

Regional Medicines Optimisation Committee Briefing

Best Value Biologicals: Adalimumab Update 1

The purpose of this briefing is to provide an update for provider trusts and commissioners which summarises:

- Advice on the next steps for commissioners and providers;
- NHS England's position on biosimilar adalimumab;
- Progress to date in planning for the patent expiry of the originator adalimumab product Humira® in October 2018;
- Further information on biosimilars.

The ambition is for the NHS to achieve a recurrent annual saving of £200-300 million by 2021 through the increased use of all biosimilar medicines. Achievement of £170m savings on biosimilars has been reached so far this year (January 2018 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. Actions for trusts and CCG commissioners

Actions for commissioners:

- Note the information provided in this update and maintain awareness of procurement plans as advised by regional pharmacy procurement leads.
- Commence planning locally for best value adalimumab implementation in October 2018, ensuring that any local contracts do not run beyond this point in time.
- Include adalimumab transition as a standing agenda item for local 'Drugs and Therapeutics Committees' (or equivalent).
- Review the local usage of adalimumab for discussion between the relevant trust(s) and commissioner(s); to include patient numbers, indications, route of supply.

Actions for trust medical directors and chief pharmacists:

- Liaise with lead clinicians, lead pharmacists and clinical nurse specialists to commence local planning and identify challenges.
- Commence informing and engaging with patients on the future availability of adalimumab biosimilar products, taking into account the time needed to tender for products and to change homecare provision.

- Consider the practical arrangements for transition of any patients to the best value biological including the potential barriers, infrastructure requirements, and scheduling; the following should be noted:
 - o The duration and delivery frequency of supply on prescriptions for homecare patients;
 - o The consent process, which can be started immediately, which will require all existing and new patients to sign a generic registration and consent form (please liaise with your regional homecare specialist/NHMC for more information regarding the consent process
NHMC contact: susan.gibert@berkshire.nhs.uk)

- For support and advice please contact the regional lead pharmacist for NHS England/NHS Improvement:
 - South – Steve Brown – Stephen.Brown17@nhs.net;
 - London – Bill Rial - wrial@nhs.net;
 - Midlands and East – Richard Seal - richard.seal1@nhs.net;
 - North – Michele Cossey - michelecossey@nhs.net

2. Background to biosimilar medicines

Biological medicines are medicines that are made or derived from a biological source and as such are complex, with inherent variability in their structure. A biosimilar medicine is a biological medicine which is highly similar to another biological medicine already licensed for use; biosimilars have been shown not to have any clinically meaningful differences from the originator biological medicine in terms of quality, safety and efficacy.

Biosimilar medicines are not considered generic equivalents to their originator biological medicine because the two products are not identical although are similar. However, they will have met regulatory requirements in terms of comparative quality, safety and efficacy and all biosimilar medicines introduced into the UK market are authorised by the European Medicines Agency (EMA).

Where NICE has already recommended the originator biological medicine, the same guidance will normally apply to a biosimilar of the originator. Continuing development of biological medicines, including biosimilar medicines, creates increased choice for patients and clinicians, increased commercial competition and enhanced value propositions for individual medicines.

The decision to prescribe a biological medicine for an individual patient, whether an originator or biosimilar medicine, rests with the responsible clinician in consultation with the patient. At the time of dispensing, a biosimilar medicine should not be automatically substituted for the originator by the pharmacist. In line with MHRA guidelines, biological medicines, including biosimilar medicines, must be prescribed by brand name to support on-going pharmacovigilance of the individual products.

NHS England, NHS Improvement and NHS Clinical Commissioners, in line with the Commissioning Framework for Biological Medicines, support the appropriate use of biosimilars which will drive greater competition to release cost efficiencies to support the

treatment of an increasing number of patients and the uptake of new and innovative medicines.

Adalimumab has the highest global turnover of any medicine, and in 2016/17 the NHS spent over £333m on the originator adalimumab product Humira®. Biosimilars of adalimumab are expected to be available from mid October 2018, so this paper reviews progress to date in planning, and readiness for launch of those products.

The vast majority of adalimumab usage is locally commissioned by clinical commissioning groups (CCGs) in line with NICE technology appraisals for Rheumatology, Gastroenterology, Dermatology and Ophthalmology conditions. A small proportion (approximately 6%) is commissioned by NHS England Specialised Services. The product is administered by subcutaneous injection, with 57,000 patients currently receiving the medicine through a homecare supply route.

NHS England has established a working group to provide national oversight of the implementation of best value adalimumab, to co-ordinate action, to identify any potential issues, and to provide mitigating actions related to implementation where necessary.

