Blood Glucose Management in adults with type 2 diabetes

The purpose of this guideline is to support evidence based, cost effective prescribing and should be read in conjunction with NICE clinical guidelines NG28 ‘Type 2 diabetes in adults: management’ published in December 2015.

Type 2 diabetes is a progressive long term condition. Management involves optimising glycaemic levels and appropriately managing cardiovascular risk through a combination of interventions such as lifestyle changes and appropriate use of pharmacological agents to reduce both microvascular and macrovascular disease such as blindness, kidney failure, lower limb amputation, heart disease and stroke.

Choosing the right treatment for the right level of HbA1c is one of the most important decisions for timely and effective drug optimisation. This is not straightforward, as there are around 8 classes of drug treatments, all with different contraindications, cautions, side effects and when combined with individual patient factors, this makes it challenging to know the best option for individuals. The guideline provides up to date new evidence and options as well as encouraging healthcare professionals to make drug choices based on efficacy, safety, suitability to the individual and cost. Lifestyle advice and metformin remain the preferred first line drug option with a broad choice amongst second-line agents. This local guideline provides information on the benefits and cautions relating to each drug option.

This drug treatment guideline only considers glycaemic control in people with type 2 diabetes; it does not address other equally important aspects of pharmacological therapy for managing cardiovascular risk such as blood pressure, lipid management and smoking cessation.

The NICE guidance on type 2 diabetes places a strong emphasis on empowerment of people with diabetes and on individualisation of care. NICE has produced a patient decision aid to help people think about their options for controlling blood glucose - NICE Patient decision aid. This should support people that the treatment they are on is the right one for them and improve concordance which is known to be poor in those with long term conditions.

Numerous studies have shown that there can be considerable delays in drug treatment intensification or titrating the therapy where the average sub-optimal glycaemic control is 5-7 years prior to insulin initiation in people with type 2 diabetes. ‘Therapeutic inertia’ is one of the biggest challenges for healthcare professionals. Optimising treatment at the right time ensures good early glycaemic control ‘legacy effect’ and improves outcomes. There is significant evidence that good glycaemic memory reduces peoples’ risk of developing complications for the rest of their life.

The HbA1c target levels in the drug treatment algorithm included in this guideline aim to address clinical inertia, with thresholds for intensification of therapy of 48 mmol/mol (6.5%) for monotherapy initiation (this supports the importance of early tight control) and of 58 mmol/mol (7.5%) for first and second intensification. Emphasis remains on individualising glycaemic targets for each patient e.g. relaxing glycaemic target for individuals towards the end of their lives where achieving long-term risk-reduction benefits is limited. Encouraging tight targets in certain cohorts, particularly young patients with type 2 diabetes with potentially long life-spans and those in the initial stages of the diseases’ trajectory.

With increasing prevalence rate of diabetes predicted and if current trends continue, one in ten people by 2034 will develop type 2 diabetes. The personal impact of diabetes and subsequent complications on people and their families should also be considered. It is estimated that diabetes account for approximately 15-16% of deaths in England, with life expectancy for people with type 2 diabetes reduced by an average of up to 10 years. It is hoped that implementation of the latest available NICE guidance will not only reduce rates of mortality and morbidity in the future for the thousands of adults diagnosed with type 2 diabetes and registered with a GP practice in Merton and Wandsworth CCGs, it will also enable them to live their lives to the fullest.
**Blood Glucose Management in Adults with Type 2 Diabetes - Metformin Tolerant**

**Blood Glucose Management Targets**
- Involve adults with type 2 diabetes in decisions about their individualized Hba1c targets
- Agree on individualised Hba1c target based on the person needs and circumstances including preferences, comorbidities, risks from polypharmacy and tight blood glucose control, ability to achieve longer term reduction benefits, disease duration, life expectancy and motivation.
- Support them to achieve the target and maintain it unless they experience adverse effects (including hypoglycaemia), or their efforts to achieve their target impair their quality of life.
- Consider relaxing the target Hba1c level as appropriate in people who are older or frail, people with reduced life expectancy, for people in whom tight blood glucose control poses a high risk i.e. people at risk of falling, people who drive or operate machinery as part of their job and those with significant comorbidities.
- If they achieve an Hba1c level lower than their target with no hypoglycaemia, encourage them to maintain it. Be aware of other possible reasons for a low Hba1c level e.g. declining renal function, sudden weight loss.
- Measure Hba1c levels at 3 - 6 monthly intervals, until it is stable or unchanging. 6 monthly intervals are recommended once Hba1c level and drug treatment is stable.

