 1mg</p> <p>Femoston conti® Tablets Estradiol 0.5mg + dydrogesterone 2.5mg Estradiol 1mg + dydrogesterone 5.0mg</p> <p>Evorel conti® Patches Estradiol 50micrograms/24 hours + norethisterone acetate 170micrograms/24hours</p>	<p>Patches should be reserved for use in patients with diabetes, liver disease or severe side effects</p>
<p>Unopposed oestrogen – for women without a uterus</p>		
<p>First choice</p>	<p>Premarin® Tablets Conjugated oestrogen 300micrograms, 625micrograms, 1.25mg</p>	
<p>Alternatives</p>	<p>Elleste-Solo® Tablets Estradiol 1mg, 2mg</p> <p>Evorel® Patches Estradiol 25, 50, 75, 100micrograms</p>	<p>Patches should be reserved for use in patients with diabetes, liver disease or severe side effects</p>
<p>Others</p>		
	<p>Raloxifene hydrochloride Tablets 60mg</p>	<p>NICE TA161: Osteoporosis - secondary prevention including strontium</p>
<p>Subsection 6.4.1.2. Progestogens and progesterone receptor modulators</p>		
	<p>Medroxyprogesterone acetate Tablets 2.5mg, 5mg, 10mg</p> <p>Norethisterone Tablets 5mg</p>	

Progesterone receptor modulators

Additional notes:

MHRA Drug Safety Update: [Esmya \(ulipristal acetate\) and risk of serious liver injury: new restrictions to use and requirements for liver function monitoring before, during, and after treatment](#)

More than one treatment course is authorised only in women who are not eligible for surgery. Liver function monitoring is to be carried out in all women treated with Esmya:

- Before initiation of each treatment course
- During the first 2 treatment courses
- Whenever clinically indicated during subsequent treatment courses
- 2-4 weeks after completion of each treatment course.

Before initiation, discuss with women the rare risk of liver damage and advise them to seek urgent medical attention if they develop any symptoms or signs of liver injury. See [GMMMG Information Leaflet](#) for more detail.

	<p>Ulipristal acetate Tablets 5mg (Esmya®)</p>	<p>NICE CG44: Heavy menstrual bleeding: assessment and management</p>
	<p>For the treatment of moderate to severe symptoms of uterine fibroids prior to surgery</p>	<p>R NTS recommendation: Ulipristal acetate (Esmya®) for the treatment of moderate to severe symptoms of uterine fibroids prior to surgery</p>
	<p>For the intermittent treatment of moderate to severe symptoms of uterine fibroids in adult women of reproductive age who are not eligible for surgery. Approved for restricted use – see NTS recommendation</p>	<p>Gn Following specialist initiation NTS recommendation: Ulipristal (Esmya®) for the intermittent treatment of uterine fibroids</p>

Subsection	6.4.2. Male sex hormones and antagonists	
Testosterone and esters		
	<p>Intramuscular Injection Testosterone enatate 250mg/ml, 1ml amp Testosterone undecanoate 250mg/ml (Nebido®), 4ml amp</p> <p>Implant Testosterone 100mg, 200mg</p> <p>Gel 60g multi-dose dispenser Testosterone 2% (Tostran®)</p> <p>Gel 30 x 5g sachets Testosterone 1% (50mg/5ml) (Testogel®)</p> <p>Oral Testosterone (Restandol®) Capsules 40mg</p>	<p>Gn Following specialist initiation</p>
	<p>Mesterolone Tablets: 25mg</p>	
Do Not Prescribe	<p>Testosterone patches (e.g. Intrinsa®)</p>	<p><u>Criterion 1 (see RAG list)</u></p>
Other male sex hormones and antagonists		
	<p>Finasteride Tablets: 5mg</p>	<p>MHRA DSU (2017): Finasteride: rare reports of depression and suicidal thoughts</p>

