

Our Ref: DC/NB

9<sup>th</sup> August 2022

To: Prescribing Clinicians and Pharmacists within the Barnsley locality

Dear Colleague

**Re: Summary of Key Points from the Area Prescribing Committee Meeting on 13<sup>th</sup> July 2022**

The main outcomes of the meetings were: -

### **Prescribing Guidelines**

The Committee endorsed the following prescribing guidelines:

#### **Barnsley Lipid Management for Primary Prevention of Cardiovascular Disease (CVD) in Adults guidance [NEW] and Barnsley Severe Hyperlipidaemia Pathway [NEW]**

These guidelines, which have been enclosed with this memo, have been adapted for Barnsley from the [NHS Accelerated Access Collaborative Summary of National Guidance for Lipid Management for Primary and Secondary Prevention of CVD](#). Barnsley guidance on lipid management for secondary prevention of CVD in adults is in development.

Templates for the GP clinical systems will be developed to support implementation of the guidance.

The key points from the guidance are summarised below. Refer to the guideline(s) for further information.

- **Atorvastatin is the first line choice of statin** on the Barnsley Formulary. If lifestyle modification is ineffective or inappropriate for primary prevention the patient should be prescribed **atorvastatin 20mg daily** (high intensity statin). High intensity statin treatment should achieve reduction of non-HDL-C > 40% from baseline. If this is not achieved after 3 months options include; discussing treatment adherence, timing of dose, diet and lifestyle, or if at higher risk, consider increasing the dose every 2-3 months up to a maximum of atorvastatin 80mg daily.
- If patients on a high-intensity statin have side effects, offer a lower dose or an alternative statin. **If the maximum tolerated dose of statin does not achieve non-HDL-C reduction > 40% of baseline value after 3 months consider adding ezetimibe 10mg daily.**
- **Rosuvastatin (second choice statin)** may be used as an alternative to atorvastatin if compatible with other drug therapy. Rosuvastatin is a high intensity statin at doses 10mg daily and above. Some people may need a lower starting dose (see [BNF](#)).

- Low/medium intensity statins (simvastatin or pravastatin) should only be used if intolerance or drug interactions. Fluvastatin (low/medium intensity statin) has a high cost in relation to alternative statins and therefore has been assigned a formulary grey classification (previously formulary green). Refer to the guidelines for the extent of lipid lowering with available therapies and costs.
- **If statin treatment is contraindicated or not tolerated**, refer to the [AAC Statin Intolerance Algorithm](#). Ezetimibe monotherapy may be considered in line with the pathway. Ezetimibe 10mg/bempedoic acid 180mg combination (available as a combination product which is more cost effective than the separate products) may be considered when ezetimibe alone does not control non-HDL-C well enough ([NICE TA694](#)). Bempedoic acid has an amber-G classification on the Barnsley Formulary. An amber-G guideline is in development.
- In the case of **severe hyperlipidaemia** (TC>7.5mmol/L and/or LDL-C>4.9mmol/L and/or non-HDL-C>5.9mmol/L) refer to the Barnsley Severe Hyperlipidaemia Pathway.

The guidelines will be available on the BEST website in due course.

Prescribing guidelines are available on the BEST website:

<http://best.barnsleyccg.nhs.uk/clinical-support/medicines/prescribing-guidelines/>

The Barnsley Joint Formulary can be accessed at the link below:

<http://www.barnsleyformulary.nhs.uk/>

### **Shared Care Guidelines**

There were no new/updated shared care/amber-G guidelines endorsed by the Committee this month.

Shared Care and Amber-G guidelines are available on the BEST website:

<http://best.barnsleyccg.nhs.uk/clinical-support/medicines/shared-care-guidelines/>.

Prescribers (including secondary care clinicians) are encouraged to report any problems they experience with shared care or other medicines related issues, particularly where guidelines are not being complied with, to the following email address: [BarnsleyAPCReport@nhs.net](mailto:BarnsleyAPCReport@nhs.net).

The Barnsley Interface Issues Form should be used to report such problems:

<http://www.barnsleyccg.nhs.uk/members-professionals/area-prescribing-committee.htm>

### **Other**

#### **Aripiprazole Drug Shortage**

There are currently supply issues with some formulations of aripiprazole. The enclosed memo produced by SWYFT provides further advice regarding the shortage.

### **Traffic Light Classifications**

The Committee assigned the following classifications to the products included in the table below:

<b>Drug</b>	<b>Formulary Indication</b>	<b>Traffic light status (Drugs with a provisional classification are not currently included on the Barnsley formulary)</b>
<b>SPS New Medicines Newsletter May 2022</b>		
Netilmicin (Nettacin®) eye drops	Topical treatment of external infections of the eye	Non-formulary provisional red

Netilmicin + dexamethasone (Netildex®) eye drops	Treatment of inflammatory ocular conditions of the anterior segment of the eye, including post-operative cases	Non-formulary provisional red
Olanzapine (Zyprexa®) injection	Schizophrenia or manic episode	Non-formulary provisional red
<b>Other</b>		
Fluvastatin	Statin	Formulary grey (previously formulary green)  Fluvastatin has a high cost in relation to alternative statins. Refer to the 'Barnsley Lipid Management for Primary Prevention of CVD in Adults' guideline.
Dapagliflozin	Chronic Kidney Disease	Formulary amber-G for this indication.  Note that the traffic light classification of dapagliflozin varies depending on the indication.  Amber-G guidance in development.

