

Chapter 6. Endocrine

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Key

	<p>Red drug see GMMMG RAG list Click on the symbols to access this list</p>
	<p>Amber drug see GMMMG RAG list Click on the symbols to access this list</p>
	<p>Green drug see GMMMG RAG list Click on the symbols to access this list</p>
	<p>If a medicine is unlicensed this should be highlighted in the template as follows Drug name U</p>
	<p>Not Recommended</p>
	<p>Over the Counter In line with NHS England guidance, GM do not routinely support prescribing for conditions which are self-limiting or amenable to self-care. For further details see GM commissioning statement.</p>
Order of Drug Choice	<p>Where there is no preferred 1st line agent provided, the drug choice appears in alphabetical order.</p>

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 MHRA DSU: Direct-acting antivirals for chronic hepatitis C: risk of hypoglycaemia in patients with diabetes (December 2018) 			
First choice	Actrapid® (Insulin human, Novo Nordisk)		
	<ul style="list-style-type: none"> 10ml vial 		
Alternatives	Humulin S® (Insulin human, Eli Lilly)		
	<ul style="list-style-type: none"> 3ml cartridge (via Autopen® Classic or HumaPen®) 10ml vial 		
Rapid acting insulin analogues			
First choice	Trurapi®▼ (Insulin aspart, Sanofi)		
	<ul style="list-style-type: none"> 3ml cartridge (via JuniorSTAR®, Tactipen®, AllStar® and AllStar PRO® pens) 3ml prefilled disposable pen 10ml vial 		
Alternatives	<p>Apidra® (Insulin glulisine, Sanofi)</p> <ul style="list-style-type: none"> 3ml cartridge (via ClikSTAR® or Autopen® 24) 3ml prefilled disposable pen 10ml vial <p>Admelog®▼ (Insulin lispro, Sanofi)</p> <ul style="list-style-type: none"> 3ml cartridge (via JuniorSTAR®, Tactipen®, AllStar® and AllStar PRO® pens) 3ml prefilled disposable pen 10ml vial <p>NovoRapid® (Insulin aspart, Novo Nordisk)</p> <ul style="list-style-type: none"> 3ml cartridge (via FlexPen® or FlexTouch® devices) 3ml prefilled disposable pen, 10ml vial 1.6ml PumpCart (for infusion pumps) 		

<p>Grey drugs</p> <p>Items which are listed as Grey are deemed not suitable for routine prescribing but may be suitable for a defined patient population</p>	<p>Fiasp® (Insulin aspart, Novo Nordisk)</p> <ul style="list-style-type: none"> 3ml cartridge (via FlexTouch® devices) 3ml prefilled disposable pen 10ml vial <p>Only for use in patients who:</p> <ul style="list-style-type: none"> Are pregnant or planning a pregnancy Have post-prandial glucose >10 mmol at 2 hours 	<p>G_n following specialist advice</p> <p>Criterion 3 (see RAG list)</p>
	<p>Lyumjev® (Insulin lispro, Eli Lilly)</p> <ul style="list-style-type: none"> 100 units/mL prefilled disposable pen, cartridge or vial 200 units/mL prefilled disposable pen <p>Only for use in patients with type 1 and type 2 diabetes, including patients using insulin pumps, who have significant post-prandial hyperglycaemia (>10 mmol/L at 2 hours) despite optimised use of conventional rapid acting insulin analogues (Humalog®, Novorapid® or Apridra®).</p> <p>Available in strengths of 100 units/mL and 200 units/mL. Care should be taken to ensure the correct dose is selected for prescribing, dispensing and administration.</p>	<p>G_n following specialist advice</p> <p>Criterion 2 (see RAG list)</p>

Subsection 6.1.1.2 Intermediate and long acting insulin

Additional notes

- 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 Key Therapeutic Topics on [type 2 diabetes medicines optimisation priorities](#) and [safer insulin prescribing](#) for more 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. Insuman® Basal, Insulatard®, or Humulin I®) **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.**

