

Type 2 diabetes mellitus (T2DM) prescribing guidelines for use in adults in South West London

Target audience

This document is aimed for use by healthcare professionals within NHS South West London to support them with diagnosis and management of their T2DM patients.

Introduction

The document has been produced following the publication of <u>NICE guideline</u> [NG28] Type 2 diabetes in adults: management and combines this national guidance with additional information, including diagnosis of T2DM, general principles to managing T2DM, local services and formulary medicine choices.

Risk factors for patients

Patients can get a better understanding of their risk factors for T2DM by accessing the <u>Diabetes UK website</u>, as well as using the <u>'Know Your Risk' online tool</u> to establish if their own risk is low, increased, moderate or high.

Complications

It is important for patients with T2DM to have regular diabetes check-ups and blood sugar control, as uncontrolled T2DM can lead to:

- Heart disease and stroke
- Loss of feeling and pain (nerve damage)
- Foot problems like sores and infections
- Vision loss and blindness
- Miscarriage and stillbirth
- Renal impairment
- Erectile dysfunction

How to diagnose T2DM

Signs and symptoms of diabetes:

- Increased thirst
- Polyuria (including nocturia)
- Unintentional weight loss
- Infections (thrush, abscesses)
- Poor wound healing
- Blurred vision
- Tiredness and lethargy

Since 2011, diabetes has been diagnosed based on these World Health Organisation (WHO) criteria:

If symptoms present:

A single fasting plasma glucose more than or equal to 7.0mmol/L or



- A single random plasma glucose more than or equal to 11.1mmol/L (not recommended) or
- An HbA1c (Glycated haemoglobin) more than or equal to 48mmol/mol (6.5%)

If no symptoms present:

- A fasting plasma glucose more than or equal to 7.0mmol/L on two separate occasions or
- A single random plasma glucose more than or equal to 11.1mmol/L on two separate occasions (not recommended) or
- An HbA1c more than or equal to 48mmol/mol (6.5%) on two separate occasions **or**
- An HbA1c more than or equal to 48mmol/mol (6.5%) **and** a single elevated plasma glucose as above

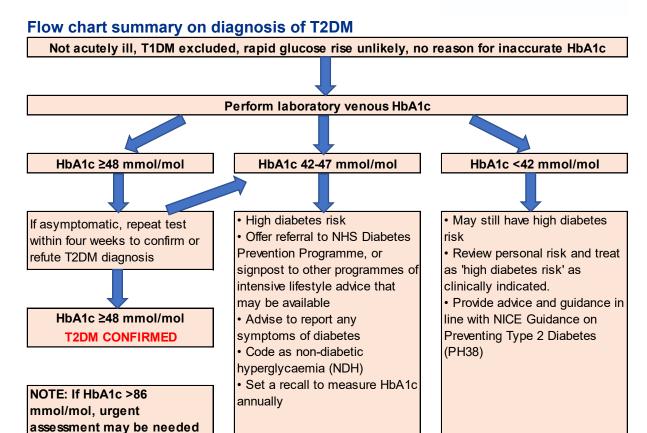
In the absence of symptoms, two abnormal results are required to make a diagnosis of T2DM.

The WHO concluded that HbA1c can be used as a diagnostic test for diabetes, provided there are no conditions present which preclude its accuracy (see 'Situations where HbA1c is not appropriate for diagnosing diabetes' section below).

HbA1c of more than or equal to 48 mmol/mol is diagnostic of diabetes. However, a value less than 48 mmol/mol does not exclude diabetes diagnosed using glucose tests (such as fasting glucose or Oral Glucose Tolerance Test). Individuals with a HbA1c less than 48 mmol/mol may be at risk of developing diabetes and should be monitored according to the following recommendations:

- Ensure patient is able to produce a reliable HbA1c (i.e. not acutely ill, type 1 diabetes mellitus (T1DM) excluded, rapid glucose rise unlikely, no reason for inaccurate HbA1c)
- 2) Perform laboratory venous HbA1c:
 - If HbA1c is less than 42 mmol/mol; patient may still have high diabetes risk. Review personal risk and treat as 'high diabetes risk' as clinically indicated
 - If HbA1c is 42-47 mmol/mol; patient has high diabetes risk. Offer referral to <u>NHS Diabetes Prevention Programme</u>, or signpost to other programmes of intensive lifestyle advice that may be available. Advise to report any symptoms of diabetes. Code as non-diabetic hyperglycaemia (NDH). Set a recall to measure HbA1c annually
 - If HbA1c is more than or equal to 48 mmol/mol and patient is asymptomatic, repeat venous HbA1c to confirm diagnosis within 4 weeks (preferably with the same test) to confirm or refute T2DM diagnosis. If patient is symptomatic (or second test is more than or equal to 48 mmol/mol), T2DM diagnosis is confirmed
 - If HbA1c is more than or equal to 86 mmol/mol, urgent assessment may be needed





