Regional Medicines Optimisation Committee Briefing
Best Value Biologicals: Adalimumab Update 2

Adalimumab RMOC Update 1:
https://www.sps.nhs.uk/articles/rmoc-briefing-paper-on-adalimumab/

The purpose of this briefing is to provide a progress update for provider trusts, clinicians and commissioners which summarises:
- Advice on the next steps for commissioners and providers;
- Practical advice in the context of homecare services
- Progress to date in planning for the patent expiry of the originator adalimumab product Humira® in October 2018.

The ambition is for the NHS to achieve a recurrent annual saving of £200-300 million by 2021 through the increased use of best value biological medicines. Achievement of £210m savings from the use of biosimilar medicines has been reached so far (2018/19 figures).

Implementing best value biological medicines enables the NHS to continue to improve patient care and provide new treatments now and into the future. It is a key element of NHS England's Medicines Value Programme, which is aimed at continuing to give people the medicines they need and want, making the best use of the NHS’ budget, and ensuring the NHS remains a world leader in the use of medicines.

1. What is the focus for trusts and CCGs?

Current priorities for action

- Discuss communications and local processes at Drugs and Therapeutics Committees and Area Prescribing Committees.
- Detailed planning between acute trusts and CCGs on how the transition will be managed.
- Engage with clinicians (medical, clinical nurse specialists and pharmacists) in each relevant clinical specialty.
- Engage with patients who are currently receiving adalimumab to make them aware of the forthcoming biosimilar medicines.
- Get ready for potential switching when new biological medicines become available.
- Ensure the process for switching patients on homecare supply can be implemented promptly, and that prescriptions issued during quarters 1 and 2 of 2018/19 will not delay transition.

- We request that you do not enter into new contracts or agreements with medicines manufacturers lasting beyond 16 October 2018. Further guidance will be issued by NHS England for future contracts in due course.
- As part of the planning between acute trusts and CCGs, it is appropriate to recognise the costs of transition and the potential requirement for local incentives to uptake of best value biological medicines. This is presently being discussed at a national level and further advice will be shared.

2. Briefing to share with clinicians

- This update incorporates a briefing for clinical staff about best value biological medicines (see Appendix). This provides an overview of the ‘Commissioning Framework for Biological Medicines’, its application to medical, nursing and pharmacy clinical staff, and provides links to more comprehensive supporting information.

- Please make this briefing available to relevant clinical staff by 8 June 2018.

3. Procurement strategy

- The NHS England Commercial Medicines Unit (CMU) is scheduling the procurement process for adalimumab after the loss of patent exclusivity in October 2018. Current indications are there will be four products available in the UK at this time (the originator and three biosimilars). Further detail is being investigated with regard to the potential products and this will be circulated to the NHS in due course.

- It is likely that the contract will be in place by December 2018, although NHS England continues to explore the possibility of a contract being in place during October. Work is being undertaken by CMU to finalise the contract model, timeline and arrangements, and this will be communicated when it is available.

- Useful resources are available from the Specialist Pharmacy Service website.

4. Considerations regarding homecare

Homecare provider

- Manufacturers may offer adalimumab both with and without an associated pharmaceutical industry funded homecare service and it may be financially advantageous for the NHS to fund the delivery element in addition to the drug price. Assuming that an NHS funded service is financially advantageous:
  o Discuss the availability and potential uptake of NHS funded homecare services for adalimumab within your hospital.

- Manufacturers may offer a choice of homecare provider, so this may be the ideal opportunity to switch to an alternative:
  o Consider switching to an alternative provider
  o Identify the barriers to a potential switch.

Homecare patient information
- It is important to engage with clinical teams and patients regarding homecare plans. Existing patients should be made aware of the forthcoming biosimilar medicines and any potential changes to their homecare service as early as possible. We will be sharing a template patient letter on the RMOC web pages in June.

- It is advisable to record that patients have been given information regarding these potential changes. This can be done by requesting that patients sign an unbranded homecare patient information record form. Once signed, this form should be kept in the patients’ medical records (see Appendix for template form). The form is a record that patients understand that there may be changes to their service.

- Prior to switching, patients must be given specific information regarding the exact new product and/or new homecare provider and this information should be recorded in the patients’ medical records. Patients should be informed at least two weeks prior to any switch to give an opportunity to raise concerns.

- Homecare providers will not require NHS hospitals to send a new homecare registration form in order to switch provider or product but it is considered good practice for NHS hospitals to have a copy of the appropriate registration form in the patients’ medical records.

- The National Homecare Medicines Committee (NHMC) is working with homecare providers to design new registration forms for best value adalimumab homecare schemes for new patients starting on alternative schemes after 16 October 2018; these will be rolled out in due course. If you require any further information, please contact susan.gibert@berkshire.nhs.uk or your regional homecare specialist.

- It is advisable for all NHS hospitals to ensure that their hospital Data Protection Officer approves any new forms (including the Patient Information Record Form attached to this update) which should also include a link to the relevant Privacy Notice(s).

5. Regional Medicines Optimisation Committees (RMOCs)

- In previous transitions to best value biological medicines there have been significant variations in the pace of transition between and within regions, so the four RMOCs are focusing on the variations in uptake locally. Where there are significant local issues or barriers these should be escalated.

- RMOC regional pharmacist (NHSE/NHSI) contact details are as follows:
  - South East and South West – Stephen.brown17@nhs.net
  - London - wrrail@nhs.net
  - Midlands and East - richard.seal1@nhs.net
  - North - michelecossey@nhs.net
6. Commissioning support unit – enabling work

- CSUs as a collaborative (led by Midlands and Lancashire CSU) are working with a range of stakeholders to deliver an implementation tool for adalimumab which will signpost CCGs and trusts to resources and identify the actions to achieve uptake. This tool will support self-assessment of implementation plans and local delivery. This is expected to be published by 9 July on the SPS’s RMOC website.

- Webinars are also being arranged by the CSUs in conjunction with the RMOCs in order to provide further updates for those involved in adalimumab transition in a trust or CCG. These will be scheduled for June/July.

7. Communications and engagement

- A communications plan is in place and a fortnightly national communications meeting is happening involving NHSE, NHSI and NHSCC.

- This RMOC update will be published monthly and a briefing will be sent to national patient groups every two months, following the first which was shared in April 2018.

- A monthly Adalimumab Communications Working Group has been set up involving patient groups and NHS colleagues, which had its first meeting on 23 May 2018. It is focusing on engaging with patient groups and networks, and developing patient information including the template patient letter, patient information leaflet and some FAQs, all of which we aim to publish on the RMOC website in June. At the meeting the group agreed to request that provider trusts recommend to patients that they should get in touch with the relevant national patient group for their condition via its website to ensure they have necessary information and support.

- An NHS England communications manager has been appointed to work with the RMOCs to help develop and enable regional clinical engagement. The first briefing aimed at clinical staff has been published with this RMOC update and will also be shared with national professional bodies. A briefing will shortly be shared with homecare nurses.

- The programme continues to work with NHS Choices to develop public-facing information on biosimilars and medicines generally.

All communications will be shared via the Specialist Pharmacy Service website’s RMOC web pages which are here
Appendix

Briefing for Clinicians – Biological Medicines – please share by Friday 8 June 2018:

Biosimilars Briefing for Clinicians.docx

Homecare Patient Information Record Form:

homecare patient information form.docx