### **MHRA Drug Safety Update**

The June 2022 MHRA Drug Safety Update can be accessed at the following link:

[https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/1084085/June-2022-DSU-PDF.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1084085/June-2022-DSU-PDF.pdf)

Issues relating to primary care:

<p><b>Metformin and reduced vitamin B12 levels: new advice for monitoring patients at risk</b></p> <p>Decreased vitamin B12 levels, or vitamin B12 deficiency, is now considered to be a common side effect in patients on metformin treatment, especially in those receiving a higher dose or longer treatment duration and in those with existing risk factors. We are therefore advising checking vitamin B12 serum levels in patients being treated with metformin who have symptoms suggestive of vitamin B12 deficiency. We also advise that periodic monitoring for patients with risk factors for vitamin B12 deficiency should be considered.</p> <p><b>Advice for healthcare professionals:</b></p> <ul style="list-style-type: none"> <li>• metformin can commonly reduce vitamin B12 levels in patients, which may lead to vitamin B12 deficiency</li> <li>• the risk of low vitamin B12 levels increases with higher metformin dose, longer treatment duration, and in patients with risk factors for vitamin B12 deficiency</li> <li>• test vitamin B12 serum levels if deficiency is suspected (for example, in patients presenting with megaloblastic anaemia or new-onset neuropathy) and follow current clinical guidelines on investigation and management of vitamin B12 deficiency (for example, see <a href="#">Clinical Knowledge Summary from NICE</a>)</li> <li>• consider periodic vitamin B12 monitoring in patients with risk factors for vitamin B12 deficiency (see list of risk factors in full MHRA alert)</li> <li>• administer corrective treatment for vitamin B12 deficiency in line with current clinical guidelines; continue metformin therapy for as long as it is tolerated and not contraindicated</li> <li>• report suspected adverse drug reactions associated with metformin on a <a href="#">Yellow Card</a></li> </ul> <p><b>Advice for healthcare professionals to give to patients or carers:</b></p> <ul style="list-style-type: none"> <li>• if you are taking metformin, seek medical advice if you develop new or worsening symptoms of extreme tiredness, a sore and red tongue, pins and needles, or pale or yellow skin – these can be signs of low vitamin B12 levels</li> </ul>
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- you may need blood tests to find out the cause of your symptoms; these symptoms can also be caused by diabetes or other unrelated health issues
- you can keep taking metformin while vitamin B12 levels are being corrected
- do not stop your treatment without first discussing this with your doctor

**Roche Accu-Chek Insight insulin pump with NovoRapid PumpCart insulin cartridges: alert following cases of insulin leakage**

The MHRA have issued a National Patient Safety Alert following serious reports of harm associated with insulin leakage during use of the Accu-Chek Insight Insulin pump with NovoRapid PumpCart prefilled insulin cartridges. Patients should be moved onto alternative insulin pumps where possible.

It was noted in the APC meeting that the Barnsley Diabetes Service were progressing the actions in relation to this alert.

**Advice for healthcare professionals:**

- the Accu-Chek Insight Insulin pump used with NovoRapid PumpCart prefilled insulin cartridges has been associated with insulin leakage events, including cases of severe hyperglycaemia and diabetic ketoacidosis in UK patients
- follow the steps set out by your organisation to action the [National Patient Safety Alert](#), including to identify and review patients using Roche Accu-Chek Insight insulin pumps and discuss moving them to an alternative insulin pumps where possible
- pharmacists should continue to dispense the NovoRapid PumpCart cartridges but ask patients whether they use the Accu-Chek Insight insulin pump and provide advice and education to minimise the risks (as below)
- report suspected adverse drug reactions or adverse incidents to the [Yellow Card Scheme](#)

**Advice for healthcare professionals to give to patients or carers:**

- the MHRA has taken action following cases in which insulin has leaked from the glass cartridge in the Accu-Chek Insight insulin pump – some cases were associated with severely high blood sugar and diabetic ketoacidosis
- your healthcare professional team has been asked to discuss with you changing to another insulin pump where possible
- while you continue to use the Accu-Chek Insight Insulin pump:
  - check the pump and cartridge regularly for damages, for example cracks or leakage. If you smell insulin (a strong antiseptic chemical smell) this could also indicate a leakage.
  - follow the advice in the [latest customer notice](#) to replace previous designs for pump adaptors and tubing
  - do not use the cartridge if cracks or leakage are seen or if the cartridge was dropped. Follow the instructions of your Accu-Chek Insight user manual for replacing a cartridge and for cleaning the cartridge compartment in the insulin pump.
  - during the day and before going to sleep please carefully check that your insulin pump is delivering insulin and there are no leakages.
  - never change treatment delivery methods without first consulting a relevant healthcare professional.
  - failure of insulin delivery due to leakage may not result in an alert notification from the insulin pump and cracks and leakages may not always be visible. You should check blood glucose levels multiple times throughout your day while using pumps.
  - tell your healthcare professional immediately if you suspect a problem with your insulin delivery.

Regards



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cc: Medicines Management Team  
Rebecca Hoskins, BHNFT  
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Area Prescribing Committee Members (Secretary to the APC to circulate)  
Local Medical Committee (Secretary to the LMC to circulate)  
Gary Barnfield, South Yorkshire ICB (Sheffield)  
Alex Molyneux, South Yorkshire ICB (Doncaster)  
Stuart Lakin, South Yorkshire ICB (Rotherham)

Enc: Barnsley Lipid Management for Primary Prevention of Cardiovascular Disease in Adults  
Barnsley Severe Hyperlipidaemia Pathway  
Aripiprazole Shortage Memo