Chapter	6	Endocrine
Section	6.5	Hypothalamic and pituitary hormones and anti-oestrogens
Subsection	6.5.1.	Hypothalamic and anterior pituitary hormones and anti-oestrogens
Anti-oestrogens		
First choice	Clomifene Tablets: 50mg	R
Additional notes		
<ul style="list-style-type: none"> Clomifene is only indicated for patients in whom ovulatory dysfunction has been demonstrated and other causes of infertility have been excluded or adequately treated 		
Anterior pituitary hormones – Corticotrophins		
This section is managed in Specialist care therefore is not considered in this formulary.		
Anterior pituitary hormones - Gonadotrophins		
This section is managed in Specialist care therefore is not considered in this formulary.		
Growth hormone		
	Somatropin Injection (s/c) 6mg (16unit cartridge) (Humatrope®) 12mg (36unit cartridge) (Humatrope®) MiniQuick® injection (s/c) Genotropin® (MiniQuick®) injection 0.2mg (0.6unit), 0.4mg, 0.6mg, 0.8mg, 1mg, 1.2mg, 1.4mg, 1.6mg, 1.8mg, 2mg	A NICE TA64: Growth hormone deficiency (adults) August 2003 R Adults, except in proven primary and secondary hypopituitarism.
Growth hormone receptor antagonists		
	Pegvisomant (Somavert®) Injection 10mg,15mg, 20mg	R
Hypothalamic hormones		
This section is managed in Specialist care therefore is not considered in this formulary		

Subsection	6.5.2 Posterior pituitary hormones and antagonists	
Posterior pituitary hormones		
First choice	<p>Desmopressin</p> <p>Tablets</p> <p>100microgram, 200micrograms</p>	
Alternatives	<p>Desmopressin</p> <p>Sublingual tablets</p> <ul style="list-style-type: none"> • 60micrograms (DDAVP® melt) • 120micrograms (Desmomelt®) • 240micrograms (Desmomelt®) <p>Nasal spray 6ml (60 sprays)</p> <ul style="list-style-type: none"> • 10micrograms per metered spray 	
Additional notes		
<ul style="list-style-type: none"> • MHRA DSU: Desmopressin nasal spray: Removal of the primary nocturnal enuresis (bedwetting) indication, Sept 2007 		
Antidiuretic hormone antagonists		
	<p>Tolvaptan[▼] (Jinarc®) – for treating autosomal dominant polycystic kidney disease only as per NICE TA358</p> <p>Tablets</p> <p>15mg, 30mg,</p> <p>45mg and 15mg</p> <p>60mg and 30mg</p> <p>90mg and 30mg</p>	<p>R</p> <p>NICE TA358: Tolvaptan for treating autosomal dominant polycystic kidney disease</p>

Chapter	6	Endocrine
Section	6.6.	Drugs affecting bone metabolism
Subsection	6.6.1.	Calcitonin and parathyroid hormone
Additional notes:		
NICE TA160: Raloxifene for the primary prevention of osteoporotic fragility fractures in postmenopausal women		
NICE TA161: Raloxifene and teriparatide for the secondary prevention of osteoporotic fragility fractures in postmenopausal women		
NICE TA464: Bisphosphonates for treating osteoporosis		
MHRA DSU: Bisphosphonates: atypical femoral fractures, June 2011		
MHRA DSU: Bisphosphonates: very rare reports of osteonecrosis of the external auditory canal, Dec 2015		
MHRA DSU: Strontium ranelate: cardiovascular risk—restricted indication and new monitoring requirements, March 2014		
First choice	Teriparatide (Forsteo®) 250micrograms/ml 2.4ml pre-filled pens	R For Specialist use only NICE TA161: Raloxifene and teriparatide for the secondary prevention of osteoporotic fragility fractures in postmenopausal women
Alternatives	Parathyroid hormone (Preotact®) Injection s/c: 1.61mg (14 dose)	R For Specialist use only
Subsection	6.6.2. Bisphosphonates and other drugs affecting bone metabolism	
Bisphosphonates		
First choice	Alendronic acid Tablet: 70mg (Once weekly preparation) Risedronate Tablet: 35mg (Once weekly preparation)	NICE TA464: Bisphosphonates for treating osteoporosis
Alternatives	Sodium clodronate Tablets: 800mg Zoledronic acid Solution for infusion vial: 4mg/5ml Infusion bottles: 4mg/100ml, 5mg/100ml	Specialist initiation only R Specialist use only NTS recommendation: zoledronic acid
Do Not Prescribe	Alendronic acid with vitamin D Tablets	Criterion 2 (see RAG list)

