The North West London health and care partnership

North West London Diabetes Guidelines

Helping healthcare practitioners manage adults with diabetes

We would like to acknowledge and thank all healthcare partners and people with diabetes across North West London who contributed their expertise in producing and updating these guidelines

These guidelines were ratified by the North West London Diabetes Clinical Reference Group in October 2020 Next Review date - April 2021 For queries, please email: nwlccc.diabetes@nhs.net

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	WHOM TO TEST				
It is very important to identify Diabetes as early as possible: 50% of newly presenting people with Type 2 Diabetes already have 1 or more complications at diagnosis ¹					
Diabetes is often missed in the elderly	 People PRESENTING WITH THE FOLLOWING SYMPTOMS: Excess thirst Polyuria (especially if nocturia) Weight loss Urinary incontinence Tiredness Pruritus Vulvae / recurrent candidiasis 				
At least half of people with Type 2 Diabetes are asymptomatic ²	 Pruntus vulvae / recurrent candidasis Recurrent infections / abscesses Balanitis Blurred Vision / changes in visual acuity Erectile Dysfunction Pain / Numbness / foot ulcers Non specific or unexplained symptoms 				
Finger prick capillary results can not be used to diagnose Diabetes ³	 People AT INCREASED RISK OF DIABETES: People with BMI > 30 People aged over 40 with BMI 25-30 (overweight) People aged 25–39 of South Asian, Chinese descent (especially those with BMI > 23) People with a family history of diabetes 				
Glycosuria on its own does not confirm Diabetes	 Women with polycystic ovary syndrome. Coronary disease, Cerebrovascular disease, peripheral vascular disease or hypertension/hyperlipidaemia. people on prolonged steroid therapy. people on atypical anti-psychotic drugs. 				
 UKPDS Group. UK Prospective Diabetes Study 6. Complications in newly diagnosed Type 2 diabetic people and their association with different clinical and biochemical risk factors. Diabetes Research. 1990;13:1-11 World Health Organisation. Report of a WHO Consultation 1999 The Expert Committee on the diagnosis and Classification of Diabetes Mellitus. Diabetes Care. 1997;20 (7); 1183-1203 	 People AT HIGH RISK OF DIABETES: Women who have had Gestational Diabetes (screen at 6 weeks and one year post-partum, and then yearly) Those known to have impaired glucose tolerance, HbA1c 42-47mmol/mol or oral glucose tolerance test 2-hour value between 7.8 mmol/l and 11.1 mmol/l (Impaired Glucose Tolerance IGT) or fasting glucose 5.5 - 6.9mmol/l (Non Diabetic Hyperglycaemia NDH). 				

ROUTINE DIAGNOSIS OF DIABETES

DIAGNOSTIC CRITERIA FOR DIABETES

Diabetes may be diagnosed on any of the following criteria (WHO 2006, John 2012).

	Diabetes	High risk of Diabetes	Normal
HbA1c	≥ 48 mmol/mol	42-47 mmol/mol	< 42 mmol/mol
Fasting glucose	≥ 7 mmol/L	5.5 -6.9 mmol/L	≤ 5.4mmol/L
2 hr glucose in OGTT	≥ 11.1 mmol/L	7.8-11.0 mmol/L	≤ 7.7 mmol/L
Random glucose	≥ 11.1 mmol/L		

Consider an urgent direct access CT scan (to be performed within 2 weeks), or an urgent ultrasound scan if CT is not available, to assess for pancreatic cancer in people aged 60 and over with weight loss and the new onset of diabetes. https://www.nice.org.uk/guidance/ng12

When diabetes and pancreatic adenocarcinoma coexist a diagnosis of diabetes usually precedes the diagnosis of PDAC by 24 months in 74–88% of people

WHICH TEST IS BEST?

National and international expert groups do not know. Relevant groups (WHO, ADA, NICE) simply advise that HbA1c is now an option for diagnosing Diabetes.

NWL guidance recommend HbA1c – except in those groups where HbA1c may be unreliable and glucose should be used.

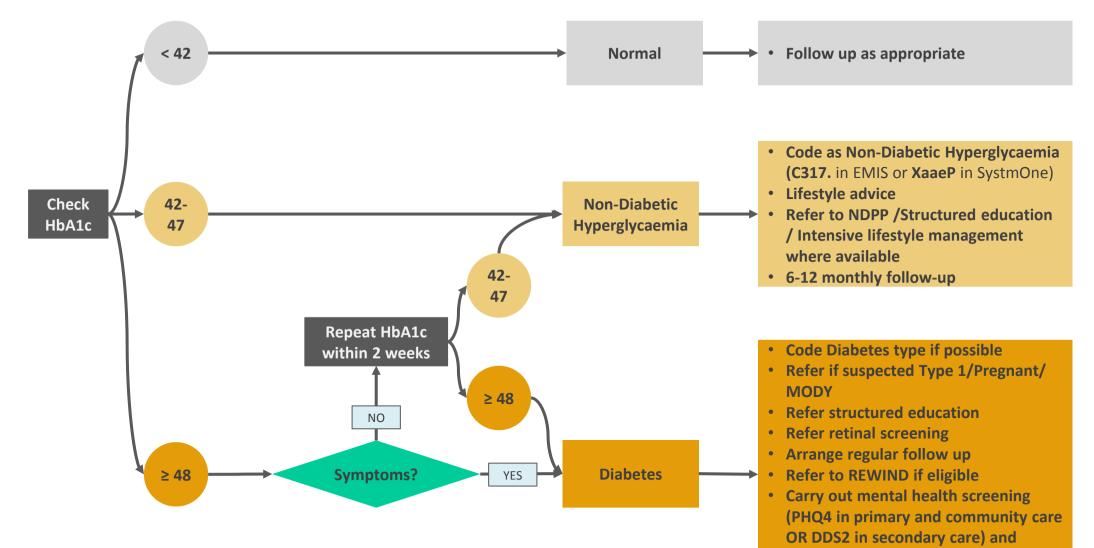
SHOULD A POSITIVE TEST BE REPEATED?

For glucose – yes, in most cases, a repeat glucose test is advised, unless there are classical osmotic symptoms of diabetes. Glucose measurements have greater biological variability compared to HBA1c.

For HbA1c − yes, in asymptomatic people. National guidance now advises a repeat HbA1c within two weeks in asymptomatic cases, as mislabelled samples or lab error are possible. Both results must be ≥48 mmol/mol to diagnose Diabetes; if the results are discordant, the lower is used.

The repeat sample must be sent with clinical detail (e.g. "repeat HbA1c to confirm diagnosis of Diabetes"), as repeats within 30 days may be rejected by the lab.

Do not delay urgent care while awaiting second test. For young, very symptomatic, or ill people, check ketones and seek specialist advice if necessary.



N.B. HbA1c is the recommended test for NDH due to practical benefits. However HbA1c is not suitable for use in everyone, and should not be used in people with anaemia, haemoglobinopathies or other causes of abnormal red cell turnover.

Date of preparation: October 2020. For review: April 2021 5

consider referral to IAPT or other

(see slide 29)

relevant part of local pathway if +ve



ROUTINE DIAGNOSIS OF DIABETES

WHEN NOT TO USE HBA1C TO DIAGNOSE DIABETES

These are the most common situations where HbA1c is not suitable.

Except in pregnancy, diagnose by fasting glucose \geq 7.0 mmol/L twice, or once with symptoms or a random blood glucose \geq 11.0 mmol/L with symptoms.

In pregnancy, follow NICE guidelines.

1. Rapid onset of Diabetes – an increase in HbA1c may not be detected until a few weeks later.

- a. Suspected Type 1 Diabetes rapid onset of symptoms, weight loss, ketosis.
- b. Children because most will have Type 1 Diabetes.
- c. Steroids, antipsychotics & immunosuppressants can raise blood glucose, rarely precipitously.
- d. After pancreatitis or pancreatic surgery.

2. Pregnancy. Multiple factors make HbA1c lower in pregnancy. The diagnosis of gestational Diabetes should be made by using glucose measurements in line with NICE guidance.

3. Conditions with reduced red blood cell survival may lower HbA1c markedly.

a. Haemoglobinopathy which will normally be detected by the lab, but should be suspected in racial groups where there is a high prevalence of sickle trait, sickle disease or thalassaemia.

- b. Haemolytic anaemia
- c. Severe blood loss
- d. Splenomegaly
- e. Antiretroviral drugs

Fasting glucose or OGTT is recommended for diagnosis and fructosamine should be used in these people for monitoring.

4. Increased red cell survival may increase HbA1c e.g. splenectomy.

5. Renal dialysis people have a markedly reduced HbA1c especially if treated with erythropoietin.

6. Iron and B12 deficiency and their treatment. May raise or lower HbA1c, but the effect is small.

WHAT IF YOU HAVE GLUCOSE VALUES AND AN HBA1C ON A SINGLE PATIENT?

If one only is abnormal then a further abnormal test result, using the same method, is required to confirm the diagnosis.

For people with Type 2 diabetes and their healthcare team the possibility of achieving remission can provide motivation and hope – something to aim for. It can help to improve how people engage in their diabetes management, not only because of the need to reduce risk of complications, but also because there is a possibility of minimising the day-to-day impact of their condition.

For the local health economy there are benefits in reduction of the cost of medications and diabetes complications.

INTENSIVE LIFESTYLE INTERVENTIONS

Intensive lifestyle interventions that result in weight loss have been reported to lead to about 10-15% remission rates at one-year follow-up. Evidence for long-term remission following lifestyle interventions is limited though increasing.

Various dietary interventions such as **low fat diets**, **low carbohydrate diets**, **Mediterranean diets**, **very low-calorie diets**, and **meal replacements** have been used to achieve weight loss in people with Type 2 diabetes. An individualised approach is recommended.

The Counterbalance study tested the theory that normal blood glucose levels could be achieved through a very low-calorie diet and showed that those people with shorter duration Type 2 diabetes who achieved normal glucose control maintained this for at least six months.

The Look Ahead study, which aimed at weight loss through intensive lifestyle intervention, reported a remission rate of 7% at four-year follow-up. The Predimed study which involved an intervention with Mediterranean diets also reported remission rate of 5% at six-year follow-up.

Remission through lifestyle interventions appears more likely in people newly diagnosed with Type 2 diabetes and those with lower baseline HbA1c

Results from the larger long-term **DiRECT** study demonstrated a 46% remission rate in routine Primary Care using a low-calorie diet and supportive follow up at 1 year, with 36% remaining in remission at 2 years.

BARIATRIC (METABOLIC) SURGERY

Different remission rates have been reported depending on the procedure used, criteria for defining remission among other factors. An international consensus statement endorsed by 45 international diabetes associations including Diabetes UK and the ADA reported that Type 2 diabetes remission occurs in about 30–60% of people following surgery. To date, there is no reliable data to view surgery as a permanent cure, although remission of up to 15 years has been reported. Generally, the **median diabetes-free years** for people with Type 2 diabetes undergoing surgery is about **eight years**, depending on the procedure and available data suggest an erosion of remission over time.

Some studies have reported relapse rates of approximately 20% at three years and 25–35% at five years.

Whilst most of the long-term benefits of bariatric surgery can be attributed to weight loss, it has been suggested that some improvements in glucose control may occur independent of weight loss, via changes in gut hormones, microbiota, bile acid metabolism, intestinal glucose metabolism and nutrient sensing

TYPE 2 DIABETES – REMISSION DEFINITION



86% of obese people who manage to lose 15kg of weight within 6 years of diagnosis achieved remission from Type 2 diabetes

COMPLETE REMISSION OF T2DM

Type 2 Diabetes Remission can be confirmed if a person has achieved all of the following criteria:

i) Weight loss

ii) Fasting plasma glucose or HbA1c below the WHO diagnostic threshold (<7mmol/l or <48mmol/mol) on two occasions separated by at least 6 months

iii) The attainment of these glycaemic parameters following complete cessation of glucose-lowering therapies

Ref: https://abcd.care/sites/abcd.care/files/resources/ABCD-and-PCDS-final-statement-3March2019.pdf)

However, remission is a fluid state and relapse can occur in various circumstances, especially if weight is regained. Patients need to continue to have regular monitoring at least annually and will need to remain on Diabetes QOF registers. The codes used below allow patients to remain on the register.

The following codes should be used for complete Type 2 remission: C10P1 (EMIS) or Xaagf (SystmOne)

PARTIAL REMISSION OF T2DM

There are various definitions of partial remission including those included in this article: <u>https://www.bmj.com/content/358/bmj.j4030/rr-0</u> The key point is that there is significant patient benefit even if complete remission isn't achieved.

WHAT IS THE IMPACT OF REMISSION ON DIABETES COMPLICATIONS?

Little is known about the actual effect of diabetes remission on new onset diabetes complications or progression of existing complications. A long-term follow-up observational study has concluded that bariatric surgery was associated with higher remission rates and fewer microvascular and macrovascular diabetes complications.

Systematic reviews have suggested that bariatric surgery may:

Protect against new cases of diabetic retinopathy, and its progression in people with Type 2 diabetes

Prevent the incidence and progression of albuminuria and stop the decline of renal function

It is recommended however that people diagnosed with diabetes continue with annual retinal and renal screening for life, even if they are in remission. The same targets for risk factors such as blood pressure and lipids should apply

Remission from Type 2 diabetes is most likely through significant weight loss (this is normally 10-15kg of weight or 10-15% of body weight).

Achieving significant weight loss is possible through a number of approaches including those below:

A Very Low Calorie Diet or VLCD (800 calories/day). The best research evidence on how to achieve remission is based on the DiRECT study which was published in 2017. In that study, 46% the people who went on an 800 calorie Very Low Calorie Diet achieved remission at one year and 36% remained in remission at 2 years.

Importantly, 78% were successful in stopping their diabetes medication.

Nearly 86% of people who lost more than 15kg were in remission at one year.

The VLCD course normally lasts for 24 weeks: 12 weeks replacing all meals with soups, shakes and snacks from a specially formulated diet plan, and then 12 weeks gradually reintroducing food. This approach is challenging, but offers the highest chance of achieving sufficient weight loss over a short period.

There are clear inclusion and exclusion criteria

Other studies 1.2.3 have shown that **Low Carbohydrate** and **Mediterranean style** diets are very effective in helping people achieve improvements in blood glucose and body weight whilst reducing need for medication, although there have been no formal remission trials like with VLCD. The key is to reduce the amount of starchy carbohydrates and sugary food eaten.

The **Prospective Urban Rural Epidemiology (PURE)** epidemiological cohort <u>study</u> demonstrated potential benefits of a low carb diet across a population. Dietary intake of 135,335 individuals was recorded using validated food frequency questionnaires.

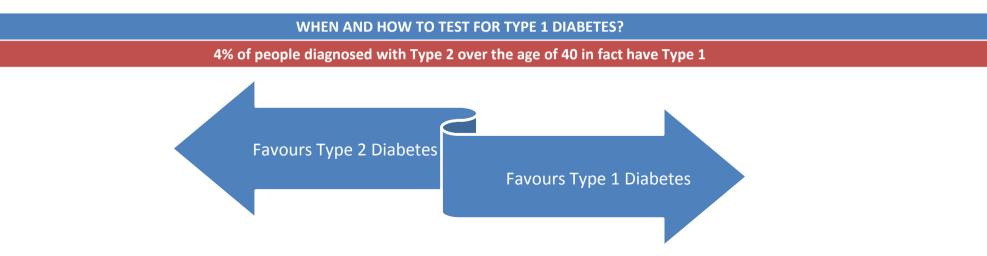
High carbohydrate intake was associated with higher risk of total mortality, whereas total fat and individual types of fat were related to lower total mortality. Total fat and types of fat were not associated with cardiovascular disease, myocardial infarction, or cardiovascular disease mortality, whereas saturated fat had an inverse association with stroke. The authors recommended that Global dietary guidelines should be reconsidered in light of these findings.

Many people with Type 2 diabetes consume large quantities of carbohydrates. The Carbs and Cals <u>World Foods</u> book is a useful resource to aid conversations with people and demonstrate the impact of starchy carbs on glycaemic control.

Intermittent fasting is the other approach that has been demonstrated to be effective in supporting weight, blood glucose and medication reduction. This includes:

- 5:2 diet (eating normally for 5 days a week then eating only 500-600 calories on the other two days) and
- **Time Restricted Eating** where the patient has a long period in the day when they don't eat. With time restricted eating, most people choose a 16:8 cycle, which involves not eating for 16 hours in the day. Sometimes this is also referred to as an 8-hour eating 'window'. All meals are eaten within an 8-hour time period and the patient fasts for the remaining 16 hours. Generally, this is done daily or almost daily. There is some evidence that suggests that the best period for eating is earlier in the day

DIABETES - TYPE 1 OR TYPE 2?



Less likely	y to be Type 1 DM
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Family history of Type 2 No family history of Type 1 Diabetes BMI > 28 kg/m2 Age > 45 yrs. Non-white ethnic group Dyslipidaemia, HDL < 1.0

Consider testing for Type 1 DM using GAD* antibodies and paired C-Peptide*Glucose, or refer to secondary care

No family history of Type 2 1st or 2nd degree relative with Type 1 Diabetes BMI < 28 kg/m2 Age < 45 yrs. White European Any autoimmune disease HDL > 1.5 mmol/l

GAD antibodies* are autoantibodies against the enzyme glutamic acid decarboxylase found in pancreatic islet cells. GAD antibodies are detectable in the serum ≈80% of people with Type 1 diabetic at the onset of Diabetes

C- peptide* can be considered in situations of diagnostic uncertainty, but must be paired with a glucose level to have any significance. Discuss with a specialist colleague first to avoid inappropriate expensive testing.

DIAGNOSING MODY

Could the diagnosis be maturity-onset Diabetes of the young (MODY)? See <u>http://www.Diabetesgenes.org</u>

Unusual Diabetes

• Very strong maternal or paternal family history of Diabetes often in three generations with early onset, before 30yrs. With some family members diagnosed with Type 1 others with Type 2 Diabetes

Unusual response to treatment

• Highly sensitive to sulfonylurea. Or having excellent control on small amounts of insulin without having hypoglycaemia or becoming ketotic if stopping insulin

No microvascular complications

• They and family members have few if any diabetic complications

Refer to Secondary care where screening tests can be undertaken to make the diagnosis

DIABETES – NEW DIAGNOSIS

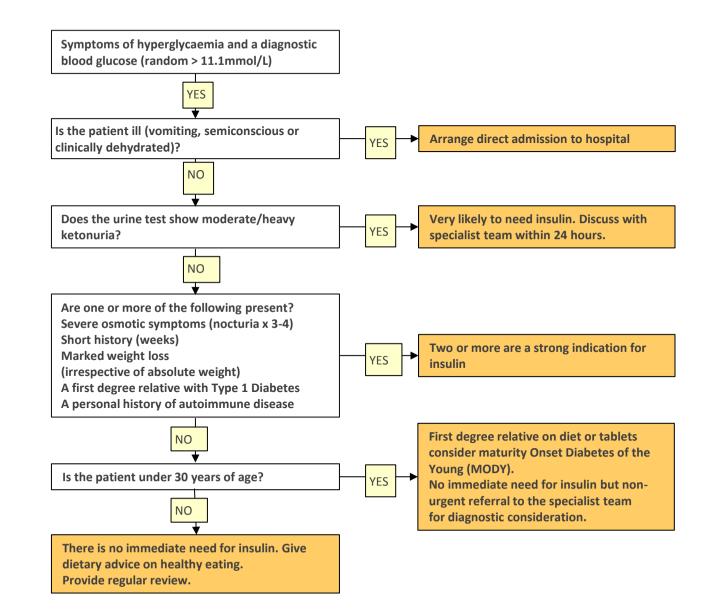
TREATMENT DECISION TREE FOR EARLY INSULIN INITIATION

PRINCIPLES OF TREATMENT

- Offer structured education advice to all newly diagnosed people according to local availability (i.e. X-PERT, DESMOND or conversation maps). Usually wait 6-12 weeks before glucose lowering agents are introduced unless patient is symptomatic.
- Carry out mental health screening (PHQ4 in primary and community care OR DDS2 in secondary care) and refer to IAPT or other relevant part of local pathway if +ve (See slide <u>29</u> for details of tools)
- Metformin is recommended for all people with Type 2 Diabetes at/soon after diagnosis in view of its cardioprotective effects (UKPDS legacy effect). However:

Introduce oral hypoglycaemic agents early if fasting plasma glucose >15mmol/l and symptomatic.

- Ensure people are shown how to monitor their own diabetes if appropriate , and know what to do if results do not fall in the target range.
- Regular monitoring will identify the need to actively titrate treatment.
- Measure HbA1c every 2-6 months.
- Target HbA1c 48mmol/mol/6.5% in newly diagnosed Type 2 Diabetes and those on up to 2 oral hypoglycaemic agents unless individual target more appropriate. Involve the person in discussions about individual HbA1c target.
- In South Asian people BMI underestimates adiposity. Weight measurements need to be considered. Range for healthy weight is BMI 18.5-22.9 in South Asian people.
- Consider end of life care needs



NICE recommends that well-designed and well-implemented structured education programmes are likely to be cost-effective for people with diabetes and should be offered to every person and/or their carer at and around the time of diagnosis, with annual reinforcement and review.

Structured education programmes for people with Type 2 diabetes are an essential component of effective diabetes management. Most people will spend only 1.5 hours with a health care professional per year, the rest of the time they are required to make daily lifestyle decisions that may have a significant impact on their health and overall quality of life

The aim of structured education is for people with diabetes to improve their knowledge, skills and confidence, enabling them to take increasing control of their own condition and integrate effective self-management into their daily lives. High-quality structured education can have a profound effect on health outcomes and can significantly improve quality of life.

