# NORTHERN IRELAND MEDICINES MANAGEMENT

Health and Social Care Board

**April 2014** Volume 5, Issue 2

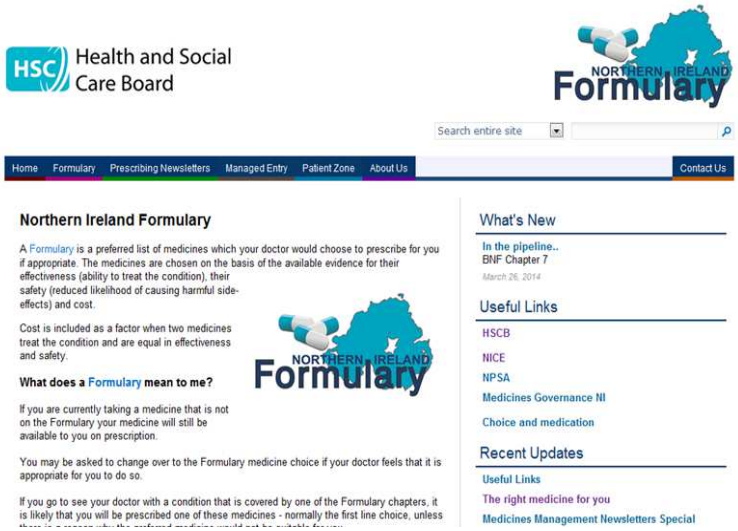
**NEWSLETTER**


## In This Issue



## NORTHERN IRELAND FORMULARY LAUNCH

The aim of the Northern Ireland Formulary is to promote safe, clinically effective and cost-effective prescribing of medicines.




### What medicines will be covered by the Formulary?

The Formulary provides guidance on first and second line drug choices and will cover the majority of prescribing choices in Northern Ireland. Whilst the Formulary will aim to standardise practice and ensure a level of consistency, it is recognised that individual patients may require medicines which lie outside such guidance.

The Formulary is intended to cover the majority of prescribing decisions and is therefore focused on non-specialist prescribing choices.

### Who will use it?

It is intended to be used across both primary and secondary care sectors in Northern Ireland to ensure consistency and continuity of supply. This will benefit all patients who require medicines.

The website is intended to be used by healthcare professionals and patients, with a dedicated 'Patient Zone'.

### Will any other information be available on the NI Formulary website?

Prescribing newsletters and Managed Entry decisions will also be supported on the NI Formulary website.

**The official website of the Northern Ireland Formulary was launched on 26th March 2014.**

**You can view the latest version on the internet at** http://Niformulary.hscni.net

**You may wish to keep it open on desk-top when in surgery.**

**The website will be under ongoing review so we value your feedback both on presentation and content.**

# NEW MANAGED ENTRY PROCESS FOR NORTHERN IRELAND

Managed Entry is a process for managing the introduction of new medicines. The HSC Board has been developing new arrangements for the Managed Entry of medicines, with the aim of ensuring timely and equitable access to those medicines for which there is an evidence base on efficacy and cost-effectiveness.

Drugs recommended for use by NICE will be accepted for use within Northern Ireland.

However, for medicines that NICE do not appraise, the HSC Board will look to the Scottish Medicines Consortium (SMC) to make a decision as to whether a drug is accepted or not accepted for use in Northern Ireland.

The HSC Board will communicate decisions as follows:

- A monthly e-mail which will detail the drugs not accepted for use.
- A dedicated webpage on the Northern Ireland Formulary website will include all information regarding the Managed Entry of medicines.
- A dedicated section in the Medicines Management newsletter which will now be published on a monthly basis.

Further details can be found on the new Northern Ireland Formulary website http://Niformulary.hscni.net

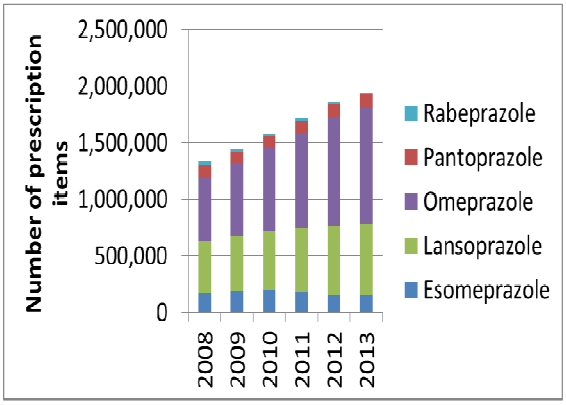
**Action**

Prescribers are asked to check the website regularly and ensure that all relevant personnel are updated as appropriate regarding the Managed Entry of drugs.