Other drugs affecting bone metabolism

Denosumab (Prolia®) – Osteoporosis in men & women
 Injection s/c
 60mg/ml x 1ml

Denosumab (Xgeva®) - Oncology indication
 Injection s/c
 120mg/ml x 1.7ml



R Specialist use only

[NTS recommendation: denosumab for the treatment of osteoporosis in men](#)
[NICE TA204: Denosumab – Osteoporotic fractures](#)
[MHRA DSU: denosumab, Feb 2013](#)
[MHRA DSU: denosumab, Sept 2014](#)
[MHRA DSU: denosumab and osteonecrosis of the jaw, July 2015](#)
[MHRA DSU: denosumab \(Prolia, Xgeva\): reports of osteonecrosis of the external auditory canal](#)
[MHRA DSU: denosumab \(Xgeva\)- risk of clinically significant hypercalcaemia following discontinuation](#)
[MHRA DSU: denosumab \(Xgeva\) – study data show new primary malignancies reported more frequently compared to zoledronate](#)

Chapter	6	Endocrine
Section	6.7.	Other endocrine drugs
Subsection	6.7.1.	Bromocriptine and other dopaminergic drugs
First choice	<p>Bromocriptine Tablets 1mg, 2.5mg</p> <p>Cabergoline Tablets 500micrograms</p>	See BNF chapter 4, section 4.9.1. for use in Parkinson's disease
Additional notes		
<ul style="list-style-type: none"> MHRA: Ergot derived dopamine agonists: risk of fibrotic reactions in chronic endocrine uses (2014) 		
Subsection	6.7.2	Drugs affecting gonadotrophins
Gonadorelin analogues		
First choice	<p>Goserelin Intradermal implant 3.6mg (every 28 days) 10.8mg (3 monthly)</p> <p>Leuprorelin Prefilled dual chamber syringe (DCS) 3.75mg (monthly) 11.25mg (every 3 months)</p>	<p>A (for licensed indications) See section 8.3.4.2. – leuprolinor use in prostate cancer and section 8.3.4.1. for use in breast cancer</p> <p>R (for long term, >6 months use, for precocious puberty, testosterone castration in sex offenders and all unlicensed uses)</p> <p>A (for licensed indications) See section 8.3.4.2. – for use in prostate cancer</p> <p>R (for long term, >6 months use, for precocious puberty, testosterone castration in sex offenders and all unlicensed uses)</p>
Alternatives	<p>Buserelin Nasal spray 150micrograms/metered spray Injection (s/c) 1mg/ml</p> <p>Nafarelin Nasal spray 200micrograms/metered spray</p>	R
Additional notes		
<ul style="list-style-type: none"> Goserelin and leuprorelin are included in this section for endometriosis only. Please refer to chapter 8 for other indications. Gonadorelin analogues are contraindicated for use longer than 6 months (do not repeat), where there is undiagnosed vaginal bleeding, in pregnancy and in breast-feeding. 		

Subsection	6.7.3. Metyrapone	
	Metyrapone Capsules 250mg	For specialist use only
Additional notes <ul style="list-style-type: none"> Metyrapone is used for Cushing’s syndrome, often in a lower dose combination with aminoglutethamide to reduce side effects. 		