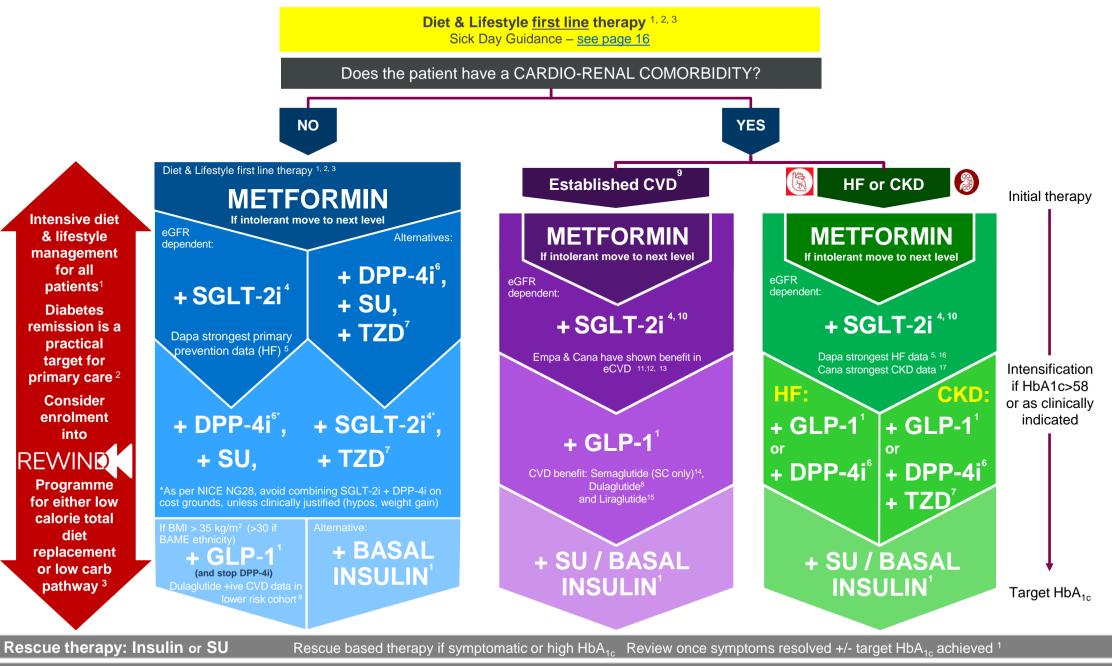
The referrer will play a huge role in successfully engaging the person with diabetes and increasing uptake of an education course.

Diabetes UK patient focus groups have shown that the attitude of health care professionals and information given at time of diagnosis can have a profound impact on people's ability to self-manage their condition effectively.

If the person is not keen to engage, screen for psychological difficulties (PHQ4 in primary and community care OR DDS2 in secondary care) and refer to IAPT or other relevant part of local pathway if +ve, as well as assessment using Patient Activation Measure (PAM). See slide 29 for details of tools

STRUCTURED EDUCATION COURSES	
DESMOND	Group education delivered by trained educators: Two half day sessions or one full day
X-PERT	Group education delivered by trained educators: 2.5 hr sessions over 6 weeks with annual follow-up sessions
X-PERT Insulin	Group education delivered by trained educators: 2.5 hr sessions over 6 weeks with annual follow-up sessions
DIGITAL STRUCTURED EDUCATION	 NHS England accredited options include: Changing Health OurPath Oviva These will be available through the Know Diabetes information and support service and provide combinations of app, coaching (by dietitian or health coach), self measurement of weight / activity and in the case of OurPath, 3G-connected scales. Length of course varies from 6 weeks to 6 months, but can be fitted around working hours or other activities.

TYPE 2 DIABETES – MANAGEMENT ALGORITHM



When initiating a SGLT2i

Consider a 25% dose reduction in any concomitant SU or Basal insulin & monitor for evidence of hypoglycemia

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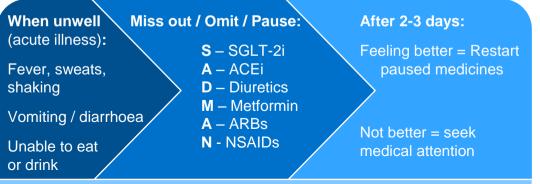
TYPE 2 DIABETES – DOSE ADJUSTMENT IN RENAL /HEPATIC IMPAIRMENT

Drug	CKD stage 1 eGFR >90 mL/min	CKD stage 2 eGFR 60-90 mL/min	CKD stage 3a eGFR 45-59 mL/min	CKD stage 3b eGFR 30-44 mL/min	CKD stage 4 eGFR 15-29 mL/min	CKD stage 5 eGFR <15 mL/min	Mild to moderate hepatic impairment	Severe hepatic impairment
Metformin	~	v	v	Max 500mg BD	*	×	Specialist initiation only	×
Gliclazide	~	~	<i>v</i>	~	Use lowest effective dose	×	<i>v</i>	×
Linagliptin	 	 	v	 	 	~	v	v
Sitagliptin	100 mg	100 mg	100mg	50mg	25mg	25mg	~	×
Alogliptin	25mg	25mg	25mg	12.5mg	6.25mg	6.25mg	~	×
Pioglitazone (TZD)	V	V	~	V	V	V	×	×
Dapagliflozin	Start 10mg	Start 10mg	Continue 10mg	*	×	×	~	✓ 5mg
Canagliflozin	Start 100-300mg	Start 100-300mg	Start 100mg	Start 100mg, only if uACR >30mg/mmol	Continue 100mg if uACR >30mg/mmol	Continue 100mg if uACR >30mg/mmol	~	×
Empagliflozin	Start 10-25mg	Start 10-25mg	Continue 10mg	×	×	×	~	×
Ertugliflozin	✓ Start 5-15mg	Start 5-15mg	Continue 5-15mg	×	×	×	~	×
Liraglutide	~	v	×	v	v	×	v	×
Semaglutide	~	~	~	~	V	×	~	Caution: limited information
Dulaglutide	~	v	v	v	~	×	×	v
Insulin	~	~	~	~	~	~	~	~
		Diminished glycaem	ic effect of SGLT-2i wi	th eGFR < 45 mL/min, I	nowever sustained car	dio-renal protection		
Кеу	 Initiate No new initiation; 	continue at stated dose						

X Discontinue

TYPE 2 DIABETES – ADDITIONAL GUIDANCE

Sick Day Guidance - to be reiterated to patients at every opportunity



Increase blood glucose monitoring during acute illness and check for ketones. If you are using daily insulin or an SUs, you may need to increase (or decrease) the amount taken to maintain appropriate glucose control. Ensure fluid intake to minimise dehydration.

Adapted from Imperial College Healthcare NHS Trust Renal Sick Day Rules

Lifestyle Counselling - to be reiterated to patients at every opportunity

Dietary Guidance

Seek dietitian input. Individualised approach: low fat diet, low Glycaemic Index diet or Mediterranean diet etc. Alternatives include low calorie total diet replacement programmes (NWL REWIND).

Physical Activity

Realistic targets should be set. The benefits of regular exercise should be explained and people should be advised to perform regular aerobic activity. Clinical studies show that walking for 30 minutes every day has cardiovascular benefits.

Weight Management

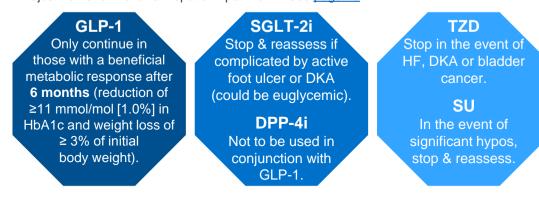
Weight loss can help the patient achieve Type 2 diabetes remission. Realistic initial weight loss target of 5% to 10% of starting weight. Consider drug therapy, e.g SLGT-2i or GLP-1. Consider surgical intervention.

Smoking Cessation & Alcohol consumption

Assess patients for smoking status and refer to Smoking Cessation Teams for support. Alcohol may influence blood glycose control (Hyper/Hypo glycaemia respectively).

Medication review

Reassess the person's needs and circumstances at each review (3-6 months) and think about whether to stop any medicines that are not effective. Adjustments for Renal & Hepatic Impairment – see page 15.



Diabetes Remission Programme

Oknow diabetes REWIND

Diabetes remission is a practical target for primary care². Consider enrolment into NWL REWIND Programme for either low calorie total diet replacement or low carb pathway³.

> For more details, click here For full pathways, click here

Given the recent wealth of publications regarding cardiovascular & renal outcome trials in type 2 diabetes, this Type 2 Diabetes Management Algorithm is meant as a quick reference guide as we move away from glucose-centric prescribing, based on current evidence as of August 2020. For more in-depth guidance please refer to full <u>North West London Diabetes Guidelines</u>, the <u>EASD-ADA Consensus Document</u>, or other [inter]national guidelines. <u>Also see CaReMe multi-association</u> position statement.

Lifestyle management should be part of the ongoing discussion with individuals with T2DM at each visit. Increasing physical activity and reducing body weight improves glycaemic control and should be encouraged in all people with T2DM¹. Glycaemic treatment targets should be individualised based on patient preferences and patient characteristics, including frailty and comorbid conditions¹. All drugs can cause side effects, consult BNF or summary of product characteristics for full side effect profile of individual drugs. Always offer advice on sick day guidance for patients on Metformin and/or SGLT-2i¹. Stop SGLT-2is peri-operatively or if restricted food intake or dehydration¹. Patients on insulin treatment should always be advised never to stop or significantly reduce their insulin as part of the sick day response¹. SU & TZD both have low acquisition cost, this should be taken into consideration alongside increased risk of weight gain and hypoglycaemia risk (SU).

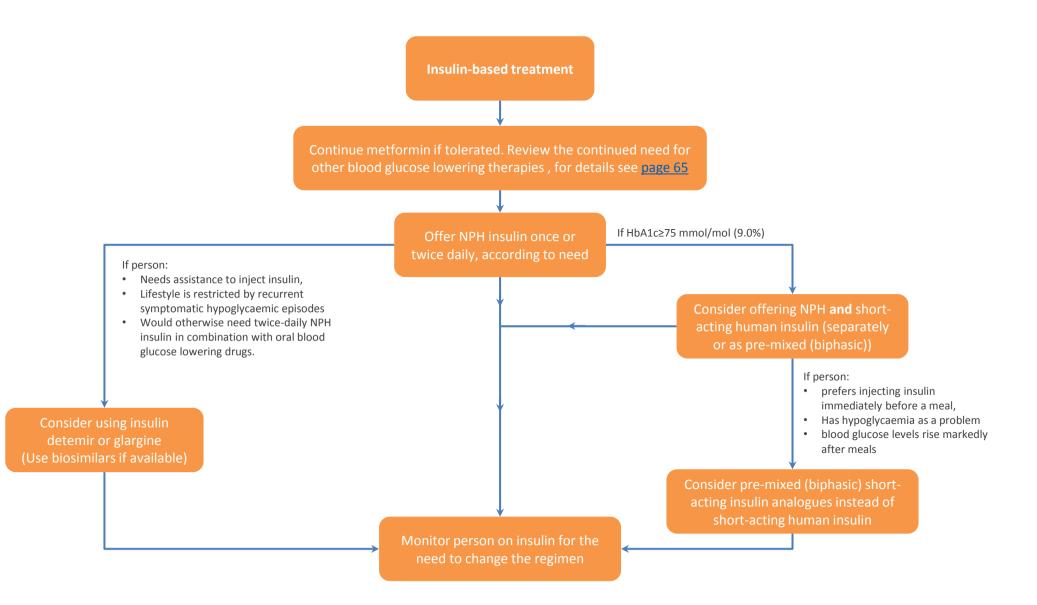
Abbreviations:

T2DM; type 2 diabetes mellitus; NWL REWIND; North West London Reducing Weight with Intensive Dietary support, eGFR, estimated glomerular filtration rate; SGLT-2i, sodiumglucose cotransporter-2 inhibitor; DPP-4i, dipeptidyl peptidase 4 inhibitor (gliptin); SU, sulfonylurea; TZD, thiazolidinedione; BMI, body mass index; GLP-1, glucagon-like peptide-1 receptor agonist; +ive, positive; CVD, cardiovascular disease; eCVD, established cardiovascular disease; MI, myocardial infarction; Cana, canagliflozin; Dapa, dapagliflozin; Empa, empagliflozin; HF, heart failure; CKD, chronic kidney disease; HbA_{1c}, hemoglobin A1C; BD, twice daily; ACEi, Angiotensin-converting enzyme inhibitors; ARB, Angiotensin II receptor blocker; NSAID, Non-steroidal anti-inflammatory drug; DKA, diabetic ketoacidosis.

References:

- 1. For further guidance please refer to full North West London Diabetes Guidelines http://tiny.cc/p4egfz
- 2. DiRECT; Lancet 2018; 391: 541-51 https://doi.org/10.1016/S0140-6736(17)33102-1
- 3. NWL REWIND Programme (Reducing Weight with Intensive Dietary support) For more details, click here For full pathways, click here.
- 4. When prescribing an SGLT-2i, consider risk of volume depletion, euglycemia DKA in insulin deficient cohorts and lower limb amputation (class warning, but only observed in Cana and Eurtu). Caution in frail patients and always follow sick day rules. For more information, refer to full <u>North West London Diabetes Guidelines</u>
- 5. DECLARE TIMI 58; N Engl J Med 2019; 380:347-357; DOI: https://doi.org/10.1056/NEJMoa1812389
- 6. FDA Drug Safety Communication: FDA adds warnings about heart failure risk to labels of type 2 diabetes medicines containing saxagliptin and alogliptin https://bit.ly/2ZZCNni
- 7. TZD (Pioglitazone) to be avoided in patients with heart failure. PROactive; Lancet. 2005 Oct 8;366(9493):1279-89 https://doi.org/10.1016/S0140-6736(05)67528-9
- 8. REWIND (Dulaglutide CVOT); Lancet 2019; 394: 121–30; DOI: https://doi.org/10.1016/S0140-6736(19)31149-3
- 9. Patients with established atherosclerotic cardiovascular disease having had an ischemic event (e.g myocardial infarction or stroke)
- 10. Consider initiating Met + SGLT-2i rather than stepwise. This is in line with Position Statement by Primary Care Diabetes Europe; S. Seidu, et al., A disease state approach to the pharmacological management of Type 2 diabetes in primary care: A position statement by Primary Care Diabetes Europe, Prim. Care Diab. (2020), https://doi.org/10.1016/j.pcd.2020.05.004. Alternatively, the European Society of Cardiology (ESC) diabetes guideline states that SGLT-2i could be considered as first line ahead of metformin in patients with eCVD, HF or CKD European Heart Journal (2019) 00, 169; doi: https://doi.org/10.1093/eurheartj/ehz486
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- 17. CREDENCE; N Engl J Med 2019; 380:2295-2306; DOI: https://doi.org/10.1056/NEJMoa1811744

TYPE 2 DIABETES – INSULIN REGIMES



NB: Only offer a GLP-1 mimetic in combination with insulin with specialist care advice and on-going support from a consultant-led multidisciplinary team

TYPE 2 DIABETES – SUMMARY OF ANTI-DIABETIC AGENTS

The North West London health and care partnership

	Please see individual drug monographs on pages <u>34-38</u> and <u>59-60</u> for more details.							
	Hypoglycaemia	Weight	GI side effects	Cardiovascular risks/benefit	Renal dosing	Liver impairment		
				Benefits	eGFR 30-44:	Withdraw if risk of tissue		
Metformin	No	Loss	Common	Caution in chronic stable heart failure	Max 1g daily dose Contraindicated if eGFR<30	hypoxia, predisposes to lactic acidosis		
					See page 15 for indivi	dual drug breakdown		
Sulfonylureas	Associated risk	Gain	Common	Neutral	Higher risk of hypoglycemia; increase patient monitoring	If severe, reduce dose (risk of hypoglycemia)		
			No known risks	Neutral	See page 15 for indivi	dual drug breakdown		
DPP-4i (-gliptins)	Only when combined with SU/Insulin	Neutral	Alogliptin - Common	Caution with Alogliptin and	Dose reduction may be	Vildagliptin has a risk of liver		
			Saxagliptin - Possible	Saxagliptin in moderate- severe heart failure	required	toxicity		
Thiazolidinediones (Pioglitazone)	Only when combined with SU/Insulin	Gain	No known risks	Risk Contraindicated in people with heart failure or a history of heart failure	None	Avoid, risk of liver toxicity		
				Established benefits	See page 15 for individual drug breakdown			
SGLT-2i (-flozins)	Only when combined with SU/Insulin	Loss	No known risks	Caution in significant PVD due to increased risk of digital amputation	Dose reduction may be required	Excluding dapagliflozin, avoid If severe		
					See page 15 for individual drug breakdown			
GLP-1 Agonist (-tides)	No	Loss	Common	Semaglutide, Liraglutide, Dulaglutide have CV benefit	Except Lixisenatide and Exenatide	Avoid if Liraglutide		
Repaglinide	Associated risk	Gain	Common	CVD as a rare side effect	Use with caution	Avoid if severe		
Acarbose (AGI)	If prescribed in addition to other blood glucose lowering drugs	Neutral	Common	Neutral	Avoid if eGFR<25	Avoid if severe		
			No known risks	Neutral				
Insulin	Associated risk G	Gain		Cardiac failure risk when used concurrently with Pioglitazone	Dose reduction required, higher risk of hypoglycemia	Reduced dose required		

	INDIVIDUALISING HBA1C	TARGETS				
HBA1C TARGET RECOMMENDATIONS:	APPROACH TO MANAGEME	NT OF HYPERGLY	CAEMIA			
People with Type 2 Diabetes should normally have their HbA1c maintained between 48 and 58 mmol/mol.						Least intensive
Clinicians should aim to involve people in decisions about their individual HbA1c target level, which may in some cases be above that of 48-58 mmol/mol set for people with Type 2 Diabetes in general.		42mmol/mol		53mmol/r	nol	64mmol/mol
Target HbA1c level should be informed by a number of factors including duration of Diabetes, life expectancy, comorbidities including established vascular complications and available support.	Patient attitude and expected treatment efforts	Highly motivated,	adharant		Loss motivat	ed, non-adherent
Tighter targets (6.0 - 6.5% / 42 – 48 mmol/mol) younger, healthier	Hypoglycaemia risk	Excellent self-care				elf-care capacities
Looser targets (7.5 - 8.0% ^{+/} 58-64 mmol/mol older, CKD, comorbidities, hypoglycaemia prone, End of Life		Low			Moderate	High
Encourage the person to maintain their individual target unless the resulting side effects (including hypoglycaemia) or their efforts to achieve this impair their quality of life.	Disease duration	5	10		15	20
Offer therapy (lifestyle and medication) to help achieve and maintain the HbA1c target level	Life expectancy					
Inform a person with a higher HbA1c that any reduction in HbA1c towards the agreed target is advantageous to future health.		Long				Short
Avoid pursuing highly intensive management particularly in elderly and frail people in whom the risk of hypoglycaemia is high.	Important comorbidities	None		Few/Mild		Multiple/Severe
HBA1C IFCC UNITS:	Established vascular complications					
HbA1c values should be expressed in mmol/mol instead of percentages as follows: DCCT (%) IFCC (mmol/mol)		Absent				Severe
6.0 42 6.5 48 7.0 53	Resources, support system	Readily available				Limited
7.5 58 8.0 64 9.0 75	From Ismail-Beigi, et al. Individu		in Type 2 Diab	etes mellitus: imp	lications of recent	clinical trials. Ann

From Ismail-Beigi, et al. Individualizing glycemic targets in Type 2 Diabetes mellitus: implications of recent clinical trials. Ann Intern Med. 2011 Apr 19;154(8):554-9.

INDIVIDUALISATION OF HBA1C

Age	<	65	65	-70	>7	70	Severe frailty or Residential care	End of Life Care
Duration > 10 years Latest HbA1c > 64-75 Complications: CVD, CKD, retinal, foot Hx of Hypoglycaemia On SU / Insulin	N	Y	N	Y	N	Y	Y	Refer to: <u>Diabetes UK</u> <u>End of Life</u> <u>Diabetes Care</u> <u>Clinical</u> <u>Recommendations</u> for advice on targets and potential deprescribing
Target HbA1c	<48	48-53	<48	53-58	53-58	58-64	58-69	

Adapted from Khunti and Davies 2010

DIABETES – MONITORING GLYCAEMIC CONTROL



KEY PRINCIPLES OF PRACTICE

- 95% of the care people with Diabetes receive is self-care and all people should have access to high quality structured education programmes e.g. X-PERT, DESMOND, conversation maps
- The ability to monitor their own glucose level gives people with Diabetes the feedback they need in order to learn how to manage their condition optimally.
- The ability to self-monitor may be affected by their mental health: use PHQ4 (in primary and community care) to screen for anxiety and depression OR DDS2 (in secondary care) to screen for diabetes distress. Use 6 item COG for cognitive impairment (more prevalent in Diabetes after age 50). See slide <u>31</u> for tools
- Monitoring should be based on the individual's clinical needs and in the context of Diabetes education and selfmanagement.
- People should receive appropriate training in the technique and the actioning of the results.
- The frequency of testing will be different for different people and will change with their circumstances. Any guidelines can only be used as a framework and then adapted to meet individual needs.
- People may move between different methods of monitoring dependent on their needs at that time.
- Equipment used for monitoring should be based on choice and agreed with patient.

TYPE 2 DIABETES

- Routine self-monitoring of blood glucose is not usually required if people are achieving targets on therapy without the potential to cause hypoglycaemia (see the table on the next page).
- HbA1c is important in assessing the adequacy of blood glucose control and should be tested every 3-6 months.
- Structured education is essential for people with newly diagnosed and existing Diabetes.
- Checking for wellbeing is essential as 40% of people with diabetes have poor mental health (see slide 31) and this affects their ability to self-care
- People with Type 2 Diabetes usually have more stable glycaemic control. In practice, the level of monitoring will vary according to the treatment regimen used and the target level of glycaemic control set for/with the patient.
- DVLA requirements for testing when driving apply to people with Type 2 Diabetes treated with insulin, gliclazide, glimepiride, glibenclamide or another sulfonylurea, nateglinide or repaglinide.

TYPE 1 DIABETES

- Approaches and targets should be individualised and agreed in consultation with people, as part of the care planning process.
- In addition to self-monitoring, HbA1c should be measured every 3-6 months.
- People prescribed insulin should be taught how to adjust therapy in line with their blood glucose monitoring and recognise patterns in their test results. This facilitates adjustments to medication to achieve targets for fasting and postprandial blood glucose, which both contribute to HbA1c.
- Checking for wellbeing is essential as 40% of people with diabetes have poor mental health and this affect their ability to self-care be alert to eating disorders and insulin dose manipulation if there is poor glucose control, low BMI or over concern with body shape and weight
- All results should be recorded with the time and date to provide a cumulative record as a basis for day-to-day changes in therapy. Most meters will store this information and some will allow download to a computer or smart phone

DIABETES AND DRIVING

People with Diabetes must inform the DVLA.

- Those on insulin or oral hypoglycaemic agents which carry a risk of hypoglycaemia, such as sulfonylureas should monitor their glucose before driving. https://www.gov.uk/government/publications/information-for-drivers-with-diabetes
- Group 2 drivers (bus and lorry), on insulin or oral medicines which carry a risk of hypoglycaemia, are still required to check their blood glucose using finger prick testing for the purposes of driving.
- Must have awareness of hypoglycaemia. If there is a total loss of 'hypo' warning signs their license will be withdrawn.
- Must not have had >1 episode of severe hypoglycaemia requiring third party assistance while awake within the preceding 12 months. If they have had more than one episode they must inform the DVLA and their licence will be withdrawn for one year following the first episode.
- Trend Driving Leaflet; DVLA: A guide to insulin treated diabetes and driving
- All results should be recorded with the time and date to provide a cumulative record as a basis for day-to-day changes in therapy. Most meters will store this information and some will allow download to a computer or smart phone
- People with blood glucose levels <5.0mmol/L should not drive until they have eaten; If <4.0mmol/L they should not drive.

