

BEXLEY TREATMENT GUIDELINES

For Type 2 Diabetes 2011 update

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VERSION CONTROL SHEET

**This clinical guideline is an update of:
Type 2 Diabetes Treatment Guidelines 2009-10**

The following sections have been updated and approved in November 2011

1. Guidance (Education and Lifestyle Changes)
2. Appendix 1: Bexley Led Walks Programme Appendix 1)
3. Diagnostic Algorithm For Diabetes Mellitus (Appendix 6)
4. Stepped Approach To Glucose Lowering Therapies In Type 2 Diabetes
5. Bexley Guidance on use of (DPP-4 Inhibitors/Gliptins) Sitagliptin ▼
Saxagliptin ▼ Linagliptin ▼ Vildagliptin ▼
6. Bexley Guidance on Thiazolidinediones (Glitazones) Prescribing
7. Bexley Guidance on GLP-1 (Glucagon-like peptide-1) Receptor
Agonists: Exenatide ▼, Liraglutide ▼
8. Bexley Guidance on Diabetic symptomatic neuropathic pain management
9. Addition of DVLA requirements In Appendix 3: SMBG

The following new sections have been added and approved in November 2011

1. Insulin Passport Information – National Patient Safety Association, June 2011
2. Insulin safety guidance – National Patient Safety Association, June 2011

CONSULTATION PAGE

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Consultation Exercise

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INTRODUCTION

Diabetes is a complex chronic disorder, involving lifestyle changes, self management and a holistic approach around the patient regarding treatment. To enable the patient to make informed decisions, all healthcare professionals will find this guidance supportive, ensuring the care received is to an appropriate and equivalent clinical level across the Bexley area.

Definition of Type 2 Diabetes (NICE May 2008)

The guideline recommendations were developed using the World Health Organization (WHO) definition of diabetes, which requires a degree of high plasma glucose levels sufficient to put the individual at risk of the

microvascular complications of diabetes. This definition was re-confirmed by WHO in 2006* but, like earlier versions, it does not contain a specific definition for type 2 Diabetes.

A person is normally thought to have type 2 Diabetes if he or she does not have type 1 Diabetes (rapid onset, often in childhood, insulin-dependent, ketoacidosis if neglected), monogenetic diabetes or other medical conditions or treatment suggestive of secondary diabetes.

*(*International Diabetes Federation (2006) Definition and diagnosis of diabetes mellitus and immediate hyperglycaemia: report of a WHO/IDF consultation. Geneva: World Health Organization.)*

Scope

These guidelines replace existing guidance produced in May 2010 and are designed to be used by all clinicians in Bexley Care Trust & Queen Mary's Hospital for treatment of people with Type 2 Diabetes.

Purpose

To replace existing treatment information which is in need of updating following the updating of NICE guidance March 2010 (CG96) and October 2010 (TA 23).

GUIDANCE, PATIENT EDUCATION & LIFESTYLE MODIFICATION

Education:

One to one education at diagnosis within the GP Practice

X-PERT Education Programme

Suitable for people with Type 2 Diabetes who are either newly diagnosed, have poor control (HbA1c above 7.5%) or who would like to attend a group education programme. It is an evidence based, nationally recognised structured six week group education programme.

If a patient declines a referral to group education sessions, they should be provided with information & education within their own GP practice.

Management of Depression:

Follow the recommendations in 'Depression: management of depression in primary and secondary care clinical guideline' (NICE clinical guideline 23).

<http://www.nice.org.uk/Guidance/CG23>

Lifestyle Changes:

In Bexley there are a number of options to support patients who need to make lifestyle changes. The following links provide further information:

Active Bexley Guide

<http://www.bexley.gov.uk/CHttpHandler.ashx?id=9232&p=0>

Outdoor and Indoor Activities

<http://www.bexley.gov.uk/sports>

<http://www.bexley.gov.uk/parks>

<http://www.bexley.gov.uk/movemore>

Stop Smoking Service

Bexley has a team of practice based, and community pharmacy based Stop Smoking advisors. Patients can self-refer & gain more information on this service by telephoning: **0208298 6147**, alternatively you can access the following website:

<http://www.smokefreebexley.co.uk>

Bexley Stop Smoking Services offers weekly drop-in services, without an appointment as well as a free, six-week course at the following locations:

- Queen Mary's Hospital, Sidcup – Tuesdays 6.30 to 8pm (session one) 7 to 8pm (sessions two to five)
- Erith District Hospital, Park Crescent, Erith – Friday afternoons 2 to 3pm

All Bexley GP practices have a stop smoking advisor based at the practice; patients should be encouraged to contact their surgery for further information.

The national service can be accessed by telephone on **0800 0224 332** (Mon to Fri 9am to 8pm, Sat and Sun 11am to 5pm) or by accessing the website at <http://www.smokefree.nhs.uk>

ASIAN LANGUAGES QUITLINE NUMBERS	Multilingual services are available for the following Asian Languages: Bengali, Urdu, Punjabi, Gujarati and Hindi where counsellors offer confidential, friendly help and advice in these languages. Many Asian smokers who speak English fluently appreciate that they can discuss the cultural issues surrounding smoking with someone who understands.	
	Lines are open Monday to Friday 9am to 8pm and Saturday and Sunday 11am to 5pm.	
	Urdu	0800 169 0 881
	Punjabi	0800 169 0 882
	Hindi	0800 169 0 883
	Gujarati	0800 169 0 884
	Bengali	0800 169 0 885

QUIT (a national charity to support people who want to stop smoking) also has a free phone helpline **0800 002200** & a webpage: <http://www.quit.org.uk>

Bexley Led Walks Programme (For more information: See Appendix 1)

Bexley has an accredited programme of led walks available on most days of the week across the borough. The walks are designed to help an individual start taking more exercise in a supportive atmosphere with like minded individuals.

The walks available do change from time to time as the programme is volunteer led.

For more information please contact:

Charlene Williams **02082986265**,
email: Charlene.williams@bexley.nhs.uk
Website: <http://www.bexley.gov.uk/movemore>

"Steps to Health"- Exercise Referral and Swim on Referral

Target Group - Adults with Medical Conditions

- A supervised exercise programme and swim on referral programme for inactive residents with medical conditions.
- The twelve-week, exercise/swim programme is designed and supervised by qualified fitness instructors.
- Venues: Erith and Crook Log Leisure Centre

For more information contact: **0208298 6265**

The referral Forms are available from **GP ZONE**

Bexley 'Simply Active Programme' Referral Programme

Target Group - Adults with Medical Conditions

- A supervised exercise programme for inactive residents with medical conditions
- This is a community based 14 week referral programme designed and supervised by suitability qualified instructors
- Venues: Pincott Hall, Bexleyheath, Nemesis Gym Erith, Hurst Community Centre, Sidcup

For more information contact: **0208 298 6265**

The referral Forms are available from **GP ZONE**

Bexley Health Trainers

Bexley Health Trainers Programme is a partnership programme between Mind in Bexley, Age Concern Bexley and Inspire Community Trust and funded by Bexley Care Trust.

A Health Trainer is someone who has been specially trained to provide one to one support to people who would like to improve their health and lifestyle.

The Health Trainer will help with setting goals, providing motivation and support the individual to achieve their goals. Patients can self refer or be referred by their GP.

For Further Information please contact:

Bexley Health Trainers on **020 8303 8932 (option 4)** or email info@bexleyhealthtrainers.org.uk or Book Online at: <http://www.bexleyhealthtrainers.org.uk/>

The Referral Forms are available from **GP ZONE**

Dietetic Support

Provide basic dietary healthy eating guidance to support lifestyle changes, offer referral to community service.

Weight Management

Follow the recommendations in 'Obesity: the prevention, identification, assessment and management of overweight and obesity in adults and children (NICE clinical guideline 43)

<http://www.nice.org.uk/Guidance/CG43>.

All GP practices offer advice & support on weight management.

Diabetic patients with a BMI of >27 & waist circumference of more than 79cm/31.5 inches (women) or 92.5cm/37 inches (white or black men) or 87.5cm/35 inches (Asian men) require support to manage their obesity and risk of diabetic complications.

(*Bariatric surgery is 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.)

NICE has approved Orlistat (see table overleaf) for use in the NHS to support patients diagnosed with Diabetes with BMI>28 when lifestyle & dietary adjustments have been insufficient for an individual patients to reduce their weight alone.

N.B. Ideally any patient who is being considered for weight reducing medication should demonstrate weight loss, or a correction of diet and lifestyle, before medication is prescribed. However in some situations & where the BMI is **>35**, for example, where patients have plateau-ed despite correct diet and lifestyle, medication may be considered from the start.

“Newly diagnosed” people need to continue to maintain a reduced calorific diet (600kcal below average required intake) & should be encouraged to keep a food diary (suggested for minimum of 4 weeks) to help with dietary changes.

Initial prescriptions should be issued for a 28 days supply and patients should be required to attend the surgery for a review & weight assessment before a further prescription is issued.