Situations where HbA1c is not appropriate for diagnosing diabetes:

- All children and young people
- People of any age suspected of having T1DM
- People at high diabetes risk who are acutely ill (e.g. those requiring hospital admission), post severe trauma or cardiovascular disease (CVD) event
- People taking medication that may cause rapid glucose rise (e.g. steroids, antipsychotics)
- People with acute pancreatic damage, including pancreatic surgery
- In pregnancy
- In those with end-stage renal disease
- People being treated for HIV infection with antivirals
- Interpret HbA1c with caution if abnormal red blood cell lifespan e.g. iron deficiency anaemia, thalassaemia
- Note: Be aware that severe hyperglycaemia in people with acute infection, trauma, circulatory or other stress may be transitory and is not diagnostic of diabetes

General principles for managing Type 2 Diabetes Mellitus

- The goal of treatment is remission in eligible or appropriate patients
- Adopt an individualised approach to diabetes care that is tailored to the needs and circumstances of adults with type 2 diabetes, considering their personal preferences, comorbidities and risks from polypharmacy, and their likelihood of benefiting from long-term intervention. However, all patients should;



- Be offered diabetes structured education
- o Have their mental health status assessed
- Be assessed and, if appropriate, offered weight loss interventions such as <u>'Low Calorie Diet' (LCD)</u> for remission or weight loss for improved glycaemic control and CVD risk and individual advice from a dietitian
- o Be advised to commence or increase their physical activity level
- Be offered support to help stop smoking if appropriate
- Offer structured education to adults with T2DM at the time of diagnosis, with annual reinforcement and review. Explain to people that structured education is an integral part of diabetes care. Refer patients to resources within <u>SWL Health & Care Partnership Diabetes Toolkit</u>, including <u>Diabetes Book and Learn</u>, as appropriate
- A diagnosis of diabetes can have a great impact on mental health, leading to stress, insomnia and depression. Patients with diabetes are twice as likely to have depression. Support for patients is available via the above toolkit, including resources on <u>Diabetes UK</u> and <u>helplines</u>. Monitor and review patients regularly for signs and symptoms. Use the PHQ9 questionnaire which is available on the diabetes EMIS template, or alternatively the <u>PHQ4 questionnaire</u>. Patients, provided they fulfil the referral criteria, can be referred to a <u>variety of services</u> provided by South West London and St George's Mental Health NHS Trust as part of the Department of Health's Improving Access to Psychological Therapies (IAPT) initiatives
- For adults with T2DM who are overweight or obese, discuss and agree an initial body weight loss target of 5% to 10%. Weight loss is the most significant intervention for a patient to work towards improving glycaemic control and decrease CVD risk. Refer to the NHS Digital Weight Management programme, or the Tier 3 weight management services at St George's Hospital if appropriate and eligible (referred to the Endocrinology and Metabolic Medicine team via NHS e-referral service)
- Remission is when HbA1c remains below 48mmol/mol or 6.5% for at least six months, usually without needing to take any diabetes medication. There is strong evidence to suggest that diabetes is mainly put into remission by weight loss. Patients should aim to lose approximately 15kg, as soon as possible after diagnosis. This is not a 'cure' for T2DM, and it is important for patients to continue their diabetes appointments while in remission. Therefore patients in remission should be coded using the remission code, and not 'resolved'. T2DM only tends to be 'resolved' if steroid-induced. Refer eligible patients to the Low Calorie Diet (LCD) programme provided by OVIVA to support with this. Searches are available to identify eligible patients
- Provide individualised and ongoing evidence based nutritional advice from a
 healthcare professional with specific expertise and competencies in nutrition, in a
 form sensitive to the person's needs, culture and beliefs, being sensitive to their
 willingness to change and the effects on their quality of life. <u>Evidence-based</u>
 nutrition guidelines for the prevention and management of diabetes can be
 accessed via Diabetes UK
- Encourage adults with T2DM to follow the same <u>healthy eating advice</u> as the general population, additional <u>healthy eating advice</u> is available on <u>Diabetes UK</u>, as well as <u>suggested meal ideas</u>. The British Dietetic Association have produced



a <u>food fact sheet</u> that can be printed and given to patients. Please note that based on co-morbidities, specialist dietetic advice may be needed