**If Hba1c rises to 48mmol/mol (6.5%) despite 3 months of lifestyle interventions, offer first line therapy with metformin**

**Provide and explain the NICE Review treatment plan and reinforce advice about diet, lifestyle & adherence to drug treatment.**

- If GI intolerance occurs, try metformin modified release or reduce dose to previously tolerated dose.
- Aim for Hba1c level of 48mmol/mol (6.5%).

**FIRST LINE THERAPY - Metformin (MONOTHERAPY)**
- Start at a dose of 500mg daily with food. Increase by 500mg every 2 weeks to reach a target dose of 1g twice daily or maximum tolerated dose.
- Before starting metformin, check corrected eGFR and note renal precautions (see box overleaf).
- If GI intolerance occurs, try metformin modified release or reduce dose to previously tolerated dose.
- Aim for Hba1c level of 48mmol/mol (6.5%).

**SECOND INTENSIFICATION: If Hba1c rises to ≥58mmol/mol* (7.5%) add in 2nd line therapy.**

- Add Gliptins (DPP-4 inhibitor)
- Alogliptin is the preferred gliptin locally**

**SECOND THERAPY - DUAL THERAPY (Metformin + either of the following classes of drugs below)**

- Provide and explain the NICE Patient Decision Aid (PDA) document to help adults with type 2 diabetes make informed decisions about taking a second medicine for blood glucose control. Tailor the information to reflect the person’s clinical circumstances as necessary (e.g. if certain medicines are contraindicated).
- Review treatment plan and reinforce advice about diet, lifestyle & adherence to drug treatment.
- Aim for Hba1c level of 53 mmol/mol (7.0%)*

- Add Gliclazide or
- Gliclazide is the preferred SU locally**

- Add Sulfonylurea (SU)
- Gliclazide is the preferred SU locally**

- Add SGLT-2i inhibitor (SGLT-2i)
- Only to be used if SU not tolerated/contraindicated or person at significant risk of hypoglycaemia or its consequences.

- Empagliflozin is the preferred SGLT-2i locally**

- Do not initiate if eGFR <60/ml/min

**THIRD LINTENSIFICATION: If Hba1c rises to ≥58mmol/mol* (7.5%) add in 3rd line oral therapy or insulin.**

- Add in either:
- Glitazone
- Pioglitazone
- GLP-1 agonists are recommended as an option with metformin and gliclazide when oral triple therapy is not effective/not tolerated/contraindicated for adults who:
  - Have a BMI ≥35kg/m² in those of European descent (adjust accordingly for ethnicity)*** and specific psychological or other medical problems associated with obesity OR
  - Have a BMI <35kg/m² and for whom insulin therapy would have significant occupational implications, or weight loss would benefit other significant obesity related co-morbidities.
  - Therapy must be reviewed at 6 and 12 months

- Treatment should only be continued after 6 months if reduction of 1% (11mmol/mol) in Hba1c is achieved and a weight loss of 3% of initial bodyweight

**Drug Treatment Choice & Review**

- Base the choice of drug treatment on:
  - Effectiveness, safety - (see MHRA guidance), tolerability, the persons individual clinical circumstances, comorbidities, preferences, needs, licensed indications, and cost (if two drugs in same class appropriate - select one with lowest acquisition cost).
  - Ensure renal & hepatic monitoring for individual drugs is taken into consideration - see SPC.
  - Reassess the person’s needs & circumstances at each review and stop any medicines that are not effective.

**Insulin Initiation**

- Refer to local community/hospital diabetes team for insulin initiation through a structured programme.
- Continue to offer metformin for people without contraindications or intolerance. Review the continued need for other blood glucose lowering therapies.
- NB: In line with NICE, human isophane (NPH) insulin (Insulatard, Humulin I and Insulman Basal) is recommended as first line basal insulin. Long lasting insulin analogues should be reserved for patients meeting criteria.