GROUP 2 ENTITLEMENT

People with Diabetes on insulin can apply for any Group 2 licence providing the patient has:

- Had no episodes of hypoglycaemia requiring third party assistance within the previous 12 months.
- Full awareness of hypoglycaemia and can demonstrate understanding of its risks.
- Meter recorded evidence of regular monitoring (twice a day and at times relevant to driving).
 - Been reviewed annually by an independent consultant diabetologist and provide at least 3 continuous months of readings.

Visit www.dft.gov.uk/dvla/medical

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DIABETES – FREQUENCY OF BLOOD GLUCOSE TESTING

	ADULTS WITH TYPE 2 DIABETES			ADULTS WITH TYPE 1 DIABETES
Treatment	Diet and exercise Metformin Pioglitazone DPP-4 inhibitors SGLT-2 inhibitors GLP-1 analogues*	sulfonylureas/meglitinides alone or in combination with other suitable hypoglycaemic agents except insulin	Insulin for Type 2 Diabetes: basal, twice daily fixed regimens or mixed insulins	Insulin: basal bolus or delivered by a pump <u>https://www.nice.org.uk/guidance/ta15</u>
Usual Monitoring	Not usually necessary (* except when initiating GLP-1 analogues in people taking a sulfonylurea – see next column) Do not offer a meter unless a clear action based on test results has been agreed and for short term use only, e.g. to allow patient to adjust lifestyle when newly	4 tests per week, usually testing once week before each of the three daily meals and before bedtime See advice on Diabetes and driving on previous page.	Basal insulin:1-2 tests per dayPremixed insulin:2-4 tests per dayPeople who rely on others for administration of mixed insulins may	Usually 4 to 8 tests daily. Test before meals and at bedtime as a minimum Include two hour post meal testing to check correct carbohydrate ratios Additional testing may be required to enable people with Type 1 Diabetes to drive safely
Intensive Monitoring	diagnosed	Before meals and 2 hours after evening meal *Intensive monitoring is essential during initiation of GLP-1 analogues for people already on sulfonylureas until stabilised	require more frequent testing, which is recommended prior to administration. See advice on driving Before meals and 2 hours after main meal Tests before breakfast are essential to achieve the target fasting glucose Additional tests pre-meal or 2 hours after food are helpful if fasting glucose is at target but HbA1c remains high	Additional post prandial tests may be required to optimise the dose of the rapid acting insulin; include testing before meals and 1-2 hours after the largest meals During periods of intensive monitoring additional supplies of strips may be required
Prescribing	Prescribe the minimum appropriate number of strips on acute	Prescribe on repeat Additional supplies may be necessary for driving and intensive monitoring	Prescribe on repeat Additional supplies may be necessary for driving and intensive monitoring	Prescribe on repeat. Restricting access to strips may destabilise control and adversely affect people's quality of life
		Intensive monitoring may be required i	n any of these situations	
Osmotic symp Postprandial h Terminal care,	teroid therapy toms nyperglycaemia	mission programme i.e. REWIND)	To prevent development of acute complica Pre-conception and pregnancy Increased or regular intensive exercise When HbA1c testing is unavailable Impaired awareness of hypoglycaemia	tions

PRINCIPLES

People and health care professionals should be clear about what they hope to achieve by self-monitoring blood glucose because monitoring in itself does not improve control. It is the interpretation of the result and the action taken that makes the difference.

Assessment of monitoring at least once a year is desirable and should include:

- Self-monitoring skills including the cognitive ability of the person using 6 item cognitive impairment test (especially if there are microvascular changes in other organs apart from the brain)
- The quality and frequency of testing
- The use made of the results obtained
- The continued benefit
- The impact on quality of life
- The equipment used

If the patient does not benefit from monitoring or if it is adversely affecting their quality of life, then it should be stopped.

Self-monitoring of blood glucose does not replace HbA1c testing, which should be carried out at suitable intervals as part of regular care.

Remember other health education (healthy diet, regular physical activity, maintaining a healthy psychological state ,maintaining a normal body weight and avoiding tobacco) to help people reduce their risk of Diabetesrelated complications.

Provide Diabetes lifestyle leaflets and actively promote structured education and referral to IAPT if necessary.

CHOOSING A BLOOD GLUCOSE METER

For people with type 2 diabetes, prescribed blood glucose test strips should cost less than £10 for a pack of 50 strips. A wide variety of blood glucose meters are available where the cost of test strips is less than £10 per pack of 50. For people with type 1 diabetes the preferred option is a combined ketone and blood glucose meter which utilises ketone strips (pack of 10) and blood glucose strips (pack of 50) costing less than £10 per pack for each (see slide <u>25</u>). Meters for testing glucose and ketones are usually provided free of charge from the manufacturer/supplier.

People prescribed FreeStyle Libre sensors on the NHS may be prescribed FreeStyle Optium blood glucose test strips (£16.30 per pack of 50) and FreeStyle Optium β -ketone test strips (£21.94 per pack of 10). Prescribers should check usage levels and prescribe appropriate quantities for these FreeStyle test strips.

People who need a meter with an in-built bolus adviser system should use an Accu-Chek Aviva Expert meter, Agamatrix Wavesense Jazz DoseCoach (basal insulin advisor for Type 2 diabetics only) or FreeStyle Libre Reader. Aviva blood glucose test strips (£16.21/pack 50), Wavesense Jazz (£8.74/ pack 50) and FreeStyle Optium blood glucose test strips (£16.30/pack 50) can be prescribed for people who have been advised to use these meters for the bolus adviser functionality.

People using insulin pumps with an in-built blood glucose meter should be prescribed blood glucose test strips compatible with their insulin pump system (see slide <u>26</u>).

A decision to change meters should be used as an opportunity to review the purpose of testing and the interpretation of results as well as provide basic lifestyle advice and leaflets. If usage is low enough that one pot of strips lasts longer than its expiry date, review of the need for blood glucose monitoring is recommended.

The choice of meter and its functionalities and features should reflect the needs of the user. Some of the key functionalities to consider are show in the table below.

Function/Feature	Comments
Memory	Memory of at least 500 and cannot be deleted by the user
Display screen	Size and readability of the information displayed on the screen
Voice function	For users who are blind or have visual impairment
Replacement batteries	Does the manufacturer replace batteries free of charge?
Customer support	Does the manufacturer provide a freephone number to a customer support service?
External data output	Can data be transferred from the meter? Is data transfer wireless or via a cable?
Compatibility with Remote diabetes management software	Is the meter compatible with remote diabetes management software (e.g. Diasend or Tidepool)?

TYPE 1 DIABETES – COMBINED KETONE AND GLUCOSE METERS

The North West London health and care partnership

	Combined ketone and glucose meters							
Meter	4SURE Smart Duo	CareSens Dual Meter	Fora Advanced Pro GD40	GlucoMen Areo 2K	GlucoRx HCT & Ketone			
Compatible strips - glucose	4SURE £8.99 for 1x50* Expiry: 24 months from date of manufacture	CareSens PRO blood glucose test strips £9.95 for 1x50* Expiry: 12 months from first opening vial	Fora Advanced Pro GD40 (glucose) £9.25 for 1x50* Expiry: 6 months from first opening vial	GlucoMen Areo Sensor £8.25 for 1x50* Expiry: 12 months after first opening vial	GlucoRx HCT £8.95 for 1x50* Expiry: 6 months after first opening vial			
Compatible strips - ketone	4SURE β-ketone £9.92 for 10*	KetoSens £9.95 for 10*	Fora Advanced Pro GD40 (ketone) £9.25 for 10*	GlucoMen areo Ketone Sensors £9.95 for 10*	GlucoRx HCT Ketone Test Strips £9.95 for 10*			
*Drug Tariff October 2020	Expiry: up to expiry date on foil packet (18 months from date of manufacture)	Expiry: up to expiry date on foil packet		Expiry: up to expiry date on foil packet	packet (18 months from date of manufacture)			
Lancets	Any lancets which $cost \le \pm 5.00$ for 200	Any lancets which cost ≤ £5.00 for 200	Any lancets which cost ≤ £5.00 for 200	Any lancets which cost \leq £5.00 for 200	Any lancets which cost ≤ £5.00 for 200			
Memory (no. of tests)	1000	1000	1000	730 Glucose + 100 Ketone	1000			
Replacement batteries	1 x 1.5V AAA (replaced free of charge by company)	2 x 3.0V lithium (CR2032) (replaced free of charge by company)	2 x 1.5V AAA	2 x 3v CR2032 (replaced free of charge by company)	2x AAA Batteries (replaced free of charge by company)			
External output (e.g. to PC, phone)	Bluetooth V4.0 or Micro USB	Bluetooth or PC via free cable supplied on request	Bluetooth connectivity	USB cable to PC. Smartphone via Bluetooth adapter	PC interface cable			
Software and compatibility	Diasend Uploader	Diasend Uploader SmartLog app	iFORA HM app	Diasend Uploader GlucoLog software on PC or GlucoLog App on smartphone	Diasend Uploader			
Insulin Bolus Advisor app on smartphone	Diabetes:M	N/A	N/A	RapidCalc	N/A			
Company contact	Diagnostics-uk@nipro-group.com Freephone 0800 0858808	info@spirit_healthcare.co.uk 0116 2865000	online support form https://foracare.com/patient -related-inquires/	myglucomen@menarinidiag.co.uk Freephone 0800 243667	info@glucorx.co.uk Freephone 0800 007 5892			

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TYPE 1 DIABETES – INSULIN PUMPS – COMPATIBLE BLOOD GLUCOSE TEST STRIPS The North West London health and care partnership

	Omnipod	Accu-Chek Insight	Accu-Chek Combo	Medtronic	Cellnovo	
Compatible	FreeStyle Lite	Accu-Chek Aviva	Accu-Chek Aviva	Contour Next	Accu-Chek Aviva	
strips *Drug Tariff October 2020	£16.41 per 1x50*	£16.21 per 1x50*	£16.21 per 1x50*	£15.16 per 1x50*	£16.21 per 1x50*	
Compatible lancets	Any lancets which cost ≤ £5.00 for 200	Any lancets which $cost \le \pm 5.00$ for 200	Any lancets which $cost \le \pm 5.00$ for 200	Any lancets which $cost \le \pm 5.00$ for 200	Any lancets which cost ≤ £5.00 for 200	
Expiry of test strips upon opening	6 months	12 months	Expiry on outer packaging	6 months	6 months	

Flash Glucose Monitoring Systems

Flash glucose monitoring is only available on the NHS in North West London for people with Type 1 diabetes, aged four years or over, who meet one of the criteria listed below:

Indication 1: People with type 1 diabetes on multiple daily injections or insulin pump therapy who test frequently (>8 times per day).

Indication 2: People with type 1 diabetes unable to routinely self-monitor blood glucose due to disability who require carers to support glucose monitoring and insulin management. **Indication 3**: People with type 1 diabetes for whom the specialist diabetes MDT determines have occupational (e.g. working in insufficiently hygienic conditions to safely facilitate finger-prick testing) or psychosocial circumstances that warrant a 6 month trial of flash glucose monitoring with appropriate adjunct support.

Indication 4: People with any form of diabetes on haemodialysis and on insulin treatment and are clinically indicated as requiring intensive monitoring >8 times daily.

Indication 5: People with diabetes associated with cystic fibrosis on insulin treatment.

Indication 6: Pregnant women with type 1 diabetes (eligible for 12 months' supply of flash glucose monitoring inclusive of post-delivery period).

Indication 7: For those with type 1 diabetes and recurrent severe hypoglycaemia or impaired awareness of hypoglycaemia, NICE suggests that Continuous Glucose Monitoring with an alarm is the standard. Other evidence-based alternatives with NICE guidance or NICE TA support are pump therapy, psychological support, structured education, islet transplantation and whole pancreas transplantation. However, if the person with diabetes and their clinician consider that a flash glucose monitoring system would be more appropriate for the individual's specific situation, then this can be considered.

Initiation of people on flash glucose monitoring will be done by local diabetes specialist teams **ONLY** as per NHS London Clinical Networks recommendations and guidance produced by the North West London Collaboration of CCGs <u>https://www.hounslowccg.nhs.uk/news,-publications-and-policies/publications.aspx?n=3850</u> FreeStyle Libre® measures the glucose in interstitial fluid and is not a complete substitute for finger-prick blood glucose testing.

Finger-prick blood glucose measurements will still be required in certain circumstances, including meeting requirements set by the Driver and Vehicle Licensing Authority (DVLA).

BLOOD GLUCOSE TEST STRIP REQUIREMENTS			LANCET REQUIR	EMENTS		INSULIN PEN NEEDLE REQUIREMENTS			
Test strips usually come in packs of 50 which cannot be split. This table indicates quantities for usual testing. Additional supplies may be necessary for intensive testing e.g. to meet DVLA requirements for driving. If people are required to test regularly please prescribe on repeat prescriptions. People should be encouraged not to over order or stockpile supplies. Additional supplies to meet a short term need should be prescribed on acute prescriptions.			Prescribe a low cost brand of lancets (≤ £5 per pack of 200) Lancers (the finger pricking devices) are not available on prescription and replacement lancing devices are available from companies (usually free of charge). Lancets are for single use only and should be prescribed in quantities which correspond to the expected frequency of testing.			INSOLIN PEN NEEDLE REQUIREMENTS Prescribe a low cost brand of insulin pen needles (≤£4 per pack of 100 pen needles). Most brands of pen needles are compatible with all devices. Pen needles come in packs of 100. Shorter needle lengths reduce the risk of intramuscular injection of insulin. The Forum for injection Technique (FIT) Uk considers the 4mm needle to be the safest pen needle for adults and children regardless of age, gender and body mass index (BMI). For those currently using longer pen needle lengths (8mm or longer), it is advisable to change to a shorter needle length (6mm or less) but only after discussion with a healthcare professional, to ensure they receive advice on the correct injection technique.			
Tests per day	Tests/28 days	Packs/frequency	Tests per day	Tests/28 days	Packs/frequency	Injections per day	28 days	Packs/frequency	
1	28	8 /year	1	28	2 x 200 packs / year	1	28	4 x 100 packs /year	
2	56	1 pack /month; 14 packs/year	2	56	4 x 200 packs / year	2	56	8 x 100 packs /year	
4	112	2-3 packs/month; 29 packs/year	4	112	8 x 200 packs / year	3	84	11 x 100 packs /year	
6	168	3-4 packs/month; 44 packs/year	6	168	11 x 200 packs / year	4	112	15 x 100 packs /year	
	224	4-5 packs/month; 58 packs/year	8	224	15 x 200 packs / year				

DIABETES – CARE PLANNING (1)

'An ongoing process of two-way communication, negotiation and joint decision-making in which both the person with Diabetes and the healthcare professionals make an equal contribution to the consultation.'

THE HOUSE OF CAR	RE:				PERSON CENTRED:			
CommissioningAutonomous, engag	ed inforn onals cor esses	ne importance of each part o med people with diabetes mmitted to partnership work puse collapses		cess:	If we want to be more helpful to people who are trying to make changes but are finding it difficult, we need to base consultations on <i>their</i> concerns, <i>their</i> goals and the practical actions <i>they</i> wish to follow. This does not mean that the HCP is passive, unresponsive or does not have a view – the consultation shares the expertise and experience of both parties in order to influence the outcome. See <u>Language Matters</u> , <u>Language and Diabetes</u> for guidance on principles and practices for better communication with people with diabetes.			
Send test re beforeha	esults	T: Clinical record of care plannir Organisational processes	Co	ntact numbers d safety netting	Many people may not really have considered a lifestyle or behaviour change, or may feel ambivalent about making a change. In this situation, pushing or encouraging them to plan to change may not be appropriate. Indeed, a possible goal for that person might be to decide whether they do want to make a change. Their action plan may be to work out the 'pros and cons' of both making the change and not making the change, along with assessing its importance to them. If they are struggling with their mood or anxiety or coping with diabetes they usually want to be asked about this as this may be the thing that is standing in their way.			
Prepared for consultation	Eng		HCP	Consultation skills / attitudes	Goal setting and action planning are inextricably linked but they should be seen as separate stages.			
Information /	;ageo	Collaborative care planning consultation	HCP committed to partnership working	Integrated multi-	THE INFORMATION SHARING PROCESS:			
structured education Emotional and psychological support	ged informed patient			disciplinary team and expertise Senior buy-in and local champions to support and role model	Information gathering: The patient attends for an appointment with the Health Care Assistant or Nurse to have their 'annual review' tests (e.g. blood and urine tests, blood pressure, weight +/- foot, eye screening and mental health screening -PHQ4 (in primary and community care) OR DDS2 (in secondary care). Use 6 item Cog if over 60. See slide <u>31</u> for tools.			
	Identify and Procured time for Quality assure fulfil needs consultations, training and measure and IT				Information sharing: The annual review test results are included into a letter and posted to the patient to arrive at least one week before the Care consultation. Prompts and questions in the letter encourage the patient to consider the results and other aspects of their Diabetes before the consultation			
tul Useful tools:					Consultation and joint decision making: The patient attends the Care Planning consultation with the practice nurse or GP, who have received training in partnership working. This should include the elements outlined later in the guide (goal setting and action planning).			
Partners in Care: Diabet		uide to care planning 2): a questionnaire for unde	rstanding	patient's perception of	Agreed and shared care plan: The agreed care plan is produced and shared with the patient			

<u>Consultation Quality Index (CQI-2)</u>: a questionnaire for understanding patient's perception of clinician skills

either immediately or subsequently by post or electronically

DIABETES - CARE PLANNING (2)

Gather and share storiesExplore and discussGoal a	setting Action planning Review
GOAL SETTING:	AGREEING ACTIONS:
SUMMARISE AND PRIORITISE	FOLLOW people' PRIORITIES
Goal setting involves summarising and prioritising the various issues that have been explored and discussed so far in the consultation. For instance the healthcare professional might say "what, of all the concerns we have talked about, rise up for you as the important things to aim for in relation to your Diabetes, over this coming year?"	If we want to be more helpful to people who are trying to make changes but are finding it difficult, we need to base consultations on <i>their</i> concerns, <i>their</i> goals and the practical actions <i>they</i> wish to follow. This does not mean that the HCP is passive, unresponsive or does not have a view – the consultation shares the expertise and experience of both parties in order to influence the outcome.
ASSESS IMPORTANCE	SMART GOALS
 When changing something is difficult, the reason for change, the place where someone would like to be, has to be worth the effort of changing. If the goal is of low importance, but the difficulty of achieving it is high, then it is unlikely to be successfully achieved. Why would you want to put yourself through that? The value to someone can be assessed quite simply by asking the person to consider how important the goal or outcome is for them using a rating scale of 0 – 10 where 0 is low and 10 is high importance. For instance: <i>"If I asked you to tell me how important this change is for you, where zero was not important at all and 10 was really, really important, where would you put yourself between zero and ten?"</i> If they score e.g. 6, you could ask why it isn't 7 and ask what would need to happen to make it 7. You could also ask why it isn't 5 as this will help you and them explore why it IS important. This process illuminates their ambivalence and facilitates a motivational conversation. 	Key ingredients of successful action planning: • Plans need to be SMART • Success is addictive • Barriers to success need to be considered • Rating scales to assess confidence and readiness • Success really is addictive • Take the time to do it 'SMART' is a well known acronym, the letters of which stand for the following: S = Specific M = Measurable A = Action R = Realistic T = Time-scaled If an action plan can 'tick the boxes' of the above features, it is more likely to be successfully achieved
REASSESS IMPORTANCE	ASSESS CONFIDENCE
If the score is lower than 7 then the reason for picking that goal needs to be explored.	Rating confidence: Self efficacy theory holds that a key determinant of a person's ability to take action is the confidence they have in their ability to successfully undertake that action. So, a further way of assessing how realistic a plan is to ask the person to rate their confidence that they will be able to do it. This can be done in a similar way that we rated the importance of goals: <i>"If I asked you to rate how confident you feel you are to be able to do this, where zero was not at all and 10 was absolutely definitely, where would you put yourself between zero and ten?"</i> If they score e.g. 6, you could ask why it isn't 7 and ask what would need to happen to make it 1 You could also ask why it isn't 5 as this will help you and them explore what skills they DO have This process illuminates the support and skills they can draw upon including you.

