**Regional Medicines Optimisation Committee Briefing**

**Best Value Biologicals: Adalimumab Update 4**

|  |
| --- |
| Biosimilar versions of the original biological medicine adalimumab (brand name Humira®) are due to be introduced in the NHS as part of a formal framework agreement from 1 December 2018 after the patent for Humira® expires in October 2018 |

This briefing provides a regular update for provider trusts, clinicians and commissioners. 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.

1. **Supporting materials in one place**

Supporting materials including previous briefings, the [toolkit for best value biological implementation](https://www.sps.nhs.uk/articles/adalimumab-toolkit-for-commissioners-and-providers/) and [information resources for patients](https://www.sps.nhs.uk/articles/adalimumab-resources-to-use-with-patients/) are available on the Specialist Pharmacy Service’s (SPS) website: [www.sps.nhs.uk/adalimumab](http://www.sps.nhs.uk/adalimumab) Please register to receive email updates.

1. **Procurement update**

The final adalimumab tender strategy has been agreed. The tendering strategy is a first step towards development of a sustainable market. The main aims of the procurement are to achieve the best possible value for the NHS, while also maintaining plurality of supply. The strategy also enables access to a citrate-free biosimilar product.

The invitation to tender documentation was issued on 19September and the closing date for tenders is 22October. The duration of the framework agreement is 1 December 2018 to 30November 2019 with options to extend for up to 24 months.

The strategy includes a biosimilars element, which will be awarded as four lots. This strategy is based on the assumption that there will be four biosimilar products and four bids by 1December. If only three offers are received, then three lots will be awarded as three distinct lots and so on. The size and shape of each lot will depend on the offers received and the relative prices.

Lots allocated a biosimilar which contains citrate as their first choice will also have access to a citrate-free option as a second choice.

The strategy means that no supplier of adalimumab will be awarded the whole market but will have a strong incentive to offer their best price at the point of tender. If all tendered prices are similar, the shares awarded will on an equitable basis. If there are price differentials, awarded shares will be higher for the most competitively priced suppliers, but all suppliers will get access to at least some of the market upon receipt of a compliant bid to avoid dominance.

The branded adalimumab product Humira® will be a separate line in the tender and subject to receipt of a compliant bid. All the lots will have access to the terms submitted. With regard to the 20mg presentation, upon receipt of compliant bids, an award will be made for a choice of products for all regions.

As part of the award process, companies will be notified to which regions they have been awarded. It is anticipated that this process will be completed by 1November. After a mandatory 10-day standstill period, the details of the awards will be shared with the wider NHS (around 11 November).

Suppliers may offer early discounts that could be put in place before the tendered prices become available. We advise trusts not to sign up to these, or make any firm commitments, until details of tender outcomes are available, as it will be important not to encourage repeated switching of patients within the space of a few months.

1. **System incentives**

NHS England is seeking to set a national reference price to incentivise the system to uptake best value adalimumab products at scale and pace. Providers and commissioners will be expected to make commissioning arrangements for adalimumab which reflect the national reference price for adalimumab. NHS England’s [commissioning intentions for adalimumab](https://www.sps.nhs.uk/articles/adalimumab-commissioning-intentions/), published in September 2018, includes more information on reference prices. For queries about reference prices contact england.biosimilars@nhs.net

1. **Patient group engagement**

Patient engagement is crucial to implementing a successful best value biologics programme and the implementation toolkit includes a section on engaging with patients.

NHS England has been working closely with the national groups that represent the majority of patients who are being treated with adalimumab, including the National Rheumatoid Arthritis Society, the National Ankylosing Spondylitis Society, the Psoriasis Association and Crohn’s & Colitis UK and produced a template patient letter, patient FAQs, and a template patient newsletter article, all of which have been endorsed by the patient groups, and which are on the SPS website.

Further patient materials on biosimilar medicines can also be found on the [European Medicines Agency’s](https://www.ema.europa.eu/) (EMA) website including resources in other European languages.

1. **Clinical engagement**

We have been working with professional bodies including the British Association of Dermatology, the British Society of Gastroenterology, the British Society of Rheumatology, the Neonatal Paediatric Pharmacists’ Group, the Royal College of Nursing and the UK Clinical Pharmacy Association. Organisations are working with us to ensure their members are kept up to date as well as providing their insights into how medical, pharmacy and nursing teams can support a successful best value biologics programme locally. We are currently working with the RCN to produce a briefing for specialist nurses in October.