**Self-Monitoring Blood Glucose**

- Do not routinely offer blood glucose self-monitoring for patients with type 2 diabetes unless:
  - The person is on insulin or
  - On oral medication likely to cause hypoglycaemia e.g. SU while driving or operating machinery or
  - There is evidence of hypoglycaemia or
  - The person is pregnant, or planning to become pregnant or
  - Unless clinically requested by a specialist.

**Check Hba1c 3 months after ANY therapy change. Move to next step of therapy if target is not achieved. Discuss/refer to diabetes team if clinical concern at any stage.**

*other individual target
**this local recommendation must only be taken into account after a patient & prescriber have discussed all treatment options & only if they have no preference about which medicine they want to use *** adjust accordingly for people from Afro-Caribbean. Asian and other minority ethnic groups

Produced: January 2017
Review Date: January 2019
Blood Glucose Management in Adults with Type 2 Diabetes - **Metformin Contraindicated or Intolerant**

After diagnosis initiate lifestyle changes (smoking cessation, healthy eating, weight control & increased physical activity) and refer to structured education - DESMOND. Consider a bariatric surgery referral in appropriate patients. At ALL appointments reinforce advice on diet, lifestyle and adherence to drug treatment.

If HbA1c rises to 48mmol/mol (6.5%) despite 3 months of lifestyle interventions, offer first line therapy

**FIRST LINE THERAPY** - (MONOTHERAPY) - consider one of the following:
- Support the person to aim for an HbA1c level of 48mmol/mol (6.5%) on a DPP-4i or pioglitazone or an SGLT-2i.
- Support the person to aim for an HbA1c level of 53mmol/mol (7.0%) for people on an SU.
- Aim for HbA1c level of 48mmol/mol (6.5%).

**SECOND INTENSIFICATION**: If HbA1c rises to ≥58mmol/mol* (7.5%) add in 2nd line therapy.

**ADD IN EITHER:**
- Pioglitazone
- Gliclazide
- GLP-4 inhibitor
  - Sitagliptin is the preferred glitn in monotherapy

**THIRD LINE THERAPY** - Insulin-based treatment
- Aim for HbA1c level of 53 mmol/mol (7.0%)*

**ADD IN EITHER:**
- Glimepiride
- Glibizide
- Gliclazide
- Gliptin

**Insulin Initiation**
Refer to local community / hospital diabetes team for insulin initiation through a structured programme. Review the continued need for other blood glucose lowering therapies.

For detailed advice refer to preconception diabetes clinic.

Metformin contraindicated or not tolerated
It is estimated that approximately 5-15% of people cannot tolerate metformin, this may vary; people can develop metformin intolerance over time.

Preconception Advice
Women of child bearing age should be regularly informed that establishing good glycaemic control before conception and continuing this throughout pregnancy will reduce the risk of miscarriage, congenital malformation, stillbirth and neonatal death. For detailed advice refer to preconception diabetes clinic.

Drug Treatment Choice
All NICE-approved drugs are available to prescribe in line with their Technology Appraisal (TA) recommendation. If all other factors are equal prescribe the locally preferred agent **

Review
Reassess the person’s needs & circumstances at each review and think about whether to stop any medicines that are not effective.

Check HbA1c 3 months after ANY therapy change. Move to next step of therapy if target is not achieved. Discuss/refer to diabetes team if clinical concern at any stage.

* other individual target
** local recommendation must only be taken into account after a patient & pre

If you have any comments, please contact Rajiv Dhir, Senior Prescribing Adviser - Wandsworth CCG: Rajiv.Dhir@wandsworthccg.nhs.uk
Metformin (biguanide) **Action:** reduces insulin resistance and inhibits glucose production from the liver

Metformin reduces cardiovascular events in overweight and obese patients to a greater extent than predicted by its glucose lowering effects.

**Standard release**—the usual dose is 2g daily, but doses up to 3g daily in 3 divided doses can be used in exceptional circumstances.