	OVERCOMIN	NG RESISTANCE
 ENGAGE Build rapport by matching people body language, words and tone. Actively listen. Ask curious questions that keep your map out of their world. 	l don't want I must do / should do	What do you want? According to whom?
 GUIDE Guide out of stuck state, what could they have differently (X) and the importance of it "Regarding your health, what would you like to have happen? And is there anything else about that X? What kind of X is that X? What is important to you about that X?" 	i must do y snould do	What would happen if you did? What would happen if you didn't?
 EVOKE & ENVISAGE What will it be like when they have it? Visualise this "What would happen if you did? What would happen if you didn't? What wouldn't happen if you did? What wouldn't happen if you didn't? Can you give me another example of this?" 	I can't	According to whom? When can you? What can you do? What happens when you do? What happens when you
 FOCUS FORWARDS Clarify purpose of stuck behaviours (Y) & explore behaviour specifics to remove obstacles "For what purpose are you doing Y? What does doing Y give you? What does Y stop you doing? When / where / how / with who specifically do you Y?" Summarise goals here - collectively recall back & transition X towards the future 	l never I always	don't? Never? When Specifically?
 PLAN in STEPS Develop a change plan & self-owned strategies to make it happen (cf SMART) Repeat a "next steps" question until broken into manageable chunks and first step of action: "What needs to happen for that / X to happen? Right, in order to do that, what do you need to do? So what needs to happen for that to happen?" Summarise agreed action, commit to first step & a time-bound follow up - shake on it. 	l've tried that before	So what did you learn? And knowing what you learnt then, what needs to happen now?
 CELEBRATE & BUILD Follow up and celebrate success! Congratulate every small step and shift away from the stuck state with positive affirmations. Learn from mistakes Keep building on goals and actions and carry on the conversation "So knowing all that you know from the last time we met –what do you want to have happen now?" 	and Jo Wilson, NLP Co	or Yasmin Razak, GP Educator ach from Beyond Training ation with Diabetes UK

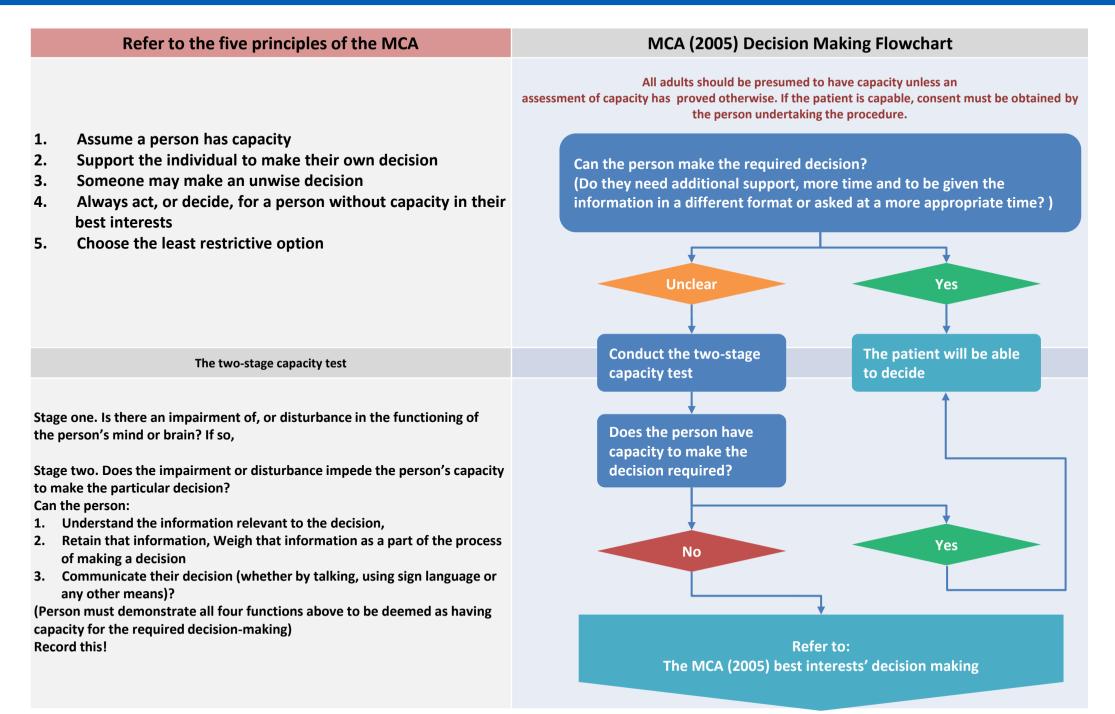
DIABETES – PSYCHOLOGICAL ASPECTS

OVERVIEW	CLINICIAN RECOMMENDATIONS
Approximately 40% of people with Diabetes suffer with poor psychological well- being:	pecially when people have off target HbA1c or are not engaged with treatment, be alert to : Diabetes distress, clinical or subclinical depression, anxiety. Use the screening tools that are at
The rate of depression and anxiety is more than doubled in people with Diabetes	bottom of this page-DDS2 (In secondary care), PHQ4 (in primary or community care) as a screen and refer to IAPT or other relevant local pathway if +ve. See here for other considerations and
 Other conditions such as diabetes distress, eating disorders, alcohol and substance use and needle phobias are more prevalent in diabetes People with poorly controlled diabetes and vascular changes in feet, eyes and kidneys have a higher likelihood of such changes in their brains leading cognitive impairment. People with type 2 diabetes are more likely to have experienced childhood adversity People with severe mental illness such as schizophrenia and bipolar affective disorder are at higher risk of developing type 2 diabetes . Atypical antipsychotics increase this risk. 	 options, how to introduce medication etc. For moderate to severe depression, consider an antidepressant in the form of an SSRI, e.g. citalopram (20mg od, titrate up to maximum 40 g od) or sertraline (50mg od, titrate up to maximum of 200mg od). Give them at least 6 weeks at maximum dose before trialling a different antidepressant. Don't switch from one SSRI to another as they work in the same way. Try a different agent and/ or refer to mental health trust. Don't use dosulepin. Don't use anxiolytics for anxiety. This is contraindicated. CBT is the NICE treatment of choice- so refer to IAPT Alcohol and drug use- often used as a coping strategy when people are feeling distressed, anxious, overwhelmed or depressed. Ask about this using the AUDIT tool (see below) and whether they
mpact of all these conditions in Diabetes if not addressed is: Difficulty with motivation, hope for the future, cognitive function and self-esteem leading to difficulty with self-care	would like referral to local drug and alcohol services Eating disorders and insulin dose manipulation if there is poor glucose control, low BMI or ove concern with body shape and weight. Early, and occasionally urgent, referral to local eating disorder services should be considered. <u>Eating Disorder Resources</u>
Treatment for psychological conditions has been shown to lead to reduced symptoms . and improved glycaemic control, as well as the costs of healthcare. Person Centred approach	Cognitive impairment (delirium or dementia) if they have other complications-even in people as young as 50 and even if they appear to be compos mentis. Use 6 item Cog test (see below) and consider discussion with or referral to dementia services locally. Add in extra support if required e.g. administration of medication
 People with diabetes want to be asked about their psychological wellbeing and how they are managing living with Diabetes . People with Diabetes want a menu of choices in terms of interventions, including peer support and self-help including online resources (see below) 	Relapsing or new onset of psychosis may put the person with diabetes at greater risk of poor self- care for their diabetes. Aripiprazole is the recommended anitpsychotic if the person has diabetes. If the person's psychosis is stable, consider titrating the antipsychotic dose down slowly and carefully with close monitoring. Discuss with team psychiatrist if in doubt.
Mental health scree	ning tools and other resources

Alcohol screening tool "AUDIT" Diabetes Distress scale (DDS2 and DDS longer version) PHQ4 (depression and anxiety brief screen) PHQ9(depression) GAD 7(anxiety) 6 item Cog Eating Disorder screening for primary care Award winning self-help leaflets about a number of different mental health issues (available in easy to read, audio available) MIND Charity for information and support Samaritans for support in a crisis

TYPE 2 DIABETES – MENTAL CAPACITY ACT (1)





TYPE 2 DIABETES – MENTAL CAPACITY ACT (2)

Refer to the five principles of the MCA

- Must ensure that the proposed action/treatment is in the best interests of the person.
- The decision maker needs to check if there is an Advance Decision (AD), Lasting Power of Attorney [LPA] or Deputy covering health and welfare or if there is a friend/carer of person nominated by the person to consult.
- Advance Decision must be relevant to this decision.

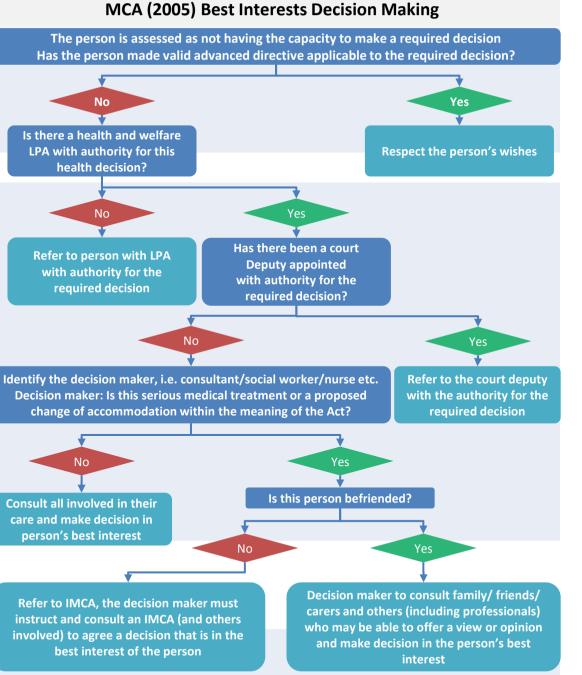
The best-interest checklist

When making a decision in someone's best interests one must:

- Involve the person as much as possible
- Find out the person's wishes and feelings
- · Consult people who know the person well
- · Consider all relevant information in time
- Avoid making the decision if it is likely that the person might regain capacity
- · Think about what would be the least restrictive option and not:
- Make assumptions based on the person's age, appearance, condition or behaviour
- Make a decision involving life-sustaining treatment that is motivated by a desire to end the person's life.
- Consult with all relevant others, i.e. the person, medic/GP, carers, Allied Health Professionals, social care staff, Advocate/IMCA, or people who know the person well, i.e. LPA or Deputy or Enduring Power of Attorneys
- · Consider all the relevant circumstances relating to the decision in question
- Be able to justify and evidence their decision making
- Ensure that other least restrictive options are always explored (complete best interests decision record).

A formal best interests meeting is not always needed. It is important that consultation has taken place and the decision maker follows the guidance above with all relevant others and this is documented on the agreed paperwork.

Record keeping: it is important that you accurately record and evidence any decisions made with regards to best interests.



TYPE 2 DIABETES – ORAL HYPOGLYCAEMIC AGENTS (1)

NB: All information presented is in line with the Summaries of Product Characteristics (SPC) of each drug or the BNF.

BIGUANIDES (METFORMIN)

• Decreases gluconeogenesis and increases peripheral utilisation of glucose. Improves insulin sensitivity.

					Dose adjustme	nts			Dos Initially 40-80mg o	
Preparation	tion Dose		Moderate impairme (eGFR= 30	nt	Severe renal impairment (eGFR<30		Hepatic Impairment:	Preparation		
			mL/min/1	L.73 m²)	mL/min/1.73	m²)		Gliclazide	titrated until glyca	
Metformin	500mg – 2g daily in divid doses, With or after a meal	ed			Withdraw if			achieved before m Maximum daily do twice daily		
Metformin modified- release	500mg - 2g once daily w evening meal If glycaemic control is no achieved, 1g twice daily should be considered.				Contraindicated		tissue hypoxia likely.	Glimepiride	1mg once daily, tit of 1mg every 1-2 v once daily if need 6mg once daily . S daily, shortly befo main meal	
as lactic acid ketoacidosis acute or chr may alter re insufficiency cardiac and/	/min/1.73 m ² , etabolic acidosis (such losis, diabetic i), onic conditions that nal function, hepatic	and I feed Can I in pro and	nancy breast- ing: be used egnancy stfeeding	(moni and re functi • May c Vitam malab • Risk fa	ic stable failure tor cardiac enal on)	• GI (e. ab na dis	side effects: side effects .g. diarrhoea, idominal pain, susea, taste sturbance and miting.)	 Severe ren insufficien Gliclazide - porphyrias with system 	of ketoacidosis aal or hepatic cy – Acute 5, interaction	
	quirements: SFR when initiating and if s utely worsen renal functio	-	antihypert	ensive, diur	etics and NSAIE	Ds or oth	ner conditions			

• Withhold short term if dehydrated (including diarrhoea and vomiting), severe infection or shock (i.e. post-MI) and re-start once fully hydrated

Additional information:

- All people, irrespective of eGFR, should be educated on good sick day guidance (see page <u>16</u>).
- Metformin MR is an option for people poorly tolerant on standard-release
- Based on clinical experience of increased side-effects, maximum dose for metformin immediate-release medicines in BNF Publications differs from product licence.
- Reduces cardiovascular disease in overweight or obese people

SULFONYLUREAS (GLICLAZIDE, GLIMEPIRIDE)

• Stimulates insulin release from the pancreas.

					C	Dose adjustments		
	Hepatic	Preparation	Do	ose	Mild-moderate renal impairment	Severe renal impairment	Hepatic Impairment:	
1	Impairment: Withdraw if tissue hypoxia likely.	Gliclazide Glimepiride	Initially 40-80mg titrated until glyd achieved before Maximum daily o twice daily 1mg once daily, f of 1mg every 1-2 once daily if need 6mg once daily . daily, shortly bef main meal	aemic control meals. dose: 160mg titrated in steps weeks to 4mg d be. Maximum Similar time	Use with care in mild to moderate Avoid renal Avoid impairment.		Avoid in severe hepatic insufficiency; use of insulin is recommended	
GI (e. ab na dis vo	ide effects: side effects g. diarrhoea, dominal pain, usea, taste turbance and miting.) er conditions	 Contraindications: Presence of ketoacidosis Severe renal or hepatic insufficiency Gliclazide – Acute porphyrias, interaction with systemic and oromucosal miconazole 		Pregnancy and breast- feeding: Avoid	 Cautions: Elderly due to a possible age-relate increased risk of hypoglycaemia People with G6PD deficiency Concomitant use o sulfonylureas and insulin should be avoided in people severe renal impairment (<45mL/min/1.73m 	• GI sid abdou nause diarrh const • Weig f • Pleas drug BNF f side-e	 Class side effects: GI side effects (e.g. abdominal pain, nausea/vomiting, diarrhoea and constipation) Weight gain Please see individual drug monograph in the BNF for a complete side-effect profile 	
n or	shock (i.e.	Monitoring re	quirements: Blood	glucose (See pag	e <u>23</u>)			
		Additional inf	ormation:					

- Risk of hypoglycaemia when used with SGLT2i, DPP4i, pioglitazone and acarbose- consider reducing dose of sulfonylurea.
- ALL people should be told about recognition and management of hypoglycaemia when prescribed a sulfonylurea.

TYPE 2 DIABETES – ORAL HYPOGLYCAEMIC AGENTS (2)



NB: All information presented is in line with the Summaries of Product Characteristics (SPC) of each drug or the BNF.

THIAZOLIDINEDIONES (PIOGLITAZONE)

Reduces peripheral insulin resistance, leading to a reduction of blood-glucose concentration.

Decembra	Deer	Dece			Dose adjustments				
Preparation	Dose		Renal Impairment			Hepatic Impairment:			
Pioglitazone	Initially 15–30 mg once of adjusted according to response up to 45 mg or daily with or without foo Elderly - initiate with low possible dose and increas gradually.	No dose adjustment is necessary			Should not be used in people with hepatic impairment (Therapy with pioglitazone should not be initiated if the ALT is > 2.5 times the upper limit of normal or with any other evidence of liver disease.)				
 Contraindications: Cardiac failure / Hx of cardiac failure (NYHA stages I to IV) hepatic impairment diabetic ketoacidosis current bladder cancer or a history of bladder cancer uninvestigated macroscopic haematuria 			nancy breast- ing: d	Cautions: Potentiates the hypoglycaemic effects of insul and sulfonylureas (see page <u>32/6</u>	: in	 Side effects: Bone fracture (particularly in women); Increased risk of infection; numbness; visual impairment; weight increased 			
Monitoring requ	uirements:								

Review treatment after 3–6 months and regularly thereafter

- Liver function tests prior to commencing therapy, and periodically thereafter
- Whilst on pioglitazone, if ALT levels are increased to 3 times upper limit of normal, liver enzyme levels should be reassessed as soon as possible. If ALT levels remain > 3 X the upper limit of normal, therapy should be discontinued
- Weight

Additional information:

- Important safety information Please see hyperlinks for more detailed advice
 - MHRA/CHM advice: Pioglitazone cardiovascular safety (December 2007 and January 2011)
 - People should be informed on the signs and symptoms of DKA, discontinue treatment with the SGLT2 inhibitor immediately if DKA is suspected or diagnosed
- Pioglitazone: risk of bladder cancer (July 2011)
 - Pioglitazone should not be used in people with active bladder cancer or a past history of bladder cancer, or in those who have uninvestigated macroscopic haematuria.
- Weight gain which may be due to fat accumulation, and in some cases associated with fluid retention. In some cases weight increase may be a symptom of cardiac failure, therefore weight should be closely monitored.

DPP-4 INHIBITORS: DIPEPTIDYLPEPTIDASE-4 INHIBITORS (SITAGLIPTIN, SAXAGLIPTIN, LINAGLIPTIN, VILDAGLIPTIN, ALOGLIPTIN)

• Inhibits dipeptidylpeptidase-4 to increase insulin secretion and lower glucagon secretion.

			Dose adjustmen	ts			
	Dose	Moderate renalSevere renalimpairment (eGFR=impairment (eGFR=mL/min/1.73 m²)mL/min/1.73 m²)		=	Hepatic Impairment:		
25 m	g once daily	eGFR 30–50: 12.5 mg once daily	-	No dose adjustment necessary if mild/moderate			
5 mg	once daily	N	/A		impairment. Use with caution		
100 r	ng once daily	eGFR 30–45: 50 mg once daily	eGFR <30: 25 mg once daily		Therapeutic experience in severe		
5 mg once daily		eGFR <45: 2.5mg once daily			hepatic impairment is limited and therefore use is not recommended by manufacturer.		
50 m the n used	g once daily in norning when in combination	eGFR <50: 50 mg once daily			Should not be used in people with hepatic impairment		
	Pregnancy and breast- feeding: Avoid	 Cautions: Potentiates the hypoglycaemic effects of insulin and sulfonylureas (see page <u>32/65</u>) People with a history of pancreatitis. 			 Potentiates the hypoglycaemic effects of insulin and sulfonylureas (see page 32/65) People with a history of pancreatitis. Headache/dizz Headache/diz Headache/dizz Headache/dizz		Headache/dizziness Please see individual drug monograph in the BNF for a complete side-effect
	5 mg 100 r 5 mg 50 m 50 m the n used	25 mg once daily 5 mg once daily 100 mg once daily 100 mg once daily 5 mg once daily somg twice daily 50 mg once daily in the morning when used in combination with a sulfonylurea ons: Pregnancy and breast-feeding:	25 mg once daily impairment (eGFR= mL/min/1.73 m²) 25 mg once daily eGFR 30–50: 12.5 mg once daily 5 mg once daily N 100 mg once daily eGFR 30–45: 50 mg once daily 5 mg once daily eGFR 30–45: 50 mg once daily 5 mg once daily eGFR 2.5mg once daily 50 mg twice daily eGFF 2.5mg once daily 50 mg twice daily eGFF 50 mg once daily in the morning when used in combination with a sulfonylurea ons: Pregnancy and breast- feeding: Avoid Cautions: • Potentiates the hy effects of insulin a (see page 32/65)	DoseModerate renal impairment (eGFR= mL/min/1.73 m²)Severe renal impairment (eGFR= mL/min/1.73 m²)25 mg once dailyeGFR 30–50: 12.5 mg once dailyeGFR <30: 6.25 mg once dail Use with caution5 mg once dailyeGFR 30–45: 50 mg once dailyeGFR <30: 25 mg once daily100 mg once dailyeGFR 30–45: 50 mg once dailyeGFR <30: 25 mg once daily5 mg once dailyeGFR 30–45: 50 mg once dailyeGFR <30: 25 mg once daily5 mg once dailyeGFR 30–45: 50 mg once dailyeGFR <30: 25 mg once daily5 mg once dailyeGFR <50: 50 mg once dailyeGFR <50: 50 mg once daily50 mg twice daily used in combination with a sulfonylureaCautions: • Potentiates the hypoglycaemic effects of insulin and sulfonylureas (see page 32/65)	Impairment (eGFR= mL/min/1.73 m²) Impairment (eGFR= mL/min/1.73 m²) 25 mg once daily eGFR 30–50: 12.5 mg once daily eGFR <30: 6.25 mg once daily; Use with caution 5 mg once daily eGFR 30–45: 50 mg once daily eGFR <30: 25 mg once daily 100 mg once daily eGFR 30–45: 50 mg once daily eGFR <30: 25 mg once daily 5 mg once daily eGFR 30–45: 50 mg once daily eGFR <30: 25 mg once daily 5 mg once daily eGFR <45: 2.5mg once daily 25 mg once daily 50 mg twice daily eGFR <45: 50 mg once daily s 50 mg twice daily eGFR <50: 50 mg once daily s 50 mg once daily in the morning when used in combination with a sulfonylurea eGFR <50: 50 mg once daily s ons: Pregnancy and breast- feeding: Avoid • Potentiates the hypoglycaemic effects of insulin and sulfonylureas (see page 32/65) Cla		

- Discontinue if symptoms of acute pancreatitis (persistent, severe abdominal pain)
- Vildagliptin associated with liver toxicity; seek medical attention if nausea, vomiting, abdominal pain, fatigue, and dark urine develops. Monitor liver enzymes 3 month interval for first year, periodically after.

Additional information:

*Alogliptin not licensed for monotherapy

TYPE 2 DIABETES - ORAL HYPOGLYCAEMIC AGENTS (3)

NB: All information presented is in line with the Summaries of Product Characteristics (SPC) of each drug or the BNF.

SGLT-2 INHIBITORS: SODIUM GLUCOSE CO-TRANSPORTER 2 AGENTS (CANAGLIFLOZIN, DAPAGLIFLOZIN, EMPAGLIFLOZIN, ERTUGLIFLOZIN)

• Inhibit sodium-glucose co-transporter 2 (SGLT-2) in the proximal renal tubule to reduce glucose reabsorption and increase urinary glucose excretion.

