27 May 2020

Dear colleagues,

Supply of additional direct oral anticoagulants (DOACs) during COVID-19

To help protect patients and staff during the COVID-19 pandemic the Clinical guide for the management of anticoagulant services during the coronavirus pandemic advises moving patients from warfarin to a DOAC, where clinically appropriate. This is to reduce the need to visit anticoagulant hubs and to reduce demand on nursing staff to carry out international normalised ratio (INR) monitoring.

To support this, we have secured additional DOAC supply for up to 200,000 patients in England. We have secured a supply of Bristol Myers Squibb’s apixaban for up to 160,000 patients and Bayer’s rivaroxaban for up to 40,000 patients.

Therefore, for patients switching from warfarin to a DOAC, unless there is a patient specific clinical reason to do otherwise, CCGs are encouraged to utilise apixaban and rivaroxaban in proportion to the 80:20 split secured. CCGs will also need to ensure patients, and their carers, are involved in the decision to switch their medication (see page 12 of the clinical guide).

It is for CCGs to adopt these arrangements; however, we strongly advise that clinicians are made aware of this and adopt the procurement outcome for any patients yet to switch from warfarin.

More detail about these new arrangements are provided in Annex 1. Annex 2 contains some questions and answers about the arrangements.

Thank you for your support with implementing these important changes to help safeguard patients during the COVID-19 pandemic.

Blake Dark, Commercial Medicines Director
NHS England and NHS Improvement
Annex 1 Summary of arrangements

These agreements are for a fixed term only.

Commencement: 1 May 2020

Eligible patients: ONLY patients in England switched from warfarin to apixaban or rivaroxaban between 1 May 2020 and 31 December 2020.

Existing and new patients: Existing patients (those already prescribed any DOAC) and new (anticoagulant naïve) patients are outside the scope of these arrangements. Therefore, for those patients’ local protocols and arrangements for rebates should continue.

Discounted prices: The discounted prices are confidential.

For the period 1 April 2020 to 31 July 2020, the incremental additional medicines costs, in excess of CCG allocations, associated with switching patients will be met as part of the retrospective non-recurrent adjustment process to CCG allocations. Details of the proposed funding mechanism beyond 31 July 2020 will be shared with CCGs in due course.

Due to the discounts offered, the acquisition cost of apixaban and rivaroxaban, for patients switching from warfarin, are significantly lower than the acquisition costs available for current and new patients. During this period, we will review the operation of the scheme and determine the appropriate future funding mechanism in light of the financial framework that will be in place for the remainder of the year.

Price validity: The discounted prices are valid for apixaban and rivaroxaban, dispensed in primary care to eligible patients, until 30 April 2021 or until 30 September 2021 (if the agreements are extended by NHS England and NHS Improvement) unless superseded earlier by the anticipated procurement.

Product usage: Unless there is a patient specific clinical reason to do otherwise, apixaban should be used for 80% and rivaroxaban should be used for 20% of patients switching from warfarin.

Supply arrangements: Community pharmacies will continue to fulfil prescriptions and be reimbursed as per current arrangements.
Volume guarantees: Neither the volume nor split of usage is guaranteed. However, we have committed to monitor usage and to encourage use of apixaban and rivaroxaban in proportion to the supply secured.

Centralised rebate: Suppliers will pay NHS England and NHS Improvement the difference between the list and the discounted price for each pack/tablet supplied for eligible patients. We will monitor and report the quantity of each product used for patients switching from warfarin, manage the discount process with suppliers and the process to fund CCGs for the additional cost.

We will monitor and report DOAC and warfarin usage by CCG based upon the NHS Business Services’ community pharmacy reimbursement data. This enables DOAC usage to be counted for patients who were previously prescribed warfarin (switched patients) as opposed to patients who were not previously prescribed either warfarin or a DOAC (new patients) and are not part of this arrangement. Usage information will be shared with the CCG finance and medicines management teams.