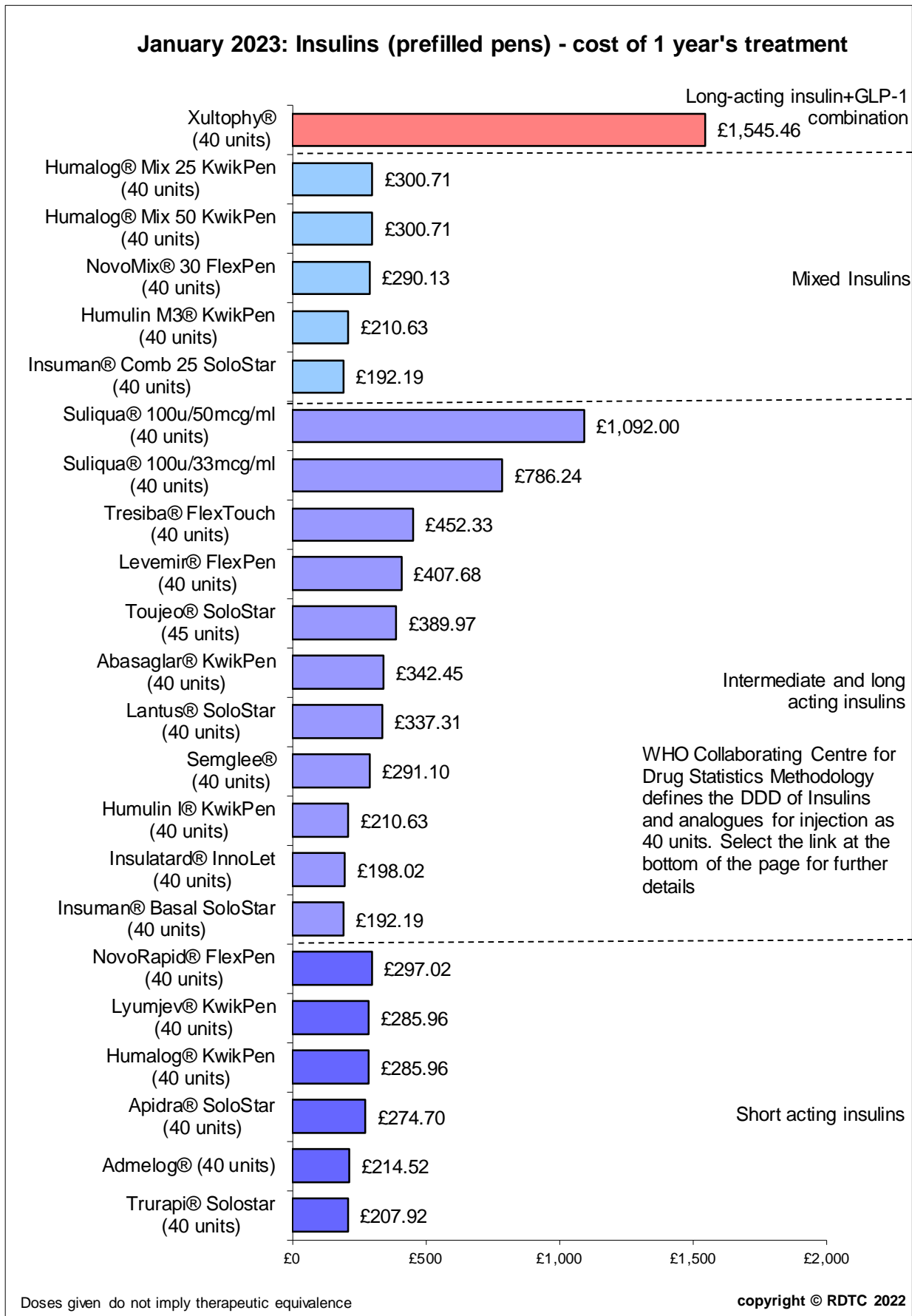
Intermediate Acting Insulin (Isophane)

<p>First choice</p>	<p>Humulin I® (Lilly)</p> <ul style="list-style-type: none"> 3ml cartridge (via HumaPen® Luxura device) 3ml prefilled disposable pen – KwikPen® 10ml vial 	<p>NICE NG28: Type 2 diabetes in adults: management</p>
<p>Alternatives</p>	<p>Insulatard® (Novo Nordisk)</p> <ul style="list-style-type: none"> 3ml cartridge (via NovoPen® 5 device) 3ml prefilled disposable pen - InnoLet® 10ml vial 	