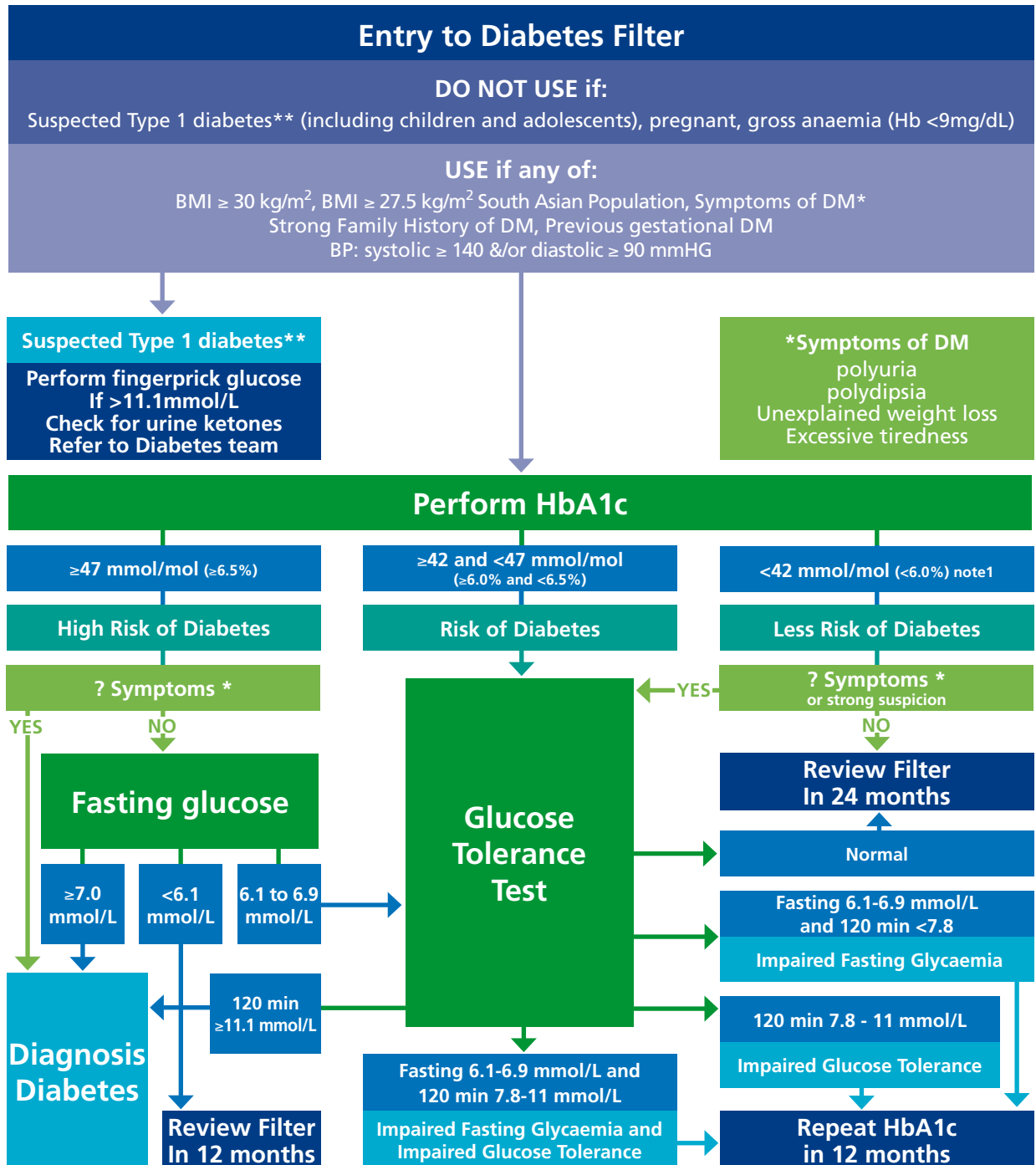
After the first prescription, the maximum could be increased to 56 days as clinically appropriate for that individual. (No drug to support weight loss should be prescribed on repeat issues). If a patient “fails” to achieve weight loss on one drug, a new treatment should not be issued immediately, allowing the patient time to re-focus on possible personal barriers to weight loss & dietary changes. A further treatment can be considered as appropriate within 3 to 6 months depending on the individual's clinical needs.

Please refer to the SPC (Summary of Product Characteristics) for more in depth description on the above medication. The above recommendations are meant for adults only.

MEDICATION	ORLISTAT XENICAL (ROCHE)
NICE approved	Yes
WHO	BMI > 30; BMI > 28 with co-morbidities (e.g. diabetes)
DURATION	Treatment should only be continued beyond 12 months after discussing potential benefits and risks with the patient. Stop if <5 % weight loss in 3 months from starting medication (target may be lower with type 2 diabetes)
CONTRAINDICATIONS	Malabsorptive syndromes, Coeliac Disease, Inflammatory Bowel Disease, Hypersensitivity to the active substance or to any of the excipients, Breast-feeding.
CAUTIONS	Prolonged use may cause liposoluble micronutrient deficiency (Vit A,K,D,E)
SIDE EFFECTS	SIDE EFFECTS Steatorrhoea, faecal incontinence
OTHER OUTCOMES	Drop in LDL, Triglycerides
SPC LINK	http://emc.medicines.org.uk/emc/industry/default.asp?page=displaydoc.asp&documentid=1746
SPONSORED SUPPORT PROGRAMME	MAP http://www.amapassist.co.uk

SCREENING AND DIAGNOSTIC ALGORITHM FOR DIABETES MELLITUS

Written by: Richard Mainwaring-Burton (Consultant Biochemist), Dr Sharaf Ibrahim (Consultant Diabetologist), Dr Steven Berg (GP Lead for Diabetes)
Adapted From: NHS Health Check Diabetes Filter Pathway for South East London



STEPPED APPROACH TO GLUCOSE LOWERING THERAPIES IN TYPE 2 DIABETES

STEP 1

Step 1 in addition to lifestyle measures: Aim for HbA1c < 48mmol/mol (6.5%)

Start METFORMIN 500mg & titrate to 2g daily or maximum tolerated dose over one month
MR formulation can be considered for patients with concordance issues or intolerable GI side effects

Alternative consider:
*SULPHONYLUREA (SU) symptomatic at diagnosis (for short term use) or Intolerance to Metformin) *see note below

STEP 2

Step 2: HbA1c > 53mmol/mol (7%) after 3/12 on single medication or as individually agreed consider additional oral therapy up to maximum tolerated dose

First choice: Add SULPHONYLUREA (Or consider Post Prandial Regulators: Repaglinide or Nateglinide if a short acting therapy is needed where patient's lifestyle & eating habits are erratic. Only licensed in combination with Metformin. Consider Risk of Hypoglycaemia for drivers & the elderly, SMBG REQUIREMENTS & concordance issues

Alternative instead of SU:
EITHER Add DPP-4 INHIBITOR if weight gain is an issue or risk of hypoglycaemia (see guidance for Bexley)

OR Add PIOGLITAZONE (See guidance for Bexley)

OR Add GLP-1 RECEPTOR AGONISTS (See guidance notes for Bexley)

Consider discussing Insulin as potential therapy at Step 2 if clinically appropriate for the individual patient & their management.
First-line - Human NPH insulin (intermediate-acting insulin) at bedtime or twice daily

STEP 3

Step 3: HbA1c > 53mmol/mol (7%)

Consider Triple Therapy if target is not achieved on maximal doses of two oral treatments

Consider adding GLP-1 RECEPTOR AGONISTS HbA1c > 7.5% (See separate guidance)
Initiation by Accredited GP practice or Bexley Community Diabetes team

Consider adding Insulin therapy
First-line - Human NPH insulin (intermediate-acting insulin) at bedtime or twice daily (See separate guidance & step 4 below)

STEP 4

Step 4: HbA1c > 58mmol/mol (7.5%)

Choice of Insulin regime +/- Oral therapy should be discussed with patient & support/training received from accredited health professional (see Insulin guidance document) Please prescribe insulin by brand to ensure patient safety (Advanced practice or Bexley Community Diabetes team only)

For more information on: Metformin, Sulphonylureas, Glitazones, DPP4 Inhibitors & GLP-1 Receptor Agonists : Please access the latest edition of the BNF Online: <http://bnf.org/bnf/index.htm> See also <http://www.medicines.org.uk> to access individual Summary of Product Characteristics for each product

***N.B.** A short acting Sulphonylurea should be considered, in Bexley the first line recommendation is Gliclazide in standard formulation. Please refer to Bexley SMBG guidelines in Appendix 3

BEXLEY GUIDANCE ON USE OF (DPP-4 INHIBITORS/GLIPTINS) SITAGLIPTIN ▼ SAXAGLIPTIN ▼ LINAGLIPTIN ▼ VILDAGLIPTIN ▼

Ref: NICE CG87, May 2009 ▼ <http://www.nice.org.uk/CG87>

Mode of Action

Sitagliptin ▼, Saxagliptin ▼ Linagliptin and Vildagliptin ▼ belong to a class of Oral Antidiabetic Drugs called dipeptidyl peptidase 4 (DPP-4) inhibitors also referred to as "Gliptins". Linagliptin ▼ is a newly launched Gliptin, further details are listed below. They enhance the levels of active incretin hormones including glucagon-like peptide 1 (GLP-1) and glucose-dependent insulinotropic peptide (GIP), which are released steadily by the intestine throughout the day and are increased in response to a meal. Incretin hormones enhance insulin secretion, lower glucagon secretion and hence reduce blood glucose levels. The activity of GLP-1 and GIP is rapidly inactivated by the DPP-4 enzyme, which the DPP-4 inhibitors help to prevent. These are useful where postprandial sugars are known to be high.

There is currently a lack of long term safety & outcome data for all four drugs from clinical trials. Reporting of any adverse events to the MHRA (Yellow card) is required since all treatments are black triangle drugs: <http://www.yellowcard.gov.uk>

Please refer to individual SPC (Summary of Product Characteristics) for the most up to date information regarding contra-indications, special warnings and precautions for use as well as side effects for each individual DPP-4 inhibitors:

<http://www.medicines.org.uk/EMC/default.aspx>

All DPP-4 inhibitors are weight neutral. Further studies would be required to confirm this finding in larger study groups.

All DPP-4 inhibitors are licensed for use in type 2 diabetes in combination with metformin (in combination with metformin, when metformin alone, with diet and exercise, does not provide adequate glycaemic control), please see below for further information on the licensed uses for each individual DPP-4 inhibitor and refer to each individual SPC(Summary of Product Characteristics) for the most up to date information by following the link: <http://www.medicines.org.uk/EMC/default.aspx> . Treatment should only be continued if HbA1c is reduced by at least 0.5% within 6 months of initiation.