			Dose adjustments							
Preparation	Dose		Initiating in eGFR <60 mL/min/1.73 m ² :	If taking as current treatment- eGFR <60 mL/min/1.73 m ² :		ere Renal Impairment IL/min/1.73 m²):	Hepatic Impairment:			
Canagliflozin	 100 mg once daily Increased if tolerated to 300 mg once daily if required Preferably before breakfast 10 mg once daily, Increased up to 25 mg once daily, If necessary with or without food. <i>Initiation not recommended in adult ≥85 years</i> 5 mg once daily Increased to 15 mg once daily if necessary and if tolerated Dose to be taken in the morning. 10 mg once daily With or without food 		100mg once daily	Reduce dose to 100 mg once daily	Can be contir renal transp	D: Do not initiate; nued until dialysis or lantation if urinary nine ratio > 300 mg/g	No dose adjustment necessary if mild/moderate impairment.			
Empagliflozin				Reduce dose to 10 mg once daily	If eGFR persistently <45: Discontinue/Avoid		Therapeutic experience in severe hepatic impairment is limited and therefore use is not			
Ertugliflozin			Avoid initiation	10 mg once daily Increase monitoring of renal function			recommended by manufacturer.			
Dapagliflozin				10 mg once daily Monitor renal function at least 2-4 times a year			Initial dose 5 mg daily in severe hepatic impairment, can increase to 10mg according to response/tolerability			
Contraindications: Pregnancy and breast-feeding:			Cautions:			Class side effects:				
Diabetic ketc	bacidosis	Avoid—toxicity in animal studies	- People at ris dehydration	k of hypotension/hypovolaemia)	(e.g. Elderly,					
 Monitoring requirements: Renal function - before treatment and at least annually thereafter, and before initiation of drugs that may reduce renal function and periodically thereafter. Volume status and electrolytes 			fore - Please see s cautions er Potentiates	- Please see specific drug monograph in the BNF for complete			 Polydipsia urinary disorders Please see individual drug monograph in the BNF for a complete side-effect profile 			

Additional information:

• Important safety information – Please see hyperlinks for more detailed advice:

- MHRA/CHM advice (updated April 2016): SGLT2 inhibitors: updated advice on the risk of diabetic ketoacidosis (DKA)
 - People should be informed on the signs and symptoms of DKA, discontinue treatment with the SGLT2 inhibitor immediately if DKA is suspected or diagnosed
- MHRA/CHM advice (MHRA/CHM advice March 2017): SGLT2 inhibitors: updated advice on increased risk of lower-limb amputation (mainly toes)
 - SGLT2i's may increase the risk of lower-limb amputation (mainly toes). All people taking an SGLT2i should be counselled on good preventive foot care. Review if lower limb complications develop (e.g. skin ulcer, osteomyelitis, or gangrene). Monitor people with risk factors for amputation, signs and symptoms of water or salt loss.
 - MHRA/CHM advice: SGLT2 inhibitors: reports of Fournier's gangrene (necrotising fasciitis of the genitalia or perineum) (February 2019)
 - if Fournier's gangrene is suspected, stop the SGLT2 inhibitor and urgently start treatment (including antibiotics and surgical debridement as required)
- MHRA/CHM advice: SGLT2 inhibitors: monitor ketones in blood during treatment interruption for surgical procedures or acute serious medical illness (March 2020)
 - SGLT2 inhibitor treatment should be interrupted in people who are hospitalised for major surgical procedures or acute serious medical illnesses and ketone levels measured, preferably in blood rather than urine. Treatment may be restarted when the ketone values are normal and the person's condition has stabilised. Date of preparation: October 2020. For review: April 2021 36



SGLT2 inhibitors: safe prescribing guidance

INTRODUCTION

- In a number of drug trials various members of the SGLT-2i class have been shown to have cardio renal protective effects over and above their glycaemic effectiveness. Data on these cardio renal effects is emerging rapidly and this may be reflected in changes to the licensing arrangements for individual members of this class
- This guidance is only designed to be used for the prescription of SGLT-2i inhibitors within each individual drug's current licence (see slide 36)
- The prime purpose of this guideline is to ensure that, where an SGLT-2i is prescribed in a patient with type II diabetes for cardiorenal protection, it is undertaken safely. This can be achieved by ensuring that these agents are only prescribed for the appropriate patients and that the appropriate information is given to patients to ensure safety.

CAUTIONS

- Frail elderly
- Potential for pregnancy
- SGLT-2i should NOT be prescribed to people with type 1 diabetes unless under the direction of a diabetologist
- SGLT-2i should not be prescribed to people with type 2 diabetes at increased risk of euglycaemic diabetic ketosis see below**
- · Always offer advice on sick day guidance when introducing these agents and reiterate at every opportunity i.e. stop perioperatively or if restricted food intake or dehydration.
- Reiterate that if on an SGLT-2i, very low carbohydrate diets (or ketogenic diets) carry an increased risk of ketosis.
- In people with reasonable glycaemic control and risk of hypoglycaemia, consider reducing other hypoglycaemic agents when introducing SGLT-2i.
- · In people on diuretics, consider reducing the dose.
- Give advice to seek medical attention (via GP, urgent care centre or pharmacy) should they develop symptoms of a genital infection.
- · Caution is advised if the person has active peripheral vascular disease including active arterial ulceration or claudication.

** TYPE 2 DIABETIC PEOPLE AT INCREASED RISK OF EUGLYCAEMIC DIABETIC KETOSIS

- · Those who rapidly progressed to requiring insulin (within 1 year of diagnosis)
- Past history of diabetic ketoacidosis (DKA)
- History of pancreatic disease including alcoholic pancreatitis as a cause of their pancreatitis
- BMI<27
- The possibility of Latent Autoimmune Diabetes in Adults

TYPE 2 DIABETES – ORAL HYPOGLYCAEMIC AGENTS (4)

NB: All information presented is in line with the Summaries of Product Characteristics (SPC) of each drug or the BNF.

ALPHA GLUCOSIDASE INHIBITORS (ACARBOSE)

 Acarbose, an inhibitor of intestinal alpha alucosidases, delays the digestion and absorption of starch and sucrose; it has a small but significant effect in lowering blood glucose.

	Dose		Dose adjustments			
Preparation			Renal Impairment	Hepatic Impairment:		Prepar
Acarbose	Initially 50 mg daily, Titrated up to maximum of 200 mg 3 times a day, if required. Before food		As Acarbose has not been studied in people with severe renal impairment, it should not be used in people with a creatinine clearance <25 ml/min/1.73m ²	Contraindicated in people with hepatic impairment		Repaglini
 Contraindications: Hepatic impairment Hernia; inflammatory bowel disease; predisposition to partial intestinal obstruction; previous abdominal surgery 		Pregnancy and breast- feeding: Avoid	Cautionary use in: • Potentiates the hypoglycaemic effects of insulin and sulfonylureas (see page 32/65), hypoglycaemic episodes may be treated with oral glucose, but not with sucrose.	Side effects:Abdominal painDiarrhoeaFlatulence		Contraind • Ketoa • Conco gemfil
Monitoring requirements:						Monitorir

• It is recommended that liver enzyme monitoring is considered during the first 6 to 12 mont treatment. If elevated transaminases are observed, withdrawal of therapy may be warranted particularly if the elevations persists. In such circumstances, people should be monitored at weekly intervals until normal values are established.

Additional information:

- For use in people inadequately controlled by diet alone, or by diet with oral anti-diabetic drugs.
- Poorer anti-hyperglycaemic effect than many other antidiabetic drugs.
- Low incidence of hypoglycaemia.

MEGLITINIDES (REPAGLINIDE)

• Stimulates insulin secretion.

			Dose adj	ustments
ient:	Preparation	Dose	Renal Impairment	Hepatic Impairment:
in people airment	Repaglinide	 Initially 500 micrograms (max. per dose 4 mg), adjusted according to response at intervals of 1−2 weeks. Maximum daily dose: 16 mg per day in divided doses. Initiation not recommended in adults ≥75 years To be taken within 30 minutes before main meals 	Use with caution in renal impairment	Avoid in severe liver disease
ain	 Contraindications: Ketoacidosis Concomitant us gemfibrozil 	e of Avoid	 Cautionary use in: Debilitated people; Malnourished people 	 Side effects: Abdominal pain; diarrhoea; hypoglycaemia
nths of ted, at	 Monitoring require It is recommend treatment 	ements: ded that liver enzyme monitoring	is considered during the fir	rst 6 to 12 months of

Additional information:

- Licensed as monotherapy, or in combination with metformin, when metformin alone inadequate.
- Rapid onset of action and short duration of action. ٠
- Substitute insulin during intercurrent illness (such as myocardial infarction, coma, infection, and ٠ trauma) and during surgery.

TYPE 2 DIABETES – CRITERIA FOR REFERRAL TO LEVEL 2



The aim of the Diabetes level 2 service is to provide a high quality service for safe initiation and optimization of injectable therapy within GP networks.

INCLUSIONS

Initiation or optimisation of injectable therapy will be provided to people with Type 2 Diabetes who satisfy the following criteria:

- 1. Type 2 people that are registered with a GP in the CCG over the age of 18
- 2. Are not achieving HbA1c targets with maximum-tolerated oral combination hypoglycaemic therapy and/or insulin/GLP-1, compliant with combination therapy without any significant improvement in HbA1c:
 - a. Triple therapy (three different oral agents)
 - b. Dual therapy (two different oral agents)
- 3. In people who have significantly poor glycaemic control that is unlikely to respond to triple therapy OR in people who express a desire to start injectable therapy OR need to do so for occupational reasons (e.g. GLP-1 in taxi drivers)
- 4. The patient or carer is deemed capable of safely managing their injectable, including being able to undertake home blood glucose monitoring, inject insulin and adjust their own dose
- 5. Express an intention to start injectable, having been advised of what this involves and the risks associated with the treatment

EXCLUSIONS (REFERRAL TO ACUTE SPECIALIST CLINIC REQUIRED)

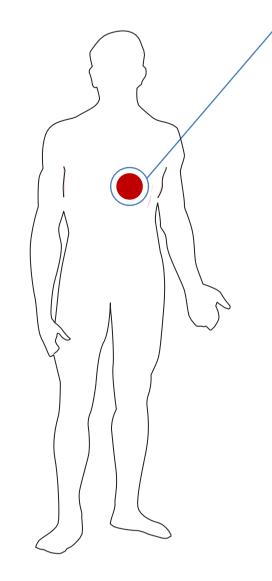
- 1. Pregnancy
- 2. People aged under 18



WOMEN OF CHILDBEARING AGE WITH DIABETES or PREVIOUS GESTATIONAL DIABETES (GDM)

50% of all	pregnancies are unplanned		
All women with Diabetes	Offer contraceptive advice		
	All forms of contraception may be used for women with Diabetes		
	Pre-conception care		
	Stress the importance of: Folic acid Good glycaemic control Medicines review (stop ACE, ARBs and statins) Ensure retinal screen and microalbuminuria test performed within the last 12 months		
All women with Type 1 Diabetes actively seeking pregnancy	Refer to secondary care for pre-conception counselling		
	for consideration of pump therapy to optimise their glycaemic control. Start folic acid 5mg OD		
All women with Type 2 Diabetes actively seeking pregnancy	Refer to secondary or intermediate care for pre-conception counselling		
	Discontinue all oral agents and injectable therapies except Metformin and insulin Optimise glycaemic control with a basal bolus regime if needed Start folic acid 5mg OD		
For women with a previous history of gestational Diabetes	Emphasise importance of annual review		
	Check a HbA1c yearly to exclude Diabetes Give dietary and weight management advice Explain the high probability that GDM will recur in any future pregnancy and need for early booking		
On confirmation of pregnancy	Refer immediately to the Diabetes Antenatal Clinic		
	Refer to retinal screening		
	Ensure folic acid 5mg OD is being taken and ACE , ARBs and statins stopped		

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CARDIOVASCULAR RISK FACTOR INTERVENTION

All people with Diabetes are considered to be at high cardiovascular risk.

All require lifestyle advice and multifactorial risk factor intervention.

However note lipid guidelines now recommend QRISK2 assessment for statin initiation.

LIFESTYLE INTERVENTION

BLOOD PRESSURE

Smoking cessation

should be encouraged, with use of Stop Smoking clinics as required. **Dietary intervention**

- Should include weight loss for those with high waist circumferences
 - >94cm in Northern European white male >80cm in Northern European white females >90cm in South Asian males
 - >80cm in South Asian females

and, for all should include advice about a low fat diet high in fruit and vegetables (at least 5 portions per day).

- Should include advice to decrease total dietary fat to <30% of total energy intake
- Should include advice to decrease saturated fats to <10% of total fat intake.
- Should include advice about lowering salt intake to be less than 6g of salt (=2.4 g sodium chloride) per day.
- Alcohol intake should be discussed, with the advice for males to limit to 14units per week.
- Regular intake of oily fish and other sources of omega 3 fatty acids (at least 2 portions of fish per week)

Exercise

The benefits of regular exercise should be explained and people should be advised to perform regular aerobic activity. Clinical studies show that walking for 30 minutes every day has cardiovascular benefits All people with Diabetes (Type 1 or Type 2) should be treated to a target of 140/80 with a combination of lifestyle intervention (see above) and drug therapy. If kidney, eye or cerebrovascular damage set a target <130/80.

Up to half the people with Type 2 Diabetes will need 3 or more antihypertensive agents, and it is important for people to be made aware of this when discussion around hypertension occurs.

ACE inhibitors and ARBs are preferred first line therapy in people with any degree of nephropathy (micro- or macroalbuminuria).

In all people measure renal functions and electrolytes 1-2 weeks after initiation of ACE inhibitors and ARBs and with each increase in dose.

The British Hypertension Society's Guidelines should be followed.

Assess blood pressure at least 3 monthly until targets are achieved, and monitor every 4-6 months once targets are achieved.

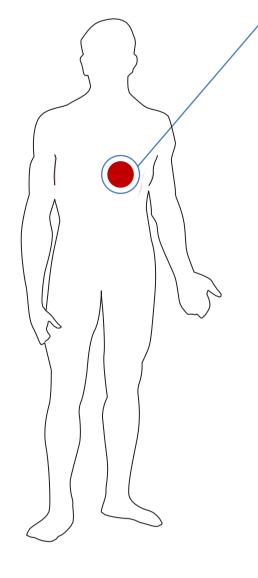
People who do not achieve target should be referred for further management. Remember that, if the patient does not achieve target despite greatest efforts by the multidisciplinary team, any improvement towards the target is better than the patient's baseline.

Smoking

Please assess people for smoking status and refer to Smoking Cessation Teams for patient support.

Lifestyle advice is integral to the management of Diabetes and should be reinforced at every available opportunity.

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Lifestyle advice is integral to the management of Diabetes and should be reinforced at every available opportunity.

LIPIDS

PRIMARY PREVENTION IN TYPE 1 DIABETES:

Consider statin treatment for the primary prevention of CVD in all adults with Type 1 Diabetes

Offer statin treatment for the primary prevention of CVD to adults with Type 1 Diabetes who:

- are older than 40 years or
- have had Diabetes for more than 10 years or
- have established nephropathy or
- have other CVD risk factors.

PRIMARY PREVENTION IN TYPE 2 DIABETES:

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. Estimate the level of risk using the **QRISK2** assessment tool.

PEOPLE WITH CKD

Increase the dose if a greater than 40% reduction in non-HDL cholesterol is not achieved and eGFR is 30 ml/min/1.73 m² or more. Agree the use of higher doses with a renal specialist if eGFR is less than 30 ml/min/1.73 m²

EXCEPTION - WOMEN OF CHILD-BEARING POTENTIAL/PREGNANT

TREATMENT TARGETS

Dietary interventions alone only reduce cholesterol by <10%. To reach targets, often drug therapy will be required. The initial target is to achieve a total cholesterol of <4.0 mmol/l and an LDL of <2.0 mmol/l. Statins are first line drugs for this indication. In accordance with NICE guidelines **Atorvastatin 20mg** is first choice. Increase from atorvastatin 20mg/day to **atorvastatin ≥40mg/day** unless total cholesterol level is below 4.0mmol/l or LDL cholesterol level is below 2.0mmol/l. Also consider intensifying to atorvastatin ≥40mg/day if there is existing or newly diagnosed CV disease, or increased albumin excretion rate.

If Atorvastatin is not tolerated consider using Rosuvastatin.

Monitor LFTs 6 weeks post initiation of statin. If normal check annually

In females who are planning a pregnancy or who are pregnant these drugs should be withheld until breast feeding has ceased

Ezetimibe should be prescribed as per <u>NICE's guidance</u>.(TA 385)

- If a greater than 40% reduction in non-HDL cholesterol is not achieved:
- discuss adherence and timing of dose
- optimise adherence to diet and lifestyle measures
- consider increasing the dose if started on less than atorvastatin 80 mg and the person is judged to be at higher risk because of comorbidities, risk score or using clinical judgement

It is important to note that the target triglyceride level is a fasting target, so an individual with a non-fasting result >2.3 mmol/l should be invited back to have a fasting triglyceride estimation. HDL and triglyceride interventions include lifestyle (predominantly weight loss and exercise) and drug therapies. The drug of choice is a fibrate, usually **Fenofibrate 160mg**. If using a combination lipid lowering regimen, monitoring of ALT and CK is appropriate.

Monitor lipids 6 weekly until targets have been achieved, and annually thereafter.

Remember that, if the patient does not achieve target despite greatest efforts by the multidisciplinary team, any improvement towards the target is better than the patient's baseline.

Fibrates should not be commenced if eGFR is <45. They should be discontinued with deterioration of renal function.

ANTI-PLATELET AGENTS

Aspirin 75 mg daily is indicated for all people with Diabetes who have any form of cardiovascular disease. In those who are also hypertensive the blood pressure should be controlled to 145/90 or below before commencement of aspirin. If aspirin is not tolerated or is contraindicated, clopidogrel 75 mg daily should be considered. **BACKGROUND POINTS**

escalation in therapy.

before is important.

INTERVENTIONS

and obesity surgery.

1kg

Lifestyle intervention

General points

GUIDANCE

Obesity is a major modifiable risk factor in the development of

improve Diabetes control enormously without the need for

Type 2 Diabetes, Decrease in weight in those who are obese can

Weight loss can help the patient achieve Type 2 diabetes remission

Those people with Diabetes whose adipose tissue mass is likely to

contribute to the progression of their Diabetes control should be offered the opportunity to discuss their weight. The benefits to the

patient of weight loss should be made clear. If the individual does not wish to consider making any changes then this should be

and health care professional. Consideration of what has been tried

reviewed at future consultations. Any choice of weight loss

Interventions include lifestyle advice, specific drug therapy

Realistic targets for weight loss should be discussed
Maximum weekly weight loss of 0.5-

Aim to lose 5-10% of original weight

Realistic targets for exercise will vary greatly depending on the individual. Ideally, individuals should be encouraged to take up to 45 minutes of exercise per day, 5 times per week. Encouragement to join a commercial weight loss organisation can be beneficial. Check for mental health factors using PHQ4 in primary and community care), DDS2 (in secondary care) and refer bariatric surgery or IAPT or other relevant part of the local pathway if +ve.

This is the mainstay of obesity management. Any advice offered is

professionals offer the advice in an enthusiastic manner. Ideally, a

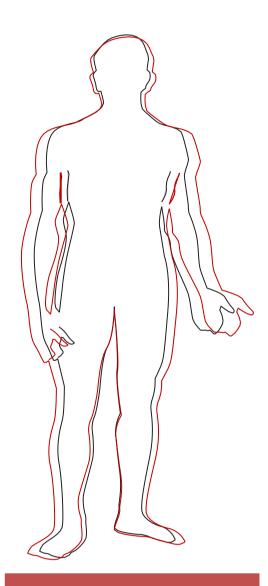
more likely to be accepted by the patient if we as health care

combination of reduction of calorie intake and an increase in

energy expenditure should be considered.

such as metformin in combination with either SGLT2 or GLP1

intervention should be negotiated between patient



Lifestyle advice is integral to the management of Diabetes and should be reinforced at every available opportunity

OBESITY

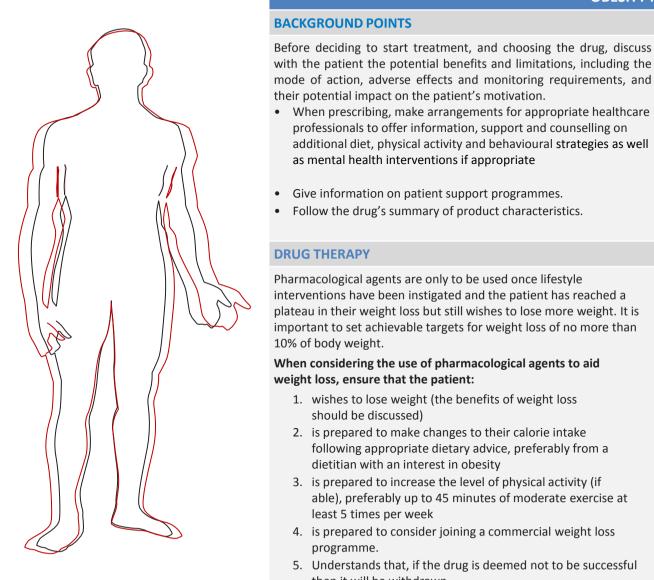
OBESITY SURGERY

Surgical intervention is considered appropriate option for adults with obesity if all of the following local criteria are fulfilled:

- they have Type 2 Diabetes and a BMI of 35 kg/m2 or more
- all appropriate non-surgical measures have been tried but have failed to achieve or maintain adequate, clinically beneficial weight loss for at least 6 months
- the person has been receiving or will receive intensive management in a specialist obesity service
- the person is generally fit for anaesthesia and surgery
- the person commits to the need for long-term follow-up.

Bariatric surgery is also recommended as a first-line option (instead of lifestyle interventions or drug treatment) for adults with a BMI of more than 50 kg/m2 in whom surgical intervention is considered appropriate.

Bariatric services provides intensive psychological interventions prior to surgical intervention-the aim is to consider and screen for binge eating disorder, depression and alcohol use disorder; to refer onward or provide self help information for these conditions as they will affect the people' ability to effectively implement any lifestyle, medication or surgical intervention offered.



Lifestyle advice is integral to the management of Diabetes and should be reinforced at every available opportunity.

OBESITY MEDICATION

professionals to offer information, support and counselling on

as mental health interventions if appropriate

Give information on patient support programmes. Follow the drug's summary of product characteristics.

1. wishes to lose weight (the benefits of weight loss

2. is prepared to make changes to their calorie intake

3. is prepared to increase the level of physical activity (if

4. is prepared to consider joining a commercial weight loss

All studies showing the greatest benefit with the weight loss drugs

involved lifestyle intervention as part of the management.

5. Understands that, if the drug is deemed not to be successful

dietitian with an interest in obesity

following appropriate dietary advice, preferably from a

able), preferably up to 45 minutes of moderate exercise at

should be discussed)

least 5 times per week

then it will be withdrawn.

programme.

additional diet, physical activity and behavioural strategies as well

SPECIFIC ADVICE ON ORLISTAT

NICE guidance available

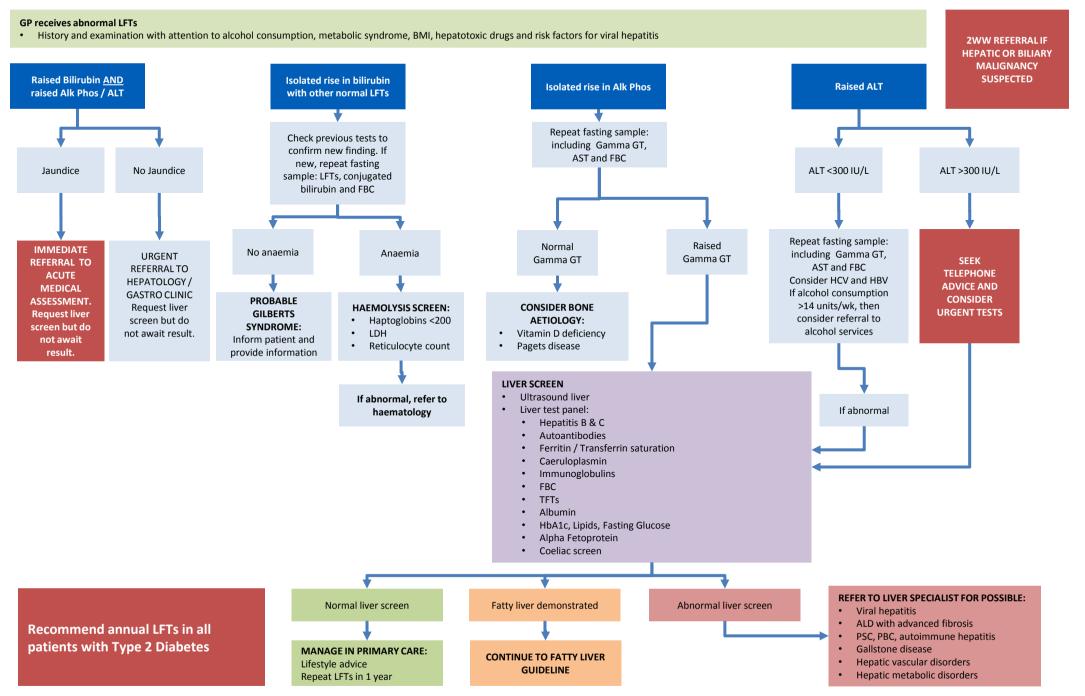
- Use only in those with Diabetes or endocrine conditions who have a BMI > 28kg/m2
- Continue beyond 3 months of therapy only if the patient has lost at least 5% of their body weight.
- Continue beyond 12 months for weight maintenance only after discussion of potential benefits and limitations with the patient.