Long Acting Insulin Analogues

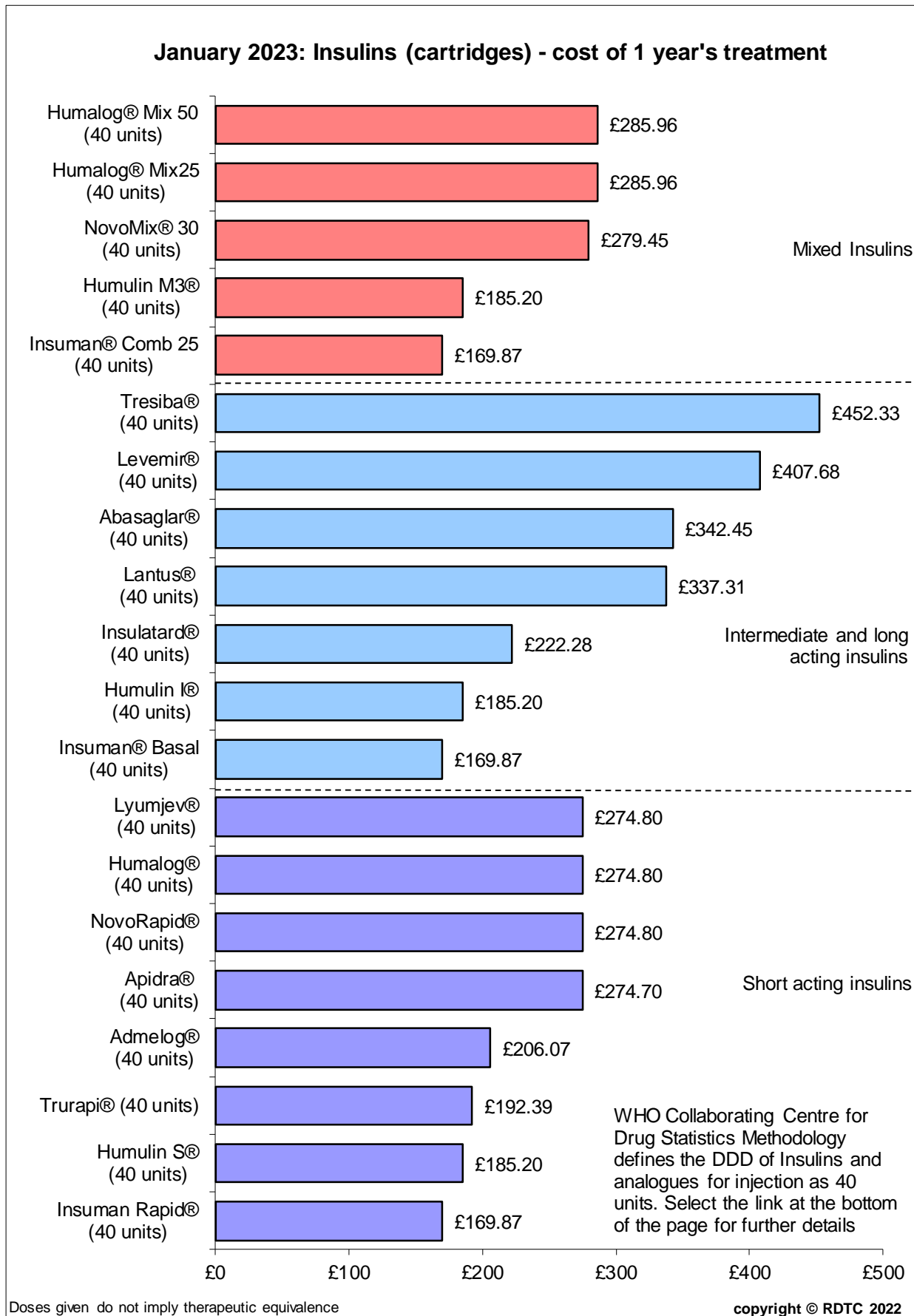
<p>First choice</p>	<p>Semglee®▼ (Insulin glargine, Mylan)</p> <ul style="list-style-type: none"> • 3ml prefilled disposable pen <p>Abasaglar® (Insulin glargine, Eli Lilly)</p> <ul style="list-style-type: none"> • 3ml cartridge (via HumaPen Savvio®) • 3ml prefilled disposable pen (via KwikPen®) 	<p>NICE NG28: Type 2 diabetes in adults: management</p>
<p>Alternatives</p>	<p>Levemir® (Insulin detemir, Novo Nordisk)</p> <ul style="list-style-type: none"> • 3ml cartridges (via NovoPen ® 4 device) • 3ml prefilled disposable pen - FlexPen® or Innolet® (only for patients with manual dexterity problems) 	<p>NICE NG17: Type 1 diabetes in adults: diagnosis and management</p>
<p>Grey drugs</p> <p>Items which are listed as Grey are deemed not suitable for routine prescribing but may be suitable for a defined patient population</p>	<p>Toujeo® (insulin glargine 300 units/mL, Sanofi)*</p> <ul style="list-style-type: none"> • 1.5mL prefilled disposable pen (SoloStar®) • 3ml prefilled disposable pen (DoubleStar®)** <p>Toujeo is a high-strength insulin* preparation. It may be considered as an option in people with Type 1 or Type 2 diabetes when one or more of the following criteria are met:</p> <ol style="list-style-type: none"> There is a requirement for flexible timing of injection (+/-3 hours) due to reliance on 3rd party assistance to administer insulin. There is pain as a consequence of high injection volumes of standard-strength insulin (high insulin dose alone is not a reason to switch). There are unacceptable nocturnal hypoglycaemic episodes despite intensive management on other basal analogues. This must be supported by appropriately recorded data (e.g. glucose monitoring device/blood glucose diaries) <p>* Toujeo preparations must always be prescribed by brand and device to minimise the risks associated with the prescribing, dispensing, and administration of high strength insulins.</p> <p>** Toujeo DoubleStar administers two units of insulin per click: there is a risk patients could receive double the dose of insulin if the wrong Toujeo product is dispensed or the Toujeo DoubleStar is used incorrectly by assuming one click is equivalent to one unit of insulin.</p>	<p>G_n following specialist advice</p> <p>Criterion 2 (see RAG list)</p> <p>FMESG recommendation</p>

	<p>Tresiba® (insulin degludec, Novo Nordisk)</p> <ul style="list-style-type: none"> • 100 units/mL prefilled disposable pen or cartridge • 200 units/mL prefilled disposable pen <p>For treatment of type 1 or type 2 diabetes, only for use:</p> <ol style="list-style-type: none"> If there is particular concern about nocturnal hypoglycaemia despite optimisation of medication regimen For patients with an unpredictable lifestyle (e.g. shift workers) For patients who need help from a carer or healthcare professional to administer injections [NEW from NICE NG17] <p>Available in strengths of 100 units/mL and 200 units/mL. Care should be taken to ensure the correct dose is selected for prescribing, dispensing and administration.</p>	<p>G_n following specialist initiation Criterion 3 (see RAG list)</p>
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Biphasic Insulin

First choice

Soluble/isophane Mixtures

Humulin M3[®] (Lilly)

- 3ml cartridge (via *HumaPen[®] Luxura* device)
- 3ml prefilled disposable - *KwikPen[®]*
- 10ml vial

Alternatives

Intermediate Acting Analogue Mixtures

NovoMix[®] 30 (Novo Nordisk)

- 3ml cartridge (via *NovoPen[®] 4* device)
- 3ml prefilled disposable pen - *FlexPen[®]*

Humalog[®] Mix25 (Lilly)

- 3ml cartridge (via *HumaPen[®] Luxura* device)
- 3ml prefilled disposable pen - *KwikPen[®]*
- 10ml vial

Humalog[®] Mix50 (Lilly)

- 3ml cartridge (via *HumaPen[®] Luxura* device)
- 3ml disposable prefilled pen - *KwikPen[®]*