# PPI VOLUME GROWING DESPITE THE RISKS [7-9]

Despite ongoing concerns in relation to adverse effects associated with long-term proton pump inhibitor (PPI) use, the amount of PPIs prescribed in Northern Ireland continues to rise.

For many indications PPI therapy is required only for a short-term basis, however, lack of review or robust systems means that in some cases medication is not stepped down or discontinued as recommended. NICE guidance encourages people who need long-term management of dyspepsia symptoms to reduce their use of prescribed medications stepwise: by using the lowest effective dose, by trying "as needed" use when appropriate, and by returning to self-treatment with antacid and/or alginate therapy (unless there is an underlying condition or co-medication that needs continuing treatment).




**Action**

- When appropriate, prescribe PPIs as short courses of treatment appropriate to the indication and consider adding a stop date to the directions e.g. take one daily until 30th June 2014
- Review the indication and appropriateness of PPIs in long-term users periodically
- Consider prescribing alginate cover to help manage rebound symptoms when stepping down or stepping-off
- Enrol for one of the May 2014 workshops "Advanced Clinical Practice: Upper GI disease" facilitated by NICPLD by visiting http://www.medicinesni.com/courses/type.asp?ID=WS&page=1

**Risk of adverse effects associated with long-term use:**

- Increased risk of hip, wrist or spine fractures
- Increased risk of Clostridium difficile associated diarrhoea (CDAD)
- Increased risk of pneumonia
- Hypomagnesaemia
- Vitamin B12 deficiency
- Acute interstitial nephritis
- Rebound acid hypersecretion.

# NEW JEXT® [5]

Following a class 2 recall in December 2013, Jext® (single-use adrenaline auto-injector) is available again in the UK, through Sangers wholesalers in Belfast.

Please note, Jext® now has a shorter expiry date of 18 months from date of manufacture (previously 24 months).

## OVER-PRESCRIBING OF LIRAGLUTIDE (VICTOZA®)? [2]

There have been reports of some very large quantities of liraglutide (Victoza®) prescribed at over frequent intervals to patients. This is a reminder of how long a prescription should last.

Victoza® comes in a pre-filled multi-dose disposable pen containing 3mL of liraglutide.

NICE do not recommend liraglutide 1.8mg daily, because the available evidence does not suggest any significant additional benefit with the higher dose. Therefore, 1.2mg is the most usual dose of liraglutide.

A 3mL pen contains 15 doses of 1.2mg.

There are two pack sizes — a two-pen pack and a three-pen pack.

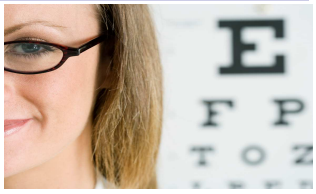
**One two-pen pack will therefore be enough for a 30 day supply at a dose of 1.2mg.**

It may be easier to synchronise a patient's Victoza® supply with other monthly medicines if the two-pack is prescribed. Each pen currently costs £39.24 regardless of pack size.

### Action

Consider prescribing liraglutide (Victoza®) pens in the two-pen pack in order to synchronise supply with other monthly medicines.

## MACUSHIELD® EYE SUPPLEMENTS —NOT RECOMMENDED FOR NHS SUPPLY [11,12]



### What is Macushield®

Macushield® is a food supplement containing meso-zeaxanthin (MZ) 10mg, lutein (L) 10mg and zeaxanthin (Z) 2mg in a capsule form. It is marketed as a preparation that contains 'antioxidants that help shield the macula against potential free radical and blue light damage.'

### What is the evidence?

The Macushield® website refers to a study in the journal Investigative Ophthalmology and Visual Science (2011 Nov 29;52(12):9207-17).

This was a small study of 44 healthy subjects. It was a randomised controlled trial in which subjects were given either MZ (10.6 mg) + L (5.9 mg) + Z (1.2mg) or placebo. Results showed increases in serum concentrations of these carotenoids and a subsequent increase in central macular pigment optical density was reported.

**However, there is no evidence that this supplement improves patient outcomes in patients with age-related macular degeneration.**

### Action

Supplements containing meso-zeaxanthin, lutein and zeaxanthin should not be prescribed on the NHS.

## REMINDER TO PRACTICES — LEUKOTRIENE ANTAGONISTS IN HAYFEVER [7]

Leukotriene antagonists (montelukast and zafirlukast) are indicated for the treatment of asthma. Montelukast is licensed in hay fever but only in those asthmatic patients in whom it is indicated in asthma. Zafirlukast is only licensed in treatment of asthma.

