

South East

Clinical **senate**

**Clinical Synopses: Clinical Pathways
Identified as Areas of Uncertainty and
Differing Opinion**

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Direct Oral Anticoagulants (DOACs)

The two main classes of oral anticoagulants are vitamin K antagonists and direct oral anticoagulants (DOACs). Vitamin K antagonists were the only oral anticoagulants available for several decades and warfarin was the most commonly used. These agents act by inhibiting vitamin K dependent clotting factors (II, VII, IX, X) in addition to the anticoagulant proteins C and S.

DOACs (apixaban, dabigatran, edoxaban, and rivaroxaban) are anticoagulants with a novel mode of action:

- apixaban, edoxaban, and rivaroxaban are direct and reversible inhibitors of factor Xa (inhibition of factor Xa prevents thrombin generation and thrombus development).
- dabigatran is a reversible inhibitor of free thrombin, fibrin-bound thrombin, and thrombin-induced platelet aggregation.

The most common adverse effect of all anticoagulants is bleeding and in order to ensure safety and efficacy the vitamin K antagonists require regular international normalized ratio (INR) monitoring. DOACs do not require INR monitoring but still require follow up to review treatment and assess for adverse effects, including bleeding.

Warfarin is licensed for:

- prophylaxis of systemic embolism in people with rheumatic heart disease and atrial fibrillation
- prophylaxis after insertion of prosthetic heart valves
- prophylaxis and treatment of venous thrombosis and pulmonary embolism
- and prophylaxis and treatment of transient ischaemic attacks.

Apixaban, dabigatran, edoxaban, and rivaroxaban may be prescribed instead of vitamin K antagonists for many indications including¹:

- prevention of stroke and systemic embolism in adults with non-valvular atrial fibrillation and at least one risk factor, such as heart failure, hypertension, previous stroke or transient ischaemic attack, age 75 years or older, or diabetes mellitus
- treatment of pulmonary embolism (PE) and deep vein thrombosis (DVT)
- prevention of recurrent DVT and PE
- and prophylaxis of venous thromboembolism after elective hip or knee replacement surgery (edoxaban is not currently licensed for this indication).

Rivaroxaban is also licensed for prophylaxis of atherothrombotic events following an acute coronary syndrome with elevated cardiac biomarkers (in combination with

¹ NICE. (2025) Clinical Knowledge Summary. Anticoagulation - oral. Available online at: [Anticoagulation - oral | Health topics A to Z | CKS | NICE](#). Accessed 20.5.25

aspirin alone or aspirin and clopidogrel) and for prophylaxis of atherothrombotic events in adults with coronary artery disease or symptomatic peripheral artery disease at high risk of ischaemic events (in combination with aspirin).

Vitamin K antagonists, apixaban, dabigatran, and rivaroxaban have antidotes for reversing their anticoagulant effects. There is currently no antidote for edoxaban.

There are considerations and precautions for use of DOACS that apply to all agents and some that are more specific to individual agents. The aim of this synopsis is to ensure a consistent approach to guidance for monitoring and safeguarding patients initiated on DOACs.

1. Contraindications and precautions

DOACs are contraindicated in:

- People with liver disease associated with coagulopathy
- People with prosthetic heart valves (efficacy not established)
- Antiphospholipid syndrome
- Active bleeding and significant risk of major bleeding
- Women who are pregnant or breast feeding (safety not established)

There are certain key drug interactions that are common to all DOACs and concurrent administration should be avoided if possible²:

- Nonsteroidal anti-inflammatory drugs (NSAIDs) are predicted to increase risk of bleeding.
- Concurrent prescription of other anticoagulants and/or anti-platelet agents increase the risk of bleeding and should be avoided if possible.
- Strong inhibitors of both cytochrome P450 3A4 (CYP3A4) and P-glycoprotein (P-gp) such as itraconazole, ketoconazole and HIV protease inhibitors increase plasma concentration of DOACs and concurrent use should be avoided.
- Weak inhibitors of CYP3A4 and P-gp such as amiodarone, clarithromycin, diltiazem, fluconazole, quinidine, and verapamil, have a lesser effect on DOAC concentrations but patients should be monitored for bleeding and anaemia.
- Strong inducers of both cytochrome CYP3A4 P-gp, such as carbamazepine, phenytoin, rifampicin and StJohn's wort reduce plasma concentration of DOACs and may compromise efficacy.
- Concurrent serotonin reuptake inhibitors such as citalopram, duloxetine and venlafaxine may increase bleeding risks with DOACs and concurrent use should be avoided.

² Specialist Pharmacy Service. (2024) Managing interactions with direct oral anticoagulants (DOACs). Available online at: [Managing interactions with direct oral anticoagulants \(DOACs\) – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice](#)

Use of DOACs in people undergoing operation or undergoing interventional procedures at risk of bleeding:

- There is a balance between risk of thromboembolic event from stopping DOACs versus bleeding risk associated with the procedure. Most surgical or interventional procedures with bleeding risk take place in secondary/tertiary care but some may also be performed in the community such as dental interventions, minor surgery, cataract or glaucoma surgery and endoscopy with or without biopsy.
- If the decision is not to stop DOAC therapy it is advised that procedures take place 12-24 hours after the last dose, or 18-24 hours after the last dose with the next dose taken 6 hours post-procedure (effectively meaning that one dose will be missed).
- If the decision is is to stop DOAC therapy for low bleeding risk procedures DOACs should be stopped at least 24 hours beforehand, or if kidney function is impaired at least 36 hours beforehand depending on the agent and the level of kidney function.
- For high risk procedures DOACs should be stopped 72 hours beforehand or longer, depending on the agent and the level of kidney function.

2. Assessment for initiation of DOACs

Before initiation the following are required:

- Baseline clotting screening, seek advice if abnormal
- Current body weight, seek advice if <50 kg or >120 kg
- Full blood count, seek advice if Hb <100 g/L and no identifiable cause or if platelets <100 x10⁹/L
- Liver function tests, seek advice if ALT/AST >2x upper limit of normal or bilirubin >1.5x upper limit of normal
- Serum creatinine (for creatinine clearance), urea and electrolytes
- Blood pressure, manage uncontrolled or new hypertension
- Alcohol intake, aim for < 14 units/week and counsel re bleeding risk
- Review for concurrent medications (see above)

In patients with atrial fibrillation the use of risk scores for bleeding, such as the [ORBIT Bleeding Risk Score for Atrial Fibrillation](#) or [HAS-BLED Score for Major Bleeding Risk](#)^{3,4}, may help categorise patients into low, moderate and high risk groups and guide decision making. Use DOACs cautiously with scores of 3 or above.

Assess kidney function using [Creatinine Clearance \(Cockcroft-Gault Equation\)](#) (CrCl) rather than estimated glomerular filtration rate (eGFR), this is important because DOAC safety profiles are based on CrCl, not eGFR.

³ O'Brien EC et al. (2015) The ORBIT bleeding score: a simple bedside score to assess bleeding risk in atrial fibrillation. *European Heart Journal*. 36:3258-3264.

⁴ Pisters R et al. (2010) A novel user-friendly score (HAS-BLED) to assess 1-year risk of major bleeding in patients with atrial fibrillation: the Euro Heart Survey. *Chest*. 138(5):1093-100.

3. DOAC Agents for prophylaxis of stroke and systemic embolism in adults with non-valvular atrial fibrillation

Table 1. DOAC Agents for prophylaxis of stroke and systemic embolism in adults with non-valvular atrial fibrillation

Agent	Apixaban	Dabigatran	Edoxaban	Rivaroxaban
Standard dose	5 mg BD	150 mg BD	60 mg OD	20 mg OD (with food)
Reduced dose	2.5 mg BD	110 mg BD	30 mg OD	15 mg OD (with food)
Criteria for reduced dose	CrCl 15-29 mL/min Or ≥2 of <ul style="list-style-type: none"> •age ≥ 80 yrs •weight ≤60 kg •SCr ≥133µmol/L 	Either age ≥ 80 yrs or on verapamil Consider reduced dose for reflux/gastritis, age 75-80yrs, CrCl 30-50 mL/min or “Bleed Risk”	≥1 of <ul style="list-style-type: none"> •weight ≤60 kg •CrCl 15-50 mL/min •On ciclosporin, dronedarone, erythromycin, ketoconazole 	CrCl 15-49 mL/min
Contraindications	CrCl <15 mL/min	CrCl <30 mL/min	CrCl <15 mL/min (caution if CrCl > 95 mL/min)	
Rapid reversal	Andexanet alfa	Idarucizumab	No specific agent	Andexanet alfa

BD = twice a day; OD = once a day; CrCl = creatinine clearance; SCr = serum creatinine

4. Recommended DOAC dosing for other indications.

The reduced dose criteria and contraindications in Table 1 also apply to DOAC dosing for other indications, see agent Summary of Product Characteristics (SPCs) ^{5,6,7,8} or British National Formulary (BNF) for full dosing information.⁹

Table 2. Recommended DOAC Dosing for other indications

Treatment of DVT and PE			
Apixaban	Dabigatran	Edoxaban	Rivaroxaban
10 mg BD for 7 days, then 5 mg BD for 3 months minimum	150 mg BD after 5 days parenteral anticoagulation	60 mg OD after 5 days parenteral anticoagulation	15 mg BD for 21 days then 20 mg OD for 3 months minimum
Prophylaxis of recurrent DVT and PE in adults after full 6 months treatment			
Apixaban	Dabigatran	Edoxaban	Rivaroxaban
2.5 mg BD	150 mg BD	60 mg OD	10 mg OD or 20 mg OD for high risk of recurrence

⁵ Electronic Medicines Compendium. (2024) Apixaban Summary of Product Characteristics. Updated January 2024. Available online at: [Eliquis 5 mg film-coated tablets - Summary of Product Characteristics \(SmPC\) - \(emc\) | 2878](#). Accessed on 20.5.25.

⁶ Electronic Medicines Compendium. (2025) Dabigatran Summary of Product Characteristics. Updated January 2025. Available online at: [Pradaxa 150 mg hard capsules - Summary of Product Characteristics \(SmPC\) - \(emc\) | 4703](#). Accessed on 20.5.25.

⁷ Electronic Medicines Compendium. (2024) Edoxaban Summary of Product Characteristics. Available online at: [Lixiana 30mg Film-Coated Tablets - Summary of Product Characteristics \(SmPC\) - \(emc\) | 6906](#). Accessed on 20.5.25.

⁸ Electronic Medicines Compendium. (2024) Rivaroxaban Summary of Product Characteristics. Available online at: [Xarelto 20mg film-coated tablets - Summary of Product Characteristics \(SmPC\) - \(emc\) | 2793](#). Accessed on 20.5.25.

⁹ British National Formulary (BNF). Updated 30 April 2025. Available online at: [BNF \(British National Formulary\) | NICE](#). Accessed on 20.5.25.

Table 2 continued. Recommended DOAC Dosing for other indications

Prophylaxis of VTE following hip replacement surgery			
Apixaban	Dabigatran	Edoxaban	Rivaroxaban
2.5 mg BD for 32-38 days from 12-24 hrs post surgery	110 mg 1-4 hrs post surgery then 150 mg OD for 28-35 days	-	10 mg OD for 35 days from 6-10 hrs post surgery
Prophylaxis of VTE following knee replacement surgery			
Apixaban	Dabigatran	Edoxaban	Rivaroxaban
2.5 mg BD for 10-14 days from 12-24 hrs post surgery	110 mg 1-4 hrs post surgery then 220 mg OD for 10 days	-	10 mg OD for 14 days from 6-10 hrs post surgery

DVT = deep vein thrombosis; PE = pulmonary embolism; BD = twice a day; OD = once a day; VTE = venous thromboembolism

5. Monitoring following initiation and once stable on treatment

Ideally the first review should take place after 1 month of therapy and then a minimum of annually, with more frequent monitoring every 4 months if CrCl <60 mL/min, age over 75 years and/or significantly frail; also if new concurrent medications affecting liver or kidney function are prescribed; if liver function changes or when intercurrent illness occurs. Adherence, adverse reactions to DOACs and treatment efficacy should be checked at all reviews¹⁰.

¹⁰ Specialist Pharmacy Service. (2025) DOACS (Direct Oral Anticoagulants) monitoring. Available online at: [DOACs \(Direct Oral Anticoagulants\) monitoring – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice](#). Accessed on 20.5.25.

Table 3. Monitoring following initiation of DOAC

First review	Annual review
Check for side effects (refer to SPC/BNF for each DOAC) – seek advice and guidance from haematology clinic if present or a concern	Age and weight – check if DOAC dosage adjustment required
Check for bruising/bleeding – refer for further investigation according to local pathways as indicated	FBC, investigate any Hb fall without identifiable cause and if platelets <100 x10 ⁹ /L
U&Es, SCr and FBC if indicated by a change to clinical state of patient: Check CrCl and review DOAC dosing	LFTs, seek advice and guidance if ALT/AST >2x ULN or bilirubin >1.5x ULN
Check medication adherence and anticoagulant alert card	U&Es, SCr. Check CrCl and review DOAC dosing
Schedule repeat prescriptions and reviews	Medicines review for any interacting or new medications, adjust DOAC dosing as required

SCr = serum creatinine; CrCl = creatinine clearance; ULN = upper limit of normal

Disease Modifying Anti-Rheumatic Drug (DMARD) Monitoring

The treatment of autoimmune rheumatological disease, but also several other diseases, including certain skin, bowel, respiratory and neurological disorders, is increasingly reliant on disease modifying agents, both non-biologic and biologic (including targeted synthetic DMARDs). For the purposes of this document DMARDs explicitly refers to non-biologic disease modifying agents.

Some of the most commonly used agents are Methotrexate (oral or subcutaneous), Leflunomide, Azathioprine, Mycophenolate Mofetil, Mercaptopurine, Hydroxychloroquine, Cyclosporin and Tacrolimus. These agents interfere with critical

pathways in the inflammatory cascade and have a broad immune suppressing effect which may take a month or more to provide a therapeutic benefit.