Additional notes

- 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

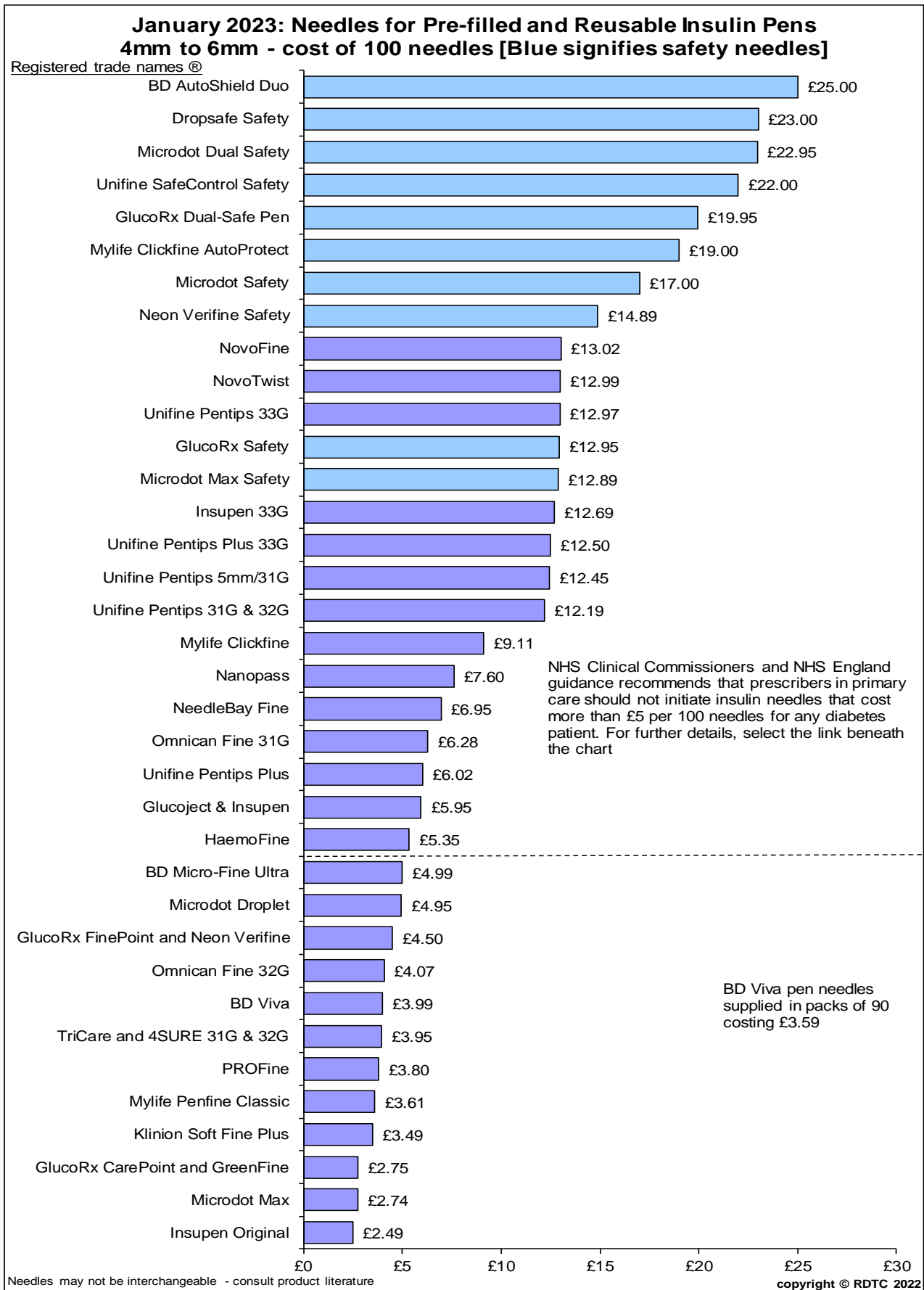
6.1.1.2 Animal insulins

Bovine and Porcine Insulin

Additional notes

- 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 *Autopen Classic[®]* 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	
Lancets, needles, syringes and accessories are listed under Hypodermic Equipment in Part 1XA of the Drug Tariff .		
Lancets		
Additional notes		
<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		
<ul style="list-style-type: none"> 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 Pen needles costing in excess of £5 per 100 See cost comparison chart below	<u>Criterion 1 (see RAG list)</u> <u>Criterion 2 (see RAG list)</u> <u>NHS England Items which should not be routinely prescribed in primary care: Guidance for CCGs</u>
Insulin pumps		
Insulin pumps and pump consumables specifically used for the deployment of the device are commissioned via Monitored Approval within CCGs, in line with NICE TA151		



[Items which should not routinely be prescribed in primary care: Guidance for CCGs](#)

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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	<u>MHRA DSU: Metformin and reduced vitamin B12 levels: new advice for monitoring patients at risk, June 2022</u>
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 <u>NICE NG3: Diabetes in pregnancy</u> and <u>MHRA DSU: Metformin in pregnancy: study shows no safety concerns, March 2022</u> 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 <u>NICE PH38: Type 2 diabetes: prevention in people at high risk</u>, 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	<p>Pioglitazone Tablets 15mg, 30mg, 45mg</p>	<p>NICE NG28: Type 2 diabetes in adults: management</p> <p>NICE NG49: Non-alcoholic fatty liver disease (NAFLD): assessment and management</p> <p>MHRA DSU: Pioglitazone bladder cancer, Aug 2011</p> <p>MHRA DSU: Pioglitazone cardiovascular safety, Jan 2011</p>
Dipeptidylpeptidase-4 inhibitors (gliptins)		
<p>Notes</p> <p>MHRA DSU: Gliptins: Risk of pancreatitis, Sept 2012</p> <p>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.</p> <ul style="list-style-type: none"> • 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. 		
First choice	<p>Sitagliptin Tablets 25mg, 50mg, 100mg</p>	<p></p> <p>NICE NG28</p> <p>MHRA DSU: DPP4 inhibitors: risk of acute pancreatitis (Sept 2012)</p> <p>Linagliptin is an alternative for use in patients with moderate or severe renal impairment (CrCl <50ml/min, eGFR <59ml/min)</p>
Alternatives	<p>Alogliptin Tablets 6.25mg, 12.5mg, 25mg tablets</p> <p>Linagliptin Tablets 5mg</p> <p>Saxagliptin Tablets 5mg</p>	
Gliptin plus metformin		