See guidance from DVLA for **DPP4 Inhibitors** from "At a Glance Guide to the Current Medical Standards of Fitness to Drive"

<http://www.dft.gov.uk/dvla/medical/ataglance.aspx>

Sitagliptin ▼

- Licensed for use in type 2 diabetes in combination with metformin or a sulfonylurea (if metformin inappropriate) or pioglitazone, when treatment with either metformin or a sulfonylurea or pioglitazone fails to achieve adequate glycaemic control
- Sitagliptin ▼ is also licensed for use as monotherapy (if metformin inappropriate), or in combination with both metformin and a sulfonylurea, or both metformin and pioglitazone when dual therapy with these drugs fails to achieve adequate glycaemic control and when insulin is unacceptable because of lifestyle or other personal issues, or because the patient is obese.
- The combination of sitagliptin ▼ and insulin (with or without metformin) is also licensed for use when a stable dose of insulin has not provided adequate glycaemic control.
- Consider where a Glitazone is contra-indicated or not tolerated or further weight gain will exacerbate weight related problem.
- Consider in patients not controlled on Metformin instead of SU if high risk of hypoglycaemia e.g. elderly living alone and certain jobs e.g. working at heights.
- Consider in combination with a Glitazone when SU and Metformin are contraindicated.
- Avoid in moderate to severe renal impairment. Suitable For in use patients with mild renal impairment, no dose adjustment is required.
- Avoid in severe hepatic impairment. Suitable For in use in patients with mild to moderate hepatic impairment, no dose adjustment is necessary
- Has been approved for use within Bexley as clinically appropriate & as licensed, and can be considered at Step 2 in the management of blood glucose management (please refer to algorithm).

Saxagliptin ▼

- Licensed for use in combination with metformin or a sulfonylurea (if metformin inappropriate) or pioglitazone, when treatment with either metformin or a sulfonylurea or pioglitazone fails to achieve adequate glycaemic control
- Consider using in Patients not controlled on Metformin where a SU or Glitazone has been added in and is not tolerated or contraindicated
- Avoid in severe hepatic impairment and use in caution with moderate hepatic impairment
- Suitable For in use patients with mild renal impairment, no dose adjustment is required.

- In March 2011, the EC granted a license extension for saxagliptin ▼ (Onglyza®) to include use in type 2 diabetes patients with moderate (eGFR 30-59ml/min/1.73 metre squared) or severe renal impairment (eGFR 15-29ml/min/1.73 metre squared), where it would be required to halve the dose (2.5mg). As experience in patients with severe renal impairment is very limited, saxagliptin ▼ should be used with caution in this population and is not recommended for patients with end-stage renal failure.
- Assessment of renal function is recommended prior to initiation of saxagliptin ▼ and in keeping with routine care; renal assessment should be done periodically thereafter.
- Has been approved for use within Bexley as clinically appropriate & as licensed, and can be considered at Step 2 in the management of blood glucose management (please refer to algorithm).

Linagliptin ▼

In September 2011 Linagliptin ▼ 5-mg tablets were licensed in the UK for the treatment of type 2 diabetes in adults as:

- Monotherapy in patients inadequately controlled by diet and exercise alone and for whom metformin is inappropriate due to intolerance, or contraindicated due to renal impairment.
- Combination therapy with metformin when diet and exercise plus metformin alone do not provide adequate glycaemic control, or in combination with a sulphonylurea and metformin when diet and exercise plus dual therapy with these medicinal products do not provide adequate glycaemic control.
- For patients with renal impairment, no dose adjustment for Linagliptin ▼ is required.
- Pharmacokinetic studies suggest that no dose adjustment is required for patients with hepatic impairment but clinical experience in such patients is lacking

Vildagliptin ▼

- Has not been approved for use within Bexley.
- Avoid in moderate to severe renal impairment. Suitable For use in patients with mild renal impairment (eGFR 60-89 ml/min/1,73m squared), no dose adjustment is required.
- Not suitable for hepatic impairment. Liver dysfunction reported rarely with vildagliptin ▼. Monitor liver function before treatment then every 3 months for the first 12 months and annually thereafter.
- Vildagliptin ▼ should not be used in patients with cardiac failure or a history of cardiac failure (NYHA class I to IV).

BEXLEY GUIDANCE ON THIAZOLIDINEDIONES (GLITAZONES) PRESCRIBING

- *Rosiglitazone is no longer recommended because it had its licence suspended due to increased cardiovascular risk (September 2010).*
 - Pioglitazone is currently the only glitazone licenced in the UK.
 - Pioglitazone reduces peripheral insulin resistance and is associated with weight gain and may cause fluid retention.
 - Not recommended in patients with known heart failure (See individual SPC for full guidance)
 - Consider patient's risk of developing heart failure, bladder cancer or potential for distal fractures (increased risk of bone fractures reported in females, in particular those that are postmenopausal, in feet, lower leg, hands and lower arms).
- Check LFT prior to starting treatment, after initial 2 months of treatment, then annually thereafter.
 - NICE recommends a glitazone can be used as second line therapy together with either metformin or a sulphonylurea if one of these two drugs is not tolerated or contra-indicated or as third line therapy together with metformin and a sulphonylurea if insulin therapy is not acceptable.
 - Pioglitazone is licensed for use with Insulin in people with insufficient glycaemic control on insulin for which metformin is not appropriate due to intolerance or contraindications. Pioglitazone is useful where fasting sugars are known to be high.
 - Treatment should only be continued if HbA1c is reduced by at least 0.5% within 6 months of initiation.

EMA Guidance Pioglitazone: Risk of bladder cancer (July 2011) & MHRA Drug Safety Update (August 2011)

<http://www.mhra.gov.uk/Safetyinformation/DrugSafetyUpdate/CON125962>

The European Medicines Agency has advised that there is a small increased risk of bladder cancer associated with pioglitazone use. However, in patients who respond adequately to treatment, the benefits of pioglitazone continue to outweigh the risks.

Pioglitazone should not be used in patients with active bladder cancer or a past history of bladder cancer, or in those who have uninvestigated macroscopic haematuria. Elderly patients should be considered carefully before and during treatment with pioglitazone, using the lowest possible dose because of associated increased risks of bladder cancer and heart failure, which also increase with age.

Before initiating treatment with pioglitazone, patients should be assessed for risk factors of bladder cancer (including age, smoking status, exposure to certain occupational or chemotherapy agents, or previous radiation therapy to the pelvic region) and any macroscopic haematuria should be investigated. The safety and efficacy of pioglitazone should be reviewed

after 3–6 months and pioglitazone should be stopped in patients who do not respond adequately to treatment.

NICE guidance recommends pioglitazone should only be continued if there is a reduction in HbA1c of at least 0.5 percentage points in six months.

<http://www.nice.org.uk/cg87>

Patients already receiving treatment with pioglitazone should be assessed for risk factors of bladder cancer and treatment should be reviewed after 3–6 months, as above. Patients should be advised to report promptly any haematuria, dysuria, or urinary urgency during treatment.

BEXLEY GUIDANCE ON GLP-1 (GLUCAGON-LIKE PEPTIDE-1) RECEPTOR AGONISTS: EXENATIDE▼, LIRAGLUTIDE▼

- GLP-1 receptor agonists stimulate glucose dependent insulin secretion and suppress glucagon secretion in response to food. They also delay gastric emptying.
- They are given by subcutaneous injection and are associated with the prevention of weight gain and possible promotion of weight loss.
- There are currently two GLP-1 mimetics licensed in the UK; exenatide and liraglutide
- Exenatide▼ and Liraglutide▼ should only be initiated by suitably trained staff (In Bexley Tier 2, 3 and 4 accredited healthcare professionals and members of tier 1 healthcare professionals who have completed module one of the injectables training).
- Exenatide▼ and Liraglutide▼ are both licensed in combination with metformin or a sulphonylurea, or both, or with pioglitazone (only exenatide▼), or with both metformin and pioglitazone, in patients who have not achieved adequate glycaemic control with these drugs alone or in combination.

Exenatide▼ (NICE CG 87) and liraglutide▼ 1.2 m (NICE TA 203) are approved by NICE (triple therapy) when glycaemic control is inadequate with metformin and sulphonylurea **Or**

For liraglutide▼ (NICE TA 203) dual therapy in combination with metformin or a sulphonylurea **ONLY** if the patient is intolerant of / contraindications to either metformin / sulphonylurea **AND** the patient is intolerant of / contraindications to a thiazolidinedione and a DPP4 inhibitor.

Exenatide▼ and liraglutide▼ then should be considered if the patient meets the following criteria:

- HbA1c >53mmol/l (7.5%)
- A BMI of 35kg/m² or over and is of European descent (with appropriate adjustment for other ethnic groups) and weight-related psychological or medical problems **Or**
- A BMI of less than 35 kg/m², and insulin would be unacceptable for occupational reasons or weight loss would benefit other significant obesity-related co morbidities.
- Driving affects livelihood (See guidance from DVLA)
<http://www.dft.gov.uk/dvla/medical/ataglance.aspx>

In addition the following should also be considered:

- i) Contra-indication to Glitazone and maximum tolerated doses of dual therapy has not achieved target HbA1c and insulin would be the next step (Licensed use)
- ii) **Exceptional** cases where insulin is causing significant weight gain affecting HbA1c control or quality of life (Unlicensed use)

The initiating Clinicians are responsible for the ongoing management & audit requirements associated with exenatide and liraglutide for the **first 6 months** of treatment.

NICE recommends that the treatment should continue beyond 6 months only if the following apply:

- Continue exenatide▼ and liraglutide▼ 1.2 mg daily (triple therapy) only if the person has a reduction in HbA1c of at least (1%) and/or a weight loss of at least 3% of initial body weight within 6 months of starting treatment. (Following Evidence from ABCD)
- When liraglutide is used as dual therapy it should only be continued if the person has a reduction in HbA1c of at least (1%) at 6 months.
- If response is not seen as stated above within 6 months of therapy, the patient should be initiated onto a clinically appropriate insulin regime or suitable alternative, stopping the exenatide▼/liraglutide▼ therapy.

Conversely, there is limited evidence that exceptional cases (type 2 Diabetic patients only) where insulin is causing significant weight gain affecting HbA1c control or quality of life, a trial of exenatide▼ or liraglutide▼ after controlled reduction and stopping the insulin therapy may be clinically beneficial. These exceptional cases should be transferred onto exenatide▼ by a tier 3 or 4 clinician or specialist and monitored closely for benefit for at least six months.

Exenatide▼

- Exenatide▼ should not be used in people with Type 1 Diabetes & should not be used in Type 2 patients with known Beta Cell failure (SPC) i.e. where there is no insulin produced by the pancreas.
- A very common side effect of this treatment is nausea, an anti-emetic is **NOT** recommended if patient continues to experience nausea. 40-50% of patients initiated on this therapy experience one episode of nausea. Most episodes experienced by patients are mild to moderate with the frequency & severity decreasing on continued therapy. However, 4% of patients may stop this treatment due to intolerable nausea (SPC)
- There have been a number of Yellow Card reports relating to Acute Pancreatitis in patients using Exenatide▼. However, the available evidence suggests no increased incidence compared to the background incidence in patients with diabetes.