Inflammatory arthritis, including rheumatoid arthritis, is a significant disease burden in the UK, affecting over 400,000 people¹¹, with data from the National Early Inflammatory Arthritis Audit (NEIAA) 2024 indicating an incidence of circa 20,000 per annum¹². Delays in treatment may lead to disability, poor quality of life and loss of workforce productivity, 75% of patients in the audit who were unemployed at diagnosis said that this was due to their arthritis. Of those patients in work, either their work role or work hours had been adversely affected in a fifth of cases. Variability in DMARD initiation practices was an issue with the potential to introduce significant delays, often extending waiting times by several weeks. Some hospitals relied on GPs in the community to start DMARDs, while others referred people living with early inflammatory arthritis to nurse-led clinics. Referral and treatment via a defined pathway maximised timely treatment and probability of remission within 3 months (Figure 1) and across the South East region there was a greater than 2-fold variation in remission rates, indicating significant scope for improvement.

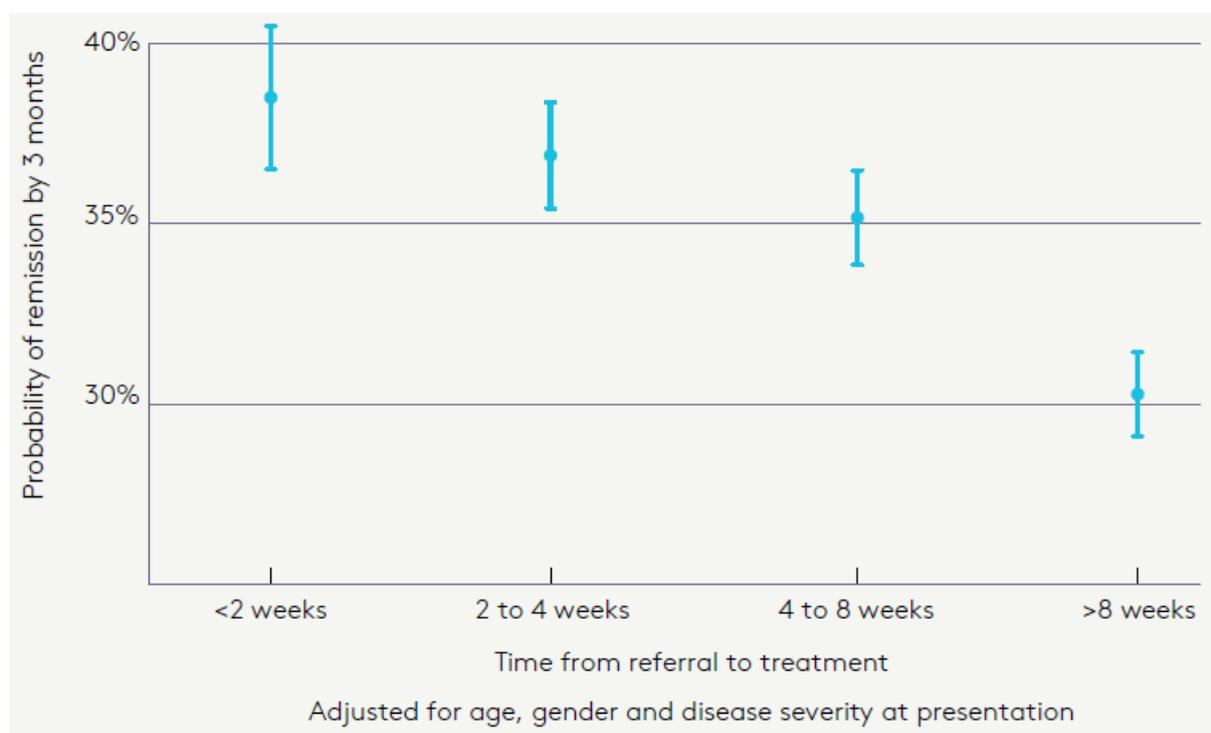


Figure 1 – Relationship between remission rates and treatment timeliness across all six years of NEIAA (reproduced from reference 12)

¹¹ Russell MD et al. (2022) 'Incidence and management of inflammatory arthritis in England before and during the COVID-19 pandemic: a population-level cohort study using OpenSAFELY.' *The Lancet Rheumatology*. 4: 12: E853-E863.

¹² British Society for Rheumatology. (2024) National Early Inflammatory Audit: State of the Nation Summary Report 2024. Available online at: [Ref.-428-NEIAA-SoN-Report-2024-revised-March-25.pdf](#). Accessed 16.5.25.

Accurate and up-to-date estimates of trends in incidence and prevalence of other conditions for which non-biologic DMARDs are prescribed are uncertain. However, from interrogation of electronic patient records from primary care Pasvol et al identified 65,700 cases of inflammatory bowel disease (IBD) with an overall crude incidence estimate of 28.6/100,000 person years (95% CI 28.2 to 28.9) and a point prevalence estimate on 31 December 2018 of 725/100,000 people¹³. Their methodology for checking the accuracy of diagnostic coding included prescription for a drug commonly used to treat IBD (including azathioprine, mercaptopurine, methotrexate and ciclosporin), affording a crude guide to the potential load from non-biologic DMARD monitoring.

Across the NHS as the prevalence of non-biologic DMARD prescription has increased general practice has been increasingly employed in ensuring that these agents continue to be used safely by undertaking drug monitoring and patient safety surveillance, often through shared care guidelines developed for these purposes, particularly as many of the drugs used have potential for harm as well as benefit. Potential harms include myelosuppression; gastrointestinal, renal, hepatic, and pulmonary toxicity; neuropathy; retinal damage (hydroxychloroquine); and increased risk of infection. A full list of adverse effects can be found in manufacturer's Summaries of Product Characteristics (SPC) and in the British National Formulary (BNF)¹⁴.

Shared Care

Shared care guidelines recognise that although the agents are generally initiated by secondary care teams, once patients have been stabilised on treatment, they may be subject to transfer for primary care monitoring and prescribing. Safe prescribing and monitoring guidance has the express aim of detecting and acting on side effects which may occur with the use of DMARDs. The monitoring of the clinical aspects of the disease itself generally remains with secondary care clinicians and it should be implicit that the responsibilities of all parties involved are both agreed and implemented to a standard which ensures the avoidance of harm and equitable access to the same high standard of care.

¹³ Pasvol TJ et al. (2020) 'Incidence and prevalence of inflammatory bowel disease in UK primary care: a population-based cohort study'. *BMJ Open*. 10(7):e036584.

¹⁴ British National Formulary (BNF). Available online at: [BNF \(British National Formulary\) | NICE](#). Accessed 16.5.25.

Monitoring and Management

For all agents there are some general considerations that apply¹⁵:

- DMARD prescription is initiated in secondary/tertiary care following guideline recommended baseline assessments
- Ongoing DMARD monitoring in primary care only commences once a patient is stable
- Patients must be provided with comprehensible education and information about their treatment and potential adverse effects
- Monitoring should not be less frequent than that stated in the table below
- With all agents monitoring should be more frequent in those patients at risk of toxicity (often those aged 65+ and/or with renal insufficiency)
- Whilst absolute values are useful indicators, trends are equally important. Any rapid rise or fall, or consistent downward or upward trend in any parameter warrants extra vigilance
- Monitoring of patients on more than one DMARD should be based on the DMARD which requires the most frequent monitoring
- Always refer to the agent's SPC or to the BNF for potential drug interactions
- All vaccinations should be kept up to date but live vaccines are not recommended in patients on immunosuppression¹⁶.

Table 4. DMARD Monitoring Recommendations

DMARD agent	Monitoring Tests	Frequency	Notes
Azathioprine	FBC, U&Es, LFTs	Every 12 weeks [†]	Every 4 weeks for thiopurine methyl transferase (TPMT) deficiency heterozygotes. Be aware of drug interactions (Allopurinol in particular).
Ciclosporin*	FBC, U&Es, LFTs, glucose, Blood pressure	Every 4 weeks [†]	Be aware of drug interactions. More frequent monitoring in patients at higher risk of toxicity.

¹⁵ Ledingham et al. (2017) 'BSR and BHPR guideline for the prescription and monitoring of non-biologic disease-modifying anti-rheumatic drugs'. *Rheumatology*. Volume 56, Issue 6, Pages 865–868.

¹⁶ UK Health Security Agency (2020) Guidance: Immunisation of individuals with underlying medical conditions: the green book, chapter 7. Available online at: [Immunisation of individuals with underlying medical conditions: the green book, chapter 7 - GOV.UK](#). Accessed 16.5.25.

Hydroxychloroquine	FBC, eye assessment	Every 12 months	Include optical coherence tomography in assessment
Leflunomide	FBC, U&Es, LFTs, Weight, Blood pressure	Every 12 weeks [†]	If combined with methotrexate monitor every 4 weeks until stable for 12 months. Be aware that Leflunomide has a long half-life
Mercaptopurine (also see Azathioprine which is a prodrug)	FBC, U&Es, LFTs	Every 12 weeks	Methylmercaptopurine to thioguanine ratio annually or 4 weeks after dose change
Methotrexate	FBC, U&Es, LFTs	Every 12 weeks [†]	If combined with leflunomide monitor every 4 weeks until stable for 12 months.
Mycophenolate	FBC, U&Es, LFTs	Every 12 weeks [†]	In females of child-bearing potential, exclude pregnancy whilst on treatment
Penicillamine	FBC, U&Es, LFTs, urinalysis	Every 4 weeks, increase to 12 weeks if stable for 12 months	Monitor fortnightly following dose increase until stable for 6 weeks. Continue careful monitoring in the elderly, even if stable.
Sulphasalazine	FBC, U&Es, LFTs	Every 12 weeks	Monitoring may be discontinued after 12 months for certain patients on an individual basis.
Tacrolimus*	FBC, U&Es, LFTs, glucose, Blood pressure	Every 4 weeks [†]	Be aware of drug interactions.

† Monitor fortnightly following dose increase until stable for 6 weeks; * Serum ciclosporin and tacrolimus levels and associated dose changes are usually managed by secondary care. FBC = full blood count; U&Es = urea, electrolytes, creatinine and estimated glomerular filtration rate; LFTs = liver function tests (minimum ALT and/or AST and albumin).

Considerations for stopping treatment and referring urgently to the relevant secondary care service

For all people on any DMARD there are general considerations for stopping treatment and referring urgently to the relevant secondary care service. As a rule, risks are greater with increasing age and presence of comorbidity (chronic kidney disease, diabetes mellitus, cardiovascular disease), either alone or in combination.

1. Monitoring results show any of the following:
 - White cell count less than $3.5 \times 10^9/L$
 - Neutrophils less than $1.6 \times 10^9/L$
 - Platelet count less than $140 \times 10^9/L$
 - Unexplained eosinophilia more than $0.5 \times 10^9/L$
 - Mean cell volume more than 105 fL despite normal B12, folate and thyroid-stimulating hormone levels
 - Serum creatinine has increased more than 30% over 12 months and/or estimated GFR is less than $60 \text{ mL/min/1.73m}^2$ and repeat check in a week remains more than 30% from baseline
 - ALT and/or AST more than 100 U/L
 - Unexplained reduction in albumin less than 30g/L
 - Blood pressure more than 140/90mmHg since starting treatment
 - Urinary protein 2+ or more and persisting on two consecutive measurements
2. Development of any of the following signs or symptoms:
 - Skin/mucosal reaction — for example rash, pruritus, mouth or throat ulceration
 - Sore throat
 - Fever
 - Unexplained bruising or bleeding
 - Nausea, vomiting, diarrhoea or weight loss
 - Diffuse alopecia
 - Breathlessness, infection or cough
 - Peripheral neuropathy

Monitoring Monoclonal Gammopathy of Undetermined Significance (MGUS)

Monoclonal Gammopathy of Undetermined Significance (MGUS) monitoring involves regular blood tests and assessments to track the disease's stability and detect any signs of progression to a more serious condition, with follow-up frequency varying based on individual risk factors.

MGUS is a benign but pre-malignant clonal expansion of plasma cells. It is an asymptomatic condition usually diagnosed incidentally and does not require treatment, but it carries with it a risk of conversion to multiple myeloma or other lymphoproliferative disorders at a rate of 0.5% to 1% per year¹⁷. MGUS is common, affecting more than 3% of adults over the age of 50 years and increases with age, rising to 5% in those over 70 and 10% in people over 85¹⁷. MGUS is twice as common in men than in women and people of Black ethnicity have a 2-3x increased risk of MGUS diagnosis compared to White or Asian ethnicity, although their rate of conversion is the same.

There is no screening programme for MGUS in the UK as the benefits are not thought to outweigh the costs. However, there are 2 ongoing studies that will provide insight in the future with regard to whom to screen, and the risk factors for conversion. The iSTOPMM is a population-based screening study in which 75,422 participants aged ≥40 years were screened using protein electrophoresis and measurement of free light chains. Overall, 3579 with a diagnosis of MGUS were randomised into 3 arms – no further follow up, follow up as per evidence-based guidelines, or more intensive follow up^{18,19,20,21}. The iSTOPMM study results will address the question of which targeted population to screen (except for ethnicity because the study population was almost exclusively of white ethnicity). The second ongoing study, the PROMISE study, focuses on the impact of screening individuals at high risk for multiple myeloma, including those who self-identify as Black or with a family history of haematological malignancy. PROMISE is an observational cohort

¹⁷ Kyle RA et al. (2018) 'Long-Term Follow-up of Monoclonal Gammopathy of Undetermined Significance.' *N Engl J Med.* 378(3):241-249.

¹⁸ National Library of Medicine. Clinical Trials.gov. Iceland Screens, Treats or Prevents Multiple Myeloma (iStopMM). Available online at: [Study Details | Iceland Screens, Treats or Prevents Multiple Myeloma | ClinicalTrials.gov](#).

¹⁹ Rögnvaldsson S et al. (2021) 'Iceland screens, treats, or prevents multiple myeloma (iStopMM): a population-based screening study for monoclonal gammopathy of undetermined significance and randomized controlled trial of follow-up strategies'. *Blood Cancer J.* 11(5):94.

²⁰ Sigurbergisdóttir AÝ et al. (2023) 'Disease associations with monoclonal gammopathy of undetermined significance can only be evaluated using screened cohorts: results from the population-based iStopMM study'. *Haematologica.* 108(12):3392-3398.