Only to be prescribed where there is a genuine issue with adherence to therapy


First choice	Sitagliptin plus metformin Tablets 50mg plus metformin 1g	MHRA DSU: Metformin and reduced vitamin B12 levels: new advice for monitoring patients at risk, June 2022
Alternatives	<p>Alogliptin plus metformin Tablets 12.5mg plus metformin 1000mg</p> <p>Saxagliptin plus metformin Tablets 2.5mg plus metformin 850mg / 1g</p> <p>Linagliptin plus metformin Tablets 2.5mg plus metformin 850mg/1g</p>	<p>MHRA DSU: Metformin and reduced vitamin B12 levels: new advice for monitoring patients at risk, June 2022</p> <p>Linagliptin is an alternative for patients with renal impairment (CrCl <50ml/min, eGFR <59ml/min)</p>

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

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 dulaglutide, liraglutide, semaglutide) should be considered


DAILY GLP-1 receptor mimetics

First choice	Liraglutide (Victoza®) Disposable pen 0.6mg, 1.2mg	 NICE NG28: Type 2 diabetes in adults: management
Alternatives	<p>Semaglutide (Rybelsus®) Oral tablets 3mg, 7mg, 14mg</p> <p>Where a patient expresses a preference for the oral option, prescribers should discuss that there are injectable options in the same class with proven cardiovascular benefit.</p> <p>An agent with proven cardiovascular benefit would be preferable to oral semaglutide in patients with established cardiovascular disease or high cardiovascular risk. This includes all patients with diabetes of 10 years duration plus one other risk factor (e.g. age over 50, hypertension, dyslipidaemia, smoking, or obesity).</p>	

Notes

Lixisenatide (Lyxumia®) 10 microgram and lixisenatide treatment initiation pack (10 microgram and 20 microgram) have been discontinued. This means no new patients can be initiated on lixisenatide. Patients who are currently clinically stable on lixisenatide may continue and should not be changed without clinical reason.

WEEKLY GLP-1 receptor mimetics

First choice	Semaglutide (Ozempic® ▼) Solution for injection. Disposable pen 0.25mg, 0.5mg and 1.0mg	
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	NB: semaglutide pre-filled pens contain FOUR doses per pen	NICE NG28: Type 2 diabetes in adults: management
Alternatives	<p>Dulaglutide (Trulicity®▼) Disposable pen 0.75mg, 1.5mg, 3 mg, 4.5 mg</p> <p>Exenatide (Bydureon®) Disposable pen 2mg</p> <p>NB: dulaglutide and exenatide pre-filled pens contain ONE dose per pen</p>	

Notes

NB: the GIP/GLP-1 agonist tirzepatide (Mounjaro®▼) is not approved by GMMMG. NICE guidance is [expected in April 2023](#). Tirzepatide should be considered non-formulary/not approved until guidance is available.

Sodium glucose cotransporter-2 (SGLT-2) inhibitors

Notes

- In individuals with type 2 diabetes and established cardiovascular disease, SGLT2 inhibitors with proven cardiovascular benefit should be considered. See [chapter 2](#) for use of SGLT2 inhibitors in heart failure.
- For individuals with type 2 diabetes and diabetic kidney disease, SGLT2 inhibitors with proven renal outcome benefit should be considered. See SPC for details of dosing and kidney function.

[NICE NG28: Type 2 diabetes in adults: management](#)

[NICE NG203: Chronic kidney disease: assessment and management](#)

[NICE TA390: Canagliflozin, dapagliflozin and empagliflozin as monotherapies for treating type 2 diabetes](#)

[MHRA DSU: SGLT2 inhibitors: updated advice on the risk of diabetic ketoacidosis, April 2016](#)

[MHRA DSU: Updated advice on increased risk of lower limb amputation \(mainly toes\), March 2017](#)

[MHRA DSU: SGLT2 inhibitors: reports of Fournier’s gangrene \(necrotising fasciitis of the genitalia or perineum\), February 2019](#)

[MHRA DSU: SGLT2 inhibitors: monitor ketones in blood during treatment interruption for surgical procedures or acute serious medical illness, March 2020](#)

First choices	<p>Canagliflozin (Invokana®) Tablets 100mg, 300mg</p>	NICE TA315: Canagliflozin in combination therapy for treating type 2 diabetes.
	<p>Dapagliflozin (Forxiga®) Tablets 5mg, 10mg</p>	<p>NICE TA288: Dapagliflozin in combination therapy for treating type 2 diabetes NICE TA418: Dapagliflozin in triple therapy for treating type 2 diabetes</p> <p>MHRA DSU: Dapagliflozin (Forxiga): no longer authorised for treatment of type 1 diabetes mellitus, Dec 2021</p> <p>Dapagliflozin 5mg is no longer authorised for the treatment of patients with T1DM and should no longer be used in this population.</p>
	<p>Empagliflozin (Jardiance®▼) Tablets 10mg, 25mg</p>	NICE TA336: Empagliflozin in combination therapy for treating type 2 diabetes

Alternative	Ertugliflozin (Steglatro®[▼]) Tablets 5mg, 15mg	NICE TA572: Ertugliflozin as monotherapy or with metformin for treating type 2 diabetes NICE TA583: Ertugliflozin with metformin and a dipeptidyl peptidase-4 inhibitor for treating type 2 diabetes
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Other antidiabetic agents (no class)

First choice	Repaglinide Tablets 500micrograms, 1mg, 2mg	
Alternatives	Nateglinide Tablets 60mg, 120mg, 180mg	

Additional notes

- Nateglinide only licensed for use in combination with metformin. Cautioned in moderate hepatic impairment.
- 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.

