

ANDEXANET ALFA infusion (Ondexxya® ▼) for reversing anticoagulation from apixaban, edoxaban or rivaroxaban

The Pan Mersey Area Prescribing Committee recommends the prescribing of ANDEXANET ALFA infusion (Ondexxya® ▼), by specialists only, for reversing anticoagulation from apixaban, edoxaban or rivaroxaban, when used in accordance with the criteria in NICE TA697

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[NICE technology appraisal \(TA\) 697](#) (12 May 2021)^[1] recommends andexanet alfa as an option for reversing anticoagulation from apixaban or rivaroxaban in adults with life threatening or uncontrolled bleeding, only if:

- > the bleed is in the gastrointestinal tract, **and**
- > the company provides andexanet alfa according to the commercial arrangement.

Andexanet alfa is recommended only in research for reversing anticoagulation from apixaban or rivaroxaban in adults with life threatening or uncontrolled bleeding in the skull (intracranial haemorrhage), in the form of an ongoing randomised trial mandated by the regulator.^[1]

Andexanet alfa is not recommended by NICE for reversing anticoagulation in life-threatening or uncontrolled bleeding in 'other major bleeds'.

The Pan Mersey Area Prescribing Committee (APC) also recommends the off-label use of andexanet alfa as an option for reversing anticoagulation from edoxaban provided it is used in accordance with the above recommendations made within NICE TA697 for apixaban and rivaroxaban.

The preliminary results in the efficacy population (n=20) of the ANNEXA-4 study extension show that for patients taking edoxaban, andexanet alfa significantly decreased anti-factor Xa activity (median decrease 69.2%, 95% CI 25.5-80.2%) and excellent or good haemostasis at 12 hours was observed in 75.0% (95% CI 50.9-91.3%) of patients overall.^[2]

Andexanet alfa should be used within a major bleeding protocol, under the direction of an appropriate specialist consultant.

The average cost of a course of treatment at NHS list price is £15,000 per patient. NICE estimates the cost of implementing this TA as £19,000 per 100,000 population in 2021/22, rising to £48,000 per 100,000 population by 2023/24 when steady state is assumed to have been reached. Estimates are calculated using NHS list price and so the actual cost of implementing this guidance will be less once the PAS discount is applied. However, the PAS price will not apply for off-label use of andexanet alfa to reverse anticoagulation from edoxaban as this is outside of NICE TA697 recommendations.

Note: Patients who are not eligible for treatment under this statement may be considered on an individual basis where their GP or consultant believes exceptional circumstances exist that warrant deviation from the rule of this policy. In this situation, follow locally defined processes.

References

1. National Institute for Health and Care Excellence. Technology Appraisal 697: [Andexanet alfa for reversing anticoagulation from apixaban or rivaroxaban](#), 12 May 2021. Accessed 13 May 2021.
2. Benz A P, Xu L, Eikelboom J W et al. Abstract P3: Andexanet Alfa for Acute Bleeding During Treatment With Edoxaban, Stroke. 2021; 52: AP3. Accessed online 15 November 2021 via https://www.ahajournals.org/doi/10.1161/str.52.suppl_1.P3