When initiating take into account past history of pancreatitis, active gall stone problems and excessive alcohol.

- Patients should be informed of the characteristic symptom of acute pancreatitis which is persistent, severe abdominal pain. Resolution of pancreatitis has been observed with supportive treatment. If pancreatitis is suspected, Exenatide and other potentially suspect medicinal products should be discontinued.
- No dosage adjustment of exenatide is necessary in patients with mild renal impairment (eGFR 60-89ml/min/1.73 metre squared). In patients with moderate renal impairment (eGFR 30-59ml/min/1.73 metre squared), dose escalation from 5 µg to 10 µg should proceed conservatively. Exenatide is not recommended for use in patients with end-stage renal disease or severe renal impairment (eGFR <29ml/min/1.73 metre squared))

- The EU marketing authorisation for a once-weekly exenatide▼ injection (Bydureon®) for the treatment of type 2 diabetes was approved in April 2011. In Bexley we are waiting for the Final NICE guidance to be published an update will then be circulated.
- In October 2011 NICE issued draft preliminary guidance (ACD) on prolonged release Exenatide▼ for type 2 diabetes, this can be viewed at: <http://guidance.nice.org.uk/TA/Wave22/0/Consultation/DraftGuidance>

Liraglutide▼

- Liraglutide▼ may be considered second line to exenatide if the patient has GI intolerance to exenatide▼ or if the patient cannot inject twice daily with dosing time restrictions i.e. a 60-minute period before the morning and evening meal (or two main meals of the day, approximately 6 hours or more apart).
- **Liraglutide▼ 1.8mg daily is not recommended for patients with type 2 diabetes (NICE TA 203).**
- Liraglutide is administered once a day by subcutaneous injection compared to twice a day for exenatide▼.
- Additional information for liraglutide▼; should not be used in patients with hepatic impairment and avoided if avoid if eGFR less than 60ml/minute/1.73m squared and heart failure (NYHA class III and IV).

DVLA Guidance

Please view the following link for guidance from the DVLA, updated September 2011 for patients with diabetes treated with medication, diet or both. <http://www.dft.gov.uk/dvla/medical/ataglance.aspx> and **Annex 3 Changes to Diabetes:** <http://www.dft.gov.uk/dvla/medical.aspx>

BEXLEY GUIDELINES FOR ADVANCED GP PRACTICES ON INSULIN REGIMES FOR PEOPLE WITH TYPE 2 DIABETES

*Patient has reached Step 4 on Bexley Type 2 Diabetes algorithm for blood glucose management and has not reached target on treatment, HbA1c >58mmol/ml (7.5%) on maximal tolerated oral therapy and/or a trial of Exenatide ▼ has failed or not been tolerated/not appropriate See Algorithm below

STEP A

Consider NPH Insulin (Isophane Insulin) taken at bedtime or twice daily according to need first line added to Metformin & Sulphonylurea (NICE Clinical guideline 66 May 2008) with rapid dose titration to target as discussed and agreed with the patient

N.B. It will be necessary to increase the insulin dose & intensify the regime over time, dependant on individual patient response

STEP B

Consider, as an alternative, using a long-acting insulin analogue (insulin Glargine or insulin Detemir) for a person who falls into one of the following categories:

- Those who require assistance from a carer or healthcare professional to administer their insulin injections
- Those whose lifestyle is significantly restricted by recurrent symptomatic hypoglycaemic episodes or nocturnal hypoglycaemia
- Those who would otherwise need twice-daily basal insulin injections in combination with oral glucose-lowering medications
- & as Step A rapid dose titration to target as discussed and agreed with the patient

STEP C

- Consider twice-daily biphasic human insulin (pre-mix) regimens in particular where HbA1c is elevated above 9.0%. A once-daily regimen may be an option when initiating this therapy
- Consider pre-mixed preparations of insulin analogues rather than pre-mixed human insulin preparations when:
 - immediate injection before a meal is preferred, or
 - hypoglycaemia is a problem, or
 - there are marked postprandial blood glucose excursions
- Monitor a person using pre-mixed insulin once or twice daily for the need for a further preprandial injection or for an eventual change to a mealtime plus basal insulin regimen, based on human or analogue insulins, if blood glucose control remains inadequate
- N.B. For patients on a sulphonylurea, consider stopping this therapy where a premix or basal bolus insulin regime is being initiated

Additional notes for Step A and Step B:

For people using a basal insulin regimen (NPH or long-acting insulin analogue), assess the need for mealtime insulin. If glycaemic control remains inadequate (not to agreed target levels without problematic hypoglycaemia), move to a more intensive mealtime plus basal insulin regimen using rapid acting or short acting insulins.

INSULIN SAFETY GUIDANCE – NATIONAL PATIENT SAFETY ASSOCIATION, JUNE 2010

The Rapid Response Report asks NHS organisations to ensure that:

- All regular and single insulin (bolus) doses are measured and administered using an insulin syringe or commercial insulin pen device (never using intravenous syringes);
- The term 'units' is used in all contexts. Abbreviations, such as 'U' or 'IU', are never used;
- A training programme is in place for all healthcare staff that are expected to prescribe, prepare and administer insulin;
- All clinical areas and community staff treating patients with insulin have adequate supplies of insulin syringes and subcutaneous needles.
- All Insulin should be prescribed by brand name to avoid confusion.

NHS Diabetes has developed an e-learning training course on the safer use of insulin to help healthcare professionals implement today's guidance.

Bexley recommend all healthcare professionals supporting people who use insulin, complete the course.

Visit the NHS Diabetes website:

http://www.diabetes.nhs.uk/safe_use_of_insulin

INSULIN PASSPORT INFORMATION – NATIONAL PATIENT SAFETY ASSOCIATION, JUNE 2011

The insulin passport was introduced in June 2011 by the National Patient Safety Agency and is aimed at empowering patients to take a more active role in their treatment to avoid being given the wrong insulin.

The passport is to be made available to every person using insulin. It will then be the choice of the individual patient whether they use it. The passport folds into a credit-card size and acts as a reference when insulin products are prescribed or dispensed and during emergencies.

When prescriptions of insulin are prescribed, dispensed or administered, healthcare professionals should cross-reference available information (which includes the insulin passport) to confirm the correct identity of insulin products.

For further information visit:

<http://www.nrls.npsa.nhs.uk/resources/type/alerts/?entryid45=130397>

For people already using insulin:

It will be the responsibility of the healthcare professional completing the patient's annual review to explain and distribute an insulin passport and the NPSA patient information booklet: Diabetes: insulin, use it safely

For people new to insulin:

It will be the responsibility of the healthcare professional supporting the patient when they initiate insulin to explain and distribute an insulin passport and the NPSA patient information booklet: Diabetes: insulin, use it safely

INSULIN THERAPY FURTHER INFORMATION:

(NICE guidance 66 May 08)

When other measures no longer achieve adequate blood glucose control (to HBA1c >58mmol/ml (7.5%) or other higher level agreed with the individual), discuss the benefits and risks of insulin therapy. Start insulin therapy if the person agrees.

When starting insulin therapy, use a structured programme employing active insulin dose titration that encompasses:

- structured education
- continuing telephone support
- dose titration to target
- dietary understanding
- management of hypoglycaemia
- management of acute changes in plasma glucose control
- support from an appropriately trained, accredited and experienced healthcare professional.
- frequent self-monitoring

Insulin delivery devices

Offer education to a person who requires insulin about using an injection device (usually a pen injector and cartridge or a disposable pen) that they and/or their carer find easy to use.

If a person has a manual or visual disability and requires insulin, offer a device or adaptation that:

- takes into account his or her individual needs
- he or she can use successfully.

Disposal of sharps from patient homes

Local arrangements should be in place for the disposal of sharps. (NICE 2008)

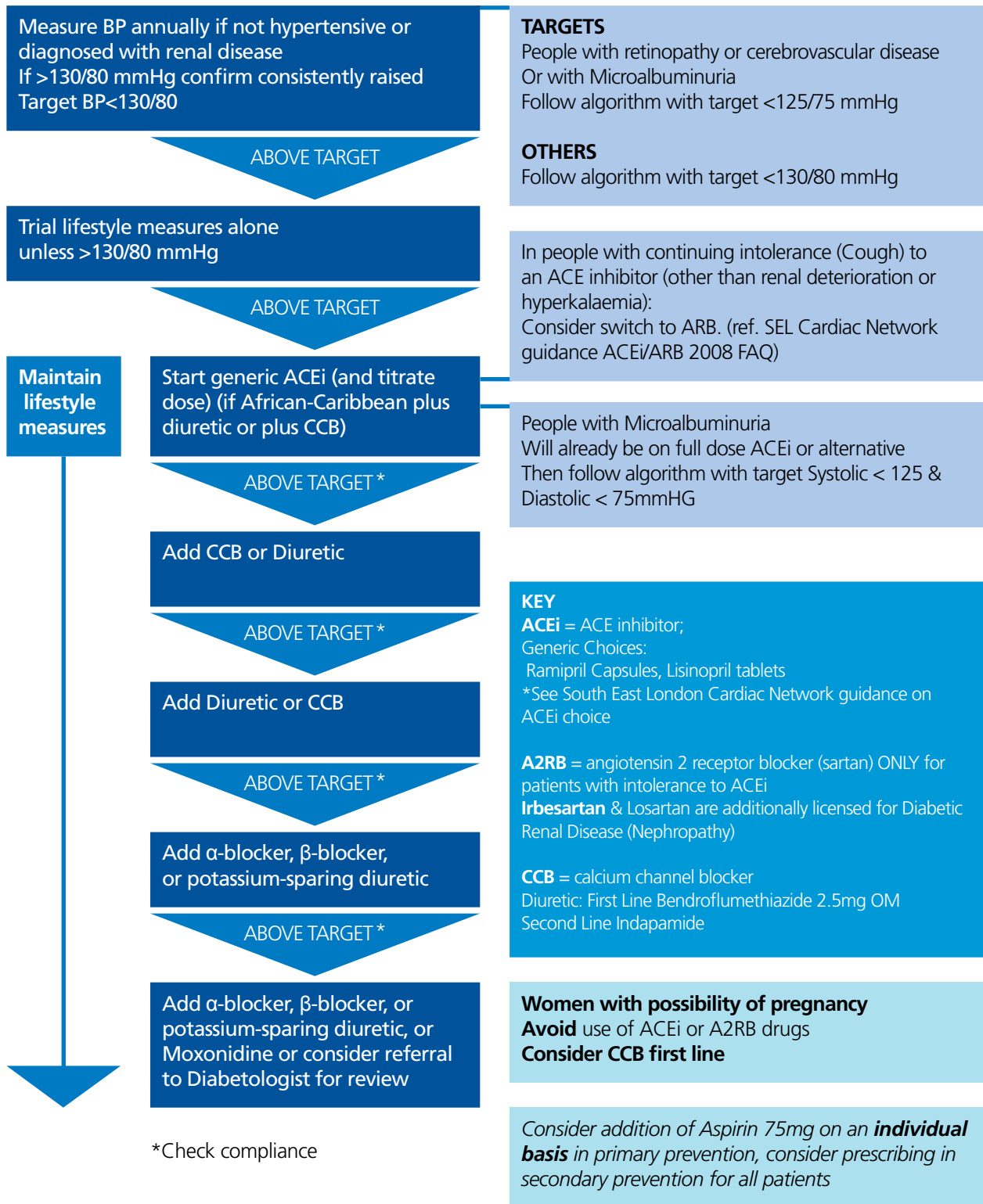
Patients should be provided with a sharps bin on FP10, and the Bexley Council CW2 form completed, and signed by the health professional. Bexley Council Waste services will collect full sharps bins from the patient's home address as necessary. *(N.B. the service should be cancelled if it is no longer required OR the patient moves to another location, in which case, a new form is required if they are still living within Bexley Council boundary)*