Healthy eating patient information (provided by SWL dietitians)

- Patients should aim to have a regular meal pattern
- Aim for at least 5 portions of fruit and vegetables per day e.g. at least 3 portions of non-starchy vegetables and 2 portions (2-3 cupped handfuls) of fruit per day
- Aim to reduce fat intake, and replace saturated fat with unsaturated where possible
- Eat lean proteins such as low fat meat e.g. chicken without skin, lean unprocessed red meat, eggs, pulses, lentils, beans, soya, tofu, fish (including oily fish such as mackerel, salmon, sardines at least once a week)
- Eat high-fibre foods such as wholegrain and low-glycaemic-index carbohydrates, aiming to fill no more than 1/3 of your plate (granary or wholemeal bread/chapati, brown rice/pasta, plantain, cassava, porridge oats)
- Reduce to a minimum added sugars and processed foods e.g. high fat/sugar snacks e.g. chocolate, sweets, crisps, Bombay mix, cakes, biscuits, take away/fast foods, full sugar fizzy drinks and fruit juice
- Avoid 'diabetic foods' such as diabetic chocolate
- Snack options include natural or plain Greek yoghurt, 25g portion of unsalted nuts, portion of fruit, 2 tbsp houmous/tzatziki and vegetable sticks, oat cakes
- Include 2-3 dairy foods per day such as yoghurt, a glass of milk, small match-box sized portion of cheese
- Try to eat grilled, baked or steamed foods rather than fried
- <u>Diabetes UK budget-friendly recipe cards</u> are available to download for free. They intend to help patients with T2DM save money and cook tasty and healthy meals, and have been developed and reviewed by their in-house dietitians
- Reduce salt intake by not adding it during cooking or at the table to meals and instead use pepper or herbs and spices to flavour food
- Drink enough water or other sugar free fluids e.g. 6-8 cups or glasses throughout the day
- Excess alcohol intake is associated with an increased risk of T2DM and can increase the likelihood of hypoglycaemia. <u>Diabetes UK</u> has further information, including guidance on alcohol consumption

Other recommendations

• Most adults should engage in 150 minutes or more moderate to vigorous intensive physical activity per week, spread over at least three days a week, with no more than two consecutive days without activity. Strengthening exercise should be included on at least 2 of these days and adults should be encouraged to reduce the amount of time they spend sitting or lying down, with activity. Adults with type 2 diabetes should be reminded that being active, such as walking after meals will be beneficial to their overall glycaemic control. Further advice on recommended exercise can be found on the SWL Health & Care Partnership Diabetes Toolkit



- For recommendations on hypertension in people with type 2 diabetes, see the <u>SWL Hypertension: Diagnosis and management guidance for primary care</u> guideline
- Smoking is associated with a higher risk of developing T2DM and increases the
 already higher risk of developing cardiovascular disease in T2DM patients.
 Patients can access NHS resources to download the free NHS Quit Smoking
 app, and find their free Local stop smoking service. Croydon residents can be
 referred to Live Well Croydon
- Do not offer antiplatelet therapy (aspirin or clopidogrel) to adults with T2DM without cardiovascular disease. For guidance on the primary and secondary prevention of cardiovascular disease in adults with type 2 diabetes, see the NICE guidelines on <u>cardiovascular disease</u> and <u>acute coronary syndromes</u>
- Offer atorvastatin 20 mg for the primary prevention of CVD to people with type 2 diabetes who have a 10% or greater 10-year risk of developing CVD, unless pregnant or planning a pregnancy

HbA1c Targets (see NICE guideline for further information)