Reviews in practices have highlighted inappropriate use of leukotriene antagonists.

A recent article in the Drug and Therapeutics Bulletin concluded that although leukotriene receptor antagonsists are included in some treatment guidelines, there is very limited evidence of efficacy. There is no evidence that they are superior to antihistamines.

### Prescribing points

- Montelukast should only be used for allergic rhinitis in patients in whom montelukast is indicated in asthma.
- Zafirlukast should not be used for allergic rhinitis.

# VALSARTAN (DIOVAN®) SUPPLY SHORTAGE [1-4]

Several suppliers are experiencing intermittent supply issues with valsartan products which may last several months. This includes both capsules and tablets. Clinicians may, in some cases, need to consider switching patients to an alternative angiotensin II receptor antagonists (A2RA).

Valsartan is licensed for the treatment of patients with hypertension, symptomatic heart failure; and after a recent (12 hours to 10 days) myocardial infarction (MI) in patients who develop symptomatic heart failure or asymptomatic left ventricular systolic dysfunction. All available A2RAs are licensed for the treatment of hypertension, but differ in their other licensed indications.

## Dose equivalence

Information on dose equivalence of A2RAs is not available. If changing a patient from one A2RA to another, the dosing range within which the dose falls should be taken into account (i.e. low, maintenance low / high, or maximum dose). For elderly patients or patients with renal impairment it is advisable to start on a lower dose than direct equivalent and titrate as required.

It should be noted that valsartan is the only A2RA licensed for use in the post MI setting and specialist advice should be sought if alternative A2RA is required.

Patients on a twice daily dosing regimen of valsartan should be advised of a change to a once daily regimen on switching to an alternative A2RA, to reduce the risk of a dosing error.

## Action

- Consider switching patients to generic losartan if they are prescribed an A2RA for hypertension, heart failure, and renal disease including diabetic nephrology.
- Consider switching patients to an ace inhibitor (ACEI) if one has not previously been tried or where there is no documented intolerance to an ACEI because of side effects such as cough.
- Blood pressure must be closely monitored following switches.


References

1. London and South East Regional Medicines Information Service. Shortage of Valsartan. March 2014. http://www.medicinesresources.nhs.uk/en/Communities/NHS/SPS-E-and-SE-England/Medicines-Information/Discontinuation-Supply-Shortage-Memos/Shortage-of-Valsartan-/
2. BMA/RPSGB. BNF, March 2014.
3. Summary of Product Characteristics for candesartan (Amias®), eposartan (Tevetan®), irbesartan (Aprovel®), losartan (Cozaar®), olmesartan (Olmetec®), telmesartan (Micardis®), valsartan (Diovan®). [http://www.medicines.org.uk/emc/] Accessed 20/02/2014.
4. NICE. NICE CG34 Hypertension. http://www.nice.org.uk/nicemedia/pdf/CG34fullguideline.pdf
5. EMC. Jext 300 micrograms solution for injection in pre-filled pen. SPC last updated on the eMC: 06/03/2014. http://www.medicines.org.uk
6. BMA/RPSGB. BNFC, July 2013—July 2014.
7. DTB. An update on the management of hay fever in adults. DTB, 2013;51(3):30-33.
8. MHRA. Drug Safety Update. Proton-pump inhibitors in long-term use: reports of hypomagnesaemia; recent epidemiological evidence of increased risk of bone fracture. April 2012.
9. NICE Updated Clinical Guideline Draft for Consultation Dyspepsia and gastro-oesophageal reflux disease: investigation and management of dyspepsia, symptoms suggestive of gastro-oesophageal reflux disease, or both. April 2014.
10. HSCB, PHA, DHSSPS. Northern Ireland Management of Infection Guidelines for Primary Care 2013 .
11. MacuShield. http://www.macushield.co.uk
12. Connolly EE et al. Supplementation with All Three Macular Carotenoids: Response, Stability, and Safety. Investigative Ophthalmology & Visual Science, 2011;52(12)9207-9217.



This newsletter has been produced for GPs and Pharmacists by the Regional Pharmacy and Medicines Management Team.

If you have any queries or require further information on the contents of this newsletter, please contact one of the Medicines Management pharmacists in your local HSCB office.

Eastern Area : 028 9055 3784
Southern Area : 028 3741 4622
Northern Area : 028 2531 1049
Western Area : 028 7186 0086