²¹ Rögnvaldsson S et al. (2024) 'Prior cancer and risk of monoclonal gammopathy of undetermined significance: a population-based study in Iceland and Sweden'. *Haematologica.* 109(7):2250-2255.

study aiming to recruit 50,000 individuals. The primary outcome measure of the study is time to progression from diagnosis of MGUS/smouldering multiple myeloma to overt multiple myeloma^{22,23}.

Evaluation and Diagnostics

Evaluation for MGUS involves serum protein electrophoresis, immunofixation and serum free light chain (FLC) assay which together identify more than 97% of patients with a monoclonal gammopathy. Immunofixation confirms that the protein detected is monoclonal and identifies the subtype (IgG, IgM etc). An alternative technique is mass spectrometry, which is more sensitive than existing techniques and can also distinguish between exogenous therapeutic antibodies, such as rituximab and infliximab, and monoclonal gammopathies.

The diagnostic criteria for MGUS are a serum M protein concentration of <30 g/L or an abnormal ratio of kappa to lambda FLC with increased levels of the involved light chain, and fewer than 10% plasma or lymphoplasmacytic cells in the bone marrow²⁴. MGUS can be divided into non-IgM MGUS, IgM MGUS and light chain MGUS. The rate of progression and associated haematological disease are summarised in Table 5 below. Classically progression of monoclonal gammopathy is from precursor MGUS to an intermediate smouldering stage to overt malignant disease. Smouldering myeloma is characterised by M protein ≥ 30 g/L, bone marrow containing 10-59% plasma or lymphoplasmacytic cells but no evidence of end-organ damage or biomarker or imaging evidence of myeloma. Smouldering myeloma progresses to overt disease at a rate of 10% per year for the first 5 years of diagnosis, 3% per year for the next 5 years and 1% per year thereafter²⁵.

²² National Library of Medicine. Clinical trials.gov. Predicting Progression of Developing Myeloma in a High-Risk Screened Population (PROMISE). Available online at: [Researcher View | Predicting Progression of Developing Myeloma in a High-Risk Screened Population \(PROMISE\) | ClinicalTrials.gov](#). Accessed on 19.3.25.

²³ El-Khoury H et al. (2022) 'Prevalence of monoclonal gammopathies and clinical outcomes in a high-risk US population screened by mass spectrometry: a multicentre cohort study'. *Lancet Haematol.* 9(5):e340-e349.

²⁴ Rajkumar SV et al. (2014) 'International Myeloma Working Group updated criteria for the diagnosis of multiple myeloma'. *Lancet Oncol.* 15(12):e538-e548

²⁵ Kyle RA et al. (2007) 'Clinical course and prognosis of smoldering (asymptomatic) multiple myeloma'. *N Engl J Med.* 356(25): 2582-2590.

UK best practice guidance recommendations

UK best practice guidance recommends that imaging and bone marrow examination can be deferred in low risk and probably low to intermediate risk MGUS patients (>50% of all MGUS patients)²⁶.

Table 5. Type of MGUS, progression and associated haematological disease

Type of MGUS	Rate of progression	Associated Haematological Disease
Non-IgM MGUS	1% per year	Multiple myeloma or AL Amyloidosis
IgM MGUS	1.5% per year	lymphoplasmacytic lymphoma Waldenstrom macroglobulinemia (or rarely IgM MM)
Light-chain MGUS	0.3% per year	AL amyloidosis or light Chain multiple myeloma

Monitoring and Management

Following identification of a monoclonal gammopathy and diagnosis of MGUS monitoring is through blood tests every 3-4 months for the first year and then every 6-12 months. MGUS can be risk stratified as recommended by the International Myeloma Working Group²⁷ (see Table 6). In addition to monitoring the paraprotein level, recommended blood tests include a full blood count, serum creatinine and electrolytes (including calcium). Where there is no access to free light chain assay urine should be tested for presence of light chains (Bence Jones protein).

²⁶ Stern S et al. 2023 'Investigation and management of the monoclonal gammopathy of undetermined significance'. *Br J Haematol.* 202:707-903.

²⁷ Kyle RA et al; International Myeloma Working Group. (2010) 'Monoclonal gammopathy of undetermined significance (MGUS) and smouldering (asymptomatic) multiple myeloma: IMWG consensus perspectives risk factors for progression and guidelines for monitoring and management.' *Leukemia.* 24(6):1121-1127.

Table 6. Risk stratification of Monoclonal Gammopathy of Undetermined Significance^{28,29}

Risk Category	Definition	Cumulative absolute risk of progression at 20 years, %	Cumulative absolute risk of progression at 20 years adjusted for competing mortality risk, %
Low risk	M protein ≤15 g/L; immunoglobulin G subtype; normal FLC ratio	5	2
Intermediate risk	Either M protein >15<30 g/L or IGM subtype or abnormal FLC ratio	21	10
	Any 2 of the above factors	37	18
High risk	All 3 of the above factors	58	27

FLC, free light chain

Data suggests the majority of progression of MGUS occurs within the first 2 years following diagnosis and gradually declines thereafter^{30,17}. For patients with an abnormal FLC ratio and ≥15 g/L serum M protein, 3.6% of patients per 100 person-years had MGUS progression, as compared with 1.1 per 100 person-years of patients in whom neither of these risk factors was seen.

²⁸ Rajkumar, S.V et al. (2005) 'Serum free light chain ratio is an independent risk factor for progression in monoclonal gammopathy of undetermined significance.' *Blood*. 106:812–817

²⁹ Liu Y and Parks AL. (2025) 'Diagnosis and Management of Monoclonal Gammopathy of Undetermined Significance: A Review.' *JAMA Intern Med*. 185(4):450-456.

³⁰ Go RS et al. (2018) 'Risk of progression of monoclonal gammopathy of undetermined significance into lymphoplasmacytic malignancies: Determining demographic differences in the USA'. *Haematologica*. 103: e123–e125.

The UK Myeloma Forum/Nordic Myeloma Study Group

Monitoring has previously recommended monitoring patients with low-risk MGUS every 3–4 months for the first year and 6–12 months thereafter if no disease progression is detected. Intermediate and high risk patients should be followed every 3–4 months³¹. The International Expert Consensus recommended monitoring patients every 4–6 months for the first 2 years and every 6–24 months thereafter for all patients with MGUS³². The European Myeloma Network recommends re-evaluating patients at 6 months from diagnosis and yearly thereafter. For low-risk patients, no follow-up is recommended if the disease is stable at 6 months from diagnosis³³. For patients with higher-risk disease, follow-up should be done annually after an initial 6-month follow-up from diagnosis.

The risk of progression to myeloma or other lymphoproliferative disease remains lifelong and that risk never disappears even if the M-protein remains stable, even after >25 years of follow up. However, current UK best practice advice places an emphasis on not following up those patients who are unlikely to progress within their lifetime.

For those patients with MGUS requiring long-term follow-up current UK recommendations are that newly diagnosed MGUS patients should have appropriate blood tests (FBC, creatinine, serum calcium, para-protein and serum FLC levels) performed 6 months after diagnosis, with annual follow-up thereafter, although the interval can be longer for patients with low- risk MGUS and further investigations reduced if life expectancy is short²¹. High-intermediate and high-risk MGUS should be followed up in secondary care. During follow-up a progressively rising M-protein or serum FLC level should raise concerns about the possibility of progression, as should the development of anaemia, a rise in ESR, renal impairment or hypercalcaemia.

³¹ Bird J et al. (2009) 'UK Myeloma Forum (UKMF) and Nordic Myeloma Study Group (NMSG): Guidelines for the investigation of newly detected M-proteins and the management of monoclonal gammopathy of undetermined significance (MGUS)'. *Br J Haematol.* 147(1): 22–42.

³² Berenson JR et al. (2010) 'Monoclonal gammopathy of undetermined significance: A consensus statement'. *Br J Haematol.* 150(1): 28–38.

³³ Van de Donk N et al. (2014) 'The clinical relevance and management of monoclonal gammopathy of undetermined significance and related disorders: Recommendations from the European Myeloma Network'. *Haematologica.* 99(6): 984–96.

Myeloma UK diagnostic tool

Myeloma UK have produced a diagnostic tool with guidance for primary care with suggested response to results from monitoring tests (Figure 2).³⁴

Response to results	
<ul style="list-style-type: none"> Any paraprotein/abnormal sFLC ratio with significant symptoms indicative of an urgent problem (e.g. spinal cord compression, acute kidney injury) 	<p>Recommend referral for immediate assessment and/or admission as per local pathways</p>
<ul style="list-style-type: none"> Moderate concentration of paraprotein (IgG > 15 g/L, IgA or IgM > 10 g/L) Identification of an IgD or IgE paraprotein (regardless of concentration) Significant abnormal sFLC ratio (< 0.1 or > 7) <ul style="list-style-type: none"> Identification of BJP 	<p>Recommend urgent suspected cancer (USC) referral to Clinical Haematology</p>
<ul style="list-style-type: none"> Minor concentration of paraprotein (IgG < 15 g/L, IgA or IgM < 10 g/L) without relevant symptoms Minor abnormal sFLC ratio (> 0.1 and < 7, but outside normal range) without relevant symptoms <p>This pattern is common in elderly patients</p>	<p>Recommend recheck serum and urine in 2–3 months to confirm pattern and assess any progression.</p> <p>Patients whose paraprotein concentration increases (25% and > 5 g/L) or develop symptoms will need an urgent referral.</p> <p>Discuss with your Clinical Haematology Department if results not clear or concerns.</p>
<ul style="list-style-type: none"> No serum paraprotein Normal sFLC ratio (0.26–1.65)* <ul style="list-style-type: none"> No BJP Normal immunoglobulin levels <p>*some laboratories may have a slightly different reference range</p>	<p>Myeloma very unlikely but symptoms may still need to be investigated with other clinical specialties</p>

Figure 2 - Response to results: Myeloma guidance for primary care

³⁴ Myeloma UK. Myeloma Diagnostic Tool: Guidance for Primary Care. Available online at: [Myeloma Diagnostic Tool: Guidance for Primary Care](#). Accessed on 19.3.25.

Table 7. Suggested MGUS monitoring by category at diagnosis

MGUS features at diagnosis	Monitoring frequency
Paraprotein ≤ 15 g/L, non-IgM, normal FLC ratio*	Check FBC, serum creatinine and calcium and protein electrophoresis for paraprotein [†] every 3-4 months for the first year and then 6-12 monthly for 2 years. If stable at 2 years, consider discontinuing
Paraprotein >15<30 g/L or IgM paraprotein or abnormal FLC ratio*	Check FBC, serum creatinine and calcium and protein electrophoresis for paraprotein [†] every 3-4 months for 2 years and then 6-12 monthly and increasing to annually if stable
Either 2 or 3 of the above or evidence of progression (rising paraprotein, increasing FLC ratio, unexplained anaemia, deteriorating kidney function or hypercalcaemia)	Secondary care monitoring

FLC = free light chains. *if available, not all laboratories offer this test. † and FLC ratio if available

Prostate Specific Antigen (PSA) Testing and Prostate Cancer

Prostate cancer is the most common solid cancer in men. Roughly 50,000 new cases are diagnosed each year in England and Wales and we know from the National Prostate Cancer Audit that 16.4% of men diagnosed with prostate cancer in England between 1st January 2015 and 31st December 2019 had metastatic disease at diagnosis. Metastatic disease was strongly linked to deprivation and also varied by region³⁵. Those in the most deprived areas were 29% more likely to have metastatic disease at diagnosis compared to those in the least deprived. People with a family history of prostate cancer in a first degree relative are 2-4x more likely to develop the disease and people of Black ethnicity have double the risk of those of White ethnicity. Men with mutations of BRCA1 (BReast CAncer gene 1) and BRCA2

³⁵ Healthcare Quality Improvement Partnership (2022) Patient and Tumour Characteristics Associated with Metastatic Prostate Cancer at Diagnosis in England. NPCA: Short Report 2022. Available online at: [NPCA Short-report-2022 Final-08.09.22.pdf](#). Accessed on 4.3.25.

(BRCA2) are at risk of earlier and more aggressive prostate cancer (BRCA genes normally produce proteins that help repair damaged DNA).

Autopsy studies have demonstrated that over a third of men age ≥ 70 years have prostate cancer³⁶ and prostate cancer is a leading cause of cancer death, causing around 12,000 deaths annually in men in the UK³⁷. One of the improvement goals identified by the National Prostate Cancer Audit was to improve the timely diagnosis and treatment of high-risk prostate cancer. The US Preventive Services Task Force (USPSTF) recommend that for men aged 55 to 69 years, the decision to undergo periodic PSA-based screening for prostate cancer should be an individual one and should include discussion of the potential benefits and harms of screening with their clinician³⁸. The USPSTF recommends against PSA-based screening for prostate cancer in men aged ≥ 70 years, because the evidence suggests no benefit on prostate cancer mortality in men aged ≥ 70 years. The UK National Cancer Screening committee do not currently recommend PSA-based screening for prostate cancer³⁹ at any age. Nevertheless, asymptomatic men aged ≥ 50 years can request PSA testing through their GP, something which is not widely known despite recent highlighting in the media⁴⁰. Most men have a PSA level less than 3ng/mL but around 75% of men with a PSA level ≥ 3 ng/mL will not have cancer and a small proportion of men with PSA levels < 3 ng/mL will later be found to have prostate cancer⁴¹.

Monitoring and Management

For men with possible symptoms of prostate cancer NICE have indicated age-specific thresholds of PSA for referral for exclusion of prostate cancer⁴², although also acknowledging that there was a lack of good quality evidence on the diagnostic accuracy of fixed and age adjusted PSA thresholds.

³⁶ Jahn JL, et al. (2015) 'The high prevalence of undiagnosed prostate cancer at autopsy: implications for epidemiology and treatment of prostate cancer in the prostate-specific antigen-era'. *Int J Cancer*. 2 137 (12):2795-2802.

³⁷ Cancer Research UK. Prostate cancer statistics: prostate cancer mortality. Available online at: [Prostate cancer mortality statistics | Cancer Research UK](#)

³⁸ Grossman DC et al. (2018) 'Screening for Prostate Cancer: US Preventive Services Task Force Recommendation Statement.' *JAMA*. 319(18):1901-1913.