- Measure HbA1c levels in non-pregnant adults with type 2 diabetes:
 - No sooner than 3 months after diagnosis/change in medication
 - Every 6 months (tailored to individual needs, as part of <u>Year of Care</u> review if appropriate)
- For adults whose type 2 diabetes is managed either by lifestyle and diet, or lifestyle and diet combined with a single drug not associated with hypoglycaemia, support them to aim for an **HbA1c level of 48 mmol/mol** (6.5%) or less
- For adults on a drug associated with hypoglycaemia, support them to aim for an HbA1c level of **53 mmol/mol** (7.0%) or less
- If HbA1c levels are not adequately controlled by a single drug and rise to **58mmol/mol** (7.5%) or higher, reinforce advice about diet, lifestyle and adherence to drug treatment and support the person to aim for an HbA1c level of **53mmol/mol** (7.0%) and intensify drug treatment
- Consider relaxing the target HbA1c level on a case-by-case basis and in discussion with people, with particular consideration to those who are older or frailer after referring to <u>SWL Type 2 Diabetes and frailty prescribing guideline</u> for further details
- NICE has produced a patient decision aid on agreeing HbA1c targets

De-prescribing advice – with a view to remission where appropriateNICE guideline NG28 recommends that the patient's needs and circumstances are reassessed at each review, and to consider:

- Stopping medicines that are not tolerated
- Stopping medicines that have had no impact on glycaemic control or weight, unless there is an additional clinical benefit, such as cardiovascular or renal protection, from continued treatment (see discontinuation criteria for Glucagonlike peptide-1 (GLP-1) therapy)
- How to optimise their current treatment regimen before thinking about changing treatments, taking into account factors such as:



- Adverse effects
- Adherence to existing medicines
- The need to revisit advice about diet and lifestyle
- Prescribed doses and formulations
- Whether switching rather than adding drugs could be effective

De-escalation of therapies should be considered for any individual **with frailty** with an HbA1c lower than the target range after referring to <u>SWL Type 2 Diabetes and frailty prescribing guideline</u> for further details.

Specific considerations include:

- Discontinuing any sulfonylurea and short-acting insulins due to risk of hypoglycaemia
- Avoiding pioglitazone due to <u>risk of heart failure</u>
- Cautious use of insulin and metformin mindful of renal function

Blood Glucose and Ketone Testing Strip Prescribing

<u>Do not routinely offer</u> self-monitoring of capillary blood glucose levels for adults with type 2 diabetes unless:

- The person is on insulin or
- There is evidence of hypoglycaemic episodes or
- The person is on oral medication that may increase their risk of hypoglycaemia while driving or operating machinery **or**
- The person is pregnant or is planning to become pregnant (see pregnancy section below, and the NICE guideline on diabetes in pregnancy)

For patients prescribed metformin/gliptins/Sodium-glucose Cotransporter-2 Inhibitor (SGLT2i) only or in combination

- <u>Do not prescribe</u> blood glucose strips for self monitoring unless short-term use advised by a specialist (e.g. when starting treatment with oral or intravenous corticosteroids or to confirm suspected hypoglycaemia). Advise patients can buy meters and blood glucose strips if they wish to
- <u>Do not prescribe</u> **ketone strips** solely for use by patients prescribed an SGLT2 inhibitor. If a patient on an SGLT2 inhibitor presents unwell, their blood ketone levels should be checked by the healthcare professional, even if blood glucose levels are in the normal range

For patients being prescribed Flash Glucose Monitoring (e.g. Freestyle® Libre)

Blood glucose testing strips should be issued as acute or variable repeat prescriptions only. Patients should not need more than **four** boxes of blood glucose testing strips per year, exceptional requests for more blood glucose strips should be considered on an individual basis.

Choosing drug treatments

NICE guideline Type 2 diabetes in adults: management [NG28] provides useful information in section 1.7 including:

 What to include in discussions with patients regarding what to base drug treatment choices on



- Rescue therapy
- First-line drug treatment
- Reviewing drug treatment
- Treatment options if further interventions are needed

The recommended first line and alternative agents for each therapeutic class can be found within Chapter 6 of the SWL Joint Medicines Formulary.