CONTINUED PRESCRIBING AND WITHDRAWAI

- Review regularly, to monitor the effect of drug treatment. and to reinforce lifestyle advice and need for adherence.
- Drug treatment may be used to help people to maintain weight loss, as well as to continue to lose weight.
- Consider withdrawing drug treatment if the person does not lose enough weight.

Agree goals with the person and review regularly

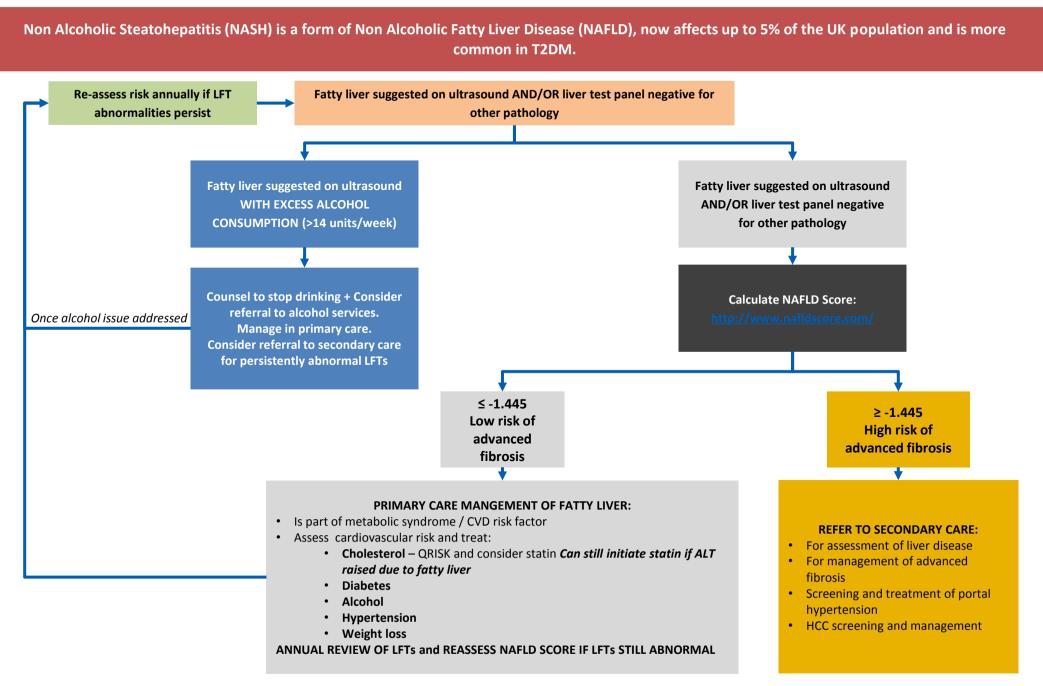
- If concerned about micronutrient intake, consider giving a supplement providing the reference nutrient intake for all vitamins and trace elements, particularly for vulnerable groups such as older people, who may be at risk of malnutrition.
- If withdrawing a person's drug treatment, offer support to help maintain weight loss because their self-confidence and belief in their ability to make changes may be low.



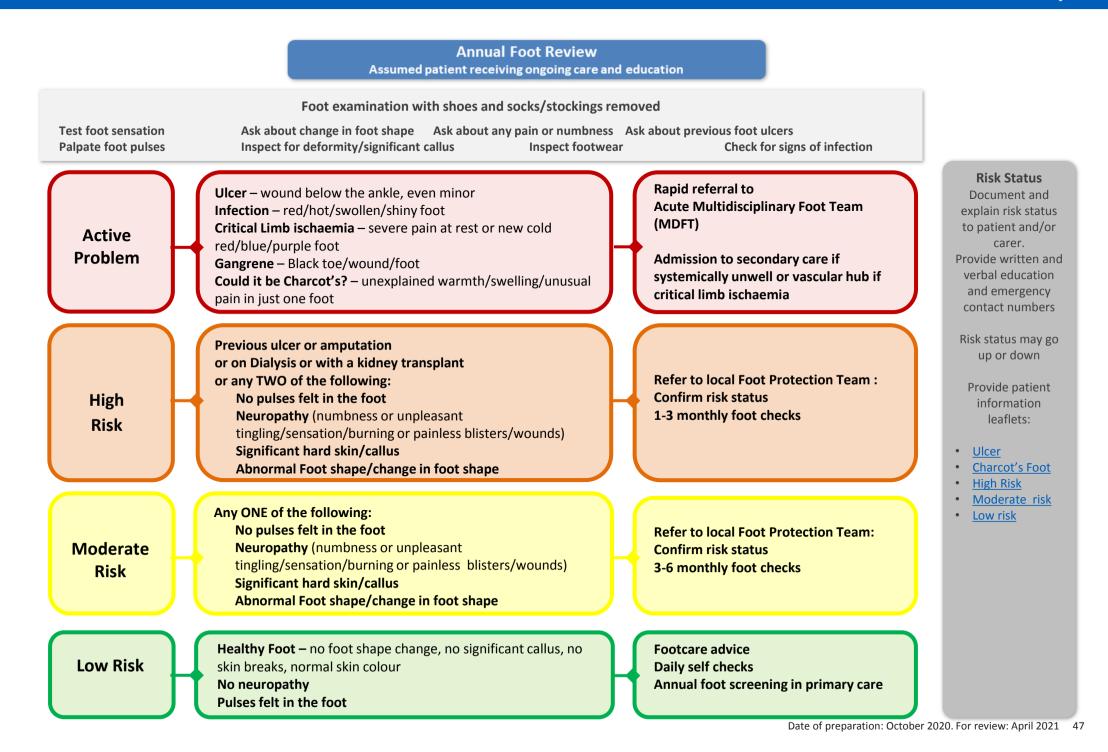
From NWL Gastroenterology Guidelines

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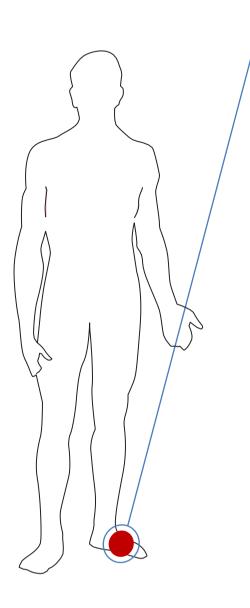
TYPE 2 DIABETES – NASH



DIABETES – FOOT SCREENING AND MANAGEMENT



DIABETES – FOOT EXAMINATION



	FINDING					
History	Previous ulcer or amputation (toe/foot leg)					
	Kidney Transplant or Dialysis					
	Impaired vision					
Inspection	Significant callus or corns					
	Abnormal foot shape: High arch/bunion/flat foot					
	Abnormal toes:: Claw toes/Hammer toes/overriding toes					
	Change in foot shape in one foot					
Neuropathy	Neuropathic pain (tingling/burning/electric shock)					
	Painless blister or wound					
	Score 8 or less on 10g monofilament testing					
Vascular Disease	Claudication (calf or buttock pain on walking, relieved by rest)					
	Any foot pulses not palpable					
Active	Change in foot shape in one foot with swelling and warmth					
Problem	Foot wound/ulcer					
	Ingrown toenail with signs of infection					
	Infection (redness/swelling/warmth/malodour/discharge)					
	Gangrene (black toe foot wound)					
	Foot/leg pain at rest, improved by hanging leg down					
	New cold foot with new blue/red/purple colour change					

All people with Diabetes should be on a register and minimum data should include annual measures for microvascular disease. Please see Cardiovascular Risk for additional requirements Mental health problems affect the ability to self-care. Check for: -Impaired memory - 6 item cog (see slide 31) Anxiety or depression – PHQ4 (see slide 31)



High arch, prominent metatarsal heads

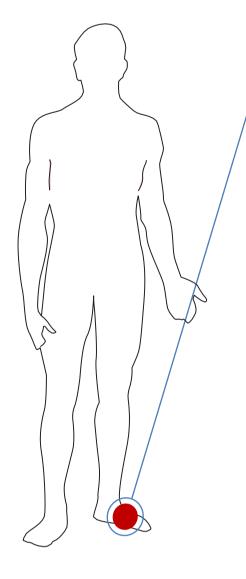






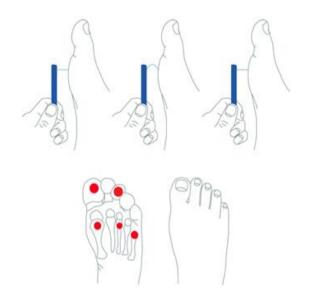
Claw toes

Photographs courtesy of Dermatonics 'A pictorial guide to diabetic foot examinations' 2016



USING A MONOFILAMENT

- Apply the filament to a sensitive area of skin (e.g. the forearm) so that the patient is aware of the sensation they are supposed to feel.
- Test 5 sites* on both feet:
 - ✓ Plantar surface of the hallux and 3rd toe
 - ✓ 1st, 3rd and 5th metatarsal heads
 - *If callus is present at any of the sites then test at the nearest non-calloused area.
- Ask the patient to close their eyes and say 'yes' every time that they feel you touch the skin on the foot
- Place the monofilament at 90° to the skin surface
- Slowly push the monofilament until it has bent ~ 1cm (don't jab)
- Hold the monofilament in this position for 1-2 seconds, then slowly release the pressure until the monofilament is straight
- Remove contact from the skin
- If the patient does not respond, repeat the test at the site twice. If there is still no response, record as a negative response
- Maximum score 10. A score of 8 or less indicates neuropathy
- Replace monofilament after 500 uses (approximately 6 monthly frequent testing, yearly infrequent testing)



	CCG	Acute Diabetes Specialist Foot Team	Foot Prote	ection Team	Vascular Hub
	H &F	St Mary's Hospital T:0203 312 5437			
Inner NW London	West LondonChelsea & Westminster Hospital T:0203 315 3161 F:0203 315 2732 E:Diabetes.TeamCW@chelwest.nhs.ukWest Middlesex Hospital E:Hounslow.RFS@nhs.net T:05511 434910		E: <u>clcht.spa.referral@nhs</u>	s.net	
			F:0300 008 3251		Inner NWL Vascular Hub: St Mary's Hospital Contact Vascular
			E:HRCH.Hounslowdiabetes@nhs.net T:05511 434910		Surgery on-call
		All Hounslow Diabetes foot referrals from GP for SystemOne Practices to be sent via TASK For EMIS practices referrals to be sent via Email to HRCH.Hounslowdiabetes@nhs.net			
Outer NW London	Brent	Central Middlesex Hospital T: 020 8453 2401/2607 F: 020 8453 2415	BIDS T:020 8963 8803 / 8804 F: 020 3963 8891 E:LNWH-tr.Diabetes-BCS@nhs.net		
	Ealing	Ealing Hospital T:020 8967 5383 F:020 8967 5507	High Risk (DICE) T:0208 383 9870 F:0208 843 1482	Moderate Risk T:0208 383 5738/ 5751 or 0208 579 5316 F:0208 383 5735 E: <u>Inwh-</u> tr.podealingcom@nhs.n et	Outer NWL Vascular Hub: Northwick Park Hospital Contact Vascular Surgery on-call M: 07976682471
	Harrow	Northwick Park Hospital: T:020 8869 2100 F: 0208 869 2961	CLCH Harrow F:0300 008 3104 E:Podiatryharrow@nhs.net		
	Hillingdon	Hillingdon Hospital T:01895 279229 E: <u>thh.diab-endo-referrals@nhs.net</u>	T:01895 485005 E: <u>cnw-tr.hchcontactcentr</u>	erefs@nhs.net	

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requirements.

	RETINOPATHY	
~ /	NSF KEY INTERVENTION	MANAGEMENT OF RETINOPATHY
	Regular surveillance for diabetic retinopathy in adults with Diabetes and early laser treatment of those identified as having sight threatening retinopathy can reduce the incidence of new visual impairment and blindness in people with Diabetes.	Optimisation of BP (<130/80), lipids and glycaemic control are oparamount importance.
	SCREENING	Those at highest risk of progression are those with rapid
	Ensure that all people (including those blind and partially sighted) with Type 2 Diabetes (from diagnosis) and those with Type 1 (from 12 months after diagnosis) > 12 yrs old are referred to and followed up with retinal screening using the CCG-commissioned community retinal screening programme.	improvement in blood glucose control, presence of raised blood pressure or renal disease. There is clear evidence that long-term lipid-lowering treatment can reduce retinopathy progression in Type 2 DM. Fenofibrate
	BACKGROUND POINTS	The FIELD study (fenofibrate alone) and a sub analysis of the
	 Diabetic retinopathy is the most common cause of blindness in people of working age. (1) Poor mental wellbeing may put people at greater risk through poor self-care -screen for depression, anxiety, diabetes distress, cognitive impairment About 26% of Type 2 diabetics have retinopathy at diagnosis.⁽²⁾ Progresses over the years: after 15 years, at least two thirds of people may have background retinopathy. 	ACCORD study (fenofibrate as add-on to statin) demonstrated a reduction in need for first laser treatment by 30-40% as well as slowing progression of diabetic retinopathy Atorvastatin A much smaller possible beneficial effect for atorvastatin was seen in the CARDS study
	ALGORITHM FOR THE PRIMARY CARE MANAGEMENT OF EYE SYMPTOMS	IN TYPE 2 DIABETES

	Sudden loss of vision	Sudden drop in visual acuity Diffuse reddening of the iris Irregular pupil Corneal haze Painful eye	Subacute drop in visual acuity (over days-weeks)	Gradual worsening of symptoms since last examination	Minimal or background retinopathy
	Possible cause				
	Retinal detachment	Pre-retinal and/or vitreous haemorrhage Rubeosis iridis	Macular oedema Preproliferative or severe retinopathy	Worsening of retinopathy	
\smile	Referral/management				
All people with Diabetes should be on a register and minimum data should include annual measures for microvascular disease. Please see	Emergency referral to Ophthalmologist / Eye Casualty Same day referral	Urgent referral to Ophthalmologist Referral within 1 week	Referral Arrange referral for specialist opinion within 4 weeks	Early review Arrange recall and review every 3-6 months	Yearly review
Cardiovascular Risk for additional	1 Audit Commission 2000 Tosti	ing Times: A Review of Diabetes Services in En	gland and Wales		

1. Audit Commission 2000. Testing Times: A Review of Diabetes Services in England and Wales.

2. Thomas RL, et al. Incidence of diabetic retinopathy in people with Type 2 Diabetes mellitus attending the Diabetic Retinopathy Screening Service for Wales: retrospective analysis. BMJ. 2012;344:e874.

CHRONIC KIDNEY DISEASE – DIABETES

microvascular disease. Please see Cardiovascular Risk for additional requirements.

		DIABETIC NEPHROPATHY					
	Diabetic Nephropathy is characterised by the excretion of abnormal amounts of albumin in the urine, arterial hypertension or progressive decline in kidney function						
$\{$	ALBUMINURIA	MANAGEMENT OF INDIVIDUAL WITH DIABETIC NEPHROPATHY					
	ALBUMINURIA Albuminuria is the earliest sign of kidney involvement in Type 2 Diabetes . This is best assessed by laboratory measurement of the urinary albumin creatinine ratio (ACR). Albuminuria is an independent risk factor for cardiovascular disease and progression to end-stage kidney disease. All patients with albuminuria should be on maximal ACEi or ARB therapy (with appropriate reminder of good sick day guidance) and have BP controlled to target (see below) People with type 2 diabetes and albuminuria should be preferentially treated with SGLT2 inhibitor according to the individual drug licences. (Please see SGLT2I safe prescribing guidance slide 37) SEEK RENAL ADVICE IF Unexplained sudden increases in albuminuria	MANAGEMENT OF INDIVIDUAL WITH DIABETIC NEPHROPATHY Patient education is an integral part of overall management Lifestyle changes, weight loss and smoking cessation should be advised Target HbA1c: Type 1 Diabetes - CKD stages 1 and 2 = 48 - 58 mmol/mol - CKD stages 3 and 4 = 58 - 62 mmol/mol - CKD stage 5 (incl on dialysis) = 58 - 68 mmol/mol Type 2 Diabetes - CKD stages 1 and 2 = 48 - 58 mmol/mol - CKD stages 3 and 4 on non-hypo inducing agents = 52 - 58 mmol/mol - CKD stages 3 and 4 on non-hypo inducing agents = 52 - 58 mmol/mol - CKD stages 3, 4 and 5 (incl on dialysis) on hypo inducing agents = 58 - 68 mmol/mol Prescribe maximal tolerated dose of ACE Inhibitors or Angiotensin 2 receptor blockers People with type 2 diabetes and albuminuria should be preferentially treated with SGLT2 inhibitor according to the individual drug licences. (Please see SGLT-2i safe prescribing guidance slide 37) Maintain blood pressure below 140/90 (130/80 if ACR > 70) - Calcium channel blocker drugs and low dose thiazide diuretics are useful second line agents - Loop diuretics are useful in the presence of volume overload (e.g. leg oedema not caused					
		by the side effects of calcium channel blockers)Additional antihypertensive therapy may be required.					
		Treat dyslipidaemia (serum cholesterol, LDL cholesterol and serum triglycerides to targets)					
All patients with Diabetes should be on a register and minimum data should include		Aspirin therapy if eGFR <60 and ACR>70					
annual measures for		Ensure patient understands sick day guidance for relevant drugs eg ACE/ARBs/					

Metformin/SGLT2Is

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weeks)

samples

Dipstick haematuria not diagnostically useful with

concurrent menstrual period, infection or in catheter

WHO SHOULD BE TESTED FOR CKD

Offer testing for CKD using eGFR, serum creatinine and urinary ACR to people with any of the following risk factors:

- diabetes
- hypertension
- acute kidnev injurv
- cardiovascular disease (ischaemic heart disease, chronic heart failure, peripheral vascular disease or cerebral vascular disease)
- structural renal tract disease, recurrent renal calculi or prostatic hypertrophy
- multisystem disease e.g.systemic lupus ervthematosus
- family history of end-stage kidney disease (GFR category G5) or hereditary kidney disease
- Haematuria

INTERPRETING eGFR VALUES

- Interpret eGFR values of > 60 ml/min/1.73 m2 with caution - estimates of GFR become less accurate as the true GFR increases
- eGFR is unreliable at extremes of body weight:
 - eGFR underestimates in people with high BMI
 - eGFR overestimated in people with low BMI
- Confirm an eGFR result of less than 60 ml/min/1.73 m² in a person not previously tested by repeating the test within 2 weeks. Allow for biological and analytical variability of serum creatinine (±5%) when interpreting changes in eGFR

CLASSIFICATION OF			
CLASSIFICATION OF	CKD USING E	GFR AND AC	K CATEGURIES

	R categories and risk of adv	erse	ACR categories (mg/mmol) description and range		Increasing
outcomes		<3 Normal to mildly increased	3-30 Moderately increased	>30 Severely increased	risk	
			A1	A2	A3	
GFR categories, description and range	≥ 90 Normal and high	G1	No CKD in the absence of markers of kidney			
	60-89 Mild reduction related to normal range for a young adult	G2	damage*			
	45-59 Mild-moderate reduction	G3a				
	30-44 Moderate-severe reduction	G3b				
	15-29 Severe reduction	G4				
	≤15 Kidney failure	G5				
					Inc	creasing risk
HAEMATU	IRIA		PROTEINU	RIA		
 Use dipstick reagent strips rather than urine microscopy Evaluate further if there is a result of 1+ or more (rpt in 2 Proteinuria is a useful marker of kidney damage and complication risk 						

- ACR is the recommended method for assessing proteinuria
- If initial ACR = 3-70 confirm with a subsequent early morning sample •
- If initial ACR > 70 mg/mmol, a repeat sample need not be tested •
- Confirmed ACR \geq 3 signifies clinically important proteinuria.

CHRONIC KIDNEY DISEASE – REFERRAL CRITERIA



URGENT

- Suspected multisystem disease with evidence of renal involvement
- Suspected acute kidney injury
- Newly diagnosed eGFR < 15
- Nephrotic syndrome
- Accelerated hypertension
- Severe hyperkalaemia

NON-URGENT

•Stage 3 CKD where diagnosis uncertain

•Asymptomatic CKD G4 or G5 with or without Diabetes

•ACR > 70 mg/mmol, unless known to be caused by Diabetes and already appropriately treated

•ACR > 30 mg/mmol together with haematuria

•Sustained decrease in GFR of \geq 25%, and a change in GFR category or sustained decrease in GFR of \geq 15ml/min within 12 months

•Hypertension that remains poorly controlled despite the use of at least 4 antihypertensive drugs at therapeutic doses

•Known or suspected rare or genetic causes of CKD

•Suspected renal artery stenosis (serum creatinine rises by >30% or eGFR falls by >25% after starting ACEI/ARB)

INVESTIGATING THE CAUSE OF CKD

Determining the risk of adverse outcomes

Agree a plan to establish the cause of CKD during an informed discussion with the person with CKD, particularly if the cause may be treatable (for example, urinary tract obstruction, nephrotoxic drugs or glomerular disease).

Use the person's GFR and ACR categories to indicate their risk of adverse outcomes (for example, CKD progression, acute kidney injury, all cause mortality and cardiovascular events) and discuss this with them.