Subsection 6.1.3 Diabetic ketoacidosis

Refer to national diabetic ketoacidosis guidance for management of this condition:
[The Management of Diabetic acidosis \(full report\)](#)

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. Pack Size: box of 3 tubes (containing 10g of glucose in each 23g tube)</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>
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Subsection 6.1.5 Treatment of diabetic neuropathy

Diabetic neuropathy

See [chapter 4](#) section 4.7.3 (Neuropathic pain), and [GMMMG Guideline for Primary Care: Neuropathic Pain in Adults](#).

Subsection 6.1.6 Diagnostic and monitoring devices for diabetes mellitus

Blood monitoring

Each locality will have their own agreed choice of blood glucose testing meters and corresponding test strips, due to local procurement arrangements.

[GMMMG recommendation on FreeStyle Libre Flash Glucose Monitoring System](#)

[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.

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
NICE NG145: Thyroid disease: assessment and management NICE NG230: Thyroid cancer: assessment and management		
First choice	Levothyroxine Tablets 25 microgram, 50 microgram, 100 microgram	MHRA DSU: Levothyroxine: new prescribing advice for patients who experience symptoms on switching between different levothyroxine products, May 2021
Grey drugs Items which are listed as Grey are deemed not suitable for routine prescribing but may be suitable for a defined patient population	Liothyronine Where levothyroxine has failed, endocrinologists treating patients under the NHS may recommend liothyronine in exceptional circumstances for individual patients after a carefully audited trial of at least 3 months duration, in line with BTA guidance. Such patients should be reviewed at least annually by their NHS Endocrinologist. Liothyronine Hypothyroid crisis and short-term use post-thyroid surgery only	G_n following specialist initiation Criterion 2 (see RAG list) R for new patients only Criterion 2 (see RAG list)
Do Not Prescribe	Liothyronine combination products and unlicensed thyroid extract products Including Armour Thyroid and ERFA Thyroid	Criterion 2 (see RAG list)
	Liothyronine For resistant depression. There is very limited evidence for thyroid hormones in depression. Where thyroid hormones are necessary due to hypothyroidism, treatment should be initiated with standard levothyroxine. All psychiatric patients currently receiving liothyronine should be reviewed by a consultant NHS psychiatrist	Criterion 2 (see RAG list) See: NHSE guidance on items not for routine prescribing in primary care , and RMOG Guidance on Liothyronine
Additional notes <ul style="list-style-type: none"> Micrograms should not be abbreviated 		
Subsection	6.2.2	Antithyroid hormones
First choice	Carbimazole Tablets 5mg, 20mg	
Alternatives	Propylthiouracil Tablets 50mg	G_n following specialist initiation Prescribing to remain with specialist care until stable.

		CKS: propylthiouracil cautions and contraindications. Adverse effects include hepatitis, hepatic failure.
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Chapter	6	Endocrine
Section	6.3	Corticosteroids
Subsection	6.3.1	Replacement therapy
First choice	Fludrocortisone acetate Tablets (scored) 100 micrograms	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	MHRA DSU: Hydrocortisone muco-adhesive buccal tablets: should not be used off-label for adrenal insufficiency in children due to serious risks (December 2018)
	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	MHRA DSU: Methylprednisolone injectable medicine containing lactose (Solu-Medrone 40 mg): do not use in patients with cows' milk allergy, Oct 2017

Additional notes

- Steroid cards should be issued to all patients who are prescribed steroids for longer than 3 weeks.

Do Not Prescribe	Prednisolone enteric coated tablets	Criterion 2 (see RAG list)
	Prednisone MR tablets (e.g. Lodotra®)	Criterion 2 (see RAG list)
	Hydrocortisone MR tablets (e.g. Plenadren®)	Criterion 2 (see RAG list)

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

Additional notes

- [NICE NG23: Menopause: diagnosis and management](#) (updated Dec 2019)
- [GM HRT Guidance for Menopause Management](#)

The MHRA provides information on risks and benefits of HRT:

- [Hormone Replacement Therapy, March 2007](#)
- [Hormone replacement therapy \(HRT\): further information on the known increased risk of breast cancer with HRT and its persistence after stopping, August 2019](#)

[Joint BMS FSRH RCGP RCOG SfE and RCN Women’s Health Forum safety alert](#) on high doses of oestrogen which exceed the product licences.

Some low dose preparations only provide relief from menopausal symptoms. Other preparations offer relief from menopausal symptoms plus osteoporosis prophylaxis – check BNF.

For information on the ongoing HRT supply disruptions, see information from:

- the Specialist Pharmacy Service, on [available HRT products](#)
- British Menopause Society, on [HRT preparations and equivalent alternatives](#)

Sequential combined therapy – for women with a uterus & last menstrual period (LMP) <12 months

Oral treatment options	Elleste Duet® Tablets Estradiol 1 mg / 2 mg + norethisterone 1mg	<ul style="list-style-type: none"> • Choice of product should be individualised based on age, symptoms and co-morbidities, after discussing potential risks, benefits, adverse effects and contraindications • Women ≥60 should be offered transdermal formulation first line
	Femoston® Tablets Estradiol 1 mg / 2 mg + dydrogesterone 10 mg	
Transdermal treatment options	Evorel Sequi® Patches Estradiol 50 micrograms + norethisterone acetate 170 micrograms	

Continuous combined therapy – for women with a uterus and LMP > 12 months

Oral treatment options	Bijuve® Capsules Estradiol 1mg + progesterone 100mg	<ul style="list-style-type: none"> • Choice of product should be individualised based on age, symptoms and co-morbidities, after discussing potential risks, benefits, adverse effects and contraindications • Women ≥60 should be offered transdermal formulation first line
	Elleste Duet Conti® Tablets Estradiol 2mg + norethisterone acetate 1mg	