Where appropriate, counsel patient on sick day rules

Additional drug information sheets have been produced for each therapeutic class:

- Biguanides metformin
- Dipeptidyl-peptidase-4 (DPP-4) inhibitor
- Glucagon-like peptide-1 (GLP-1) mimetics
- Insulin
- Pioglitazone
- Sodium-glucose cotransporter-2 inhibitor (SGLT2i)
- Sulfonylurea

Also see a visual summary below for an overview of the recommendations, and additional information to support medicines choice:



Rescue therapy – For symptomatic hyperglycaemia, consider insulin or a sulfonylurea and review when blood glucose control has been achieved First line pharmacological treatment therapy: Assess glycated haemoglobin (HbA1c), cardiovascular (CVD) risk and kidney function High risk of CVD Chronic heart failure or established atherosclerotic CVD Not at high cardiovascular disease risk Offer metformin immediate release as monotherapy to assess tolerability before considering other options, increase to maximum tolerated dose over several weeks to minimise the risk of G/I side-effects (if persistent G/I disturbance, consider modified release), provide patient information leaflet to patient as soon as tolerability is confirmed (do not wait for metformin to if metformin reach maximum tolerated dose) contraindicated Consider prescribing **DPP-4 inhibitor or** Consider prescribing a SGLT2i with Prescribe a SGLT2i with proven cardiovascular benefit pioglitazone or sulfonylurea or a proven cardiovascular benefit (canagliflozin, dapagliflozin or empagliflozin) in SGLT2i for some patients** (click on addition to metformin (or as monotherapy if metformin is (canagliflozin, dapagliflozin or empagliflozin) in addition to metformin (or hyperlinks for preferred agents per drug contraindicated) as monotherapy if metformin is class) contraindicated) At any point: HbA1c not controlled below individually agreed At any point: HbA1c not controlled below individually agreed threshold threshold Consider switching or adding treatments DPP-4 inhibitor or pioglitazone (not in heart failure) or sulfonylurea or an SGLT2i may be an option in dual therapy or triple therapy. At each point following the prescribing guidance, switch or add treatments from different drug classes up to triple therapy (dual therapy if metformin is contraindicated). When dual therapy has not controlled HbA1c to below the person's individually agreed threshold, consider insulin-based therapy (with or without other drugs). GLP-1 therapy may be considered where triple therapy is not effective, not tolerated or contraindicated (see GLP-1 mimetic treatments section) **NICE technology appraisals recommend **SGLT2i** as At any point: Cardiovascular risk or status change monotherapy options in patients: who cannot have metformin If the patient has or develops a high risk If the patient has or develops chronic heart for whom diet and exercise alone do not provide of CVD failure or established atherosclerotic CVD adequate glycaemic control. The SGLT2 inhibitors are recommended only if a DPP-4 inhibitor would otherwise be prescribed and a Consider prescribing a SGLT2i with Prescribe a SGLT2i with proven sulfonylurea or pioglitazone is not appropriate. proven cardiovascular benefit (if not cardiovascular benefit (if not already already prescribed) prescribed)



GLP-1 mimetic treatments

If triple therapy with metformin and 2 other oral drugs is not effective, not tolerated or contraindicated, consider triple therapy by switching one drug for a <u>GLP-1 mimetic</u> for adults with type 2 diabetes who:

- Have a body mass index (BMI) of 35 kg/m2 or higher (adjust accordingly for people from Black, Asian and other minority ethnic groups) and specific psychological or other medical problems associated with obesity or
- Have a BMI lower than 35 kg/m2 and:
 - For whom insulin therapy would have significant occupational implications
 or weight loss would benefit other significant obesity related comorbidities

Only continue GLP-1 mimetic therapy if the adult with type 2 diabetes has had a beneficial metabolic response (a reduction of at least 11 mmol/mol [1.0%] in HbA1c and weight loss of at least 3% of initial body weight in 6 months).

Oral semaglutide (Rybelsus®) must **only** be considered in patients with <u>genuine</u> <u>needle-phobia</u> **or** where third-party assistance from healthcare staff is required for the administration of their injectable GLP-1 mimetic. Where a patient is being considered for the oral option, prescribers should discuss with the patient that there are injectable options in the same class with proven cardiovascular benefits, and with less variation in absorption.

GLP-1 and insulin

This combination is <u>Amber-2 on the SWL Joint Formulary</u>. Initiation by a specialist, stabilisation (approximately three months), then continuation in primary care under an individual management plan.

Renal considerations

Many medications used in the treatment of T2DM require adjusting, or stopping, with established renal impairment, based on severity. This information can be found in the drug information sheets for each therapeutic class, as well as the <u>product</u> <u>licenses</u> for each medication.

Also see <u>visual summary</u> for an overview of the recommendations, and additional information to support medicines choice and dosing.



