

NHS ENGLAND BOARD PAPER

Title: Best value adalimumab product in the NHS

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Purpose of Paper:

- This paper provides an update on the readiness of the NHS to use the best value adalimumab product from 1 December 2018, following the patent expiry of the branded product (Humira®) on the 16 October.
- It provides an outline of the procurement strategy which is aimed at encouraging plurality in supply and ensuring value for money.
- It further details engagement activities that have been undertaken with key stakeholders, including patient groups, to prepare the system for the use of the best value adalimumab product.

The Board is invited to:

- Note the update on the readiness of the NHS to use the best value adalimumab product from 1 December 2018.

Best value adalimumab product in the NHS

Context and Background

1. Adalimumab is widely used in secondary care to treat inflammatory bowel disease, rheumatological (including rheumatoid arthritis) and dermatological conditions, and uveitis. In 2017/18 the NHS spent over £400m a year on the original branded adalimumab product Humira®, treating approximately 47,000 patients, making it the medicine on which the NHS currently spends the most each year.
2. Biosimilars of adalimumab have now been launched in the UK following the patent expiry for Humira® on 16 October 2018.
3. A biosimilar medicine is highly similar to the originator ('reference') biological medicine already approved by the licensing authorities for use. Biosimilars should not be confused with generics, which are copies of brand name medicines that are made by chemical synthesis and have a much simpler structure allowing production of exact copies.
4. All biosimilars have met regulatory requirements in terms of comparative quality, safety and efficacy. All biosimilar medicines introduced into the UK market are authorised by the European Medicines Agency (EMA); and where NICE has already recommended the originator biological medicine, the same guidance will normally apply to a biosimilar of the originator.
5. NHS England has recently concluded a national framework tender for adalimumab, inviting the manufacturers of biosimilar medicines and the manufacturer of the originator to offer their best prices to the NHS from 1 December 2018.
6. NHS England's *Commissioning Framework for biological medicines (including biosimilars)*, published in September 2017, set out the potential to deliver savings of at least £200-£300m a year by 2020/21. The framework tender and pricing strategy for adalimumab coupled with the extensive engagement strategy are expected to deliver a saving of in excess of £300m a year.
7. This paper sets out the:
 - Procurement Strategy; and
 - Engagement.

Procurement Strategy

8. The NHS England procurement strategy has been designed around two key objectives:
 - **plurality** – to support a managed market to ensure plurality of supply for adalimumab over the longer term, and to signal to the wider market, NHS support for the competition that biosimilars bring.
 - **best price** – to achieve competitive prices from suppliers with guaranteed shares for more competitive bids.
9. NHS England launched a national framework tender on 17 September 2018 with a minimum award period running from 1 December 2018 to 30 November 2019; this may be extended for an additional 24 months. The tender would then award access (not necessarily sales) to 11 regions based on groups of trusts. The regions were defined by NHS England's Commercial Medicines Unit.
10. Following receipt of bids resulting from the NHS England framework tender for adalimumab, the estimated savings have been revised up from £150m to in excess of £300m for the first year of the framework.

Engagement

11. In September 2018, NHS England published an adalimumab commissioning intentions note, providing guidance to commissioners and providers. The note also sets out the key principles of the tender strategy and information on our intention to set a national reference price.
12. In addition, it advised commissioners and providers to not sign up to any proposed interim offers from biosimilar companies or make any firm commitments, regardless of the potential discount, until the new framework was in place, as we expected improved prices.
13. NHS England continues to meet with patient groups on a monthly basis and, following patient feedback, anticipate developing further advice and guidance on products and services.

Conclusion

14. The Board is invited to:
 - Note the update on the readiness of the NHS to use the best value adalimumab product from 1 December 2018.