1. **Product update**

The following Adalimumab biosimilars are approved for use in the UK but not yet launched, and are expected to be included in NHS England’s procurement exercise:

* Amgevita® (Amgen)
* Hulio® (Mylan/Fujifilm Kyowa Kirin)
* Hyrimoz® (Sandoz)
* Imraldi® (Samsung Biogen).

A simplified comparison of current information for adalimumab products is:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Company** | **Product name** | **Licences** | **20mg strength available** | **Citrate excipient** | **EMA link for further product details** |
| Abbvie | Humira® |  | Yes | No | [Humira](http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000481/human_med_000822.jsp&mid=WC0b01ac058001d124) |
| Amgen | Amgevita® | Same as Humira®, except paediatric uveitis | Yes | No | [Amgevita](http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004212/human_med_002081.jsp&mid=WC0b01ac058001d124) |
| Mylan / Fujifilm Kyowa Kirin | Hulio® | Same as Humira® | No | No | [Hulio](http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004429/human_med_002302.jsp&mid=WC0b01ac058001d124) |
| Samsung Biogen | Imraldi® | Same as Humira®, except paediatric uveitis | No | Yes | [Imraldi](http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004279/human_med_002147.jsp&mid=WC0b01ac058001d124) |
| Sandoz | Hyrimoz® | Same as Humira® | No | Yes | [Hyrimoz](http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/004320/human_med_002268.jsp&mid=WC0b01ac058001d124) |

1. **Future products**

We are expecting at least two further biosimilars to become available in the UK during 2019. The first product, Cyltezo, is from Boehringer Ingelheim and already has Committee for Medicinal Products for Human Use (CHMP) approval, and the second will be brought to the market by Fresenius Kabi. An NHS re-tender for 1 December 2019 onwards would include any additional available biosimilar products.

1. **Citrate content**

Patient groups and clinicians told us that the availability of a citrate-free biosimilar was important to them as citrate can sometimes be associated with discomfort on injection. The procurement strategy ensures that each hospital group has access to a citrate-free formulation for situations where this is required.

Patient experience in this context is variable, and the evidence for the direct effect of citrate on injection site reaction is very limited. For this reason it is difficult to define clear prescribing criteria for citrate-free products. Clinicians should therefore consider the most appropriate and cost-effective treatment for each patient when making a prescribing decision. Some citrate-free formulations may be ‘second line’ treatments, so clinicians will need to decide with patients which formulation is most appropriate in such circumstances.

1. **Paediatric prescribing**

The majority of adalimumab use (approximately 94%) is commissioned by CCGs, with 6% of use commissioned by Specialised Commissioning, primarily focused on paediatrics. In paediatrics, adalimumab is prescribed for a range of indications including paediatric uveitis, juvenile idiopathic arthritis, paediatric plaque psoriasis and paediatric Crohn’s disease. The licenses for the different products vary slightly at present, as detailed in the table above. The availability of the 20mg formulation and differing citrate content may be pertinent to prescribing decisions for children requiring treatment.

1. **Homecare**

There is a comprehensive set of management information and resources to support homecare switching plans available via the implementation toolkit. This includes a timetable and suggested switch plan as well as template letters and information for patients. Further information and guidance can be found in Appendix 4c in the [Homecare Handbook](https://www.rpharms.com/resources/professional-standards/professional-standards-for-homecare-services/homecare-handbook-appendices)

1. **Homecare service injection training**

All homecare provider nursing teams will be trained on the use of all biosimilar devices prior to 1 December 2018. Patients switching from the originator to a biosimilar will be offered a telephone consultation with a homecare nurse to discuss the use of their new device and their training needs. The expectation is that the majority of patients will not require a home visit for injection training with their new device following this telephone consultation.

1. **Clinical questions**

We have been asked about antibody testing and would note that any such laboratory service is being kept separate from the contractual arrangements for the products.

1. **Contact us**

RMOC regional pharmacist (NHSE/NHSI) contact details:

* + South East and South West – Stephen.brown17@nhs.net
	+ London - richard.goodman@nhs.net
	+ Midlands and East - richard.seal1@nhs.net
	+ North - michelecossey@nhs.net

|  |
| --- |
| All resources are shared via the [Specialist Pharmacy Service’s website](https://www.sps.nhs.uk/medicines/adalimumab/) |