3. Progress to date

The Adalimumab Working Group has followed the principles set out in the [Commissioning Framework for Biological Medicines](#) which was published and cascaded to services in September 2017. The work programme is being structured as per the commissioning framework, i.e.:

- Assessment of the opportunity;
- Engagement;
- Implementation;
- Monitoring and data collection.

The following summary incorporates some of the activity that has been undertaken, and much of this work is ongoing:

3.1 Current treatment pathways

- Although every biosimilar product poses different challenges there has been a significant amount of learning from transitions to biosimilar infliximab, etanercept and rituximab, and excellent supporting work such as that outlined by the Cancer Vanguard work (see <http://cancervanguard.nhs.uk/biosimilars-adoption/>).
- Adalimumab is predominantly used in the following specialities:
 - o Rheumatology;
 - o Gastroenterology;
 - o Dermatology.
- All of these specialities have experience of implementing previous biosimilars with varying degrees of uptake, therefore work has been undertaken to ensure that lessons can be learned to enable more efficient implementation of best value adalimumab.

3.2 Regional Medicines Optimisation Committees (RMOCs)

- All four RMOCs commenced work on best value biological implementation following discussion at their inaugural meetings in mid 2017. Ongoing liaison between the four RMOCs and supporting Specialist Pharmacy Service (SPS) infrastructure aims to maintain a coherent approach across England.
- More focused RMOC work has been commenced through the committee or subgroups in order to:
 - o Coordinate support to local commissioners and providers to maximise their use of best value biological medicines.
 - o Identify the need for any focused commissioning guidance in relation to each biological.
 - o Work with the commissioning support unit leads and others to identify five trusts to input to a detailed questionnaire based review of their experiences so we could get more information on levers and barriers for shared learning.
 - o Ensure that commissioning plans are in place across England.
 - o Provide focused attention to any barriers to implementation and advise the RMOC on the most appropriate course of action.
 - o Bring together those aspects related to advice and guidance (RMOC), product selection and procurement (Pharmaceutical Marketing Support Group; PMSG), assessment of commissioning plans and finances (NHS England) and provider performance (NHS Improvement).
- A 'Best Value Biologicals Next Steps' communication was sent out to the service in December 2017 in order to provide an overview of the biosimilar implementation process (including a summary of roles to support the uptake of biosimilar medicines in delivering the commissioning framework). The South of England letter is appended in appendix 2 although other regions provided similar communications.

3.3 Clinical senate

- The South West Clinical Senate undertook a comprehensive piece of work in December 2017 to review biosimilar transition in the context of the following questions:
 - o To what extent and how should the transition to use biosimilar medicines be prioritised to enable the provision of best value care in the NHS?
 - o Does the Clinical Senate support the uptake of biosimilar medicines at pace and how can their best practice use be maximised?
- This involved patient representatives, HealthWatch, clinicians, NHS England, the MHRA and pharmaceutical industry, and resulted in the publication of recommendations on implementation of best value biologicals (see appendix 1). These have been cascaded to the national clinical senate network. The recommendations were endorsed by RMOC South in January 2018 and have been shared with the three other RMOCs. Actions to follow up practical implementation are being addressed.

3.4 Commissioning support unit (CSU) work programme

- CSUs (led by Midlands and Lancashire CSU) have been commissioned to undertake a collaborative piece of work to support the Medicines Value Programme. This work has been supported by the NHSE / NHSI regional pharmacists who have provided advice and direction.
- A CCG questionnaire on biosimilar implementation was cascaded in December 2017, and the returns have been analysed by the CSU. A report of the outcomes has identified a broad range of key issues and potential barriers. The results were used to identify those areas in each region where a more detailed analysis would be warranted in order to develop tools to support transition to the best value biological. Alongside the questionnaire, the CSU reviewed the Define[®] data on trust uptake of biosimilars. This analysis utilised the data in the 'top 10 medicines' reports by NHS Improvement. The aim is to deliver material to mitigate any barriers identified.

3.5 NHS Improvement Model Hospital

- The NHS Improvement Model Hospital dashboard incorporates a range of biosimilars in the 'top 10 medicines' analysis. Data is updated on a monthly basis so uptake is closely monitored, and adalimumab implementation will be incorporated into the future dashboard.