▶ **See Appendix 2, CW2 form**

For Guidance on Hypoglycemia in the Practice setting, please see Hypobox ® information/guidance in Appendix 7 of this guideline.

GUIDELINES FOR THE TREATMENT OF HYPERTENSION IN TYPE 2 DIABETES 2008

(Currently Under Review)



MANAGEMENT OF BLOOD LIPIDS IN TYPE 2 DIABETES

Patients diagnosed with Type 2 Diabetes aged over 40 are considered at High Risk to develop Cardiovascular Disease (CVD)
N.B. consider treating patients under 40 years after assessing their individual risk factors
Patients should be initiated on an appropriate treatment once all other modifiable risk factors have been assessed & appropriate measures put in place as clinically appropriate to each individual

N.B.: Poor Glycaemic control can affect lipid profiles.
Remember to exclude secondary causes of raised lipids i.e. familial or primary hyperlipidaemia, alcohol abuse, Hypothyroidism, renal failure, nephrosis, and cholestasis
Monitor LFT annually.

Encourage Fat Modified Diet, Optimise Glycaemic Control with intensive advice on:

- Weight Loss
- Diet
- Increased Physical Activity
- Smoking Cessation

See previous section 1.2 Lifestyle changes for more information

TARGETS:
NICE guidance CG66 & SL Cardiac & Stroke Network:
Total Cholesterol 4mmol/l and LDL cholesterol 2mmol/l

First Line: Simvastatin 40mg on, or if there are potential drug interactions or contraindications to the starting dose start either Simvastatin 20mg or offer Pravastatin at licensed doses.
Second Line: if treatment with Simvastatin 40mg fails to achieve target switch to Atorvastatin 40 mg and consider increasing to 80mg Adding Ezetimibe if targets are not reached.
Nice Lipid Modification May 08, Nice Type 2 Diabetes update C66

Follow national policy on prescribing statins
See SEL Cardiac Network information, (appendix 4 & 5, pages 33-36) for further guidance and target information

If Statins are not tolerated or contra-indicated:
Consider either a fibrate:
Bezalip 200mg TDS or
Bezalip mono 400mg OD
or
Fenofibrate 160mg OD
or
Ezetimibe alone (high cost)

Review targets after 3 months of therapy, increase dose if needed.
Check LFT 3 months, 6 months, 1 year and then annually
Check Creatinine Kinase if symptomatic
Assess CVD risk annually
If targets unmet in 12 months with Statin dose maximised, consider adjunctive therapy

Do not routinely offer Nicotinic acid or fish oil supplement or Fibrate in combination with a Statin (NICE 2008)

Referral to Diabetologist if patient has hypertriglyceridaemia for assessment & specialist treatment

Ref: NICE lipid modification clinical guideline 67 May 2008
www.nice.org.uk/Guidance/CG67, SEL Cardiac Network Statin Guidance 2009 (Appendix 4 & 5), NICE technology appraisal guidance 132
www.nice.org.uk/Guidance/TA132.

BEXLEY GUIDANCE ON DIABETIC SYMPTOMATIC NEUROPATHIC PAIN MANAGEMENT

At review appointments, discuss any newly occurring neuropathic symptoms, i.e. paraesthesiae, burning pains, shooting pains or other & record in notes as appropriate.

Assess severity if present & affect on individual's quality of life i.e. sleep disturbance, depression, affect on daily activities, and any medication already trialled. Check Blood glucose control & most recent HBA1c result and cardio vascular risk factors to look for poor control.

STEP 1

For the drug treatment of painful diabetic neuropathy

Offer Duloxetine as first-line treatment at 60 mg per day.

A lower starting dose may be appropriate for some people (for example, if tolerability is a problem).

Titrate upward to an effective dose or the person's maximum tolerated dose of no higher than 120 mg per day.

Or

Amitriptyline (off-label use)

Start with 25 mg at night (≥ 75 years old start with 10mg) and titrate up to 75 mg daily in weekly/fortnightly steps if tolerated.

Dosage higher than 75 mg daily should be considered in consultation with a specialist diabetes or pain service.

- Titrate the dosage according to response and tolerability.
- Continue the treatment if there is satisfactory improvement or refer if appropriate.
- Consider gradually reducing the dose over time if improvement is sustained.

STEP 2

If satisfactory pain reduction is not achieved with first-line drug treatment at the maximum tolerated dose

- If initially treated with Duloxetine: Switch to Amitriptyline or Pregabalin. N.B. Pregabalin may cause weight gain in some individuals so an adjustment of anti-diabetic therapy may be required
- Combine Duloxetine with Pregabalin
- If initially treated with Amitriptyline: switch to, or combine with, pregabalin
- Pregabalin: Start treatment at 150mg daily (in two divided doses). A lower starting dose may be appropriate for some (for example, people with reduced renal function). Titrate to an effective dose or the person's maximum tolerated dose of no higher than 600 MG per day (divided into two doses).

STEP 3

Step 3: If pain remains uncontrolled, consider referral to the specialist diabetes or pain clinic. A step up to Opiate pain relief as appropriate for each individual patient and psychological support would be advised on an individual basis.

While waiting for referral:

Consider a trial of tramadol, alone or in combination with second-line treatment. When used in combination therapy, tramadol should be prescribed as a rescue analgesic for breakthrough pain. Do not start treatment with opioids (such as morphine or oxycodone) other than tramadol without an assessment by a specialist pain service or a condition-specific service.

- Start with a dose of 50 to 100 mg not more often than every 4 hours.
- Titrate upward to an effective dose or the person's maximum tolerated dose, which should not exceed 400 mg daily.
- Consider a more conservative titration if tramadol is used in combination with other drugs for the treatment of neuropathic pain.

Consider topical lidocaine for treatment of localised pain for people who are unable to take oral medication because of medical conditions and/or disability. (Please note that Versatis® is currently only licensed for the symptomatic relief of neuropathic pain associated with previous herpes zoster infection (post-herpetic neuralgia, PHN).

Please see SPC for further information:

<http://www.medicines.org.uk/emc/>

Do not offer any other drug treatment unless started by a specialist. Specialist treatments may be continued in primary care under a multidisciplinary care plan or a local shared care agreement.

Consider referring the person at any stage (including at initial presentation and at regular clinical reviews) if any of the following apply:

- They have severe pain.
- Their pain significantly limits their daily activities and participation.
- Their underlying health condition has deteriorated.

For further information please refer to March 2010 NICE guideline CG96, Neuropathic pain: the pharmacological management of neuropathic pain in adults in nonspecialist settings:

<http://www.nice.org.uk/guidance/CG96>

N.B When neuropathic pain is uncontrolled; it is useful to discuss the reasons for the pain, with the affected individual patient to help them to cope, & the likelihood of remission on treatment and the importance of good compliance with all treatments for Diabetes to maintain good glycaemic control, acceptable lipid levels and blood pressure.

TESTING GUIDANCE FOR PROTEINURIA IN TYPE 2 DIABETIC PATIENTS

Microalbuminuria Screening

Albumin/Creatinine Ratio (ACR) is now the **only** urine screen used in Bexley to determine the quantity of protein in urine for people with diabetes, with or without a history of nephropathy.

NORMAL RANGE OF MICROALBUMINURIA

ACR \leq 2.5mg/mmol for men

ACR \leq 3.5 mg/mmol for women

STEP 1

Collect urine specimen
First pass urine sample ideal but not essential

STEP 2

Dipstick urine
Dipstick should highlight other parameters: ketones, blood

STEP 3

Send appropriate sample

Past history of proteinuria	Dipstick indicates negative protein	Dipstick indicates trace or more protein, no past history of proteinuria
Send for ACR	Send for ACR	Collect MSU and screen for UTI
		Once discounted or treated UTI, send for ACR

STEP 4

Review result

Past History of proteinuria and result remains above normal range	Result within normal range	Result of ACR outside normal range for first time
Looking at quantification and comparison to previous years.	Repeat annually	Send 2 more samples within a 1-month period. If 2 out of 3 results outside normal range initiate treatment

STEP 5

Ensure appropriate treatment is started and/or titrated/monitored. See treatment guidance on page 28

STEP 6

Repeat Microalbuminuria Screening once a year

Ref: NICE guidance on Chronic Kidney Disease September 2008 & NICE guidance for Type 2 Diabetes May 2008 www.nice.org.uk/Guidance/CG73.