³⁹ Gov UK National Screening Committee. Adult screening programme: Prostate Cancer. Available online at: [Prostate cancer - UK National Screening Committee \(UK NSC\) - GOV.UK](#). Accessed on 4.3.25.

⁴⁰ Reed J. (2025) Warning over rapid at-home prostate tests. BBC News. Available online at: [Prostate cancer: Rapid at-home PSA tests spark concerns - BBC News](#). Accessed on 4.3.25.

⁴¹ Office for Health Improvement and Disparities. (2024) Guidance: Advising men without symptoms of prostate disease who ask about the PSA test. Available online at: [Advising men without symptoms of prostate disease who ask about the PSA test - GOV.UK](#). Accessed on 4.3.25.

⁴² NICE. (2025) Clinical Knowledge Summary. Prostate Cancer: How should I assess a person with suspected prostate cancer? Available online at: [Assessment | Diagnosis | Prostate cancer | CKS | NICE](#). Accessed on 5.3.25.

Table 8. NICE suggested age-specific thresholds of PSA for referral for exclusion of prostate cancer

Age	PSA level
Below 40	Use clinical judgement
Between 40 and 49	more than 2.5ng/mL
Between 50 and 59	more than 3.5ng/mL
Between 60 and 69	more than 4.5ng/mL
Between 70 and 79	more than 6.5ng/mL

Multiparametric magnetic resonance imaging (mpMRI) of the prostate may allow a quarter (27%) of patients to avoid prostate biopsy and reduce diagnosis of low-grade cancers, not requiring radical treatment, by 5%⁴³. NICE now recommend pre-biopsy mpMRI as part of the diagnostic pathway for prostate cancer.

Data from the European Randomised study of Screening for Prostate Cancer (ERSPC) support PSA testing. PSA screening in the age group 55-69 years significantly reduced prostate cancer-specific mortality by 20% at 16 yr of follow-up (RR 0.80, 95% confidence interval [CI] 0.72–0.89)⁴⁴. This and similar studies led the European Association of Urology to a different stance to the UK on PSA-based screening⁴⁵. However, PSA testing for early detection of prostate cancer in asymptomatic men remains controversial with uncertainty over optimal PSA thresholds for referral, intervals for retesting and insufficient evidence to guide whether any mortality reduction from PSA-based screening outweighs the impact of overdiagnosis and overtreatment on men’s quality of life and healthcare systems.

Prostate cancer UK recently facilitated a consensus to address optimal use of PSA testing in asymptomatic men for early detection of prostate cancer⁴⁶. This consensus

⁴³ Ahmed HU et al. (2017) ‘Diagnostic accuracy of multiparametric MRI and TRUS biopsy in prostate cancer (PROMIS): a paired validating confirmatory study’. *Lancet*. 389:815–822.

⁴⁴ Hugosson J et al. (2019) ‘A 16-yr Follow-up of the European Randomized study of Screening for Prostate Cancer’. *European Urology*. 76:43-51.

⁴⁵ Van Poppel H et al. (2021) ‘Prostate-specific Antigen Testing as Part of a Risk-Adapted Early Detection Strategy for Prostate Cancer: European Association of Urology Position and Recommendations for 2021’. *European Urology*. 80:703-711.

⁴⁶ Harding TA et al. (2024) ‘Optimising the use of the prostate- specific antigen blood test in asymptomatic men for early prostate cancer detection in primary care: report from a UK clinical consensus’. *British Journal of General Practice*. 74 (745): e534-e543.

was informed by evidence⁴⁷ and challenges some aspects of PSA testing policy. Although not advocating population or targeted screening the consensus recommends proactive approaches in men aged ≥ 45 years at higher than average risk (Black men, men with a family history of prostate cancer, or men with confirmed genetic risk factor). Consensus was not reached with respect to alternatives to the current PSA threshold of ≥ 3 ng/mL for referral in asymptomatic patients age 50-69 years because of lack of high-quality evidence to support age-specific PSA thresholds in asymptomatic patients. Similarly, there was no consensus on eligibility or frequency of repeat PSA testing in patients who do not meet the threshold for referral, but there was agreement that the initial test should be performed under optimal conditions avoiding factors that may influence PSA levels.

It was noted that any increase in PSA testing would require commissioning and resourcing. Provision of PSA testing in primary care will also require GPs to provide appropriate evidence-based counselling on the potential harms and benefits of PSA testing.

GIRFT Urology 2024: Guidance for Primary Care

The Getting It Right First Time (GIRFT) Towards Better Diagnosis & Management of Suspected Prostate Cancer document also provides advice and guidance for elements of the prostate cancer pathway relating to both primary and secondary care⁴⁸.

GIRFT specifically advise:

- Men at a higher risk can have a PSA after discussion of prostate cancer risk.
- When the PSA is raised, use a urine test to exclude infection.
- No digital rectal examination (DRE) is needed if the PSA is raised.
- If DRE has been done, and is abnormal, refer to secondary care on an urgent suspected cancer pathway, even if the PSA is within normal limits.
- There is no need to repeat a raised PSA unless there are other probable causes of a raised PSA, for example a urinary tract infection or recent catheterisation.
- Patients with a PSA > 20 ng/ml should always be referred using an urgent suspected cancer pathway regardless of other potential causes.

⁴⁷ Tesfai A et al. (2024) 'Variation in harms and benefits of prostate-specific antigen screening for prostate cancer by socio-clinical risk factors: A rapid review'. BJUI Compass. 5:417-432.

⁴⁸ GIRFT Urology: Towards Better Diagnosis & Management of Suspected Prostate Cancer. April 2024. Available from: <https://gettingitrightfirsttime.co.uk/wp-content/uploads/2024/04/GIRFT-Urology-Towards-Better-Diagnosis-Management-of-Suspected-Prostate-Cancer-FINAL-V1-April-2024-1.pdf>
Accessed 18 July 2025

- Do not routinely test PSA in asymptomatic patients aged over 80 years or co-morbid patients.

GIRFT acknowledge that PSA thresholds for referral of patients for investigation of suspected prostate cancer differ between cancer alliances in NHS England and that could be one of the drivers of geographical variation in the proportion of patients who are diagnosed too late to be cured. GIRFT observed that PSA thresholds, including age-related thresholds were based on studies which pre-dated use of prostate MRI. They recommend that MRI and PSA density (PSA divided by prostate volume, ng/mL/cm³) should be used to assess the risk of prostate cancer, and the need for prostate biopsy.

For patients at low risk of clinically significant prostate cancer discharged back to primary care follow up GIRFT recommend re-referral based on PSA-density.

PSA Monitoring Following Diagnosis of Prostate Cancer (Active Surveillance)

Active surveillance of men with prostate cancer in primary care requires GPs to do more than PSA testing. They will also need to:

- Hold and maintain a register of patients who meet the criteria for ongoing surveillance
- Provide a robust and effective call recall system from the Register which will require administrative support
- Ensure patients are informed of their result, what the result means and the next steps
- Have a process in place to follow up patients who DNA
- Ensure that patients who decline active surveillance in primary care have the reasons clearly documented together with the actions that have been taken in accordance with patient choice
- Ensure there is practice liaison with the urology service to act as a conduit between the practice and urology departments regarding PSA/Prostate Cancer.

Of those men diagnosed with prostate cancer each year up to 1 in 3 are diagnosed with Cambridge Prognostic Group (CPG) 1 or 2 prostate cancer and are potentially suitable for active surveillance, in England alone (approx. 20-25,000 men/year). NICE guidance recommends offering active surveillance to people with CPG 1 prostate cancer and recommends that people with CPG 2 be offered a choice between active surveillance, radical prostatectomy or radical radiotherapy⁴⁹.

⁴⁹ NICE. (2021) Prostate Cancer: diagnosis and management. Available online at: [Overview | Prostate cancer: diagnosis and management | Guidance | NICE](#). Accessed on 5.3.25.

When patients have a biopsy the pathologist assesses the most common cell type and the second most common cell type by how normal or abnormal they look using a scale of 1 to 5 (1 being most like normal) and reporting the 2 scores together, for example 3+3 for a Gleason score of 6.

CPG 1 patients are characterised by a Gleason score of 6 on biopsy, PSA < 10 ng/mL and a T stage of 1 or 2 (T1 cancers are too small to be seen on a scan or detected by digital rectal examination and T2 cancers are confined to within the prostate). CPG 2 patients have a Gleason score of 7 (3+4) or a PSA of 10-20 ng/mL and a T stage of 1 or 2. The 10-year mortality of CPG 1 and CPG 2 are 1.2% and 4.2% respectively.

CPG 3 patients have a Gleason score of 7 (3+4) and a PSA 10-20 ng/mL and a T stage of 1 or 2 or a Gleason score of 7 (4+3) and a T stage of 1 or 2. NICE advises considering active surveillance for people with CPG 3 who choose not to have immediate radical treatment.

Patients referred to urology who have not had a biopsy and in whom the suspicion of prostate cancer is low are recommended to have a repeat PSA at 6 months and then annually. For patients referred following a raised PSA but with no evidence of prostate cancer on biopsy NICE recommends repeat testing at 2 years. Metrics NICE recommends for re-referral are either a PSA density of >0.15 ng/mL/mL and/or a rate of rise of PSA >0.75 ng/mL/year.

Problems engendered by use of threshold PSA

Two potential problems engendered by use of threshold PSA, PSA density and rate of rise of PSA are the biological and analytical variability of PSA. The former can be mitigated by ensuring standard conditions for PSA testing prior to venupuncture. These include avoiding vigorous exercise and sex/ejaculation in the previous 48 hours, use of medications including finasteride, and ensuring active urinary infection is not present. Ensuring mitigation of analytical variability is more complex, each assay will have an inherent variability and there is nonuniformity of different manufacturers assays. These differences led to the introduction of reference standards for PSA and external quality assessment schemes to improve PSA assay comparability⁵⁰. Despite this clinically significant interassay variability persists, as demonstrated in a recent study, and leading to a recommendation for standardised calibration methods and greater awareness among practitioners concerning interassay variability⁵¹. Of the 360 UK laboratories returning quality assurance data on analytes to the UK National External Quality Assurance Scheme (UK NEQAS),

⁵⁰ Chan DW and Sokoll LJ. (2000) 'WHO First International Standards for Prostate-specific Antigen: The Beginning of the End for Assay Discrepancies?' *Clinical Chemistry*. 46:1291–1292.

⁵¹ Kaufmann B et al. (2024) 'Interassay Variability and Clinical Implications of Five Different Prostate-specific Antigen Assays'. *European Urology*. 63:4-12.

323 returned data on PSA⁵². The 323 laboratories were using 9 different PSA assays with an overall coefficient of variation of all methods combined of 7.0% for a known PSA of 3 ng/mL. The implications are that the higher the biological variation of PSA (the physiological within individual variation in PSA level) the lower the confidence that a change in PSA is a true change and the greater that change would need to be to be clinically significant. Clinicians should therefore acknowledge that clinically relevant thresholds may thus depend on the specific PSA assay and that ideally the same assay is applied over time for better clinical decision making.

Table 9. PSA monitoring by disease category

Prostate cancer not diagnosed	
PSA > 3 ng/mL at first test but below age-related threshold	Repeat at 6 months and then 12 months, if stable stop monitoring, refer to urology if rate of rise > 0.75 ng/mL/yr or associated symptoms, or if PSA density > 0.12 ng/mL/cm ³ for MRI score 3 and >0.2 for MRI score 1 or 2.
PSA above age-related threshold	Either refer to urology if associated with symptoms or repeat at 6 months and then 12 months, refer if rate of rise > 0.75 ng/mL/yr depending on locally agreed policy, or if PSA density > 0.12 ng/mL/cm ³ for MRI score 3 and >0.2 for MRI score 1 or 2.
Raised PSA, prostate biopsy normal	Repeat PSA at 2 years, refer if rate of rise >0.75 ng/mL/year, or if PSA density > 0.12 ng/mL/cm ³ for MRI score 3 and >0.2 for MRI score 1 or 2.
Prostate cancer diagnosed in patients choosing active surveillance	
Monitor PSA and symptoms 6-12 monthly depending on CPG stage	

CPG = Cambridge Prognostic Group

⁵² Personal Communication from UK NEQAS.

Possible symptoms related to prostate cancer

Early prostate cancer may be asymptomatic but development of lower urinary tract symptoms may influence decision making related to PSA monitoring, these include:

- Urinary hesitancy and/or incomplete bladder emptying
- Poor urine flow and diminished stream
- Post micturition dribbling
- Urinary frequency and/or nocturia
- Urgency
- Haematuria or haemospermia

Symptoms unrelated to the urinary tract include unexplained weight loss, back pain, hip pain or pelvic pain.

Monitoring post Bariatric surgery

The annual rate of bariatric surgery procedures is increasing, both globally and in the UK, leading to a growing number of patients living with a history of bariatric surgery and requiring long term follow up and monitoring^{53,54}. Data analyses from the National Bariatric Surgery Registry, updated in November 2023, indicated that surgeons in the South East region recorded 3684 bariatric surgery procedures between April 2019 and March 2023, of which 3274 were primary procedures, roughly equivalent to an increase in patients potentially requiring monitoring of 655/year. The registry includes data from all NHS funded primary and revisional bariatric surgery but not self or insurance funded bariatric surgery; or patients who had surgery outside England or temporary weight loss interventions (eg gastric balloons) and those patients who had elective surgery to treat long term complications associated with bariatric surgery (eg gallstones).

UK best practice guidance and recommendations

The British Obesity and Metabolic Surgery Society (BOMSS) published evidence based guidance looking at 4 surgical procedures - adjustable gastric band (AGB), sleeve gastrectomy (SG), Roux-en-Y gastric bypass (RYGB) and duodenal switch

⁵³ Busetto L et al. (2017) 'Practical recommendations of the Obesity Management Task Force of the European Association for the Study of Obesity for the post-bariatric surgery medical management'. *Obes Facts*. 10:597–632.

⁵⁴ National Bariatric Registry. (2023) Surgeon Specific Outcome Reports for NHS Bariatric Surgery. Available online at: [Home | Bariatric Surgeon Reporting Website](#). Accessed 26.3.25.