	<p>Femoston conti® Tablets Estradiol 0.5mg + dydrogesterone 2.5mg Estradiol 1mg + dydrogesterone 5.0mg</p>	<ul style="list-style-type: none"> • Bijuve® contains progesterone and might help with symptoms of poor sleep
	<p>Kliofem® Tablets Estradiol 2mg + norethisterone acetate 1mg</p>	
	<p>Kliovance® Tablets Estradiol 1mg + norethisterone acetate 500micrograms</p>	
	<p>Premique® low dose Tablets conjugated oestrogen 300micrograms + medroxyprogesterone acetate 1.5mg</p>	<ul style="list-style-type: none"> • To be prescribed only in women already taking it and well tolerating this therapy • Women ≥60 should be offered transdermal formulation first line
Transdermal treatment options	<p>Evorel conti® Patches Estradiol 50micrograms/24 hours + norethisterone acetate 170micrograms/24hours</p>	<ul style="list-style-type: none"> • Choice of product should be individualised based on age, symptoms and co-morbidities, after discussing potential risks, benefits, adverse effects and contraindications • Women ≥60 should be offered transdermal formulation first line
Others – for women with a uterus and LMP > 12 months		
	<p>Tibolone Tablets 2.5 mg</p>	<ul style="list-style-type: none"> • See GMMMG HRT Guidance for Menopause Management for further information on treatment with tibolone
Do Not Prescribe	<p>Bazedoxifene/conjugated oestrogens Modified release tablets (Duavive®)</p>	<u>Criterion 1 (see RAG list)</u>
Unopposed oestrogen – for women without a uterus		
Oral treatment options	<p>Elleste-Solo® Tablets Estradiol 1mg, 2mg</p>	<ul style="list-style-type: none"> • Choice of product should be individualised based on age, symptoms and co-morbidities, after discussing potential risks, benefits, adverse effects and contraindications • Women ≥60 should be offered transdermal formulation first line
	<p>Premarin® Tablets Conjugated oestrogen 300micrograms</p>	<ul style="list-style-type: none"> • To be prescribed only in women already taking it and well tolerating this therapy • Women ≥60 should be offered transdermal formulation first line

Transdermal treatment options	Evorel® Patches Estradiol 25, 50, 75, 100 micrograms	<ul style="list-style-type: none"> Choice of product should be individualised based on age, symptoms and co-morbidities, after discussing potential risks, benefits, adverse effects and contraindications Women ≥60 should be offered transdermal formulation first line
	Estradot® Patches Estradiol 25, 37.5, 50, 75, 100 micrograms	
	Oestrogel® Gel pump pack Estradiol 600microgram per 1 gram	
	Sandrena® Gel sachets Estradiol 500microgram	
	Lenzetto® Spray Estradiol 1.5mg / spray	
Others – secondary prevention of osteoporotic fragility fractures in postmenopausal women		
	Raloxifene hydrochloride Tablets 60mg	NICE TA161: Raloxifene and teriparatide for the secondary prevention of osteoporotic fragility fractures in postmenopausal women
Subsection	6.4.1.2. Progestogens and progesterone receptor modulators	
Progesterones should be prescribed in combination with either oral or transdermal oestrogen		
Oral treatment options	Utrogestan® Oral capsules Micronised progesterone 100mg	<ul style="list-style-type: none"> Utrogestan® oral capsule is indicated for adjunctive use with oestrogen in postmenopausal women with an intact uterus, as HRT Can cause drowsiness, which might help with symptoms of poor sleep. Care should be taken when driving or using machines
	Norethisterone U Tablets 5mg	<ul style="list-style-type: none"> Unlicensed treatment for endometrial protection with unopposed oestrogen. It should be prescribed if licensed combination products are not suitable Refer to GMMMG HRT Guidance for Menopause Management for further information about dosing.
	Provera® U Tablets	<ul style="list-style-type: none"> Unlicensed treatment for endometrial protection with unopposed oestrogen. It should be

	Medroxyprogesterone acetate 2.5mg, 5mg, 10mg	<p>prescribed if licensed combination products are not suitable</p> <ul style="list-style-type: none"> Refer to GMMMG HRT Guidance for Menopause Management for further information about dosing
Intrauterine options	<p>Mirena® Intrauterine delivery system Levonorgestrel 20 micrograms/24 hours</p>	<ul style="list-style-type: none"> Mirena® is licensed for protection from endometrial hyperplasia during oestrogen replacement therapy. After insertion for HRT Mirena® should be removed after 5 years ("off label" use).
Management of threatened miscarriage		
	<p>Micronised progesterone Pessaries 200mg, 400mg (Cyclogest®) Vaginal capsules 200mg (Utrogestan®)</p>	<p>G_n following specialist initiation for management</p> <p>NICE NG126: Ectopic pregnancy and miscarriage: diagnosis and initial management</p>
Progesterone receptor modulators		
	<p>Ulipristal acetate Tablets 5mg (Esmya®) For the intermittent treatment of moderate to severe symptoms of uterine fibroids in adult women who have not reached menopause when uterine fibroid embolisation and/or surgical treatment options are not suitable or have failed.</p>	<p>R</p> <p>MHRA DSU, Ulipristal acetate 5mg (Esmya): further restrictions due to risk of serious liver injury, Feb 2021</p> <p>NICE NG88: Heavy menstrual bleeding: assessment and management</p>