Estimated Glomerular Filtration Rate (eGFR) Screening

eGFR

- A calculation using the following variables: Creatinine, age, sex
- Forms the basis for the classification and management of CKD
- Ethnicity should be factored by the clinician by multiplying the result by 1.212 in people of African-Caribbean origin

STAGE	eGFR result	Severity of CKD	Typical testing frequency	Team responsible for care pathway and ongoing testing
1	≥ 90	Normal	12 monthly	Practice diabetes team
2	60 - 89	Mild impairment		
3A	45 - 59	Moderate impairment	6 monthly*	
3B	30 - 44			
4	15 - 29	Severe impairment	3 monthly	Joint Diabetologist / Renal team
5	< 15	Established renal failure	6 weekly	Renal team

To identify progressive CKD

- Obtain a minimum of 3 GFR over a period of not less than 90 days
- In people with a new finding of GFR of <60, repeat within 2 weeks to exclude causes of acute deterioration eg UTI, Initiation of ACEI/ARB etc

Definition of progressive CKD

DROP IN EGFR > 5 IN 1 YEAR

DROP IN EGFR > 10 IN 5 YEARS

Consider referring patients with CKD 3b for assessment to joint Diabetologist / Renal team clinic

Refer patients with progressive CKD if: proteinuria or raised ACR are absent or having resistant hypertension.

Treatment for CKD

Including stage 3/4 eGFR and/or above normal ACR.

CONSIDER	ACTION
Medication	ACE inhibitor (or ARB if known tolerance). Titrate to maximum tolerated dose for greatest protection Metformin should be stopped: stage 4 CKD (eGFR <30)
Tighter BP target and aggressive treatment to achieve target	Local target < 125/75 Follow Hypertensive guidelines
Tighten all aspects of diabetes control	Review lipids, HbA1c, smoking status, retinopathy

REFERENCES:

NICE TA23 October 2010 Liraglutide for the treatment of type 2 diabetes Mellitus

SPC Bydureon®

SPC Trajenta®

SPC Onglyza ®

SPC Victoza®

Type 2 Diabetes Guidelines For Wandsworth

Type 2 Diabetes Guidelines For Bromley

NICE CG96 March 2010 Treatment Guidelines For Neuropathic pain - pharmacological management

NICE guidance 87 May 2009 Type 2 Diabetes –newer agents update

NICE guidance 66 May 2008 Type 2 Diabetes – the management of Type 2 Diabetes

NICE guidance May 2008 Lipid Modification

Scottish Medicines Consortium guidance : 408/07 Sitagliptin▼, 435/07 Vildagliptin▼, 367/07 Exenatide▼

UKMi new medicine profile Exenatide▼ May 2007, 7/06

NPC prescribing guidance on Diabetes Mellitus

National Diabetes Support team website

Diabetes UK website

REFERENCES CONT'

South East London Cardiac Network guidance on Cholesterol & Statins 2008, and update 2009

South East London Cardiac Network guidance on prescribing ACE1 and ARBs (Sartans) 3.6.2008

NICE guidance 2006 TA94 Cardiovascular disease-Statins

Martin S. et al., 2006, Diabetologia, Self-monitoring of blood glucose in type 2 diabetes and long-term outcome: an epidemiological cohort study, 2006; 49: 271-278

NICE, 2004, Guidelines for the diagnosis and management of Type 1 diabetes in children, young people and adults. Guideline Number 15. July 2004

NICE Clinical Guidance, 2002, Management of Type 2 diabetes: management of blood glucose. September 2002

The National Collaborating Centre for Chronic Conditions, written on behalf of NICE (draft for consultation), 2007, Type 2 diabetes (Update): National clinical guidelines for the management in primary and secondary care, September 2007

Diabetes UK, Care Recommendations: Self-monitoring of blood glucose, December 2006

Global guidelines for Type 2 Diabetes (<http://www.idf.org>)

Kent & Medway prescribing guidelines on Exenatide▼& Sitagliptin▼, 2008

Kent & Medway Shared Care agreement for Exenatide▼

Enfield PCT Diabetes care pathway

Nottingham Diabetes Guidelines

Yorkshire Diabetes Guidelines

SIGN guidance

West Suffolk Diabetes guidelines

SPC Byetta ®

SPC Januvia ®

SPC Galvus ®

SPC Glucophage ®

DVLA medical rules for drivers With Diabetes:

At A Glance Guide to the current Medical Standards of Fitness to Drive

<http://www.dft.gov.uk/dvla/medical/ataglance.aspx>

Annex 3 Changes to Diabetes

<http://www.dft.gov.uk/dvla/medical.aspx>

NICE guidance 73 Chronic Kidney Disease September 2008

NICE guidance 43 Obesity

APPENDIX 1

Current Short Walks Programme

Contact Charlene Williams: 0208 298 6265,
email: charlene.williams@bexley.nhs.uk

From easy to brisk and short to long, the walks are open to everyone, whatever, age, ability and aims.

Health walks

As well as being practical and free, walking is a fantastic form of exercise. It is enjoyable, easy and accessible, regardless of your age, fitness level or lifestyle. Bexley Business Support Unit, NHS South East London offer a series of healthy walks, each led by a trained walk leader.

Short walks – 30 to 45 minutes

Tuesdays, 9am from Lyndhurst Road Surgery, Barnehurst

Each week the walk takes in one of four different routes including, **Bursted Woods, Marten's Grove and Russell Park**. The walk ends at Chapel Hall, where tea and coffee is available.

Fridays, 10.30am from the Stables car park around **Danson Park**

This walk takes a circular route around the lake. This route can be a little muddy in the winter and involves mild inclines.

Saturdays, 10am, from Welling Medical Practice around **Danson Park**

Meet outside the practice front entrance (2 Danson Crescent, Welling) looking at the English gardens at Danson House and the nature reserve. This walk has a slight incline leading up to the park entrance.

Intermediate walks – 45 to 60 minutes

Mondays, 10.30am, from Fox House (off Erith Road, near the fire station)

The walk through **Franks Park** in Belvedere over grass, gravel and trodden mud paths can be slippery in the winter and when wet. This walk also includes a steep incline, up and down.

Wednesdays, 10.30am – approximately 50 minutes from Five Arches, by the Parsonage Lane Bus stop, Leafield Lane/North Cray Road junction.

This 2.25 mile walk through **Cray Meadows** can be muddy during winter – walking boots are recommended. The walk ends at the White Cross for tea and coffee.

Tuesdays, 10.30am – 45 to 60 minutes from Bostall Heath car park (Longleigh Lane)

The walk around **Bostall Woods**, through ancient woodland has a number of routes along gradient woodland trails. Sturdy footwear recommended.

Mondays, 10.30am – 80 minutes from Riverdale Road This 4.5 mile brisk, riverside walk follows a path along **River Shuttle**. Stopping halfway at the Oval for refreshments, this walk along flat paths, can be muddy when wet.

APPENDIX 2

Request for household clinical waste collection

Private & Confidential (cw2)

Contact Centre
Civic Offices
Bexley Council
Broadway
Bexleyheath
Kent DA6 7LB

I write to make a request for the collection of household clinical waste by Bexley Council.

Name of Client

Address of Client

Telephone Number

Waste Description

SHARPSBIN

Day of Collection*

*(to be supplied by Bexley Council)

Estimated Duration

A Doctor, Nurse or Pharmacist must sign all requests.

Signed

Date

Print name

Designation



Cancellation of household clinical waste collection

Name of Client

Date

Address of Client

Signed

Print name

Send Cancellation via Contact Centre (above)

APPENDIX 3

Treatment Groups & Monitoring recommendations (SMBG=Self Monitoring of Blood Glucose)

DIABETES TREATMENT GROUP	TYPE OF TESTING RECOMMENDED	FREQUENCY GUIDE All people who chose to SMBG should have full support, education & training in the use of their meter & strips, how to calibrate their meter, how and when to make records, & when it is important to see medical help
Type 1 Diabetes (adult or child) INSULIN USERS (Please refer to Driving Section in Special Circumstances)	<p>SMBG should be an integral part of the treatment.</p> <p>HbA1c should be used as an outcome measure alongside SMBG.</p>	<p>SMBG:</p> <ul style="list-style-type: none"> Up to 4 tests a day is sufficient for most people. Up to 6 tests a day may be required during periods of instability, illness, dialysis, impaired awareness of hypoglycaemia 4 - 6 tests per day should be encouraged for people using insulin pumps, more frequently during establishment of therapy, instability and illness For individuals who dislike testing routinely, a glucose profile is a useful education/ problem solving tool, especially prior to a review appointment Example: 2 – 6 tests per day at varying times pre and post meals for 1 –2 weeks <p>HbA1c: measured every 3 to 6 months depending on level and stability of control.</p>
Type 2 Diabetes using a multiple insulin regimen (3 or more injections per day)	As Type 1 Diabetes above	As Type 1 Diabetes above, excluding insulin pump therapy
Type 2 Diabetes using Once or Twice daily insulin regimen +/- oral Antidiabetic therapy	<p>SMBG should be an integral part of treatment with Insulin</p> <p>HbA1c should be used as an outcome measure alongside SMBG</p>	<p>SMBG:</p> <ul style="list-style-type: none"> When starting insulin, twice daily SMBG is a useful education tool to help assess diabetes control and allow dose titration. It also offers reassurance to the individual. This should be carried out at varied times, fasting, pre & post meal, to identify trends. (Fasting should always be included during basal insulin titration). Once stable, testing can be reduced to once daily at varying times See special circumstances on page 3 For individuals who dislike testing routinely, a glucose profile is a useful education and problem solving tool, especially prior to a review appointment Example: 2 – 4 tests per day at varying times pre and post meals for 1 -2 weeks <p>HbA1c: measured every 3 to 6 months depending on level and stability of control.</p>

APPENDIX 3 (CONTD.)