**Modified release (M/R) dose:** initially 500mg once daily, increased every 10-15 days, max. 2g once daily with evening meal. If control not achieved use 3g twice daily with meals.

- Patients taking up to 2g daily of standard release may start with same daily dose of M/R
- Metformin and alcohol
  - eGFR should be assessed before initiation and at least annually thereafter
  - Review the dose of metformin if eGFR is <45ml/min
  - Caution in those at risk of sudden deterioration in kidney function & those at risk of eGFR falling <45ml/min e.g. the elderly & consider more frequent eGFR monitoring
  - Stop metformin if the eGFR is <30ml/min

**Pioglitazone**

- **Action:** reduces insulin resistance and improves insulin sensitivity
- **Modified release/pioglitazone prolonged release**—start at 15-30mg once daily, increased to 45mg once daily according to response. Start with lowest possible dose in the elderly and increase gradually
- **Pioglitazone is contraindicated in people who have heart failure (NYHA class I - IV), history of heart failure, uninvestigated macroscopic haematuria, previous or active bladder cancer, hepatic impairment or diabetic ketoacidosis
- Caution is advised when considering use in cardiovascular disease or in combination with insulin. If used with insulin, patients should be observed for signs and symptoms of heart failure, weight gain and oedema—see MHRA advice
- Caution is advised in those at increased risk of bone fractures or those with risk factors for bladder cancer. Known risk factors for these conditions including increasing age, should be carefully evaluated before treatment—see MHRA advice

**Pioglitazone and the liver**

- Avoid in hepatic impairment. Monitor liver function before treatment and periodically thereafter. Advise patients to seek immediate medical attention if symptoms such as unexplained nausea, vomiting, abdominal pain, fatigue, anorexia and/or dark urine occur
- The safety and efficacy of pioglitazone should be reviewed after 3-6 months. It should be stopped in patients not responding adequately. Pioglitazone’s efficacy and safety should be reviewed (e.g. 3-6 months) in patients continuing therapy. See MHRA advice for further details and the summary of product characteristics (SPC).

**Empagliflozin**

- **Action:** inhibit SGLT2 in the renal proximal convoluted tubule to reduce glucose reabsorption and increase urinary glucose excretion
- **SGLT-2 inhibitors—sodium-glucose co-transporter 2,** **Empagliflozin** is the local SGLT-2i of choice
  - **SGLT-2i are a relatively new class of drug, their adverse effect profiles are still developing and long term safety data is not available.**
  - **Adequate renal function is necessary for SGLT-2i to work. Do not initiate a SGLT-2i if eGFR<60ml/min. Monitor renal function prior to initiation and then 6 monthly to at least annually thereafter. For renal function approaching <60ml/min, monitor at least 2-4 times per year.**
  - **Serious & life-threatening cases of DKA have been reported in people taking SGLT-2i or shortly after stopping the SGLT-2i (note: can occur at normoglycaemia). Risk factors include: low beta cell function reserve & conditions leading to restricted food intake or severe dehydration. Inform patients of the signs and symptoms of DKA (e.g. nausea, vomiting, anorexia, abdominal pain, excessive thirst, difficulty breathing, confusion, unusual fatigue or sleepiness); advise them to get immediate medical help if these occur. Test for raised blood ketones in patients with symptoms of DKA. If SGLT-2i treatment is stopped, DKA should be excluded.**
  - **Stop SGLT-2i in people who are undergoing major surgery or are in hospital due to serious illness, treatment may be restarted once the condition has stabilised.**
  - **Can cause diuresis and therefore volume depletion and hypotension. They should be used in caution when given with diuretics (do NOT use with loop diuretics) or in those who are volume depleted (e.g. in acute illness such as gastrointestinal illness).**
  - **Common adverse reactions include genital and urinary tract infections**
  - **The MHRA issued a drug safety update warning regarding an increased incidence of lower limb amputation (primarily of the toe) in people taking canagliflozin compared with placebo.**
  - **Empagliflozin is the preferred SGLT-2i in the light of the EMPA-Reg Outcome Study (2015), which demonstrated significant cardiovascular protection in people with diabetes and existing vascular disease**
  - **Empagliflozin-starting dose:10mg od, can be increased to:25mg od, if eGFR60-69ml/min & tighter glycaemic control is needed. If tolerating dose & eGFR>60ml/min, the dose should be adjusted to or maintained at 10mg od. Empagliflozin should be discontinued if eGFR persistently<45ml/min**