(BPD/DS) in 2020⁵⁵. The methodology for the guideline was sound and followed the AGREE principles⁵⁶, including patient representation. Evidence up to and including January 2018 was systematically reviewed and the evidence and recommendations were graded based on the Scottish Intercollegiate Guidelines Network (SIGN) methodology⁵⁷

BOMSS recommend that patients should stay within the specialist bariatric surgery service for 2 years following surgery and then be followed up in primary care annually (evidence grade D, expert opinion). NICE Quality Standards for obesity assessment and management also recommend that adults discharged from the bariatric surgery service have follow up at least annually^{58,59}. NICE suggest that an agreed shared-care model of management should be in place with collaboration between specialist weight management services and primary care as well as locally agreed monitoring arrangements and responsibilities. The onus is on commissioners to ensure commissioning of shared-care models of management between specialist weight management services and primary care to provide that lifelong follow up care.

Evidence in the BOMMS guidance for monitoring full blood count (FBC), serum ferritin, vitamin B12 and folate annually is at Good Practice Point (GPP) level only. Similarly, the evidence for annual primary care monitoring of Vitamin D, calcium and parathyroid hormone, Fat-soluble vitamins A, E and K and Trace minerals: zinc, copper, selenium and magnesium plus Thiamine is all at the GPP level assuming no other specific indication. Table 10 below indicates the recommended follow up following discharge from the bariatric surgery centre.

The main limitations of the BOMMS guidelines are the evidence base from which the guidance was developed. There are very limited numbers of randomised controlled trials (RCTs) undertaken in bariatric surgery and nutrition, leading to the GPP level recommendations. Other post bariatric surgery guidance for monitoring from the various UK surgical centres appears to follow BOMSS 2020 recommendations and although NICE published updated Obesity guidance in January 2025 there were no recommendations for what should be monitored, post-surgery monitoring and

⁵⁵ O'Kane M, et al. (2020) British Obesity and Metabolic Surgery Society Guidelines on perioperative and postoperative biochemical monitoring and micronutrient replacement for patients undergoing bariatric surgery-2020 update. *Obes Rev.* 21:e13087.

⁵⁶ Brouwers MC et al. (2010) AGREE II: advancing guideline development, reporting and evaluation in health care. *CMAJ.* 182:E839-E842.

⁵⁷ Scottish Intercollegiate Network (SIGN). (2011) SIGN 50 A guideline developers handbook. Available online at: [sign50_2011.pdf](#). Accessed on 26.3.25.

⁵⁸ NICE. (2016) Obesity: clinical assessment and management. Available online at: [Overview | Obesity: clinical assessment and management | Quality standards | NICE](#). Accessed on 30.3.25.

⁵⁹ NICE. Overweight and obesity management. In development. Expected publication date: 5.8.25. Available online at: [Project documents | Overweight and obesity management | Quality standards | NICE](#). Accessed on 30.3.25.

monitoring post bariatric surgery in both adults and in younger age patients were both research recommendations only⁶⁰.

Monitoring and management in primary care

GP practices will need to keep a register of bariatric surgery patients and record the type of procedure as follow up varies according to the type of surgery (Figure 3). Patients should be encouraged to check their own weight regularly and to attend an annual assessment with a health professional including BMI and nutritional review, review of co-morbidities such as diabetes mellitus, hypertension, hypercholesterolaemia and sleep apnoea, as well as mental health. For female patients of child-bearing age contraception should be discussed and ideally pregnancy should be avoided for at least 12-18 months post-surgery.

Parretti and colleagues undertook a population-based cohort study to investigate whether the nutritional care and weight monitoring delivered by GPs to patients 2 years post-bariatric surgery meets current UK national clinical guidance⁶¹. They found that most patients who have had bariatric surgery do not receive the recommended annual nutritional reviews or weight monitoring in general practice. There was variability in the annual recommended nutritional blood tests recorded and at 4-5 years post-surgery even common tests such as serum creatinine were only recorded in between 53.3-59.7% of patients and although also recommended annually, specific tests such as copper and zinc were seldom recorded (0.1–1.5% and 0.8-4.3% respectively). Parretti et al suggested that GP confidence and education may be barriers to patients receiving long term care post-bariatric surgery but did not address the commissioning of services from primary care. The accompanying editorial noted that there is no nationally agreed shared care model for post-bariatric surgical care and that as GPs are unlikely to frequently encounter such patients, they therefore may not feel confident in managing them⁶². The authors argued that community dietitians may be well placed to offer specialist knowledge and long-term follow-up care as part of a wider service to provide weight management support for patients with obesity in primary care.

⁶⁰ NICE. (2025). Overweight and obesity management. Available online at: [Overview | Overweight and obesity management | Guidance | NICE](#). Accessed on 26.3.25.

⁶¹ Parretti HM et al. (2021) 'Post-bariatric surgery nutritional follow-up in primary care: a population-based cohort study'. *Br J Gen Pract.* ;71:e441-e449.

⁶² Mears R et al. (2021) 'Bariatric surgery: the GP's role in long-term post-bariatric surgery follow-up'. *Br J Gen Pract.* 71:248-249.

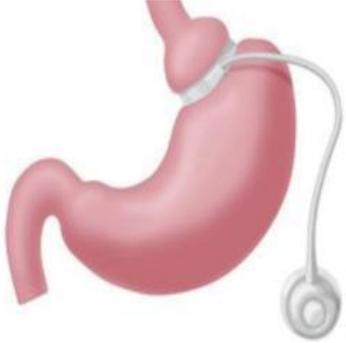
Gastric band 	Sleeve gastrectomy 	Roux-en-Y Gastric bypass  (RYGB)
No impact on absorption of nutrients, but patients may experience vomiting or regurgitation and develop food intolerances.	Iron, calcium, vitamin D, vitamin B12, zinc, copper, selenium, vitamin A absorption may be affected.	Iron, calcium, vitamin D, vitamin B12, zinc, copper, selenium, vitamin A absorption may be affected.

Figure 3- Impact of surgery on absorption

Duodenal switch - Iron, calcium, vitamin D, vitamin B12, protein, fat, fat soluble vitamins A, E and K, zinc, copper and selenium absorption are affected.

Follow up post-bariatric surgery in subjects prescribed and adhering to micronutrient supplementation after gastric by-pass procedures or sleeve gastrectomy indicated that in this setting de novo deficiency at 12 months was uncommon^{63,64}. However, adherence to supplements has been reported to decline at ≥2 years follow up and nutritional deficiencies then start to appear⁶⁵. For example, a 10 year follow up of patients following RYGB found iron deficiency (serum ferritin ≤15 µg/L) in nearly a quarter of subjects despite iron supplementation in more than half⁶⁶. The same group reported that adherence to supplements reduced the probability of vitamin and mineral deficiency, especially for thiamine, vitamin B2, vitamin B6, folate, vitamin B12, and vitamin D, but does not eliminate it⁶⁷. BOMMS have very usefully distilled

⁶³ Lewis C-A et al. (2023) 'Monitoring for micronutrient deficiency after bariatric surgery—what is the risk?' *European Journal of Clinical Nutrition*. 77:1071–1083.

⁶⁴ Zarshenas N et al. (2023) 'Investigating the prevalence of copper and zinc abnormalities in patients pre and post bariatric surgery - an Australian experience'. *Obesity Surgery*. 33:3437–3446.

⁶⁵ Zarshenas N et al. (2022) 'Investigating the prevalence of nutritional abnormalities in patients prior to and following bariatric surgery.' *Nutrition & Dietetics*. 79:590–601.

⁶⁶ Sandvik J et al. (2021) 'Iron Deficiency and Anemia 10 Years After Roux-en-Y Gastric Bypass for Severe Obesity'. *Front. Endocrinol.* 12:679066.

⁶⁷ Bjerkan KK et al. (2023) 'Vitamin and Mineral Deficiency 12 Years After Roux-en-Y Gastric Bypass a Cross-Sectional Multicenter Study'. *Obesity Surgery*. 33:3178–3185.

their guidance into a short guide for GPs detailing what should be monitored and exactly which supplements should be offered, subdivided by type of bariatric surgery⁶⁸. Further information is also available through the BOMMS website [BOMSS – British Obesity & Metabolic Surgery Society](#)

Table 10. Recommended Community Follow Up Post-Bariatric Surgery

1. Postoperative care and biochemical monitoring	SIGN evidence grade and level
People discharged from bariatric surgery service follow-up should undergo monitoring of nutritional status at least once a year as part of a shared care model of management	Grade D EL 4
Monitor Urea and electrolytes, renal and liver function tests, calcium and vitamin D annually	GPP
Monitor FBC, serum ferritin, folate and vitamin B12 annually	GPP
Monitor fat soluble vitamins A, E and K annually following malabsorptive procedures such as BPD/DS	GPP
Consider monitoring trace minerals zinc, copper, selenium and magnesium annually following SG, RYGB or BPD/DS	GPP
2. Vitamin and mineral supplementation	
A complete multivitamin and mineral supplement (containing thiamine, iron, selenium, zinc and copper) is recommended daily after all bariatric procedures	GPP
Advise people to take a complete multivitamin and mineral supplement providing 400-800 µg folic acid per day	Grade D EL 4 (1+ to 4)

⁶⁸ British Obesity and Metabolic Surgery Society (BOMSS). (2023) BOMSS post-bariatric surgery nutritional guidance for GPs. Available online at: [BOMSS post-bariatric surgery nutritional guidance for GPs](#). Accessed on 1.4.25.

Following SG, RYGB or malabsorptive procedures such as BPD/DS, recommend routine supplementation with vitamin B12 intramuscular injections	Grade B EL 2 (1+ to 2-)
Between 2000 and 4000 IU oral vitamin D3 per day may be required following SG and RYGB and higher following malabsorptive procedures such as BPD/DS	Grade D EL 4 (2 to 4)
Ensure good dietary calcium intake, recognizing that requirements may be higher in individuals who have SG, RYGB or malabsorptive procedures such as BPD/DS.	GPP
Following RYGB some people may require additional routine oral vitamin A supplementation	Grade C EL 2 (1- to 4)
Following malabsorptive procedures such as BPD/DS, supplement with additional oral vitamin A daily	Grade B EL 2 (1+ to 3)
Following malabsorptive procedures such BPD/DS, supplement with additional oral vitamin E and vitamin K daily	Grade C EL 2 (1+ to 4)
Following RYGB and SG, supplement with 15 mg zinc orally per day	GPP
Following malabsorptive procedures such BPD/DS, supplement with 30 mg zinc orally per day	Grade C EL 2
Following bariatric surgery daily selenium supplements are recommended with additional supplementation following malabsorptive procedures such as BPD/DS	Grade D EL 2 (2-) Grade B EL 2 (1+ to 2-)

BPD/DS = biliopancreatic diversion with duodenal switch; SG = sleeve gastrectomy; RYGB = Roux-en-Y gastric bypass

Eating disorders

Eating disorders are serious mental conditions, which affect people irrespective of age, ethnicity, social class and geography⁶⁹. The defining feature of an eating disorder is a substantial disturbance in eating or eating related behaviour, with various behavioural disturbances associated with each disorder⁷⁰. Types of eating disorders include:

- **Anorexia nervosa** — low body weight due to restriction of food intake or persistent behaviour which interferes with weight gain and intense fear of gaining weight.
- **Bulimia nervosa** — recurrent episodes of binge eating followed by compensatory behaviour such as self-induced vomiting, laxative abuse, or excessive exercise.
- **Binge eating disorder** — recurrent episodes of binge eating in the absence of compensatory behaviours.
- **Atypical eating disorders (otherwise known as other specified feeding or eating disorder; OSFED)** — closely resemble anorexia nervosa, bulimia nervosa, and/or binge eating but do not meet the precise diagnostic criteria.
- **Avoidant / restrictive food intake disorder (ARFID)** – restriction of food intake for reasons other than beliefs about weight or body shape e.g. negative feelings over smell, taste or texture of certain foods⁷¹.

Atypical eating disorders are most common, followed by binge eating disorders, then bulimia nervosa. Anorexia nervosa is the least common⁷². Figure 4 provides a further description for the diagnosis and classification for eating disorders⁶⁹.

⁶⁹ Beat Eating Disorders. Types of Eating Disorder. Available online at: [Types of Eating Disorder](#). Accessed on 27.3.25.

⁷⁰ Attia E and Walsh T. (2025) 'Eating Disorders A Review.' *JAMA*. 33(14):1242-1252.

⁷¹ NHS. Overview - Eating Disorders. Available online at: [Overview – Eating disorders - NHS](#). Accessed on 27.3.25.

⁷² NICE. (2024) Clinical Knowledge Summary. Eating Disorders. Available online at: [Eating disorders | Health topics A to Z | CKS | NICE](#). Accessed on 27.3.25.