<p>Type 2 Diabetes: Sulphonylureas alone or in combination with other oral Antidiabetics</p> <p>(Please refer to Driving Section in Special Circumstances)</p>	<p>SMBG should be an integral part of treatment due to the risk of hypoglycaemia</p> <p>HbA1c should be used as an outcome measure alongside SMBG</p>	<p>SMBG should be used:</p> <ul style="list-style-type: none"> • At least 3 times a week once stable, at varying times of the day, fasting, pre & post meals to identify trends. Testing may need to be increased during dose titration • If hypoglycaemia is suspected. It is important to encourage testing at the time the person feels “unwell” or suspects hypoglycaemia • More frequently 2 weeks prior to a review with HbA1c result to help identify problems • During physical activity or during changes of routine • See special circumstances on page 3 <p>HbA1c should be measured 6 monthly routinely. 3 monthly if unstable and/or changing treatment</p>
<p>Type 2 Diabetes: Healthy eating and physical activity with or without additional Metformin +/- Glitazone or other oral Antidiabetic agents</p>	<p>HbA1c provides a reliable and sufficient means of monitoring glycaemic control</p> <p>(SMBG is not usually necessary and should not be carried out routinely.)</p>	<p>HbA1c should be measured 6 monthly. 3-monthly if unstable and/or changing treatment</p> <p>SMBG is not a routine requirement. However, there may be times when SMBG is necessary:</p> <ul style="list-style-type: none"> • As an education tool, to learn about the effect of lifestyle changes. People who prefer to SMBG to proactively review and inform lifestyle changes should be encouraged to do so. • If HbA1c is suboptimal, SMBG can be used to identify problems and inform treatment • 2 weeks prior to review with HbA1c result to help identify problems • see special circumstances page 3 (excluding driving as hypoglycaemia is not associated) <p>In all the above situations, a short, intensive period of testing at various times during the day, pre and 2-hours post meals, is often more beneficial than routine testing. (NICE 2008)</p> <p>Blood Glucose Strips can be prescribed on an Acute prescription as required</p>
<p>Pre-pregnancy and pregnancy:</p> <ul style="list-style-type: none"> • Women with pre-existing type 1 or type 2 diabetes • Gestational diabetes 	<p>SMBG is an essential part of treatment, to help prevent adverse foetal outcomes and minimised both hyper & hypoglycaemia HbA1c essential as an outcome measure, used alongside SMBG</p>	<p>SMBG should be carried out at least four times per day at varying times to include fasting, pre & 1-hour post meal. N.B. In the first trimester, it may be necessary to test more than four times a day as this is when the hypoglycaemic risk is highest</p> <p>HbA1c should be measured 2-3 monthly</p>

APPENDIX 3 (CONTD.)

Special Circumstances:

Illness	SMBG is an essential part of treatment	People should be taught the “sick day rules” and understand the need to test more frequently when there is a concurrent illness in addition to their diabetes.
Concurrent steroid treatment	SMBG is an essential part of treatment HbA1c essential as an outcome measure alongside SMBG	Oral steroids will affect the level of glucose in the blood. SMBG is necessary while taking steroid medication, usually twice daily until the blood level stabilised. An individual plan for testing should be discussed between the patient and their Healthcare professional prior to starting the course of steroids where possible dose adjustments of current diabetes treatment may be necessary and/or the addition of new medication. HbA1c should be monitored 3 monthly during steroid treatment
Group 2 (LGV/PCV) drivers who start Insulin Regulations Came into Effect November 13th 2011	SMBG is essential for people who drive & use Insulin to control their Diabetes	Group 2 (LGV/PCV) drivers with diabetes mellitus who switch from tablets to insulin: http://www.dft.gov.uk/dvla/medical/Group%202%20drivers%20with%20diabetes%20mellitus%20who%20m%20tablets%20to%20insulin.aspx These drivers are required to notify DVLA when they start insulin and stop driving Group 2 vehicles. They of blood glucose readings on insulin before they can be assessed for fitness to drive a Group 2 vehicle. readings must be available on a glucose meter with a memory function to measure and record blood glucose required to test at least twice daily and at times relevant to driving.
Driving if treated with insulin or oral hypoglycaemic agents meeting DVLA regulations http://www.dvla.gov.uk/media/pdf/medical/aagv1.pdf See DVLA “At a Glance” guide for Medical practitioners & appendices DIABINF & INF18812 for more detail from webpage above	SMBG is essential for people who drive & use Insulin to control their Diabetes	SMBG is recommended for Insulin users: Before driving and regularly during a long drive (at least 2-hourly) <ul style="list-style-type: none"> • The meter used should be timed and dated accurately and have a large memory capacity • If involved in a car accident, the driver should test their blood glucose at that time, as evidence of their blood glucose level • There should be NO evidence of a hypoglycaemia requiring medical assistance in the 12 months prior to obtaining the license. At the annual review, drivers must provide evidence of 3 months records of SMBG for the period prior to their annual review appointment. Impaired awareness of hypoglycaemia is a legal requirement to stop driving • People on oral hypoglycaemic agents who drive regularly and suspect hypoglycaemia
People requiring District Nurses (D/N) to administer their insulin	Blood Glucose monitoring by D/N	<ul style="list-style-type: none"> • For the D/N to test the person’s blood glucose prior to administering insulin and record result • To ensure the patient’s meter (if used) or their own meter, is quality controlled in accordance with local guidelines

APPENDIX 3 (CONTD.)

References for monitoring guidelines

NICE guidance May 2008 Update for Type 2 Diabetes

Diabetes UK, Care Recommendations: Self-monitoring of blood glucose, December 2006

Diabetes UK Position Statement, Self-monitoring of blood glucose using urine or blood glucose testing. November 2006

Diabetes UK, Driving and Diabetes, May 2005

DVLA, For Medical Practitioners: At a glance to the current medical standards of fitness to drive, Drivers medical Group, DVLA, September 2007.
(<http://www.dvla.gov.uk/media/pdf/medical/aagv1.pdf>)

Farmer A. et al., 2007, British Medical Journal, Impact of self-monitoring of blood glucose in the management of patients with non-insulin treated diabetes: open parallel group randomised trial, 2007; 335:132 (21 July)

Martin S. et al., 2006, Diabetologia, Self-monitoring of blood glucose in type 2 diabetes and long-term outcome: an epidemiological cohort study, 2006; 49: 271-278

NICE, 2004, Guidelines for the diagnosis and management of Type 1 diabetes in children, young people and adults. Guideline Number 15. July 2004

NICE Clinical Guidance, 2002, Management of Type 2 diabetes: management of blood glucose. September 2002

Owens D. et al., 2004 Blood Glucose self-monitoring in type 1 and type 2 diabetes: reaching a multidisciplinary consensus, Diabetes and Primary Care, 2004; Volume 6(1): 8-16

The National Collaborating Centre for Chronic Conditions, written on behalf of NICE(draft for consultation), 2007, Type 2 diabetes (Update): National clinical guidelines for the management in primary and secondary care, September 2007

APPENDIX 4

South London Cardiac Networks Guidance on Lipid

This guidance represents the consensus view of the South London Cardiac and Stroke Network Cardiac Prescribing Forum. The guidance does not, however, override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

LIFESTYLE ADVICE AND BLOOD PRESSURE CONTROL

The following lifestyle issues should be addressed alongside consideration of statin therapy:

- Smoking cessation
- Diet (reduce saturated fats, include Mediterranean diet and oily fish twice a week, aim for body mass index (BMI) of 19 – 25kg/m², or a minimum of a 10% reduction in body weight)
- Alcohol moderation to within safe limits (up to 21 units per week for men and 14 units per week for women)
- Exercise (aim for a total of 30 minutes of moderate intensity physical activity (eg, brisk walking) at least 5x a week)

Blood pressure control - Treat if BP consistently over 140/90mmHg to achieve a BP of less than 140/90mmHg; more aggressive targets apply in patients with chronic kidney disease and diabetes

Management for Secondary Prevention of Cardiovascular Disease

To include all patient with diabetes (>40 years old)

LIFESTYLE ADVICE AND BLOOD PRESSURE CONTROL

Initiating Therapy Initiate a statin in all patients with a diagnosis of cardiovascular disease or other atherosclerotic vascular disease (such as ischaemic stroke or peripheral vascular disease) or diabetes (>40 years old)

First line choice: Simvastatin Initiate at a dose of 40mg* with the evening meal.

The dose may be reduced in the event of intolerance.

*Max dose 10mg daily with concomitant ciclosporin, danazol, fibrates or lipid-lowering dose of niacin; max dose 20mg daily with concomitant amiodarone or verapamil; max dose 40mg with concomitant diltiazem

Where simvastatin 40mg is contraindicated or not tolerated, initiate a lower dose of simvastatin or consider pravastatin 40mg daily as an alternative agent

Next Steps

- Repeat fasting lipid levels within three months of initiation
- In patients not achieving a total cholesterol \leq 4mmol/L or LDL cholesterol \leq 2mmol/L on simvastatin 40mg daily: 1. Reinforce lifestyle issues and check adherence to medication 2. NICE currently recommends increasing the simvastatin dose to 80mg daily as the next step 3. If this is ineffective or not tolerated, consider switching to atorvastatin 40mg daily and increasing to 80mg daily Note: Any decision to increase the intensity of statin therapy should take into account informed preference, co-morbidities, multiple drug therapy and the benefits and risks of treatment
- In line with NICE TA 132, ezetimibe 10mg daily can be considered as an adjunct in patients failing to achieve cholesterol treatment targets despite maximal statin doses, or where higher statin doses are not tolerated, although the efficacy of ezetimibe in protecting against CV events and its long-term safety is not yet established
- For secondary prevention, all patients should be treated to achieve at least a total cholesterol \leq 5mmol/L and LDL cholesterol \leq 3mmol/L and preferably to achieve a total cholesterol \leq 4 mmol/L or LDL-C \leq 2mmol/L. (Bear in mind, less than 50% of patients up-titrated on statin therapy will achieve levels of 4 &/or 2mmol/L).
- If statin therapy is contraindicated or not tolerated, consider offering a fibrate, nicotinic acid, anion exchange resin or ezetimibe as an alternative
- If total cholesterol remains raised after intensifying therapy - consider referral for specialist advice
- Patients should be reviewed annually, with lipid monitoring, to check efficacy and on-going adherence to therapy

APPENDIX 4 (CONTD.)

For more information on contraindications and cautions to statin therapies, common drug interactions with statins and for guidance on safety monitoring – see SLCSN Guidance on Prescribing Statin Therapies

References

1. NICE Clinical Guideline CG43: Obesity. December 2006
2. NICE Clinical Guideline 66 (2008) Type 2 Diabetes
3. NICE Guidance CG15: Type 1 diabetes in children, young people and adults. July 2004
4. NICE Technology Appraisal 94: Statins for the prevention of cardiovascular events. January 2006
5. NICE Clinical Guideline 67 (2008) Lipid Modification Cardiovascular risk assessment and the modification of blood lipids for the primary and secondary prevention of cardiovascular disease.