**Sulfonylureas (SU)**

**Sulfonylurea - Gliclazide** is the local SU of choice

- **Always reassess the patient and emphasise lifestyle issues before prescribing. Regarding lifestyle and diet, explain the effects of physical activity, intermittent illness and other physical and emotional influences on glucose control and risk of hypoglycaemia as well as possible weight gain (a few kilograms). If patient is obese, SU may not be a suitable early treatment option**
- **Caution use of SU in patients who are frail, elderly patients who live alone, people with poorly controlled diabetes of longer duration, those with erratic or irregular eating habits, renal impairment, Group 2 drivers (licensed to drive NGV or Public Service Vehicles), professional drivers (taxi driver), and in certain occupations e.g. operating heavy machinery, working at heights - construction workers etc and those with severe renal impairment - eGFR <30ml/min.**
- **Patients should be educated about the risks of hypoglycaemia with SU, possible symptoms and how to treat.**
- **SUs should be used with care in those with mild to moderate renal impairment (eGFR30-60ml/min)**
- For gliclazide, start at a dose of 40-80mg daily with meals up to 160mg BD as necessary. Titrate dose every 2 weeks according to pre-meal blood glucose levels. Target pre-meal blood glucose level is 4-6mmol/l (or individualised target). If the patient is not self testing, titrate dose according to Hba1c level every 3 months and check for symptoms of hypoglycaemia.
- **If pancreatitis is suspected, treatment with the GLP-1 receptor agonist should be permanently discontinued –see MHRA advice**

**Gliclazide prolonged release**

- **Action:** inhibit DPP-4 to increase insulin secretion & lower glucagon secretion when glucose is present

**Glipitins—Alogliptin is the local gliptin of choice**

- **The MHRA has warned that an increased risk of acute pancreatitis has been identified for all approved glitins. Patients should be informed of the characteristic symptoms of acute pancreatitis - persistent, severe abdominal pain (sometimes radiating to the back) - and encouraged to report these to their healthcare provider. If pancreatitis is suspected, the gliptin and other potentially suspect medicines should be discontinued**
- **If all other patient factors are equal, prescribe the gliptin with the lowest acquisition cost—currently this is alogliptin**
- **Alogliptin is available in 6.25mg, 12.5mg and 25mg tablets. In renal impairment-calcine clearance: >50ml/min no dosage adjustment, 30-50ml/min-12.5mg daily, <30ml/min-6.25mg daily**
- **If metformin is contraindicated or not tolerated and a gliptin is being considered for monotherapy, then choose sitagliptin. Alogliptin is not licensed for use in monotherapy**

**Empagliflozin is the preferred SGLT-2i of choice**

- **GLP-1 (Glucagon-like peptide 1) agonists**
  - **Dulaglutide is the preferred weekly GLP-1 of choice**
  - **Action:** increase insulin secretion, suppress glucagon secretion and slow gastric emptying
  - **Patients should be informed of the goal of treatment when GLP-1 is initiated. Arrangements must be in place for a follow up in 6 months with a view to stoping if the Hba1c has not fallen by at least a 1% (11mmol/mol) and a weight reduction of at least 3% has not been achieved.**
  - **Choice of agent should depend on whether the patient prefers daily or weekly administration. Prescriber to decide the most appropriate GLP-1 after discussion with the patient.**
  - **Dulaglutide prolonged release is the preferred once weekly GLP-1. Advantage of a weekly preparation is if compliance is an issue or patient requires regular visits from a nursing team to administer**
  - **There have been reports of necrotising and haemorrhagic pancreatitis in patients with GLP-1 agonists, some of which were fatal. If pancreatitis is suspected, treatment with the GLP-1 should be suspended immediately; if pancreatitis is diagnosed, the GLP-1 agonist should be permanently discontinued –see MHRA advice**
  - **GLP-1 agonists should be initiated in combination with insulin by a specialist team and in those with a low eGFR**