Local rebate schemes: Any local rebate schemes in place for existing and new patients will continue to apply.
Annex 2 - Questions and answers

Q. What support and advice is available for patients?
A. We have been working closely with the patient groups Anticoagulation UK and Thrombosis UK. These charities have information available on their websites for patients: [www.anticoagulationuk.org/covid-19](http://www.anticoagulationuk.org/covid-19) and [https://thrombosisuk.org/admin/resources/downloads/thrombosisuk-anticoagulation-covid-19.pdf](https://thrombosisuk.org/admin/resources/downloads/thrombosisuk-anticoagulation-covid-19.pdf)

Q. Following the procurement, are there concerns about surety of supply?
A. All DOAC suppliers responded very positively to support this initiative and demonstrated good product availability.

In addition, all suppliers have reported that they have adequate stock for existing and new patients.

Therefore, provided we continue to make use of all suppliers on existing and new patients and utilise these additional arrangements for patients switching from warfarin, based upon current information, we expect to have enough supply.

Q. What happens if patients are initiated on a drug and then we have supply issues for that drug?
A. If there are supply issues, affected patients may be switched to an alternative DOAC depending on the management plan developed by Department of Health and Social Care and the NHS England and NHS Improvement Commercial Medicines Directorate should an issue arise.

Q. Why a procurement?
A. We wanted confirmation that suppliers could cover the full 200,000 patients switching from warfarin in addition to maintaining supply for current and new patients. While all DOAC suppliers responded very positively to support this initiative and demonstrated good product availability, the fairest way to secure stock and ensure value for money for the NHS was via a procurement.

Q. Why has an 80% to 20% split been applied?
A. Suppliers were asked to confirm if they could supply enough treatments for 40k, 80k, 120k, 160k and 200k patients switching from warfarin without detracting from their ability to supply current or new patients.

While all DOAC suppliers responded very positively to support this initiative and demonstrated good current product availability, the offers from BMS and Bayer,
when combined, resulted in the lowest total acquisition cost to the NHS and a significant potential savings versus current prices.

Q. **How can an 80% to 20% split be delivered locally?**

A. We considered assigning one or other drug to each CCGs or region, however the proposal to make both available and enable clinicians to balance the usage was considered the better option to allow for individual clinical circumstances. For those patients switching from warfarin, where either apixaban or rivaroxaban is appropriate, clinicians can initiate those patients broadly based on 4 apixaban to 1 rivaroxaban.

Q. **What happens if a CCG has already switched patients from warfarin to one of the other DOAC?**

A. There is no intent that patients who have already switched from warfarin to another DOAC should be switched again to apixaban or rivaroxaban.

Q. **Does this diminish the choice afforded to clinicians when switching a patient from warfarin?**

A. It is for the prescribing clinician to determine the most clinically appropriate choice of treatment for an individual patient. However, where there is more than one clinically appropriate option that includes apixaban or rivaroxaban, then clinicians are encouraged to utilise these drugs based on an 80:20 split.

Q. **Will patients who were previously dispensed warfarin in hospital be included in the rebates?**

A. No. If warfarin is prescribed and dispensed in a hospital this will not be captured in the NHS Business Services Authority (NHSBSA) data. Patients whose warfarin is dispensed in primary care (i.e. FP10 or FP10HP) will be included in the NHSBSA data (provided the FP10HP patient number is correctly identified) and therefore included in the rebate. However, the proportion of anticoagulant dispensed in hospitals is understood to be less than 2% of the total.

Q. **What happens to the prices after these frameworks expire in a maximum of 18 months?**

A. The discounted prices for apixaban and rivaroxaban will no longer apply once the frameworks expire. Prices will either return to current prices or to new prices determined from a more strategic procurement planned later this year which will align with ambitions for reducing stroke in line with the NHS Long Term Plan.
Q. **Do these arrangements apply to current patients and patients who are new to anticoagulation?**

A. Current patients (those already prescribed any DOAC) and new (anticoagulant naïve) patients are **outside the scope** of these arrangements. Therefore, for those patients' local protocols and arrangements for rebates should continue.

Q. **Do these arrangements comply with NICE guidance?**

A. In line with [NICE guidance](https://www.nice.org.uk/guidance), if there is more than one NICE-approved medicine, for the same indication, local NHS organisations may indicate that a particular medicine is preferred if one of the medicines is less expensive than the other(s).

Q. **What happens if different suppliers win the next procurement?**

A. This will depend on the procurement design and the outcome. The procurement will be co-designed with clinicians. However, it’s possible that the next procurement could result in different recommendations.