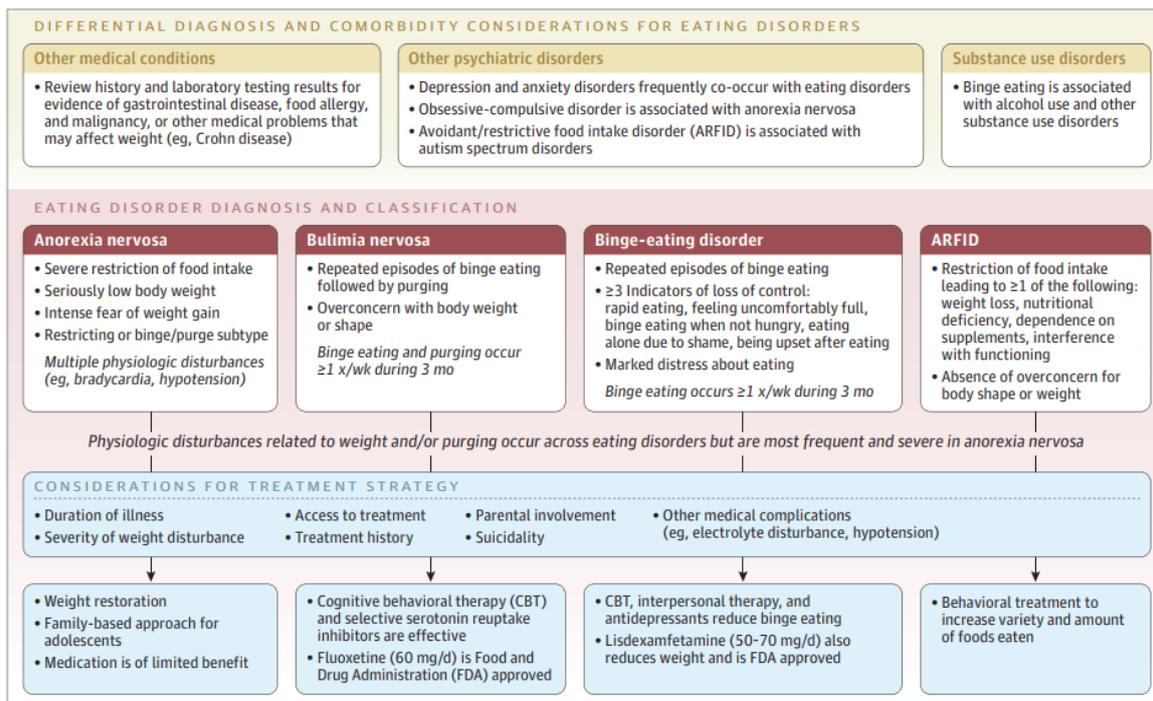


Figure 4- Classification of eating disorders

A recent meta-analysis showed the prevalence of eating disorders in the UK is higher than previously estimated, with a lifetime mean of 8.4% for women and 2.2% for men. It is estimated approximately 1.25 million people in the UK have an eating disorder⁷³. The prevalence is increasing, exacerbated by the COVID-19 pandemic⁷⁴, meaning clinicians are increasingly likely to encounter patients with eating disorders in their daily practice. Eating disorders can develop at any age, but the highest risk is for young men and women between 13-17 years old⁷⁵. The causes of eating disorders are multifactorial, including a combination of biological, psychological and social factors. Eating disorders are associated with psychological, social and physical complications, and can be fatal. People may also transition between different eating disorders over time. For example, someone with anorexia nervosa who has regained weight may later develop behaviours meeting diagnostic criteria for bulimia nervosa.

⁷³ Beat Eating disorders. Prevalence in the UK. Available online at: [Prevalence in the UK - Beat](#). Accessed on 27.3.25.

⁷⁴ Galmiche M et al. (2019) 'Prevalence of eating disorders over the 2000–2018 period: a systematic literature review'. *The American Journal of Clinical Nutrition*. 109(5):1402-13.

⁷⁵ NICE. (2020) Eating disorders: recognition and treatment. Available online at: [Eating disorders: recognition and treatment](#). Accessed on 27.3.25.

Diagnosis of eating disorders

Figure 5 provides a summary of factors which should be considered when assessing people for an eating disorder or deciding when to refer people for assessment. A diagnosis of an eating disorder should be based on suggestive clinical features, supported where possible, by corroboration from a relative or friend⁷⁶.

1. An unusually low or high body mass index (BMI) or body weight for age.
2. Rapid weight loss.
3. Dieting or restrictive eating practices (such as dieting when they are underweight) that are worrying the individual, their family members or carers, or professionals.
4. Family members or carers report a change in eating behaviour.
5. Social withdrawal, particularly from situations that involve food.
6. Other mental health problems.
7. A disproportionate concern about their weight or shape (e.g., concerns about weight gain as a side effect of contraceptive medication).
8. Problems managing a chronic illness that affects diet, such as diabetes or coeliac disease.
9. Menstrual or other endocrine disturbances or unexplained gastrointestinal symptoms.
10. Physical signs of:
 - Malnutrition, including poor circulation, dizziness, palpitations, fainting or pallor.
 - Compensatory behaviours, including laxative or diet pill misuse, vomiting or excessive exercise.
11. Abdominal pain that is associated with vomiting or restrictions in diet that cannot be fully explained by a medical condition.
12. Unexplained electrolyte imbalance or hypoglycaemia.
13. Atypical dental wear (such as erosion).
14. Whether the individual takes part in activities associated with a high risk of eating disorders (e.g. professional sport, fashion, dance or modelling).

Figure 5 - Summary of factors which should be considered when assessing people for an eating disorder

The initial assessment of a patient with a possible eating disorder should exclude alternative diagnoses, which may include gastrointestinal conditions, endocrine disorders e.g. hyperthyroidism or hypothyroidism or malignancy.

Eating disorders can present as medical emergencies in community, primary care or hospital settings⁷⁷. Early identification of eating disorders is associated with improved clinical outcomes, including more rapid recovery. However, eating disorders can be difficult to diagnose given reluctance of patients to disclose symptoms, limited training for clinicians in eating disorders⁷⁸, signs and symptoms of eating disorders having multiple aetiologies, which and are often comorbid with other

⁷⁶ NICE. (2024) Clinical Knowledge Summary. Eating Disorders: How should I assess a person with a suspected eating disorder? Available online at: [Assessment | Diagnosis | Eating disorders | CKS | NICE](#). Accessed on 27.3.25.

⁷⁷ Mughal et al. (2023) 'Assessment and management of medical emergencies in eating disorders; guidance for GPs.' *British Journal of General Practice*. 73: 232–233.

⁷⁸ Mills R et al. (2023) 'A Narrative Review of Early Intervention for Eating Disorders: Barriers and Facilitators.' *Adolescent Health, Medicine and Therapeutics*. 14: 217-235.

mental and physical health problems⁷⁶. Primary care clinicians should have a low threshold for seeking advice in the assessment of eating disorders.

NICE guidelines (2020) state people with a suspected eating disorder should be immediately referred to an age-appropriate eating disorder service for specialist assessment and management⁷⁴.

Whilst awaiting a specialist assessment, regular reviews to monitor levels of physical and mental health risk should be arranged. The frequency of these reviews is dependent on the clinical situation e.g. weekly in children⁷⁹. Additionally, for people with co-morbidities (such as diabetes) and pregnant women, advice should be sought from an appropriate specialist^{74,78}.

UK best practice guidance and recommendations

Ongoing monitoring is vital in assessing and re-assessing risk once an eating disorder has been confirmed⁸⁰.

In recommendations set out in the 'Medical Emergencies in Eating Disorders (MEED): Guidance on Recognition and Management' (2023)⁸¹ it is highlighted '*the role of the primary care team is to monitor patients with eating disorders, refer them early and provide monitoring after discharge, in collaboration with medical services and eating disorder services (EDSs) (including community eating disorder services (CEDSSs))*.

The 'Adult eating disorders: Community, Inpatient and Intensive Day Patient Care: Guidance for commissioners and providers' (2019)⁸² recommends '*medical monitoring needs to be based on local medical monitoring agreements clearly established across the CEDSSs and primary care network, with one consistent protocol agreed on by local commissioners*.' There should be a clear agreement between primary and secondary or tertiary care about the responsibility for

⁷⁹ NICE. (2024) Clinical Knowledge Summary. Eating Disorders: Scenario: Suspected eating disorder. Available online at: [Scenario: Suspected eating disorder | Management | Eating disorders | CKS | NICE](#)

⁸⁰ NHS Grampian. GP advice on physical assessment of eating disorders. Available online at: [GP ADVICE ON PHYSICAL ASSESSMENT OF EATING DISORDERS](#). Accessed on 11.4.25.

⁸¹ Royal College of Psychiatrists. (2023) Medical emergencies in eating disorders (MEED) Guidance on recognition and management. Available online at: [Medical emergencies in eating disorders \(MEED\) - Guidance on recognition and management - CR233](#). Accessed on 13.4.25.

⁸² National collaborating centre for mental health and NHS. (2019) 'Adult eating disorders: Community, Inpatient and Intensive Day Patient Care: Guidance for commissioners and providers' Available online at: [Adult Eating Disorders: Community, Inpatient and Intensive Day Patient Care: Guidance for commissioners and providers](#). Accessed on 27.3.25.

monitoring a person with an eating disorder⁸³. Table 11 provides a summary for the responsibility of medical monitoring for eating disorders. When the responsibility for medical monitoring lies with primary care, the CEDS should be accessible for primary care to consult with to ensure results are interpreted correctly.

In patients who become unwell during refeeding, GPs should consider refeeding syndrome (peripheral oedema/acute fluid overload, hypokalaemia/hypophosphatemia, or organ dysfunction: cardiorespiratory failure or deranged liver transaminases) and communicate with the treating team⁷⁶.

Table 11. Responsibility of Medical Monitoring for Eating Disorders

Community Eating Disorder Service	Primary Care
<ul style="list-style-type: none"> • Patient is at high medical risk and / or unable to reliably adhere to physical health monitoring in a primary care setting. 	<ul style="list-style-type: none"> • Patient is a low medical risk • Patient is discharged from the CEDS

For those patients who are at moderate risk, some recommendations indicate the medical monitoring could be undertaken by primary care, if the patient recognises the need for health care and seeks it. However, other recommendations indicate patients at both high and moderate risk should be referred urgently to A & E or an acute psychiatric or eating disorder unit^{76,81}.

Monitoring and management

The all-age risk assessment framework, found in the MEED guidance includes clinical assessment with investigations and is designed to aid decisions on emergency management. It is based on the best evidence and international consensus guidance but does require clinical judgment to interpret. No single parameter can be used as an adequate indicator of overall level of risk or illness, however, a patient with one or more red ratings or two or more amber ratings should probably be considered high risk. A summary of what is included within this risk assessment framework is found in the table 12. A patient whose life may be at impending risk because of an eating disorder and refuses admission or referral may require a Mental Health Act assessment⁷⁶.

⁸³ NICE. (2024) Clinical Knowledge Summary. Eating Disorders: Scenario: Confirmed eating disorder. Available online at: [Scenario: Confirmed eating disorder | Management | Eating disorders | CKS | NICE](#). Accessed on 27.3.25.

Table 12. Risk assessment framework for assessing impending risk to life (MEED guidance)

Parameter for monitoring	Red: High impending risk to life	Amber: Alert to high concern for impending risk to life	Green: Low impending risk to life	Additional information / guidance
Medical history and examination				
Weight loss	<ul style="list-style-type: none"> Recent loss of weight of $\geq 1\text{kg/week}$ for 2 weeks (consecutive) in an undernourished patient Rapid weight loss at any weight, e.g. in obesity or avoidant restrictive food intake disorder (ARFID) 	<ul style="list-style-type: none"> Recent loss of weight of 500–999g/week for 2 consecutive weeks in an undernourished patient 	<ul style="list-style-type: none"> Recent weight loss of $<500\text{g/week}$ or fluctuating weight 	<ul style="list-style-type: none"> Weight loss in children and adolescents is often more acute than in adults, due to lower body fat stores. NICE guidelines recommend a rate of weight loss of more than 1kg a week indicates the patient needs inpatient care. It is important to recognise the weigh in process may be viewed by the patient as stressful and requires sensitivity. Home weight measurements should generally be discouraged⁸⁴.
Body Mass Index (BMI) and weight	<ul style="list-style-type: none"> Under 18 years (centile charts should be used): %mBMI $<70\%$ Over 18: BMI <13 	<ul style="list-style-type: none"> Under 18: %m BMI 70–80% Over 18: BMI 13–14.9 	<ul style="list-style-type: none"> Under 18: %mBMI $>80\%$ Over 18: BMI >15 	<ul style="list-style-type: none"> There are limited studies in adults to determine the BMI at which the risks increase. BMI is an important but imprecise measure of health risk. For example, a person may have a 'normal' BMI but still be malnourished. Interpretation of weight or BMI in assessing malnutrition in young people requires particular care due to changes in weight, height and BMI during growth in childhood and through puberty. MEED guidance recommends avoiding discussing risk levels and BMI with patients as it can exacerbate symptoms. It is recommended to compare current BMI with any previous measurements.

⁸⁴ Klein et al. (2021) Eating disorders in Primary Care: Diagnosis and Management. Available online at: [p22.pdf](#). Accessed on 1.4.25.

Parameter for monitoring	Red: High impending risk to life	Amber: Alert to high concern for impending risk to life	Green: Low impending risk to life	Additional information / guidance
				<ul style="list-style-type: none"> Clinicians should be aware people may refuse to be weighed or falsify their weight by hiding heavy objects in their clothes, for example⁷⁵.
Heart rate (awake)	<ul style="list-style-type: none"> <40 beats per minute (bpm) 	<ul style="list-style-type: none"> 40-50 bpm 	<ul style="list-style-type: none"> >50 bpm 	<ul style="list-style-type: none"> Bradycardia is common in patients with anorexia nervosa. Bradycardia, <50 bpm or postural tachycardia have been highlighted as red flags⁷⁵. A normal or high pulse may present, despite very low weight or with low blood pressure (BP), possibly indicating infection or dehydration.
Cardiovascular health	<ul style="list-style-type: none"> Standing systolic BP below 0.4th centile for age or less than 90 if 18+, associated with recurrent syncope and postural drop in systolic BP of >20mmHg or increase in HR of over 30bpm (35bpm in <16 years) 	<ul style="list-style-type: none"> Standing systolic BP <0.4th centile or <90 if 18+ associated with occasional syncope; postural drop in systolic BP of >15mmHg or increase in HR of up to 30 bpm (35bpm in <16 years) 	<ul style="list-style-type: none"> Normal standing systolic BP for age and gender with reference to centile charts Normal orthostatic cardiovascular changes Normal heart rhythm 	<ul style="list-style-type: none"> Monitoring of BP for postural differences (hypotension or orthostatic hypotension are red flags) is recommended⁷⁵. Syncope and pre-syncopal symptoms are common in people suffering from undernutrition who have an eating disorder. Orthostatic hypotension is seen in undernourished people and those with rapid weight loss and is a marker of disruption of the normal homeostatic physiological cardiovascular mechanisms which control BP with change in posture.
Assessment of hydration status	<ul style="list-style-type: none"> Fluid refusal Severe dehydration (10%): reduced urine output, dry mouth, postural BP drop (see above), decreased skin turgor, sunken eyes, tachypnoea, tachycardia 	<ul style="list-style-type: none"> Severe fluid restriction Moderate dehydration (5–10%): reduced urine output, dry mouth, postural BP drop (see above), normal skin turgor, 	<ul style="list-style-type: none"> Minimal fluid restriction No more than mild dehydration (<5%): may have dry mouth or concerns about risk of 	<ul style="list-style-type: none"> Hydration status is difficult to assess in the context of malnutrition. No single sign of hypovolaemia is reliable and requires the assessment of a range of clinical parameters. In assessing hydration status, if the clinician is uncertain the assistance of a renal physician can be helpful. NICE guidelines⁷⁴ recommend fluid balance should be 'assessed in people with eating disorders who are believed to be engaging in compensatory behaviours, such as vomiting, taking laxatives or diuretics, or water loading'.