Subsection		6.4.2. Male sex hormones and antagonists
Testosterone and esters		
Intra-muscular injection	<p>Testosterone enatate 250mg/ml, 1ml amp</p> <p>Testosterone undecanoate 250mg/ml (Nebido®), 4ml amp</p>	<p>Gn Following specialist advice</p> <p>See information for primary care on testosterone preparations for hypogonadism in adult men</p> <p>MHRA DSU: Topical testosterone (Testogel): risk of harm to children following accidental exposure. Jan 2023.</p>
Implant	Testosterone 100mg, 200mg	
Gel	<p>Testosterone 2% (Tostran®) 60g multi-dose dispenser</p> <p>Testosterone 1% (50mg/5ml) (Testogel®) 30 x 5g sachets</p>	
Oral	<p>Testosterone (Restandol®) Capsules 40mg</p>	
	<p>Mesterolone Tablets: 25mg</p>	
<p>Grey drugs</p> <p>Items which are listed as Grey are deemed not suitable for routine prescribing but may be suitable for a defined patient population</p>	<p>Testosterone U</p> <p>For menopausal women with low sexual desire (hypoactive sexual desire disorder, HSDD), only if HRT alone is not effective. This treatment is unlicensed.</p>	<p>Gn following specialist advice</p> <p>Criterion 3 (see RAG list)</p> <p>NICE NG23: Menopause: diagnosis and management</p> <p>British Menopause Society: Testosterone replacement in menopause</p> <p>MHRA DSU: Topical testosterone (Testogel): risk of harm to children following accidental exposure. Jan 2023.</p>
	<p>Tostran® U</p> <p>2% gel 60g multi-dose dispenser (10mg/0.5g)</p> <p>Tostran comes in a multi-dose canister providing measured doses, thus may more easily allow administration of lower doses.</p>	
	<p>Testogel® U</p> <p>30 x 2.5g gel sachets (40.5mg/2.5g)</p>	
	<p>Testim® U</p> <p>1% gel 30x 5g tubes (50mg/5g)</p>	
Do Not Prescribe	<p>Testosterone patches (e.g. Intrinsa®)</p>	Criterion 1 (see RAG list)

Other male sex hormones and antagonists

	Finasteride Tablets: 5mg	MHRA DSU (2017): Finasteride: rare reports of depression and suicidal thoughts
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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
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Additional notes

- 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	Gn following specialist initiation NICE TA64: Growth hormone deficiency (adults) August 2003 R Adults, except in proven primary and secondary hypopituitarism.
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Growth hormone receptor antagonists

	Pegvisomant (Somavert®) Injection 10mg, 15mg, 20mg	R
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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 Tablets 100microgram, 200micrograms</p>	
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Alternatives	<p>Desmopressin 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 	
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Additional notes

- [MHRA DSU: Desmopressin nasal spray: Removal of the primary nocturnal enuresis \(bedwetting \) indication, Sept 2007](#)

Antidiuretic hormone antagonists

	<p>Demeclocycline For treating hyponatraemia associated with syndrome of inappropriate antidiuretic hormone (SIADH)</p>	<p>R for new patients only (October 2021)</p>
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	<p>Tolvaptan[▼] (Jinarc®) For treating autosomal dominant polycystic kidney disease only as per NICE TA358 Tablets 15mg, 30mg, 45mg and 15mg 60mg and 30mg 90mg and 30mg</p>	<p>R NICE TA358: Tolvaptan for treating autosomal dominant polycystic kidney disease</p>
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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 choices	Teriparatide (Forsteo®) 250micrograms/ml 2.4ml pre-filled pens	R For Specialist use only Equal first line treatment alongside romosozumab (see section 6.6.2) NICE TA161: Raloxifene and teriparatide for the secondary prevention of osteoporotic fragility fractures in postmenopausal women
Alternatives	Parathyroid hormone Injection s/c: 1.61mg (14 dose)	R For Specialist use only

Subsection	6.6.2. Bisphosphonates and other drugs affecting bone metabolism
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Bisphosphonates

Additional notes:

[NICE TA464: Bisphosphonates for treating osteoporosis](#)

First choice	Alendronic acid Tablet: 70mg (once weekly preparation)	G_n NB: not licensed for use in men, but this is common practice
Alternatives	Risedronate Tablet: 35mg (once weekly preparation)	G_n
	Ibandronic acid Tablets: 150 mg Solution for injection: 3 mg/3mL	G_n tablets R solution for injection
	Sodium clodronate Tablets: 800mg	Specialist initiation only
	Zoledronic acid Solution for infusion vial: 4mg/5ml	R Specialist use only

	Infusion bottles: 4mg/100ml, 5mg/100ml	
Do Not Prescribe	Alendronic acid with vitamin D Tablets	<u>Criterion 2 (see RAG list)</u>
Other drugs affecting bone metabolism		
	Denosumab (Prolia®) – Osteoporosis in men & women Injection s/c 60mg/ml x 1ml	A MHRA DSU: Denosumab 60mg (Prolia): should not be used in patients under 18 years due to the risk of serious hypercalcaemia, May 2022
	Denosumab (Xgeva®) - Oncology indication Injection s/c 120mg/ml x 1.7ml	R Specialist use only
	Romozozumab Pre-filled pen: 105mg	R Equal first choice alongside teriparatide (see section 6.6.1) NICE TA791: Romozozumab for treating severe osteoporosis National Osteoporosis Guideline Group (NOGG): Clinical Guideline, 2021
Additional notes:		
<ul style="list-style-type: none"> • 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 • MHRA DSU: Denosumab 60mg (Prolia): increased risk of multiple vertebral fractures after stopping or delaying ongoing treatment, August 2020 		

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>
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. 		

Other GnRH receptor antagonists

	<p>Estradiol / norethisterone / relugolix 1 mg / 0.5 mg / 40 mg tablets</p>	<p>Gn following specialist advice NICE TA832: Relugolix-estradiol-norethisterone acetate for treating moderate to severe symptoms of uterine fibroids</p>
Subsection	6.7.3. Metyrapone	
	<p>Metyrapone Capsules 250mg</p>	For specialist use only

Additional notes

- Metyrapone is used for Cushing’s syndrome, often in a lower dose combination with aminoglutethamide to reduce side effects.