Review of Omacor (omega-3-acid ethyl esters) Prescribing

Applies to

HaRD CCG employed Pharmacists and Medicines Optimisation Technicians.

These protocols are produced by the NY&AWC MM team hosted by HaRD CCG for use by their employed MM team members. They can be adopted for use by other healthcare staff working in GP practices across NY&AWC CCGs but HaRD CCG accepts no responsibility for the use and application of these protocols in these situations. External staff working to these protocols must agree with their own employer whether they are competent and able to work to these protocols.

Rationale

Omacor® (omega-3-acid ethyl esters) is licensed as an adjuvant treatment in the secondary prevention of myocardial infarction (MI), in addition to other standard therapy (e.g. statins, anti-platelet medicinal products, beta-blockers, ACE inhibitors). It is also licensed, as an adjunct to diet, for the treatment of hypertriglyceridaemia.[1]

Evidence shows that Omacor is not associated with a lower risk of all-cause mortality, cardiac death, sudden death, MI or stroke, therefore no health gains were identified.[2,3] In light of this evidence NICE recommend that Omacor should no longer be prescribed for:

- primary or secondary prevention of cardiovascular disease
- post MI
- familial hypercholesterolaemia

NICE have also reviewed the evidence for Omacor in other conditions and have also concluded that it should not be prescribed for:

- non-alcoholic fatty liver disease
- sleep problems In children and young people with autism
- multiple sclerosis

It is recommended that all existing patients should be reviewed with a view to stopping treatment. Patients should be encouraged to achieve the required level of omega 3 fatty acids by dietary means.

In November 2017 NHSE England included Omacor in their list of Items which should not routinely be prescribed in primary care advising that based on the evidence reviewed by NICE that Omacor should be included as a medicine that should not be initiated or continued to be prescribed in primary care. They identified no routine exceptions to this advice.

Method

1. Staff working to the protocol should be familiar with the current BNF advice and the Summary of Product Characteristics for medicines included in the protocol.

2. Check the practice has agreed to the protocol and a signed copy is in place.

3. Check for any extra exclusions or amendments to the protocol made by the practice.
4. Rearrange practice formulary/add "do not use" codes to prevent future inadvertent prescribing. Check prescribing support software prompts are in place where relevant.
5. Notify local pharmacies/dispensary of work being undertaken and inform any relevant practice staff e.g. dispensary staff.
6. Run a computer search to identify patients who are currently receiving prescriptions for *Omacor* (generically or by brand).
7. Use the data collection form (Appendix 1) and the medical records to record the following:
    - Patient identifier
    - Allergies checked
    - Current prescription (generic or brand)
    - Previous prescriptions
    - Contraindications
    - Exclusions
    - Patient referred to prescriber?
8. Identify patients to stop now and those needing special consideration by GP.
9. If a patient is excluded, add a consultation note listing reasons why they are unsuitable.
10. For those patients suitable to stop, cancel the repeat prescription.
11. Ensure that the old medication is archived.
12. Send a letter to the patient advising them of the change, including the leaflet embedded in Appendix 2. Liaise with practice staff to organise mail merge of letters and posting. At the end of the session, for all those changes that have been completed, a letter must be ready to send to the patient for information.
13. Use the activity log to review all changes made and to measure the effectiveness of the intervention. Estimate cost savings made and present results back to the practice and organisation
14. Continue to monitor the long term outcomes of the intervention e.g. cost savings via PPD data, complaints, any problems encountered etc.

Exclusions

There are no routine exceptions to this guidance.

To flag up for special consideration by GP – approval required via electronic task

1. Any patient recently discharged on Omacor post MI – to feed back to cardiologist.
2. Any patient that you are concerned about regarding the intervention, or other prescribing issue that you are concerned about.

Points to discuss with practice

1. Who is the contact in the practice for the project?
2. Agree content of patient letter – a possible form of words is attached below
3. Any practice additions, deletions or amendments to the protocol.

References

1. Omacor. Summary of Products Characteristics. March 2018 Accessed from http://www.medicines.org.uk/EMC/medicine/10312/SPC/Omacor/ on 13/04/2018
2. Rizos EC et al. Association between omega-3 fatty acid supplementation and risk of major cardiovascular disease events: a systematic review and meta-analysis, JAMA, 2012 Sep 12; 308 (10):1024-33.
3. Drug and therapeutics bulletin: 11; November 2012, Omega-3 fatty acid supplementation and major CVD events.
4. Items which should not routinely be prescribed in primary care: Guidance for CCGs, NHS England - https://www.england.nhs.uk/wp-content/uploads/2017/11/items-which-should-not-be-routinely-precscribed-in-pc-ccg-guidance.pdf Accessed 13/04/2018

The current BNF and the Summary of Product Characteristics must be checked as a minimum standard

Agreement to protocol

Please detail any amendments to the protocol here/or attach a copy of agreed changes:

Signature of practice prescribing lead/ manager	
Practice name	
Date	
Signed on behalf of NYAWC MMT	

Please note that the practice representative signing this protocol agrees that:

- **The practice will take responsibility for the notification of all relevant practice staff.**
- **The practice has made patients aware that their records are accessed by medicines optimisation team staff for these purposes e.g.: via practice leaflet, website or other communication and that the practice has applied appropriate restriction to the records of patients who have withdrawn consent.**

Possible letter

Dear ~*[Title/Initial/Surname]*

Your repeat prescription for Omacor (omega-3 esters)

The practice has recently reviewed the prescribing of one of the medications that you are taking – Omacor. A recent review of this medicine has shown no health benefits from taking it. Because of the lack of benefit we will not continue to prescribe it and we have therefore removed this medication from your repeat prescription.

The National Institute for Health and Care Excellence (NICE) recommends that you eat a Mediterranean-style diet (more bread, fruit, vegetables and fish; less meat; and replace butter and cheese with products based on plant oils).

Please find enclosed a leaflet with further details about the recent review of Omacor prescribing by the NHS.

If you have any queries regarding this letter please contact [insert name of contact, practice] and or [insert email of local CCG patient relations team]

All medicines should be safely stored out of the reach of children.

Yours sincerely

[Usual GP/Registered GP/GP Prescribing Lead/Other]

Agreement to letter

Please detail any amendments to the letter here/or attach a copy of agreed changes:

Signature of practice prescribing lead/ manager	
Practice name	
Date	
Signed on behalf of NYAWC MMT	

Appendix 1: Data Collection Form: Review of Omacor (omega-3-acid ethyl esters) Prescribing

Patient Identifier	Diagnosis	Date initiated	Initiated by whom	Date of last practice review	Comment/recommendations	Suitable to stop?	Flag to GP?	Patient stopped? (Y/N)	Letter sent? (Y/N)

Appendix 2: PrescQIPP leaflet to enclose with patient letter

3749-patient-informa
tion-changes-to-omeg

Activity Log: Review of Omacor (omega-3-acid ethyl esters) Prescribing

Practice:	**Date Completed:**
Work agreed on behalf of practice by:	
Reason for undertaking work e.g. cost/safety:	
Number of Patients Identified	
Number of Patients switched	
Number of Patients excluded	

Savings made (approx.)	
Approx. time taken	

Summary of findings

Difficulties encountered

Pharmacies Contacted

Points for discussion with Practice

Completed By:

Document version control

Version	State changes	New version	Actioned by
V1.00	**update**	**V1.01**	
V2.00	**Updated in line with NHSE guidance. Removed exclusions and aligned with standard template.**		**C Kilburn**

Protocol approval details

Written by	Claire Kilburn	13/04/2018
Clinically checked by		
Tested in practice by		
Authorised by		