Parameter for monitoring	Red: High impending risk to life	Amber: Alert to high concern for impending risk to life	Green: Low impending risk to life	Additional information / guidance
		some tachypnoea, some tachycardia, peripheral oedema	dehydration with negative fluid balance	
Temperature	<ul style="list-style-type: none"> <35.5°C tympanic or 35.0°C 	<ul style="list-style-type: none"> <36.0°C 	<ul style="list-style-type: none"> >36.0°C 	<ul style="list-style-type: none"> Hypothermia is found in 32% of adolescents with anorexia nervosa (<35.6 °C) and 22% of adult outpatients (<36°C), likely due to loss of body fat combined with slower metabolic rate.
Muscular function: Sit Up-Squat-Stand (SUSS) test	<ul style="list-style-type: none"> Unable to sit up from lying flat, or to get up from squat at all or only by using upper limbs to help (Score 0 or 1) 	<ul style="list-style-type: none"> Unable to sit up or stand from squat without noticeable difficulty (Score 2) 	<ul style="list-style-type: none"> Able to sit up from lying flat and stand from squat with no difficulty (Score 3) 	<ul style="list-style-type: none"> Clinical experience suggests adolescents frequently 'pass' this test, especially if they are athletic. Performing poorly is a concern, but it is important not to be falsely reassured if the person performs well.
Muscular function: Hand grip strength	<ul style="list-style-type: none"> Male <30.5kg, Female <17.5kg (3rd percentile) 	<ul style="list-style-type: none"> Male <38kg, Female <23kg (5th percentile) 	<ul style="list-style-type: none"> Male > 38kg, Female >23kg 	<ul style="list-style-type: none"> Hand grip strength can be measured using a relatively inexpensive meter (e.g. a digital hand-grip-strength meter/dyanometer) with excellent face validity and test– retest and inter-rater reliability.
Muscular function: Mid - upper arm circumference (MUAC)	<ul style="list-style-type: none"> <18cm (approx. BMI <13) 	<ul style="list-style-type: none"> 18-20cm (approx. BMI <15.5) 	<ul style="list-style-type: none"> >20cm (approx. BMI > 15.5) 	<ul style="list-style-type: none"> MUAC has been evaluated in anorexia nervosa and is a third test of muscle function available to clinicians, if weight and height are not easy to obtain (e.g. the patient is unconscious).

Parameter for monitoring	Red: High impending risk to life	Amber: Alert to high concern for impending risk to life	Green: Low impending risk to life	Additional information / guidance
Other clinical state	<ul style="list-style-type: none"> Life-threatening medical condition, e.g. severe haematemesis, acute confusion, severe cognitive slowing, diabetic ketoacidosis, upper gastrointestinal perforation, significant alcohol consumption 	<ul style="list-style-type: none"> Non-life-threatening physical compromise, e.g. mild haematemesis, pressure sores 	<ul style="list-style-type: none"> Evidence of physical compromise, e.g. poor cognitive flexibility, poor concentration 	
ECG abnormalities	<ul style="list-style-type: none"> <18 years: QTc 460ms (female), 450ms (male) 18+ years: QTc >450ms (females), 430ms (males) Or any other significant ECG abnormality 	<ul style="list-style-type: none"> <18 years: 460ms (female), 450ms (male) 18+ years: QTc >450ms (females), >430ms (males) And no other ECG anomaly Taking medication known to prolong QTc interval 	<ul style="list-style-type: none"> <18 years: QTc <460ms (female), 450ms (male) 18+ years: QTc <450ms (females), <430ms (males) 	<ul style="list-style-type: none"> NICE guidelines recommend assessing if ECG monitoring is needed in people with an eating disorder, based on the following risk factors⁷⁴: <ul style="list-style-type: none"> rapid weight loss excessive exercise severe purging behaviours, such as laxative or diuretic use or vomiting bradycardia hypotension excessive caffeine (including from energy drinks) prescribed or non-prescribed medications muscular weakness

Parameter for monitoring	Red: High impending risk to life	Amber: Alert to high concern for impending risk to life	Green: Low impending risk to life	Additional information / guidance
				<ul style="list-style-type: none"> • electrolyte imbalance • previous abnormal heart rhythm.
Biochemical abnormalities	<ul style="list-style-type: none"> • Hypophosphatemia and falling phosphate • Hypokalaemia (<2.5mmol/l) • Hypoalbuminemia • Hypoglycaemia (<3mmol/l) • Hyponatraemia • Hypocalcaemia • Transaminases (>3x normal range) • Inpatients with diabetes mellitus: HbA1C >10% (86mmol/mol) 			<ul style="list-style-type: none"> • Patients with eating disorders can be extremely medically unwell and have normal blood tests. Normal electrolytes are therefore not a cause for reassurance, although abnormal ones are a cause for concern. • NICE guidelines recommend electrolyte balance should be 'assessed in people with eating disorders who are believed to be engaging in compensatory behaviours, such as vomiting, taking laxatives or diuretics, or water loading.' • In addition to the biochemical markers highlighted, the NICE Clinical Knowledge Summary suggests monitoring the following, depending on the clinical situation; urea, liver function tests, blood glucose and creatinine and urinalysis⁷⁵. Urinalysis can help to elucidate mode of purging, for example urinary chloride will be low in vomiting and diuretic use, but high in diarrhoea caused by laxative use⁸⁵.
Haematology	<ul style="list-style-type: none"> • Low white cell count • Haemoglobin <10g/L 			<ul style="list-style-type: none"> • In addition to the haematological markers highlighted, the NICE Clinical Knowledge Summary suggests monitoring the following, depending on the clinical situation: FBC and Erythrocyte sedimentation rate (ESR) (a raised ESR may indicate an organic cause of weight loss, as usually normal in people with anorexia)

⁸⁵ Puckett L. (2023) 'Renal and electrolyte complications in eating disorders: a comprehensive review.' *Journal of eating disorders*. 11:26.

Parameter for monitoring	Red: High impending risk to life	Amber: Alert to high concern for impending risk to life	Green: Low impending risk to life	Additional information / guidance
				<ul style="list-style-type: none"> • The NICE Clinical Knowledge Summary also suggests the following further tests may be required in more severe cases or to assess complications (specialist advice should be sought): • Calcium, magnesium, phosphate. • B12, folate, and ferritin. • Thyroid function tests. • Follicle-stimulating hormone, luteinising hormone, oestradiol, prolactin, and urinalysis (including pregnancy test) may be considered if presenting with amenorrhoea⁷⁵.
Disordered eating behaviours	<ul style="list-style-type: none"> • Acute food refusal or estimated calorie intake 			
Engagement with management plan	<ul style="list-style-type: none"> • Physical struggles with staff or parents/carers over nutrition or reduction of exercise • Harm to self • Poor insight or motivation • Fear leading to resistance to weight gain • Staff or parents/carers unable to implement meal plan prescribed 	<ul style="list-style-type: none"> • Poor insight or motivation • Resistance to weight gain • Staff or parents/carers unable to implement meal plan prescribed • Some insight and motivation to tackle eating problems • Fear leading to some ambivalence but not actively resisting 	<ul style="list-style-type: none"> • Some insight and motivation to tackle eating problems • May be ambivalent but not actively resisting 	

Parameter for monitoring	Red: High impending risk to life	Amber: Alert to high concern for impending risk to life	Green: Low impending risk to life	Additional information / guidance
Activity and exercise	<ul style="list-style-type: none"> High levels of dysfunctional exercise in the context of malnutrition (>2h/day) 	<ul style="list-style-type: none"> Moderate levels of dysfunctional exercise in the context of malnutrition (>1h/day) 	<ul style="list-style-type: none"> Mild levels of or no dysfunctional exercise in the context of malnutrition (<1h/day) 	<ul style="list-style-type: none"> MEED guidance recommends males should be asked specifically about excess training and exercise and misuse of anabolic or androgenic steroids. Males and some females who overtrain may have extremely low body fat levels and larger than average muscles. Use of anabolic steroids and Vitamin D injections can lead to increased physical risk at higher levels of BMI (and age-adjusted BMI) than those quoted.
Purging behaviours	<ul style="list-style-type: none"> Multiple daily episodes of vomiting and/or laxative abuse 	<ul style="list-style-type: none"> Regular (=>3x per week) vomiting and/or laxative abuse 		
Self-harm and suicide	<ul style="list-style-type: none"> Self-poisoning, suicidal ideas with moderate to high risk of completed suicide 	<ul style="list-style-type: none"> Cutting or similar behaviours, suicidal ideas with low risk of completed suicide 		

mBMI, median body mass index

Table 12 provides a thorough overview of what should be considered within a risk assessment to aid decisions on emergency management of eating disorders, such as admission for monitoring and refeeding management.

Most current practice guidelines agree that a **full physical examination, ECG and relevant blood monitoring** should be part of an assessment for patients with an eating disorder^{74,76,79,80,86,87,88,89,90}. A physical examination should include assessment of⁷⁹:

1. Weight / BMI (adjusted for age, as appropriate)
2. Blood pressure (lying and standing)
3. Pulse
4. Muscular function e.g. Sit Up-Squat-Stand (SUSS) test
5. Hydration status (e.g. consider fluid intake, urine output, examination of skin / mucosa)

Relevant blood tests should include⁸⁰:

- Full blood count
- Urea and electrolytes (including creatinine, sodium, potassium)
- Liver function tests (including albumin, bilirubin and transaminases (liver enzymes) e.g. alanine aminotransferase, aspartate aminotransferase (AST), alkaline phosphatase (ALP), and γ -Glutamyltransferase (GGT))
- Bone profile (including phosphate, calcium)
- Glucose
- HbA1C in patients with diabetes
- Magnesium^{79,85,86}

The following blood tests may also be considered:

- Creatinine Kinase^{76,86,88}
- Urinalysis⁷⁵
- B12, zinc, folate, and ferritin⁸⁰
- Thyroid function tests

⁸⁶ NHS Devon Partnership NHS Trust. Appendix 5a - Community Eating Disorders Service (CEDs).

⁸⁷ NHS East London NHS Foundation Trust. Medical monitoring for patients with diagnoses or suspected eating disorder. Available online at: [GP A4 CEDs physical monitoring Aug 2022 draft.pdf](#). Accessed on 16.4.25.

⁸⁸ National Eating Disorders Collaboration. (2021) Eating Disorders: A professional resource for general practitioners. Available online at: [NEDC-Resource-GPs.pdf](#). Accessed on 16.4.25.

⁸⁹ NHS Oxford Health NHS Foundation Trust. Wiltshire Community Eating Disorder Service. Available online at: [Physical health monitoring - WCEDs](#). Accessed on 16.4.25.

⁹⁰ Treasure J. (2012) A guide to the medical risk assessment for eating disorders. Available online at: [Microsoft Word - GUIDE FOR MEDICAL RISK ASSESSMENT December 2012.doc](#). Accessed on 16.4.25.

- Follicle-stimulating hormone, luteinising hormone, oestradiol, prolactin, and urinalysis (including pregnancy test) if presenting with amenorrhoea.

Table 13 provides a summary for the recommendations around frequency of monitoring, which are dependent on the severity of the condition. This summary table is based on current evidence and guidelines available and highlights a suggested range for frequency of monitoring, taking into account these various guidelines^{79,86,88}.

Table 13. Recommendations for frequency of monitoring in eating disorders

BMI / weight loss	Physical examination	ECG	Relevant bloods
BMI 15-17.5kg/m², or weight loss of <0.5kg / week	Monthly – 6 monthly	On referral and annually	2 weekly – 8 weekly (can be stopped if normal for 3 months and patient making progress)
BMI 14-14.9kg/m², or weight loss between 0.5-1kg / week	2 weekly – 8 weekly	Monthly – 3 monthly	Weekly – 8 weekly
BMI <14 kg/m², or weight loss >1kg / week	Weekly – 2 weekly	2 weekly – 2 monthly	Weekly – 2 weekly
Vomiting			
Daily	Monthly	Monthly - 6 monthly	Monthly (increased monitoring recommended if vomiting more frequently. If a patient is taking potassium supplements, repeat blood tests at least twice a week) ⁸⁸
< Daily	3 monthly	To be considered - 3 monthly	3 monthly

Annual review

NICE guidelines (2020)⁷⁴ recommend GPs should offer a physical and mental health review at least annually to people with anorexia nervosa who are not receiving ongoing treatment for their eating disorder. The following should be assessed at an annual review:

- Weight or BMI (adjusted for age if appropriate)
- Blood pressure
- Relevant blood tests (as highlighted above)
- ECG, for people with purging behaviours and/or significant weight changes
- Problems with daily functioning. No standardised approach is recommended within the NICE guidelines for assessing daily functioning. There are several tools available which may be used e.g. Clinical Impairment Scale⁹¹.
- Assessment of risk (related to both physical and mental health)
- Growth and development in children and young people who have not completed puberty (for example, not reached menarche or final height)
- Discussion of treatment options

As previously highlighted, more regular monitoring is recommended depending on previous results and level of risk.

NICE guidelines (2020) provide recommendations around monitoring of bone health. A bone mineral density (BMD) scan should be considered:

- after 1 year of underweight in children and young people, or earlier if they have bone pain or recurrent fractures
- after 2 years of underweight (BMI < 18.5kg/m²) in adults, or earlier if they have bone pain or recurrent fractures.
- In people with ongoing persistent underweight, especially when using or deciding whether to use hormonal treatment.

BMD scans should not be repeated for people with anorexia nervosa more frequently than once per year, unless they develop bone pain or recurrent fractures.

⁹¹ Schaefer L M et al. (2021) 'A systematic review of instruments for the assessment of eating disorders among adults' *Curr Opin Psychiatry*. 34(6): 543–562.

Pelvic organ prolapse

Pelvic organ prolapse is common affecting 1 in 10 women over the age of 50 years with 20–40% of all women experiencing prolapse symptoms that may be bothersome and affect their quality of life⁹². Although mild prolapse is often symptom free, symptoms such as a heaviness or a dragging sensation in the pelvis worsening throughout the day, bladder and bowel symptoms and discomfort during sexual intercourse increase with severity⁹³.

