NHS England Commissioning Intentions for adalimumab following the loss of patent exclusivity for Humira®

Uptake of best value adalimumab biological medicines

- A Commissioning framework for biological medicines (including biosimilar medicines), was published by NHS England in September 2017. It set out NHS England's position and provided a framework to help commissioners develop plans for the quick and effective uptake of the best value biological medicines.

  https://www.england.nhs.uk/wp-content/uploads/2017/09/biosimilar-medicines-commissioning-framework.pdf

- NHS England's ambition is to support faster adoption of best value adalimumab medicines.
- **Our aim is that at least 90% of new patients will be prescribed the best value biological medicine within 3 months of launch of a biosimilar medicine, and at least 80% of existing patients within 12 months, or sooner if possible.**
- Biosimilar versions of the biological medicine adalimumab are expected to be available following the loss of patent exclusivity of the originator product, Humira®, on 16 October 2018.
- NHS England is undertaking a programme of work to achieve the best value possible from the investment made by the NHS on biological medicines, including biosimilars. This includes the development of a tendering and pricing strategy for adalimumab.

Key principles for the tendering strategy

- The tendering strategy is a first step towards development of a sustainable market. A *managed market share* tender approach is being proposed nationally by NHS England to ensure plurality of suppliers over the long term. This means that no one supplier of adalimumab will be awarded the whole market but it provides a strong incentive for suppliers to offer their best price at the point of tender, with competitive suppliers gaining a greater share of the market than those who price less competitively.
- In subsequent tender rounds all bidders will have the opportunity to submit offers via a competitive tender.
- This approach makes it possible to award planned market shares. If all tendered prices are low and relatively equal, shares awarded will be relatively equal. If only some tendered prices are low, 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 tendering strategy has been designed with a focus on ensuring best prices upfront and to limit the impact on patients.

- The market will be divided into eleven hospital groups which will each be awarded access to (a) Humira® (b) a first line biosimilar (either citrate containing or citrate free) and in some groups, (c) a second line biosimilar (citrate free if the first line is not citrate free).
- Patient groups and clinicians told us that the availability of a citrate free biosimilar was important to them as citrate can be associated with pain on injection. In ensuring that each hospital group has access to a citrate free biosimilar, we are taking this feedback into account.
- However, patient experience is mixed and we will require clinicians within hospitals to adopt guidance developed by the Regional Medicines Optimisation Committees, in determining which patients are prescribed a citrate free adalimumab as a 'second line treatment' if and when this is not the best value product.

Reference prices

- NHS England has determined that a national reference price is an appropriate mechanism to incentivise the system to uptake best value adalimumab products at scale and pace. The reference price will cover the cost of the best value product and the cost to hospitals of switching patients to the best value biological medicine.
- Through use of a reference price, commissioners are also expected to see a reduction in their spend on adalimumab.
- NHS England and NHS Improvement will shortly consult on changes to local pricing rules encompassed within the National Tariff guidance, enabling parties to use the reference price from April 2019.
- Providers and Commissioners will be expected to agree prices for adalimumab which reflect the national reference price for adalimumab.

GUIDANCE FOR COMMISSIONERS AND PROVIDERS

For the period 16 October 2018 to 1 December 2018

- Some CCGs/Trusts may be directly approached by suppliers of adalimumab and offered interim prices which offer significant initial discounts.

  CCGs/Trusts are advised to do nothing at this stage and to not sign up to any proposal, or make any firm commitments (regardless of how large the discount is) until the planned tender model is confirmed as we expect improved prices as part of that process.

For the period 1 December 2018 to 30 November 2019 with an option to extend

- NHS England Framework prices for adalimumab will be live from 1 December 2018 and hospital groups will be notified which adalimumab products are available to them.

- NHS England intends to set a single interim reference price for adalimumab from this date which CCGs and Trusts are welcome to use by mutual agreement. This will likely require CCGs and Trusts to agree local contract variations.

From 1 April 2019

- NHS England intends to set a national reference price from April 2019 which CCGs and Trusts are expected to use in line with proposed changes to the local pricing rules.
- CCG and Trust gains will be dependent on rate of uptake of a best value product.
- Mechanisms to ensure that gains are distributed fairly are in development and information will be shared in due course.

Data requirements

- Trusts will be required to complete the standard NHS England drugs minimum data set so that uptake of best value products can be monitored. This will need to be included in Schedule 6 of the contract between commissioners and Trusts.

  https://www.england.nhs.uk/publication/devices-and-drugs-taxonomy-and-monthly-dataset-specifications-for-2018-19/