INDICATIONS FOR RENAL ULTRASOUND

Offer a renal ultrasound scan to all people with CKD who:

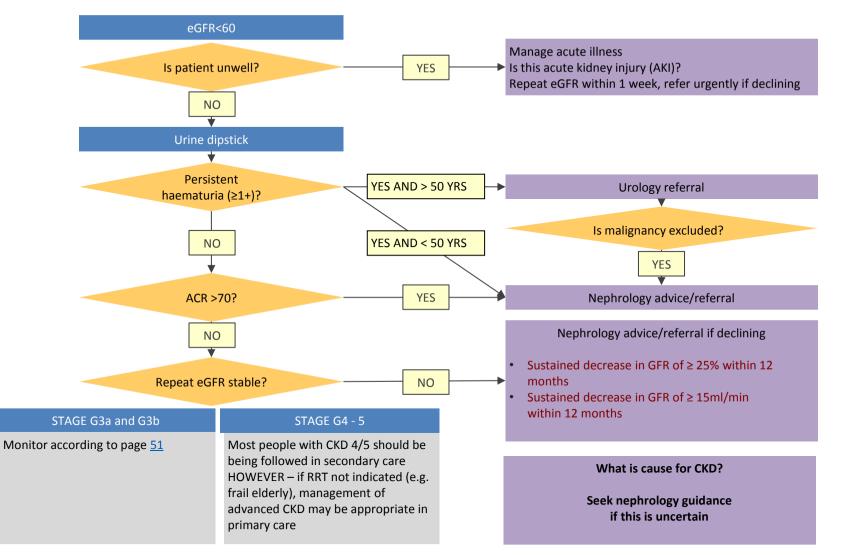
- have accelerated progression of CKD
- have visible or persistent invisible haematuria
- have symptoms of urinary tract obstruction
- have a family history of polycystic kidney disease and are aged over 20 years
- have a GFR of less than 30 ml/min/1.73 m2 (GFR category G4 or G5)
- are considered by a nephrologist to require a renal biopsy.

Advise people with a family history of inherited kidney disease about the implications of an abnormal result before a renal ultrasound scan is arranged for them.

MINIMAL INFORMATION REQUIRED FOR REFERRAL OR ADVICE

- Dates and results of all previous creatinine/eGFR measurement
- Medical history
- Drug history
- Current BP
- · Urine results: dipstick and a measure of urine proteinuria
- Renal Ultrasound result (unless exceptional reason delineated)
- HCO3 Bicarbonate < 20 mol/l, bicarbonate supplementation slows the rate of decline of renal function in stage 4 CKD, and is routinely used in the renal diabetic clinic
- Refer if:
- Sustained decrease in GFR of ≥ 25%, and a change in GFR category within 12 months
- Sustained decrease in GFR of ≥ 15ml/min within 12 months
- eGFR<20 Hb<10.5, K>6, Ca<2.1 Phosphate>1.5 (AD)

CHRONIC KIDNEY DISEASE – REFERRAL ALGORITHM



Email advice from nephrology consultants is available to North West London primary care services:

• <u>ICHC-tr.ckdadvice@nhs.net</u>

URGENT REFERRAL

Suspected multisystem disease with evidence of renal involvement

The North West London

- Acute kidney injury (without an obvious cause manageable in primary care)
- Newly diagnosed eGFR < 15
- Nephrotic syndrome
- Accelerated hypertension
- Severe hyperkalaemia (>6.5mmol/L)

Minimum information for referral

- Dates and results of previous creatinine/eGFR measurement
- Medical history
- Drug history
- Current BP
- Urine dipstick and ACR if dipstick positive

Renal Ultrasound if:

- accelerated progression of CKD
- visible or persistent invisible haematuria
- symptoms of urinary tract obstruction
- family history of polycystic kidney disease and are aged over 20 years
- eGFR of <30 ml/min/1.73 m2 (GFR category G4 or G5)

description and range

GFR categories,

MANAGEMENT OF STABLE CKD

Agree management plan with patient

Lifestyle advice Smoking cessation advice Avoid NSAIDs (even topical) Vaccinate for influenza and pneumococcus

BP:

Encourage home BP monitoring

Target BP: < 140/90 if ACR \leq 70

- < 130/80 if ACR > 70
- Caution of BP targets in frailty (See page 7)
- Prioritise ACEi/ARB with associated sick day guidance

Cardiovascular risk:

- Aspirin if CV risk at 10yrs >20%
- Proton-pump inhibitors (PPIs) esp. if higher risk of gastric irritation with aspirin. Observational data suggest PPIs may cause insidious inflammatory kidney injury – switch to ranitidine if eGFR falling
- Statins all patients with CKD3b and beyond should be on unless contra-indicated

Serum bicarbonate

 Consider sodium bicarbonate 500mg twice daily if acidotic (serum bicarbonate <22 mmol/L)

RENAL ANAEMIA

Renal anaemia can start to develop from CKD stage 3b (eGFR<45) and is common in advanced CKD5 (eGFR<15). This may require treatment with intravenous iron and erythropoietin.

Particularly in CKD stages 3b/4, renal anaemia should only be diagnosed after exclusion of other causes including iron deficiency, folate/B12 deficiency, haemolysis.

	·····
FREQUENCY OF MONITORING eGFR	INITIMBED OF TIMES DED VEAD
FREQUENCE OF MONITORING EGFR	INDIVIDER OF THVIES FER TEAR

GFR and ACR categories and risk of adverse outcomes ACR categories (mg/mmol) description and range

utcomes		<3 Normal to mildly increased	3-30 Moderately increased	>30 Severely increased				
			A1	A2	A3			
	≥ 90 Normal and high	G1	≤1	1	≥1			
	60-89 Mild reduction related to normal range for a young adult	G2	≤1	1	≥1			
	45-59 Mild-moderate reduction	G3a	1	1	2			
	30-44 Moderate-severe reduction	G3b	≤2	2	≥2			
6 of 1 co)	15-29 Severe reduction	G4	2	2	3	g risk		
	≤15 Kidney failure	G5	4	≥4	≥4	Increasing risk		
	Increasing risk							

RENIN-ANGIOTENSIN SYSTEM INHIBITORS IN CKD (ACEI and ARB)

- ACEi and ARB prevent scarring in CKD and should be used preferentially in patients with proteinuria
- Assess kidney function and electrolytes. 1-2 weeks after initiating therapy and with any subsequent dose increase, watch out for hyperkalemia
- A small rise in creatinine or a mild fall in eGFR values is expected with therapy repeat the assessment of kidney function if the rise in creatinine is greater than 15%
- STOP therapy If serum creatinine rises by >30% or eGFR falls by >25%: seek specialist advice (to exclude possible renovascular disease)
- If K>6.0 stop ACEi/ARB and start low potassium diet if the patient has proteinuria or heart failure with reduced ejection fraction and would benefit from an ACEi/ARB seek Nephrological advice as introduction of potassium binders, frusemide or bicarbonate can facilitate reintroduction of these agents
- Concomitant use of ACEi/ARB with spironolactone and other potassium sparing diuretics requires close monitoring of potassium

Kidney Ageing	MANAGEMENT OF FRAIL PEOPLE WITH CKD
 Kidney function (GFR) declines with age: ~0.8 mL/min/year after 35 years old up to 2mL/min/year after 70 years old eGFR >30mL/min in the absence of acute illness, proteinuria or uncontrolled HTN is unlikely to progress to end-stage kidney disease Focus of Care in Frail people	 Identify frailty and screen for cognitive impairment Calculate EFI score (https://doi.org/10.1093/ageing/afw039) Screen cognition using GPCOG (http://gpcog.com.au/) Medications Frail people are more susceptible to harm from medications Refer to "Drugs and CKD" page <u>53</u> Blood pressure (BP) or HbA1c targets - individualise to patient: Be wary of falls risk – check postural BPs Higher BP targets are appropriate e.g systolic BP 130-159 mmHg / diastolic BP 70-89 mm
 Should be patient and outcome centred View CKD in the context of an individual's comorbidities and personal priorities Renal replacement therapy (RRT) may not improve quality of life – focus on symptom control may be more appropriate Advance care planning should be a priority 	 Be wary of hypoglycaemia risk with insulin and oral hypoglycaemic agents Higher HbA1c targets are appropriate e.g 58-68 mmol/mol Diet – avoid protein restriction / aggressive salt restriction Monitoring of renal function If renal replacement therapy (RRT) is considered - refer to page 54 If RRT is unlikely to improve quality of life, tailor frequency to clinical need In event of sudden eGFR decline exclude common causes: UTIS Dehydration Obstructive uropathy Medications (e.g Diuretics, anti-hypertensives, NSAIDs) Consider nephrology advice if: Unexplained and sustained decline in renal function / new nephrotic range proteinuria Refractory and symptomatic anaemia (<100g/L) in advanced CKD (stages 3b – 5) may red intravenous iron +/- erythropoietin supplementation
Further advice	

- ICHC-tr.ckdadvice@nhs.net (nephrology consultant advice)
- ICHC-tr.adviceelderlymedicine-imperial@nhs.net (consultant geriatrician advice)



For the safe administration and use of insulin and GLP-1 receptor agonists you should be able to:

1. UNREGISTERED PRACTITIONER

Describe the effect of insulin on blood glucose levels. Be aware of local sharps disposal policy. Show an understanding of the ongoing nature of the therapy. Administer insulin competently where supported by local policy. Report identified problems appropriately.

2. COMPETENT NURSE AS 1, AND:

Actively seek and participate in peer review of one's own practice.

Demonstrate a basic knowledge of insulin and GLP-1 receptor agonists (e.g. drug type, action, side-effects) and administration devices used locally.

Demonstrate a high level of competency in the safe administration of insulin or GLP-1 receptor agonists.

Demonstrate and be able to teach the correct method of insulin or GLP-1 receptor agonist self-administration, including:

- Correct choice of needle type and length for the individual.
- Appropriate use of lifted skin fold, where necessary.
- Site rotation.
- Storage of insulin.
- Single use of needles.

Examine injection sites at least annually for detection of lipohypertrophy.

Identify correct reporting system for injectable therapy errors.

Complete the "Safe use of insulin" e-learning module . <u>https://www.e-lfh.org.uk/programmes/safe-use-of-insulin</u> Describe circumstances in which insulin use might be initiated or altered and make appropriate referral. Report concerns related to blood glucose or HbA1c results in a timely and appropriate fashion.

3. EXPERIENCED OR PROFICIENT NURSE

As 2, and:

Demonstrate a broad knowledge of different insulin types (i.e. action, use in regimens).

Demonstrate a broad knowledge of GLP-1 receptor agonists (e.g. drug type, action, side-effects).

Assess individual people' self-management and educational needs and meet these needs or make appropriate referral.

Support and encourage self-management wherever appropriate.

Initiate insulin or GLP-1 receptor agonist therapy where clinically appropriate.

Recognise when injection therapy needs to be adjusted.

Recognise the potential psychological impact of insulin or GLP-1 receptor agonist therapies and offer

support to the person with diabetes or their carer.

Recognise signs of needle fear/needle phobia and offer strategies to help manage this.

TYPE 2 DIABETES – GLP-1 RECEPTOR AGONISTS

WHAT ARE GLP-1s AND HOW DO THEY WORK?

- GLP-1s are injected to increase insulin secretion, suppress glucagon secretion, and slow gastric emptying.
- The incretin effect is described by the fact that an oral load of glucose induces a greater insulin response than when glucose is administered by IV. This is due to the effect on gut hormones, particularly glucagon-like peptide-1 (GLP-1s).
- Their effect includes stimulating glucose dependent insulin secretions, increasing satiety and slowing gastric emptying. These actions can lead to reduction in HbA1c with a low risk of hypoglycaemia (unless used with sulfonylureas). This action is often accompanied by weight loss.
- GLP-1 injections can be used to improve glucose control in adults with Type 2 Diabetes by reducing fasting and post prandial glucose levels. They can be used with metformin, a sulfonylurea or in combination with other antidiabetic drugs.
- Administered by subcutaneous injection.

INDICATIONS FOR CONTINUED USE

NICE recommends that treatment with GLP-1s is continued only if HbA1c has reduced by 1% AND a weight loss of 3% is achieved within 6 months of commencing treatment.

WHO SHOULD USE GLP-1s?

Treatment with GLP-1s is associated with the prevention of weight gain and possible promotion of weight loss

- GLP-1s should be considered as part of second intensification in people with a BMI of 35 kg/m² or higher (adjusted to 30 kg/m² 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 obesityrelated comorbidities
- See <u>NW London's algorithm</u> for recommendations as to where GLP-1s fit with other glycaemic treatments.

CONTRAINDICATIONS & CAUTIONS

- GLP-1s are not substitutes for insulin in insulindependent people and are not licensed for use in Type 1 Diabetes.
- Persistent and severe abdominal pain with or without vomiting may be a sign of acute pancreatitis. If this is suspected, the GLP-1 should be stopped, and if confirmed, not be resumed.
- See individual monographs for dose adjustments in renal impairments and/or hepatic impairment, and missed dose information.
- Not recommended for use in people with severe gastrointestinal disease
- People receiving a GLP-1 in combination with a sulfonylurea or insulin may have an increased risk of hypoglycaemia. The risk of hypoglycaemia can be lowered by a reduction in the dose of sulfonylurea or insulin.
- Not recommended during pregnancy or where pregnancy is planned, or for nursing mothers.
- GLP-1 agonists require some oral medications to be taken at least 1 hours before, or 4 hours after. See individual monographs.

ADVICE TO PRESCRIBERS

Dosing interval	Supply length of a single pen at maintenance dose
Once weekly	28 days
Once weekly	7 days
Once daily	15 days (1.2mg OD) 10 days (1.8mg OD)
Twice daily	30 days
Once weekly	7 days
Once daily	15 days
	interval Once weekly Once daily Twice daily Once weekly Once

ADVICE TO PEOPLE

- Provide them with patient information leaflet. **people** will need to understand the following:
- Discuss the risk of hypoglycaemia and symptoms, treatment and prevention.
- Drivers holding a Group 1 (cars and motorcycles) license may drive and need not notify the DVLA, provided the requirements set out are met and is under regular medical review (See DVLA guidance for requirements) when being treated with a GLP-1. Normal precautions to avoid low blood glucose when driving apply. Drivers holding Group 2 (Bus and lorry) licences need to inform the DVLA if they are being treated with a GLP-1.
- Discuss common side effects such as nausea, vomiting diarrhoea, dizziness, headache and dyspepsia.
- GLP-1s may reduce appetite.
- Injection techniques- Subcutaneous injection upper arm, thigh, abdomen.
- Pen needles use/supply a variety of pen needles are available, HCP should discuss which needle is best for them. A new one should be used for each injection.
- If they experience severe and persistent symptoms they must contact their health care provider as a matter of urgency.
- Please note, some GLP1 agonists are supplied with a pen needle.

STORAGE OF GLP-1 PEN DEVICES

- Unopened GLP-1 pre-filled pens should be stored in the refrigerator 2-8°C (36-46°F). Do not freeze.
- The GLP-1 pen in use can be kept at room temperature but away from direct light.
- See individual monograph for shelf-life/expiry. Once in use refer to individual drug information overleaf.

TYPE 2 DIABETES – GLP-1 MEDICINES INFORMATION (1)

NB: All information presented is in line with the Summaries of Product Characteristics (SPC) of each drug or the BNF.

LIXISENATIDE (LYXUMIA)

Indicated in combination with oral glucose-lowering medicinal products and/or basal insulin when these together do not provide adequate glycaemic control.

Dose	Dose Adjustments	Time to be taken	Storage and Shelf-life
Initially 10 micrograms once daily	Use with caution for people with an eGFR 30–50 mL/min/1.73 m ²	Within 1 hour before the first meal of the day or the evening meal	Unopened - Store in a refrigerator (2°C - 8°C). Do not freeze.
for 14 days, then increased to	Not recommended for people with eGFR <30 mL/min/1.73 m ²		After first use - Store below 30°C.
20 micrograms once daily	Dose of concomitant sulfonylurea or insulin may need to be reduced.		Shelf-life: 14 days

Missed dose: Should be injected within the hour prior to the next meal. Do not administer after a meal.

- Some orally administered drugs should be taken at least 1 hour before, or 4 hours after, lixisenatide injection.
- people receiving Lyxumia with a sulfonylurea or with a basal insulin may have an increased risk of hypoglycaemia. Reduction of the dose of the sulfonylurea or the basal insulin may be considered to reduce the risk of hypoglycaemia. Lixisenatide should not be given in combination with basal insulin **and** a sulfonylurea due to increased risk of hypoglycaemia.
- Its use does not require specific blood glucose monitoring. However, when used in combination with a sulfonylurea or a basal insulin, blood glucose monitoring or blood glucose self- monitoring may
 become necessary to adjust the doses of the sulfonylurea or the basal insulin.

LIRAGLUTIDE (VICTOZA)

Indicated for monotherapy when metformin is considered inappropriate due to intolerance or contraindications OR in addition to other medicinal products for the treatment of diabetes.

Dose	Dose Adjustment	Storage and Shelf-life
Initially 0.6 mg once daily for at least 1 week, then increased to 1.2 mg once daily. Max daily dose: 1.8mg	eGFR <15mL/min/1.73 m ² : No therapeutic experience in people with end-stage renal disease, and Victoza is therefore not recommended for use in these people . Not recommended for use in people with severe hepatic impairment.	Unopened - Store in a refrigerator (2°C - 8°C). Do not freeze. After first use - Store below 30°C. Shelf-life: 1 month

- **Missed dose:** if a dose is more than 12 hours late, the missed dose should not be taken and the next dose should be taken at the normal time.
- Pen adjusted to give either 0.6mg, 1.2mg or 1.8mg. Comes in a pre-filled pen 6mg per ml.
- Victoza can be added to existing sulfonylurea or to a combination of metformin and sulfonylurea therapy or insulin.
- Self-monitoring of blood glucose is not needed in order to adjust the dose of liraglutide. However, when initiating treatment with liraglutide in combination with a sulfonylurea or insulin, blood glucose self-monitoring may become necessary to adjust the dose of the sulfonylurea/insulin.

SEMAGLUTIDE (OZEMPIC)

Indicated for monotherapy when metformin is considered inappropriate due to intolerance or contraindications OR in addition to other medicinal products for the treatment of diabetes.

Dose	Dose Adjustment	Storage and Shelf-life	
Initially 0.25 mg once weekly for 4 weeks, then increased to 0.5 mg once weekly for at least 4 weeks, then increased if necessary to 1 mg once weekly	No dose adjustment is required for renal impairment. Experience in people with severe renal impairment is limited. Not recommended for use in people with end-stage renal disease Dose of concomitant sulfonylurea or insulin may need to be reduced.	Unopened - Store in a refrigerator (2°C - 8°C). Do not freeze. After first use - Store below 30°C. Shelf-life: 6 weeks	

- Missed dose: it should be administered as soon as possible and within 5 days after. If more than 5 days have passed, the missed dose should be skipped, and the next dose should be administered on the regularly scheduled day. In each case, patients can then resume their regular once weekly dosing schedule.
- Comes in 1.34 mg per ml in 1.5 and 3ml pre-filled pens.
- When adding to existing therapy of sulfonylurea or insulin, a reduction in the dose of sulfonylurea or insulin should be considered to reduce the risk of hypoglycaemia.
- Self-monitoring of blood glucose is not needed when adjusting the dose. When initiating treatment in combination with a sulfonylurea or an insulin, blood glucose self-monitoring may become necessary
 to reduce the risk of hypoglycaemia.
- Caution should be exercised when using semaglutide in patients with diabetic retinopathy treated with insulin.

TYPE 2 DIABETES – GLP-1 MEDICINES INFORMATION (2)

NB: All information presented is in line with the Summaries of Product Characteristics (SPC) of each drug or the BNF.

	EXENATIDE (NOTE: IMMEDIATE-RELEASE AND MODIFIED-RELEASE AVAILABLE)				
Preparation	Licensed to be used in combination with:	Dose	Dose Adjustment	Time to be taken	Storage and Shelf-life
Standard- Release (BYETTA)	 Metformin Sulfonylurea (+/-Metformin) Pioglitazone(+/-Metformin) Basal Insulin (+/-Metformin/Pioglitazone) 	Initially 5 micrograms twice daily for at least 1 month, then increased if necessary up to 10 micrograms twice daily	eGFR 30-50 mL/min/1.73 m ² : Use with caution eGFR <30 mL/min/1.73 m ² : Avoid	Within 60-minute period before the morning and evening meal (6 hours or more apart). Should not be administered after a meal.	Unopened - Store in a refrigerator (2°C - 8°C). After first use - Store below 25 °C. Do not freeze. Shelf-life: 30 days
Modified- Release (BYDUREON/ BYDUREON BCISE)	 Other glucose-lowering medicinal products including basal insulin, when the therapy in use, together with diet and exercise, does not provide adequate glycaemic control. 	2 mg once a week on the same day each week.	Avoid if eGFR less than 50 mL/minute/1.73 m ²	N/A	Unopened - Store in a refrigerator (2°C - 8°C). Do not freeze. Pens may be kept for up to 4 weeks below 30°C prior to use. After first use - suspension must be injected immediately after mixing Store in the original package in order to protect from light.

Dose of concomitant sulfonylurea may need to be reduced to reduce the risk of hypoglycaemia.

Blood glucose self-monitoring may be necessary to adjust the dose of sulfonylurea.

Standard-Release (BYETTA)

- With standard-release exenatide: some orally administered drugs should be taken at least 1 hour before, or 4 hours after, exenatide injection.
- **Missed dose:** If an injection is missed, the treatment should be continued with the next scheduled dose.

Modified-Release (BYDUREON)

- Comes as a 2 mg powder and solvent for modified-release suspension for injection in pre-filled pen.
- People switching from standard-release (Byetta) to modified-release exenatide may experience transient elevations in blood glucose concentrations, which generally improve within the first two weeks after initiation of therapy.
- Missed dose: it should be administered as soon as practical. For the next injection people can return to their chosen injection day. However, only one injection should be taken in a 24-hour period.
- •Women of child-bearing age should use effective contraception during treatment with modified-release exenatide and for 12 weeks after discontinuation.

DULAGLUTIDE (TRULICITY)

Indicated as :

•Monotherapy in people for whom the use of metformin is not tolerated or contraindicated.