Management of Lipids for Secondary Prevention Treatment Algorithm

This algorithm applies to all patients with known CVD or other atherosclerotic vascular disease, such as PVD; except those with familial hyperlipidaemia

Identify and address all modifiable risk factors: Smoking, diet, alcohol intake, BP control and physical activity

- Offer SIMVASTATIN 40mg daily
- If there are potential drug interactions or 40mg simvastatin is contraindicated, offer a lower dose of simvastatin or pravastatin

- Repeat fasting lipid profile at 3 months
- In patients not achieving a total cholesterol < 4mmol/L and LDL cholesterol < 2mmol/L on simvastatin 40mg daily:
 - Reinforce lifestyle issues and check adherence to medication
 - If this is ineffective or not tolerated, consider switching to atorvastatin 40mg to 80mg daily or adding ezetimibe 10mg daily in line with NICE TA 132
- For secondary prevention, all patients should be treated to achieve at least a total cholesterol \leq 5mmol/L and LDL cholesterol \leq 3mmol/L and preferably to achieve a total cholesterol \leq 4 mmol/l or LDL-C \leq 2mmol/L

Routine safety and efficacy monitoring should be undertaken – see SELCSN Guidance on Prescribing Statin Therapies Patients should be reviewed annually, with lipid monitoring, to check efficacy and on-going compliance with therapy Lifestyle issues should be regularly revisited

If statin therapy is contraindicated or not tolerated, consider offering a fibrate, nicotinic acid, anion exchange resin or ezetimibe as an alternative.

APPENDIX 5

SLCSN Safe Prescribing of Statins

Agreed by SEL Cardiac Prescribing Forum on 28th Jan 2009 and SWL Cardiac Prescribing Forum on 24th Feb 2009.
Review date: April 2011

Guidance on Prescribing Statins SELCN

The following issues need to be considered when prescribing a statin:

- Identifying patients in whom additional advice should be sought prior to initiation
- Contraindications and cautions
- Drug interactions
- Baseline and follow up monitoring

Seek further advice before initiating statins in patients with:

- Renal impairment (Cr >180µmol/l; CrCl<30ml/min)
- Liver disease (cirrhosis or hepatitis)
- Untreated hypothyroidism

General Contraindications and Cautions

- Hypersensitivity to the individual statin or to any of the excipients
- Active liver disease (AST or ALT level > 100iu/L) or unexplained persistent isolated elevations of serum transaminases
- Statin use is contraindicated in both pregnancy and lactation. Consideration should be given to delaying statin therapy or addressing contraceptive needs in women of child-bearing age
- Concomitant use of fibrates and statins increases the risk of muscle toxicity. Seek specialist advice. The co-administration of statins and nicotinic acid should be used with caution
- Patients with excess alcohol intake (more than 50 units per week)

SIMVASTATIN (see SPC for full detail)

In patients with severe renal insufficiency (creatinine clearance < 30 ml/min), dosages above 10 mg/day should be carefully considered and, if deemed necessary, implemented cautiously. Significant drug interactions occur with certain drugs (e.g. amiodarone, verapamil, diltiazem, erythromycin, clarithromycin, ciclosporin, itraconazole, ketoconazole, HIV protease inhibitors, nefazodone, ciclosporin). Dose reductions or cessation of therapy may be required – see FAQ / BNF for more

details. Consider an alternative agent if necessary.

- Advise patients to avoid consumption of grapefruit or grapefruit juice during simvastatin therapy
- International normalised ratio (INR) in patients on warfarin can be affected by concomitant simvastatin use. Monitor INR in patients before and more frequently during the early phase of treatment with simvastatin and after any dose changes

ATORVASTATIN (see SPC for full detail)

- For patients with prior haemorrhagic stroke or lacunar infarct the balance of risks and benefits of atorvastatin 80 mg is uncertain and the potential risk of haemorrhagic stroke should be carefully considered before initiating this dose
- For patients on interacting drugs, a lower starting dose may be required and lower maximum doses may need to be considered. Interacting drugs include ciclosporin, clarithromycin, diltiazem, amiodarone and verapamil, itraconazole, protease inhibitors - see BNF/ SPC for more details
- Concomitant intake of large quantities of grapefruit juice and atorvastatin is not recommended
- International normalised ratio (INR) in patients on warfarin can be affected by concomitant atorvastatin use. Monitor INR in patients before and more frequently during the early phase of treatment with atorvastatin and after any dose changes

PRAVASTATIN (see SPC for full detail)

- Caution should be exercised where pravastatin is prescribed for patients treated with erythromycin or clarithromycin
- Start with a dose of 10mg daily in patients with creatinine clearance < 20ml/min
- SLCSN Safe Prescribing of Statins

Agreed by SEL Cardiac Prescribing Forum on 28th Jan 2009 and SWL Cardiac Prescribing Forum on 24th Feb 2009. Review date: April 2011.

APPENDIX 5 (CONTD.)

Monitoring Statin Therapy

Lipid Levels

Total cholesterol (TC)
High density lipoprotein (HDL)
Low density lipoprotein (LDL)
Triglycerides

Secondary Prevention

Lipid levels should be measured before therapy is initiated; at 12 weeks following initiation or change of dose and at 12 monthly intervals thereafter
If total cholesterol remains persistently raised despite optimising statin therapy – follow local guidance.

Thyroid Function Tests

Check before initiating a statin to exclude hypothyroidism.

Liver Function Tests (LFTs)

Baseline liver enzymes should be measured before starting a statin. Liver function (transaminases) should be measured within 3 months of starting treatment and at 12 monthly intervals thereafter. If transaminases >3x upper limit of normal (ULN) discontinue statin and refer. For lesser increases in transaminases, which remain elevated at 6 months consider specialist advice.

Creatine kinase (CK)

Baseline CK should be measured before starting a statin. Routine CK monitoring after initiation is not recommended. CK should be measured during treatment when clinically indicated – i.e. where there are symptoms of muscle pain or tenderness, muscle weakness or muscle cramps.

Patients should be counselled on initiation of statin to report any usual muscle pain, tenderness or weakness during treatment.

IF MYOSITIS IS PRESENT OR SUSPECTED DISCONTINUE IMMEDIATELY

If muscle soreness occurs:

- Rule out common causes (e.g. exercise)
- Check TFTs (hypothyroidism predisposes to myopathy)
- Measure CK
- If CK elevated > 5 x ULN stop and seek advice
- If CK elevated < 5 x ULN
 - Monitor carefully by repeating CK level in one month
 - If remains elevated, reduce dose and recheck CK level in one month
 - If still remains elevated consider seeking advice
- If symptoms continue STOP statin and consult a specialist before re-initiating
- Note: Some Black African and Caribbeans have elevated baseline levels of CK. This is
- not a contra-indication to statin therapy. In these patients, after initiation if the CK > 5 x
- baseline - seek advice

Other adverse effects

Headache, dyspepsia or insomnia. Evaluate symptoms at each visit.

If symptoms not tolerated:

- Consider changing time of dose (after food if nauseous, morning if sleep disturbed)
- Consider decreasing dose
- Consider using an alternative agent

References

1. Pasternak RC, Smith SC, Bairey-Merz CN, et al., ACC/AHA/NHLBI Clinical Advisory on the Use and Safety of Statins. *Circulation* 2002; 106:1024 – 1028
2. Summary of Product Characteristics for Simvastatin at www.emc.medicines.org.uk (accessed 23/01/2006)
3. NICE Technology Appraisal 94: Statins for the prevention of cardiovascular events. January 2006
4. NICE Technology Appraisal 94: Statins for the prevention of cardiovascular events. January 2006
5. NICE Clinical Guideline 67 (2008) Lipid Modification Cardiovascular risk assessment and the modification of blood lipids for the primary and secondary prevention of cardiovascular disease

APPENDIX 6

HYPO BOX

Treatment of Hypoglycaemia - Primary Care

Hypoglycaemia is a blood glucose of 4 mmol/L or less. Wherever possible, check blood glucose level prior to treatment. If patient asymptomatic, repeat test.

	4 mmol/L	3 mmol/L	2 mmol/L	1 mmol/L
STEP 1	MILD Patient conscious and able to swallow Trembling, sweating, hungry, tingling, headache, anxiety, palpitations, nausea, forgetfulness	MODERATE Patient conscious and able to swallow, but in need of assistance Difficulty concentrating, confusion, weakness, giddiness, drowsiness, unsteady, headache, dizziness, difficulty focusing and speaking		SEVERE Patient unconscious and unable to swallow Fitting
	Administer 10g-20g fast acting glucose* 3-5 x GlucoTabs (4g glucose per tablet) or 1 x 59ml bottle of GlucoJuice	Administer 1-2 tubes of GlucoGel*/** (10g glucose per tube) Ensure gag reflex is present		Call for emergency assistance if required, or if hypo caused by antidiabetic drugs Check airways Place patient in recovery position intramuscular injection of Glucagon 1mg (Children weighing less than 25kg - 500 micrograms)
STEP 2	Wait 15 minutes and recheck glucose levels, and record If reading is still below 4 mmol/L, or if no physical improvement, repeat STEP 1			Once patient is conscious, give sips of GlucoJuice Recheck glucose level every 15 minutes to ensure increase to at least 4 mmol/L
ALWAYS FOLLOW UP WITH A SLOWLY DIGESTED/STARCHY CARBOHYDRATE Check glucose level. Once it is at 4 mmol/L or over and patient is recovered, eat a minimum of 15g slowly digested/starchy carbohydrate. Eg: 1 x slice/sandwich of low GI bread (ideally multigrain or granary); two digestive biscuits, glass of milk, banana, small carton of fruit juice. Recheck glucose levels after 15 minutes. NOTE: Insulin should NEVER be omitted following and episode of hypoglycaemia				

*British National Formulary, 2007

**Type 1 Diabetes: Diagnosis and Management of Type 1 Diabetes in children, young people and adults. NICE Clinical Guideline No. 15, July 2004.



Please ensure that you check the best before end dates on each of the enclosed products and replenish as necessary.

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