3.6 Implementation planning

- There are two critical success factors in implementation that require specific consideration: the procurement strategy and the homecare strategy.
- Procurement strategy: Biologic and biosimilar medicines as a group are included in NHS England's Commercial Medicines Unit (CMU) national procurement Branded Medicine strategy under the Tranche contracting process. An individual assessment of the contracting approach has been undertaken molecule by molecule since the launch of infliximab biosimilar. This assessment takes into consideration market intelligence, key stakeholders, likely dates of launch and the number of suppliers coming to market. The Humira[®] patent expiry and associated loss of exclusivity is recognised as mid October 2018 and the contract specification and timing are currently under review by the PMSG Branded and Biosimilar subgroup which includes representation from the CMU. Both factors will have an impact on the outcome of the tender and the number of entrants in the adalimumab market in England. A timeline will be issued when this has been finalised.
- Homecare strategy: A small subgroup of the PMSG Branded and Biosimilar subgroup with support from the National Homecare Medicines Committee (NHMC) has been set up to make recommendations as to the most effective plan leading up to the loss of exclusivity in October 2018. This plan will involve engagement and sign up by both providers and commissioners across the NHS in England. The NHMC recommend that Trusts look at their homecare patient distribution to ensure the transition is appropriately managed through distribution of patient volumes and services over a range of providers. The PMSG procurement model should enable trusts to increase the number of homecare providers involved.

- The strategy is focusing on achieving high quality patient care, best value, and resilient supply (in the short and medium to long term).

3.7 Engagement

- Building on the successful approach of the Cancer Vanguard, engagement with the relevant national leadership, clinician and patient groups is underway and feedback so far is supportive of the actions and direction detailed.
- The commissioning framework outlines the recommended approach for patients with regard to switching and says shared decision making between clinical prescribers and patients will be vital if the best value, clinically effective medicines are to be used. It also highlights that the decision to prescribe a medicine rests with the responsible clinician in consultation with the patient, and it is essential that prescribers and patients take account of the best clinical evidence and practice.
- Work is underway nationally to engage with patient representative groups and this will continue during 2018:
 - o NHS England held a national engagement event to discuss biosimilars with patient representative groups and national disease charities in February 2018.
 - o NHS England will be sending communications to all national patient groups about adalimumab.
 - o Patient groups are represented on the national Biosimilars Programme Board and have contributed to the development of the commissioning framework.
 - o We are working with NHS Clinical Commissioners and will involve their lay member network.
 - o The programme is working with NHS Choices to develop patient information on biosimilars and medicines generally.
- The commissioning framework also outlines the recommended approach for prescribers, providers and commissioners, asking them to work together to develop plans for the quick and effective uptake of the best value biological medicine .
- To support this, work is also underway to engage with the NHS including:
 - o Regionally led engagement via the RMOCs with clinicians, commissioners and providers.
 - o NHS England working very closely through the regional offices with doctors, nurses, pharmacists and other clinicians to develop the capacity and capability and provide the support they will need to deliver this agenda.
 - o National engagement with professional bodies including the AoMRC, RCP, RCGP, RPS, BAD, UKCPA, and other meetings to come.

4. Further information

Further information on biosimilars can be found on the following web links:

2017/18 NHS England Commissioning Intentions:

<https://www.england.nhs.uk/wp-content/uploads/2015/12/spec-comm-intent.pdf>

Key therapeutic topic: Biosimilar medicines. National Institute for Health and Care Excellence: <https://www.nice.org.uk/advice/ktt15>

What is a biosimilar medicine? Guide:
<https://www.england.nhs.uk/ourwork/pe/mo-dash/biosimilar-medicines/>

Cancer Vanguard website:
<http://cancervanguard.nhs.uk/biosimilars-getting-it-right-first-time/>

National Rheumatoid Arthritis Society patient resources:
<https://www.nras.org.uk/biosimilars>

About the Medicines Value Programme

Medicines are an important part of NHS healthcare and help many people to get well; and the development and manufacture of medicines is key to the UK's future economic growth.

However, despite the many benefits of medicines, there are challenges that we need to address around safety, clinical effectiveness and cost.

These challenges are being intensified by people living longer, expectations of healthcare rising, and more complex and innovative medicines being developed.

How can we continue to give people the medicines they need and want, make best use of the NHS' budget, and ensure the NHS remains a world leader in the use of medicines?

The Medicines Value Programme has been set up to respond to these challenges to:

- Ensure patients get access to and a choice of the most effective treatments, and the outcomes that matter to them.
- Improve the quality (safety, clinical effectiveness, patient experience) of prescribing and medicines use.
- Make how we purchase and supply medicines more efficient, while ensuring the NHS retains its position as a world-leader in medicines.

Appendices:

Appendix 1 - Clinical Senate Recommendations regarding best value biologicals



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Recommendations Bio

Appendix 2 – Regional biosimilar letter example circulated



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