Risk factors include pregnancy and childbirth with some suggesting a degree of prolapse is present for 50% of parous women attending hospital clinics⁹⁴; congenital or acquired connective tissue abnormalities; denervation of the pelvic floor: aging and menopause and factors associated with chronic raised intrabdominal pressure such as constipation⁹³.

It is possible to reduce symptoms through lifestyle changes such as stopping smoking, reducing weight, avoiding constipation and where possible heavy lifting. Treatment and management of pelvic organ prolapse is influenced by how the prolapse affects quality of life, severity, women's choice and a woman's ability to self-manage the condition and includes physiotherapy, support pessaries and/or surgery⁹².

Due to the very personal nature of pelvic organ prolapse many women suffer the consequences in silence⁹³. Compounding this is inequity of access to women's health services generally, in 2022 gynaecology waiting lists had grown by over 60% across the UK since the start of the COVID-19 pandemic⁹⁵ and have been slow to recover. Thus, best practice for women's health services and indeed highly personal conditions such as pelvic organ prolapse can not to be considered solely from a medical treatment and management viewpoint. For women's health to benefit from high quality care it needs to be accessible.

The government's first Women's Health Strategy for England⁹⁶ was written in 2022 and is based on a life course approach. This 10-year strategy has the ambition of improving the health of women everywhere and includes gynaecological conditions

⁹² Pelvic Obstetric and Gynaecological Physiotherapy and United Kingdom Continence Society. (2021) 'UK Clinical Guideline for best practice in the use of vaginal pessaries for pelvic organ prolapse.' Available online at: [uk_pessary_guideline_final_april21.pdf](#). Accessed on 14.4.25.

⁹³ Royal College of Obstetricians and Gynaecologists. (2022) Pelvic organ prolapse. Available online at: [Pelvic organ prolapse | RCOG](#). Accessed on 15.4.25.

⁹⁴ Kang J and Marsh F. How to fit a vaginal pessary for pelvic organ prolapse. Primary Care Women's Health Journal. Available online at: [pessary-fitting-for-organ-prolapse.pdf](#). Accessed on 10.4.25.

⁹⁵ Royal College of Obstetricians and Gynaecologists. (2022) Left for too long. Available online at [Left for too long | RCOG](#). Accessed on 14.4.25.

⁹⁶ Department of Health and Social Care. (2022) Policy paper: Women's Health Strategy for England. Available online at: [Women's Health Strategy for England - GOV.UK](#). Accessed on 14.4.25.

such as vaginal prolapse. The strategy acknowledges the systemic inequalities that exist for women of certain ethnicities not only in accessing care but in the negative and dismissive attitudes of health care professionals and the inequity for access to high quality care by appropriately trained professionals in women's health services generally. This gender bias is echoed in the report 'Women's health economics: investing in the 51 per cent' report⁹⁷ that makes several recommendations including ring-fenced funding for the Women's Health Strategy and recommendations for health care professional's education and training. It highlights the return on investment for every £1 invested in women's health services making a compelling argument that investment in women's health will ultimately contribute to an economy and health system that is better for everyone.

What is pelvic organ prolapse?

The ligaments and muscles known as the pelvic floor hold the organs within a woman's pelvis (uterus, bladder and rectum) in place. If these support structures are weakened by overstretching, the pelvic organs can bulge (prolapse) from their natural position into the vagina. When this happens it is known as pelvic organ prolapse⁹². There are different types of prolapse depending on which pelvic organ is bulging into the vagina. Such as prolapse of the bladder (cystocele), the rectum (rectocele) of the small intestine (enterocele). Clinical examination is necessary to determine classification and staging⁹³. It is common to have more than one type of prolapse at the same time. Distinguishing between the different types and degree of pelvic organ prolapse is important as this will influence treatment options⁹¹.

MANAGEMENT AND TREATMENT

NICE Guidance

NICE guidance for urinary incontinence and pelvic organ prolapse written in 2019⁹⁸ describes the responsibilities for local and regional multidisciplinary teams and its recommendations for the clinical composition of those teams.

The recommendations for presentation in primary care with symptoms or incidental finding of vaginal prolapse, include a thorough clinical history taking, assessment

⁹⁷ NHS Confederation. (2024) Women's health economics: investing in the 51 percent. Available online at: [Women's health economics: investing in the 51 per cent | NHS Confederation](#). Accessed on 14.4.25.

⁹⁸ NICE. (2019) Urinary incontinence and pelvic organ prolapse in women: management. Available online at: [Recommendations | Urinary incontinence and pelvic organ prolapse in women: management | Guidance | NICE](#). Accessed on 10.4.25.

and exclusion of pelvic mass of other pathology and discussion with the woman about her preferences with ongoing referral as necessary. Specialist evaluation of vaginal prolapse (in primary care or secondary care by a clinician with the clinical expertise) should involve assessing and recording the degree of prolapse using the POP-Q (Pelvic Organ Quantification) system which is an objective and standardised measure ensuring consistency. In addition, a validated pelvic floor symptom questionnaire can be used to aid assessment and decision making.

Following discussion of management options with the woman taking into account their preferences, site of prolapse, lifestyle factors, comorbidities, cognitive and physical impairments, age, wishes regarding childbearing, previous abdominal or pelvic floor surgery and benefits and risks of individual procedures NICE make recommendations for:

- lifestyle modification
- topical oestrogen
- pelvic floor muscle training
- surgical intervention.

In 2021 NICE published guidance specifically on pelvic floor dysfunction prevention and non-surgical management⁹⁹, identifying the 3 most common and definable symptoms of pelvic floor dysfunction as urinary incontinence, faecal incontinence and pelvic organ prolapse. It aims to raise awareness of pelvic floor dysfunction for all women and help women to reduce their risk.

The recommendations include producing resources on pelvic floor function in different formats such as print, broadcast and online adverts, leaflets, videos and information for social media and interactive online resources for example through the NHS App. It highlights the need to tailor information and communication for different age groups and characteristics, such as pregnancy. It also recommends the importance of targeting information for specific communities where there is evidence of healthcare inequalities. There are recommendations for teaching young women (12-17 years) in educational settings about pelvic floor anatomy and pelvic floor exercises and the importance of information, education and follow up for women using maternity services.

In addition to the above recommendations are made for assessment in primary care which include accurate history taking and assessment of symptoms; recommendations for community based MDT teams, who should consist of members with competencies related to assessing and managing pelvic floor dysfunction,

⁹⁹ NICE. (2021) Pelvic floor dysfunction: prevention and non-surgical management. Available online at: [Recommendations | Pelvic floor dysfunction: prevention and non-surgical management | Guidance | NICE](#). Accessed on 10.4.25.

lifestyle recommendations; intravaginal devices and pessaries, psychological and behavioural interventions.

In 2023 there was the introduction of a service specification for Perinatal Pelvic Health Services (PPHS) and the national Implementation Guidance for PPHS^{100,101}. PPHS will expand the core service offer beyond existing NICE and Royal College of Obstetricians and Gynaecologists (RCOG) Green-top Guidelines on care for obstetric anal sphincter injuries (OASI). The emphasis is on prevention, identification and timely treatment with the aim of reducing the number of women living with pelvic health problems postnatally and in late life⁹⁹.

The UK Clinical Guideline for Best Practice in the use of Vaginal pessaries for Pelvic Organ Prolapse

A very effective way of managing pelvic organ prolapse symptoms is through use of a vaginal support pessary. A pessary is a plastic or silicone device that fits inside the vagina to help support the pelvic organs. They are suitable for most people and a doctor or specialist nurse will advise of the type and size a woman needs with ring pessaries being the most commonly used⁹².

The UK Clinical Guideline⁹¹ for best practice in the use of vaginal pessaries for pelvic organ prolapse was launched in March 2021 to address the absence of standardised evidence-based guidance. An important component of this guideline was the inclusion throughout of pessary users to advise on the patient information section, the choice of new graphics, terminology and the clinical algorithm. As a result of service user involvement, the guidance signposts throughout to the sections that help women navigate complications and better understand prolapse.

The guideline provides a training framework available as a download to assist practitioner training to optimise consistency in pessary provision and practice. Pessaries use at different life stages are discussed indicating where short and long term goals and complications may change depending on the age of the woman.

¹⁰⁰ NHS England. (2023) Service specification: Perinatal Pelvic Health Services: Version 1. Available online at: [PRN00147-Service-specification-perinatal-pelvic-health-services.pdf](#). Accessed on 14.4.25.

¹⁰¹ NHS England. (2024) Implementation guidance: Perinatal Pelvic Health Services. Available online at: [NHS England » Implementation guidance: Perinatal Pelvic Health Services](#). Accessed on 14.4.25.

Types of pessaries

Vaginal pessaries are a quick, simple, non-surgical option that can be highly effective in helping to alleviate symptoms and improve quality of life for many women with prolapse. The aims of vaginal pessaries are to prevent worsening of the prolapse, reduce the frequency and severity of symptoms, and to either avert or delay the need for surgery⁹³.

There are a number of different pessaries available and selection largely depends on type and severity of prolapse and women's choice. Frequency and location (primary or secondary care) of clinical assessment, management and follow up is dependent on type of pessary and a woman's ability and wish to self-manage. Ring pessaries are the most commonly used and are generally managed in primary care although as the literature highlights expertise in community settings and access to these services are variable.

Below is a summary of treatment options and frequency of follow up for non-surgical treatment for pelvic organ prolapse. Information is taken from NICE guidelines NG123⁹⁷ and NG210⁹⁸ and Pelvic Obstetric and Gynaecological Physiotherapy POGP best practice guidelines for use of vaginal pessaries⁹¹ and should follow a thorough initial assessment and diagnosis in conjunction with appropriate communication, information leaflets and decision aids.

Table 14. Summary of treatment options and frequency of follow up for non-surgical treatment for pelvic organ prolapse

Treatment and Management	Frequency
<p>Pelvic floor muscle training</p> <ul style="list-style-type: none"> • Consider a programme of supervised pelvic floor muscle training for at least 4 months for women with symptomatic pelvic organ prolapse. • If the programme is beneficial, advise women to continue pelvic floor muscle training afterwards. 	<p>At least 1 week review while providing the programme and 1 review at the end of the programme</p>
<p>Topical oestrogen for post-menopausal women</p> <ul style="list-style-type: none"> • Consider vaginal oestrogen for women with pelvic organ prolapse • Consider an oestrogen-releasing ring for women with pelvic organ prolapse and genitourinary symptoms and signs associated 	<p>As per pharmaceutical guidelines and woman's need.</p>

<p>with menopause who have cognitive or physical impairments that might make vaginal oestrogen pessaries or creams difficult to use.</p>	
<p>Pessaries Consider a vaginal pessary for women with symptomatic pelvic organ prolapse, alone or in conjunction with supervised pelvic floor muscle training.</p> <ul style="list-style-type: none"> • Refer women who have chosen a pessary to a urogynaecology service if pessary care is not available locally. • Offer women using pessaries an appointment in a pessary clinic every if they are at risk of complications, for example because of a physical or cognitive impairment that might make it difficult for them to manage their ongoing pessary care. 	<p>Review following initial fitting at 4-6 weeks.</p> <p>The availability of telephone support during this time is good practice</p> <p>No longer than 6 months (between 3-6 months recommended) although following the initial review can be extended to 1 year if women is self-managing the pessary.</p>
<p>Psychological interventions Discuss the psychological impact of their symptoms with women who have pelvic floor dysfunction. Take account of this impact when developing a management plan.</p>	<p>As required.</p>

Women's Health Hub Model

One of the ways to that has been presented to address equity of access to pelvic organ prolapse services and experiences of care provided by appropriately trained members is by better integrating women's health services using the Women's Health Hub model (WHH)¹⁰² proposed by the Women's Health Strategy for England⁹⁵.

The Royal College of General Practitioners (RCGP) has a statement on its website that sets out the consensus opinion of those providing primary care, secondary care

¹⁰² Royal College of General Practitioners. Achieving success with the Women's Health Hub (WHH) model. Available online at: [Women's Health Hub \(WHH\) model](#). Accessed on 13.4.25.

and sexual and reproductive health services for women and states that this life course model provides Integrated Care Systems (ICSs) with a unique opportunity to improve the way care pathways work for women in their populations, determining priorities based on local need, promoting prevention and early intervention. It suggests guarding against strict definitions of what a WHH model should be although acknowledges that the many variations in existence risk diluting the concept to the point where services may define themselves as hubs without demonstrating improved access, experience and outcomes with DHSC accreditation being put forward as solution for this¹⁰¹. Indeed, the interim findings from the NIHR-funded study found significant variation in existing Women's Health Hubs, many of which had little in common in the way they were commissioned and delivered, and the services they offered to women¹⁰³.

Multidisciplinary Team training

It is clear when reviewing national guidance and best practice that delivering a high quality accessible pelvic organ prolapse service for women requires the skills of a range of clinical professionals including general practitioners (GPs), gynaecology specialists, nurses and physiotherapists. The variability of training for healthcare professionals, particularly with regards to pessary management has been highlighted¹⁰⁴.

The RCOG when examining the implementation of a Women's Health Hub (WHH) model, while recognising the existing workforce challenges, emphasise the importance of workforce planning and the need for this to be undertaken on a system-wide basis, to enable gaps to be identified and necessary training and development to be put in place to ensure delivery of high-quality care. They believe the hub model has the potential to improve skills, knowledge, and experience in women's healthcare across the system, particularly for primary care professionals. Hub models can facilitate collaborative working between primary and secondary care professionals, with shadowing opportunities and a two-way sharing of clinical knowledge. The RCOG advocate the use of the Additional Roles Reimbursement Scheme (ARRS) where the hub model sits within primary care¹⁰¹.

¹⁰³ Kelly D et al. Early evaluation of Women's Health Hubs: Interim summary report. Available online at: [whh-interim-summary-paper-final.pdf](#). . Accessed on 14.4.25.

¹⁰⁴ Dwyer et al. (2019) 'A review of pessary for prolapse practitioner training' *British Journal of Nursing*. 28(9):S18-S24.