**Insulin**

- **Insulin should be prescribed by brand name rather than generically**
- **The dose of insulin to be used should be stated clearly in units in the directions for basal insulin**
- **Insulins should not be recommended for use in type 2 diabetes. IS NICE**
- **Insulin-based treatment should be considered at 2nd intensification as an alternative to triple therapy in:**
  - Patients who are able to take metformin or after dual therapy in patients unable to take metformin
  - **When Hba1c remains above 58 mmol/mol despite maximum intensification with other therapies**

**Use this guideline in conjunction with discussion and education of the patient. Inform patients of targets and treatment plan. Treatment should be individualised to patient need e.g. in relation to weight gain, hypos, tolerability of medicines and how fast or slow to titrate them.**
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<th>CKD stage 1 (GFR &gt;90)</th>
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<th>3a (59-45)</th>
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N.B. In patients at extremes of weight (BMI <18.5 kg/m2 or >30 kg/m2) or age (>70yr), calculate renal function using Cockcroft and Gault equation - this can be found on EMIS under ‘Templates’, search ‘Cockcroft’


Acknowledgement: adapted with permission from Derbyshire CCGs JAPC ‘Glucose Control in Type 2 Diabetes’ – August 2016
References

European Medicines Agency, 14/10/2016, Use of metformin to treat diabetes now expanded to patients with moderately reduced kidney function.


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Review date January 2019, unless there is a significant change in clinical practice or pricing arrangements
Acknowledgements


Dr Sharvanu Saha, Consultant in Acute Medicine Unit & Endocrinology, St. George’s University Hospitals NHS Foundation Trust.

Dr Ken Earle, Consultant in Diabetes & Endocrinology, St. George’s University Hospitals NHS Foundation Trust.

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Dr Gul Bano, Consultant in Diabetes & Endocrinology, St. George’s University Hospitals NHS Foundation Trust.

Dr Fahad Ahmed, Consultant Endocrinologist, St. George’s University Hospitals.

Dr Neil Bamford, GP the Earlsfield Practice, Earlsfield.

Dr Sachin Patel, GP Mayfield Surgery, Roehampton.

Dr Farooq Rafique, GP Chatfield Health Centre, Battersea.

Dr Sayanthan Ganesaratnam, Joint Divisional Clinical Director CLCH - Merton

Dr Farooq Ahmed, GP Merton and Diabetes UK Alumni Clinical Champion

Maggie Dixon, Diabetes Specialist Nurse, Wandsworth Community Diabetes Nursing Team.

Judith Nelson, Diabetes Specialist Nurse, Wandsworth Community Diabetes Nursing Team.

Amy Slomowitz, Lead Specialist Diabetes Pump & CGM Educator - (Advanced Diabetes Specialist Nurse), St. George’s University Hospitals.

Angela Flanagan, Diabetes Specialist Nurse, St. George’s University Hospitals NHS Foundation Trust

Claire Wilson, Diabetes Specialist Nurse, St. George’s University Hospitals NHS Foundation Trust.

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Rebecca Garnett Haris, Diabetes Specialist Nurse, Queen Mary’s Hospital, Roehampton.

Sheena White, Diabetes Specialist Nurse, Queen Mary’s Hospital, Roehampton.

Diabetes Specialist Nurses, Beta Cell - Queen Mary’s Hospital, Roehampton.

Diabetes Specialist Nurses, Wandsworth Community Diabetes Nursing Team.

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Wendy Pullinger, Deputy Chief Pharmacist, St. George’s University Hospitals NHS Foundation Trust.

Gary Bradley, Senior Pharmacy Technician, NHS Wandsworth Clinical Commissioning Group.

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Sedina Agama, Chief Pharmacist & AD Medicines Optimisation, NHS Merton Clinical Commissioning Group.

Valentina Covey, Deputy Chief Pharmacist, NHS Merton Clinical Commissioning Group.

Primary Care Pharmacists Merton CCG

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Anna Hodgkinson, Senior Clinical Commissioning Pharmacist Lambeth Clinical Commissioning Group

Derbyshire Joint Area Prescribing Committee

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