Pregnancy

Further guidance for patients with diabetes that are planning a pregnancy, or become pregnant, can be found in NICE guidelines <u>Diabetes in pregnancy</u>: <u>management from preconception to the postnatal period [NG3]</u> and <u>Diabetes in pregnancy [QS109]</u>. This quality standard contains the following seven statements:

- Women with diabetes planning a pregnancy are prescribed 5 mg/day folic acid from at least 3 months before conception
- Women with pre-existing diabetes are seen by members of the joint diabetes and antenatal care team within 1 week of their pregnancy being confirmed
- Pregnant women with pre-existing diabetes have their HbA1c levels measured at their booking appointment
- Pregnant women with pre-existing diabetes are referred at their booking appointment for retinal assessment
- Women diagnosed with gestational diabetes are seen by members of the joint diabetes and antenatal care team within 1 week of diagnosis
- Pregnant women with diabetes are supported to self-monitor their blood glucose levels
- Women who have had gestational diabetes have an annual HbA1c test

Metformin in pregnancy

Metformin is now <u>licensed for use in pregnancy</u>. According to new evidence, women with diabetes may be advised to use metformin as an adjunct or alternative to insulin in the preconception period and during pregnancy. Women who are taking metformin and fall pregnant should continue and be referred to the joint antenatal diabetes team.

Following MHRA advice that vitamin B12 deficiency is now a common side-effect in people on metformin treatment, it is advisable to check vitamin B12 levels (and active B12 if total less than 200) at pre-conception counselling or antenatal booking in all high risk patients:

- T2DM women who have been on metformin for more than a year, especially more than 1700mg/day
- PCOS women who have been on metformin prior to pregnancy especially more than 1700mg/day
- Women with a macrocytic blood picture on screening bloods
- Women with a history of inflammatory bowel disease, coeliac disease or previous gastrectomy including bariatric surgery
- Women who are strict vegetarians or vegans

If the patient is found to be Vitamin B12 deficient, this will need to be corrected. The level can be repeated but not before 3 months. Caution should be exercised when giving metformin if women have severe B12 deficiency.

Other medication in pregnancy

What to use/continue to use when planning a pregnancy:



- Metformin
- Insulin

What should be stopped when planning a pregnancy:

- All other oral blood glucose lowering agents
- Statins
- Angiotensin-converting enzyme inhibitors and angiotensin-II receptor antagonists (alternative antihypertensive agents which are safe in pregnancy can be used)

Women with established diabetes should aim for an HbA1c less than 48 mmol/mol while planning a pregnancy and use contraception until they have a good glucose control. Patients with a HbA1c above 86 mmol/mol (10%) should be advised not to get pregnant until their HbA1c level is lower, because of the associated risks.

Pre-conception counselling should be offered to women with established diabetes planning a pregnancy.

Women with established diabetes who fall pregnant

Refer urgently to the joint antenatal diabetes and obstetric team.

The antenatal specialist team will control diabetes in pregnancy with metformin and/or insulin and monitor the growth of the baby with growth scans.

Metformin will be stopped in pregnancy by the antenatal specialist team if there is presence of fetal growth restriction, defined as:

- Estimated foetal weight less than 10th centile
- Oligohydramnios **or**
- Amniotic fluid index less than 2 cm or reduced end diastolic flow in the umbilical artery

This decision will be taken by the joint antenatal diabetes team and is only for information for primary care.

Established diabetes in the postnatal period

Treatment in the post natal period will be individualised. It is safe for women to continue to take metformin and/or insulin as needed in the postnatal period and during breastfeeding.

References

- Diabetes UK (last accessed 10/11/2022)
- Evidence-based nutrition guidelines for the prevention and management of diabetes (March 2018) (last accessed 10/11/2022)
- Guy's and St Thomas' NHS Foundation Trust Needle phobia and overcoming your fear (last accessed 01/02/2023)
- How to correctly diagnose and classify diabetes. Diabetes & Primary Care Vol 24
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- London Diabetes Clinical Network Key Publications (last accessed 30/01/2023)



- NICE guideline CG181: Cardiovascular disease: risk assessment and reduction, including lipid modification (last accessed 10/11/2022)
- NICE guideline NG28: Type 2 diabetes in adults: management (last accessed 10/11/2022)
- Pharmacological Management of Glycaemia in People with Type 2 Diabetes and Renal Impairment - GP notebook (last updated October 2021) (last accessed 10/11/2022)
- South West London Joint Medicines Formulary (last accessed 10/11/2022)
- South West London Type 2 Diabetes and Frailty Prescribing Guideline (last accessed 10/11/2022)

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