•Add-on therapy In combination with other glucose-lowering medicinal products including insulin, when these together do not provide adequate glycaemic control

Dose	Dose adjustments	Storage and Shelf-life
Monotherapy - 0.75 mg once weekly Add-on therapy - 1.5 mg once weekly.	eGFR < 15 mL/min/1.73 m ² : Not recommended	Unopened - Store in a refrigerator (2°C - 8°C). Do not freeze. After first use - Store below 30°C. Do not freeze. Shelf-life: 14 days

•Long-acting GLP-1

- Dose of concomitant insulin or drugs that stimulate insulin secretion may need to be reduced.
- Missed Dose: If a dose is missed, it should be administered as soon as possible if there are at least 3 days (72 hours) until the next scheduled dose. If less than 3 days (72 hours) remain before the next scheduled dose, the missed dose should be skipped and the next dose should be administered on the regularly scheduled day. In each case, people can then resume their regular once weekly dosing schedule

DIABETES – INDICATIONS FOR INSULIN

Introduce the likely need for insulin in the future early on as part of patient education

Emphasise that it is the pancreas that fails not the patient

Assess if greater compliance with oral agents and lifestyle changes could negate the need for insulin

ALWAYS	USUALLY	CONSIDER	
Type 1 Diabetes	Type 2 Diabetes failure to reach glycaemic targets using diet and non insulin therapies	Symptomatic e.g. rapid weight loss, polyuria, nocturia	
Not sure of whether the diagnosis is Type 1 Diabetes or Type 2	Type 2 Diabetes Pre and post surgery or following a MI	Women with Type 2 DM on oral agents hoping to conceive	
Pregnant women with Type 2 DM	Chronic pancreatitis	Acute neuropathies i.e. femoral amytrophy	
Gestational Diabetes Not controlled on diet or metformin	Type 2 Diabetes requiring enteral feeding	Ketosis prone Type 2 Diabetes	
Post surgical pancreatectomy		Steroid induced Diabetes	

DIABETES – INSULIN INITIATION

WHICH INSULIN SHOULD BE USED INITIALLY FOR T2DM DIABETES (T2DM)	PEOPLE WITH TYPE 1 DIABETES (T1DM)
Animal insulin is no longer used for insulin starts	In Type 1 Diabetes Insulin needs to be started within 24 hours of diagnosis
Begin with human NPH insulin injected at bed-time or twice daily according to need such as Insuman Basal, Humulin I or Insulatard . Can be given at breakfast when required e.g.: people on steriods.	If the patient is severely ketotic and or vomiting, pregnant, or a child, admission is required/ urgent referral / telephone contact to the specialist team or acute on call medical team is required
 Consider, as an alternative, using a long-acting insulin analogue such as Insulin Detemir, Insulin Glargine if: The person needs assistance from a carer or healthcare professional to inject insulin, and use of a long-acting insulin analogue (Insulin Detemir, Insulin Glargine) would reduce the frequency of injections from twice to once daily, or The person's lifestyle is restricted by recurrent symptomatic hypoglycaemic episodes, or The person would otherwise need twice-daily NPH insulin injections in combination with oral glucose-lowering drugs, or The person cannot use the device to inject NPH insulin 	T: or hospital switchboard and ask to speak to a diabetologist or paediatrician or acute on cal
 Consider twice daily pre - mixed (biphasic) human insulin (particularly if HbA1c ≥ 75 mmol/mol or 9%) Consider pre-mixed preparations that include short-acting insulin analogues, rather than pre-mixed preparations that include short acting human insulin preparations, if: A person prefers injecting insulin immediately before a meal, or Hypoglycaemia is a problem, or Blood glucose levels rise markedly after meals Consider initiation of pre - mixed insulin if the A1c is high particularly above 75 mmol/mol or 9% This would however depend on the individual people preference and convenience. 	
Other factors to consider:	
Lifestyle Meal times Employment Potential risk of hypoglycaemia High alcohol intake Malnutrition Low BMI Physical barriers Dexterity Vision Emotional barriers Needle phobia 	

THERE ARE MANY TYPES OF INSULIN TO CHOOSE FROM: ALL OF TODAY'S INSULINS ARE MANUFACTURED USING RECOMBINANT DNA TECHNOLOGY

HUMAN INSULINS	ANALOGUE INSULINS
 e.g. Insuman Rapid, Humulin S, Insulatard Human insulins are produced by recombinant DNA technology and have the same amino acid sequence as endogenous human insulin Time of action can be modified by the addition of protamine 	 e.g. Novorapid, Glargine Insulin analogues are produced in the same way as human insulins, but the insulin is modified to produce a desired kinetic characteristic, such as an extended duration of action or faster absorption and onset of action. They are more expensive When bioequivalent insulins may become available, these may be more cost-effective

Human Insulins should be the initial choice of insulin for most people with Type 2 Diabetes as they are safe and considerably cheaper than the analogue insulins Exceptions are:

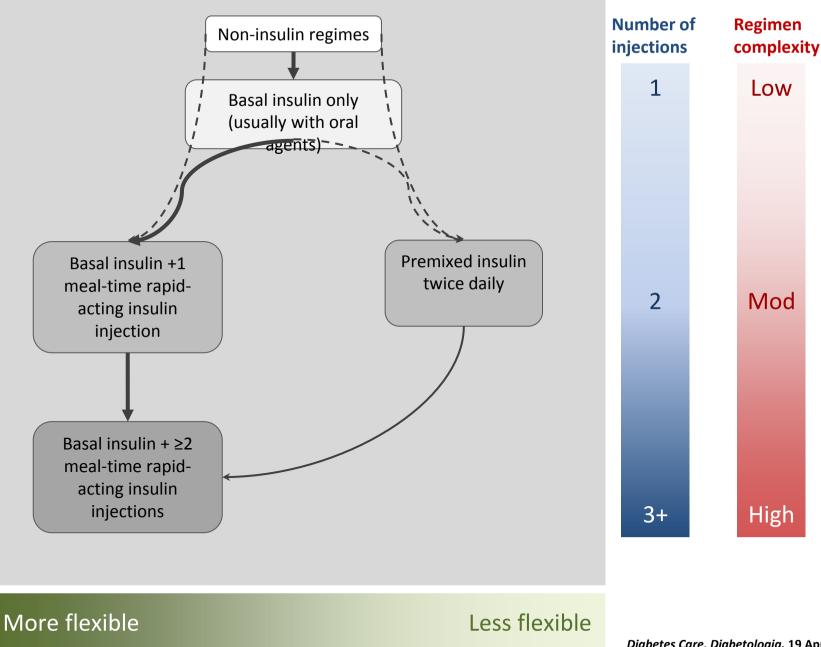
- Those at high risk of hypoglycaemia
- Low BMI, malnourished, frail and elderly, erratic eating patterns

	RAPID ACTING	SHORT ACTING	INTERMEDIATE ACTING	LONG ACTING	MIXTURES RAPID + INTERMEDIATE ACTING	MIXTURES SHORT + INTERMEDIATE ACTING
Туре	Analogue	Human	Human	Analogue	Analogue	Human
Onset of action	within 15 minutes	30 - 60 mins	1 - 2 hours	2 - 3 hours	Up to 15 mins	Up to 30 mins
Duration*	2-5 hours	up to 9 hours	11 - 24 hours	Up to 36 hours	Up to 24 hours	Up to 24 hours
Examples	Novorapid Humalog Apidra	Humulin S Insuman Rapid	Insulatard Humulin I Insuman Basal	Levemir (Determir) Abasaglar/Lantus/ Semglee (Glargine)	NovoMix 30 Humalog Mix 25 Humalog Mix 50	Humulin M3 Insuman Comb 15, 25, 50
Peak effect	0.5 - 1.5 hours	1 - 4 hours	3 - 12 hours	varies based on the dose	1 - 4 hours	2 - 8 hours

TYPE 2 DIABETES – HYPOGLYCAEMIC AGENTS WITH INSULIN

ORAL AND NON – INSULIN THERAPY	USE WITH INSULIN
Metformin	Normal and overweight people with Type 2 Diabetes can be continued on Metformin as there is evidence that this combination is insulin sparing and has other benefits including weight management glycaemic control and cardiovascular disease (CVD)
sulfonylureas (SU) Glimepiride Gliclazide	Continue with regular dose reviews if the individual is on a daily isophane or analogue insulin. Avoid concurrent use in people with severe renal impairment (<45mL/min/1.73m ²).
DPP-4 Inhibitors (DPP-4Is): Alogliptin, Linagliptin, Saxagliptin, Sitagliptin, Vildagliptin	May be used in combination with insulin. Risk of hypoglycaemia when used together, consider reducing dose of insulin.
Sodium glucose co-transporter 2 Inhibitors (SGLT-2) Canagliflozin, Dapagliflozin, Empagliflozin Ertugliflozin	May be used in combination with insulin or other antidiabetic drugs (if existing treatment fails to achieve adequate glycaemic control). Risk of hypoglycaemia when used together, consider reducing dose of insulin.
Pioglitazone	May be used in combination with insulin. <u>If pioglitazone is used in combination with insulin</u> people should be observed for signs and symptoms of heart failure, weight gain, and oedema. Risk of hypoglycaemia when used together, consider reducing dose of insulin.
Glucagon-like peptide-1 receptor agonists (GLP-1 Agonists) Exenatide modified-release (once weekly) Exenatide standard-release (twice daily) Liraglutide (once daily) Lixisenatide (once daily) Dulaglutide (once weekly) Semaglutide (once weekly injection or once daily tablet)	May be used in combination with insulin. In adults with type 2 diabetes, only offer a GLP-1 mimetic in combination with insulin with specialist care advice and ongoing support from a consultant-led multidisciplinary team.
Acarbose	Not recommended in combination with insulin. Risk of hypoglycaemia when used together, consider reducing dose of insulin. Risk of hypoglycaemia when used together, consider reducing dose of insulin.
Meglitinides: Repaglinide	Not recommended in combination with insulin.
Please see pages	34-37 and 60-61 for individual drug monographs

TYPE 2 DIABETES – SEQUENTIAL INSULIN STRATEGIES



Diabetes Care, Diabetologia. 19 April 2012 [Epub ahead of print]

TYPE 2 DIABETES – BENEFITS OF INITIATING BASAL INSULIN

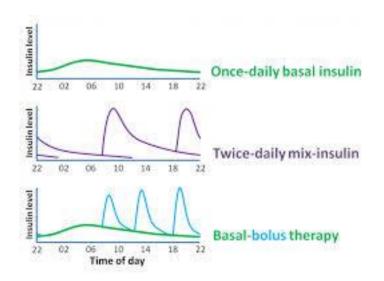
PROS

Just one injection a day

Easy for the patient to adjust the dose

Can stay on current oral agents to start with

Buys time and confidence until a twice or three or 4 times a day insulin regime is required



PROS

Provides both background and prandial cover with two injections a day

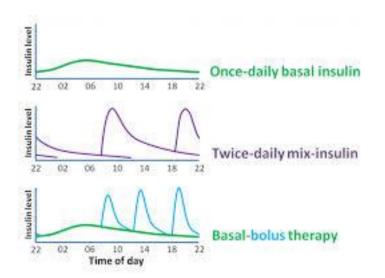
Unlike the analogue insulin mixtures provides sufficient background insulin to cover a light lunch

CONS

More difficult to titrate evening mixed insulin against pre-breakfast glucose due to risk of nocturnal hypoglycaemia

Requires people to have a regular meal pattern including breakfast and a main meal in the evening, rather than lunch time

Increased risk of hypoglycaemia if eat dinner very late at night or tendency to skip breakfast or lunch



Tell the patient they are likely to need between 20-50 units of insulin and it is safe for them to increase the insulin.

Start with 10 units before bed of insulin if <100kg (or 20 units of insulin if >100kg)

For elderly frail patients where there is no requirement for tight control, morning NPH (human basal) insulin is safe as the peak will cover breakfast and a bit of lunch, and can be given by a morning carer who can ensure the patient has eaten. In the elderly it is quite likely that NPH will have a much longer duration of action as when the eGFR falls the half life of the insulin increases.

Increase by 2 units every 3rd day until before breakfast blood glucose is 8-10 mmol/l

Reduce the Sulphonylurea dose. Continue to increase by 2 units every 3rd day aiming for before breakfast blood glucoses of 6-8 mmol/l

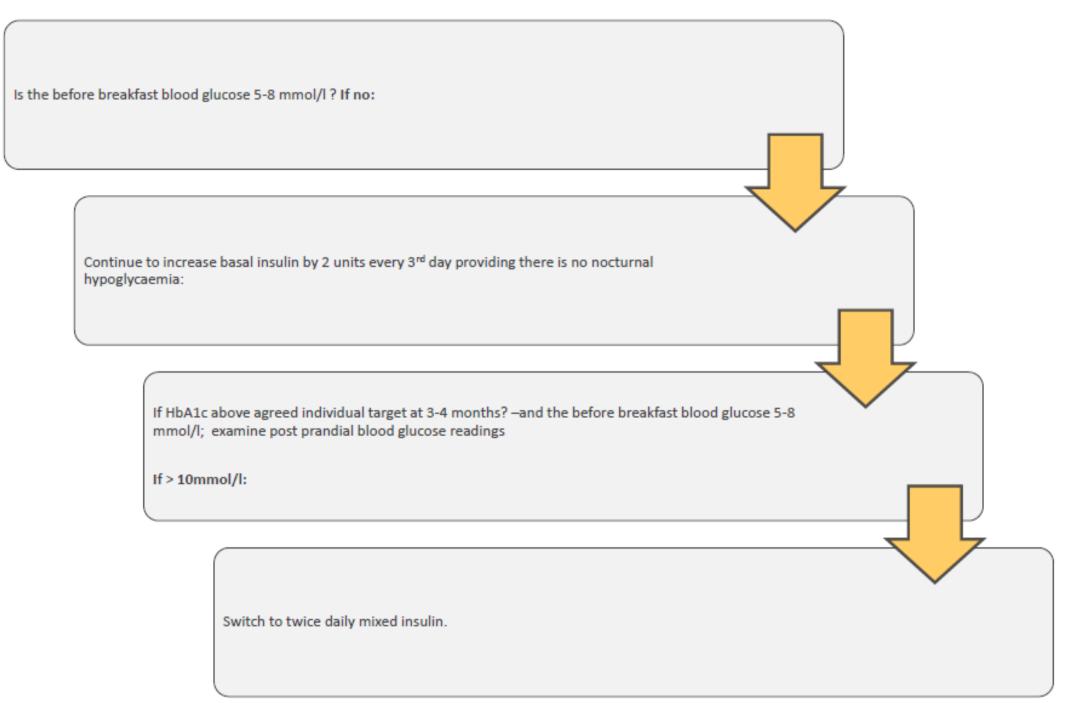
STOP INCREASING if :

symptoms of hypoglycaemia at night - go back to previous dose

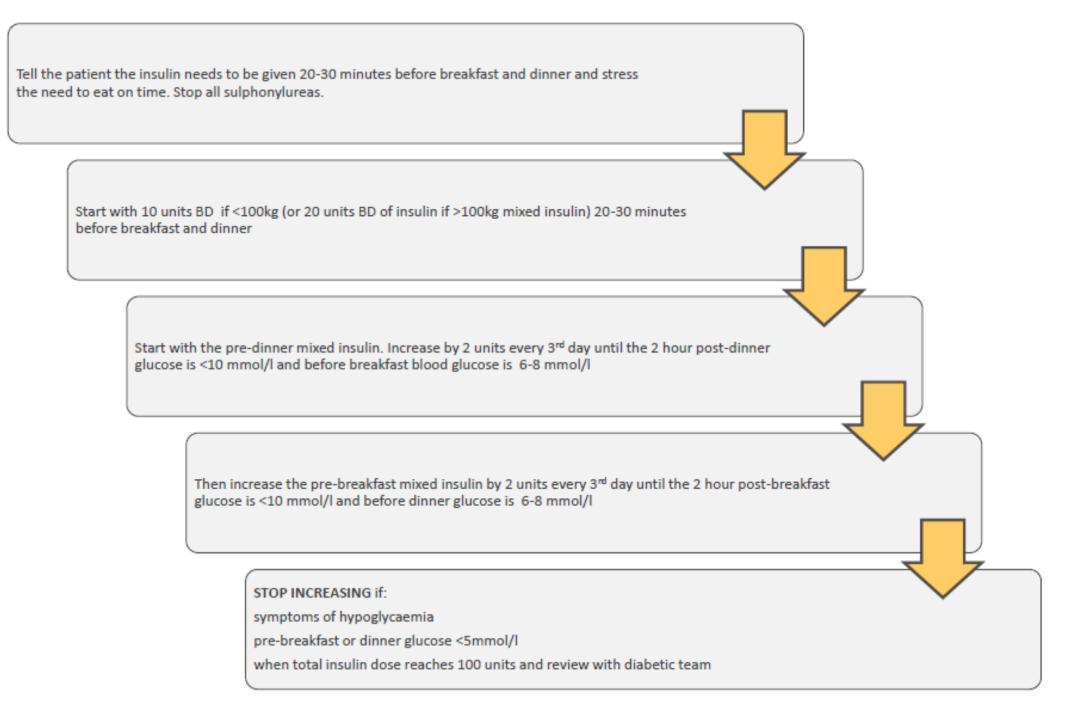
some readings are <5mmol/l

when insulin dose reaches 50 units - review with Diabetes team

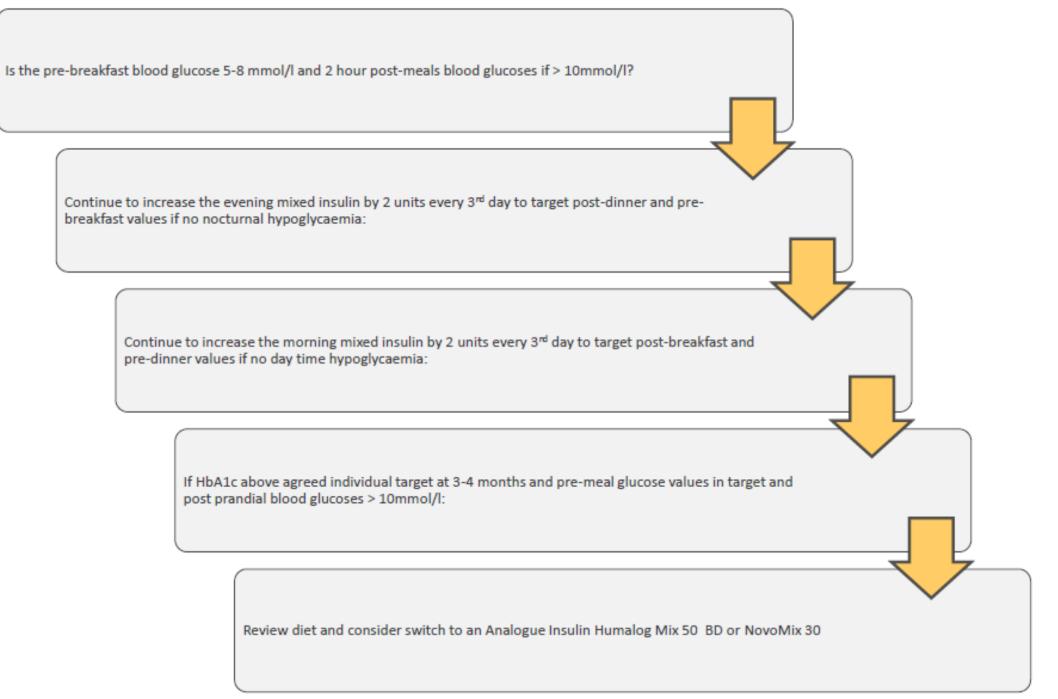
DIABETES – REVIEWING A BASAL INSULIN REGIME



DIABETES – STARTING A TWICE DAILY HUMAN INSULIN MIXTURE



DIABETES – REVIEWING A TWICE DAILY HUMAN INSULIN MIXTURE



DIABETES – REUSABLE INSULIN PEN DEVICES



DEVICE	AUTOPEN CLASSIC	AUTOPEN 24	NOVOPEN 4	NOVOPEN 5	NOVOPEN Echo	HUMAPEN SAVVIO	HUMAPEN LUXURA HD	ALLSTAR	ALLSTAR Pro	JUNIORSTAR
Dosing	1 unit (1-21) 2 units (2-42)	1 unit (1-21) 2 units (2-42)	1 unit (1-60)	1 unit (1-60)	½ unit (0.5-30)	1 unit (1-60)	½ unit (1-30)	1 unit (1-80)	1 unit (1-80)	½ unit (1-30)
General features	Plastic		Metal Blue or chrome	Metal Blue or chrome	Metal Blue or red	Metal Audible click Multiple colours	Metal Green Audible click	Purple or Teal	Blue or Silver	Blue, red or silver
Special uses	Release button or easier for some to Spring loaded rele ensures that force required to significantly less t insulin pens.	o handle ease button push the insulin is		Memory function on pen end indicates timing and units of last dose	Memory Function - Records dose and time since last injection for extra reassurance		Half unit doses so suitable for children or those with low insulin requirements			Allows for half- unit dose increments which helps to provide flexibility especially in young people.
Insulin compatibility	Lilly Humulin Humalog Abasaglar Wockhardt	Lantus Apidra	Novo Nordisk Insulatard Novorapid Novomix Levemir	Novo Nordisk Insulatard Novorapid Novomix Levemir	Novo Nordisk Insulatard Novorapid Novomix Levemir	Lilly Humulin Humalog Abasaglar	Lilly Humulin Humalog	Sanofi Insuman Lantus Apidra	Sanofi Insuman Lantus Apidra	Sanofi Insuman Lantus Apidra
Device		Autopen 24	Novem 4						Ctober 2020 Epr revi	

DIABETES – DISPOSABLE INSULIN PEN DEVICES

DEVICE	SOLOSTAR	FLEXPEN	FLEXTOUCH	INNOLET	KWIKPEN	SEMGLEE
Dosing	1 unit (1-80)	1 unit (1-60)	1 unit (1-80)	1 unit (1-50)	1 unit (1-60)	1 unit (1-80)
General features Apidra and Lantus versions of this pen have different colours (blue for Apidra, grey for Lantus) and textures to help users distinguish between the types of insulin. Insuman is a white pen. Green label for basal and blue for comb.		Pen is blue, with labels of different colours for various types of insulin.		An easy-to-use doser with a large, ergonomic dial	Buff colour for human insulin, blue for analogue. Humalog Junior Kwikpen can be differentiated by a orange and white label.	A light blue pen with white label.
Special uses			Reduced manual dexterity (due to push button not having to extend)	Poor eyesight Reduced manual dexterity (usually due to different joint related conditions)		
Insulin compatibility	Sanofi Apidra Lantus Insuman Basal Insuman Comb Insulin Lispro	Novo Nordisk NovoRapid Novomix Levemir	Novo Nordisk NovoRapid	Novo Nordisk Insulatard Levemir	Lilly Humulin Humalog Humalog Junior Abasaglar	Mylan Semglee
Device	And	NovoRapid Ricken	More/Andrew Q-	50, 5, 10 452 40 ⁻ , 35 ⁻ , 30 ⁻ , 20 35 ⁻ , 30 ⁻ , 25 (InnoLet*		Sendled Somman