



ANZCA
FPM

21 November 2023

Ms Lisa Pulver
National Coordinator
Council of Australian Therapeutic Advisory Groups

Via email: project.officer@catag.org.au

Dear Ms Pulver

Re: Consultation on draft position statement for andexanet alfa

The Australian and New Zealand College of Anaesthetists (ANZCA) welcomes the opportunity to provide feedback to the Council of Therapeutic Advisory Groups (CATAG) about the draft position statement for andexanet alfa in life-threatening bleeds.

ANZCA, including the Faculty of Pain Medicine, is committed to setting the highest standards of clinical practice in the fields of anaesthesia, perioperative medicine, and pain medicine. As one of the largest medical colleges in Australia, ANZCA is responsible for the postgraduate training programs of anaesthetists and specialist pain medicine physicians, in addition to promoting best practice and ongoing continuous improvement that contributes to a high-quality health system.

ANZCA broadly supports the proposed position statement. We concur with the authors' observations about andexanet alfa and the poor quality of evidence underpinning its use.

ANZCA's response to CATAG's four recommendations is as follows:

- *Do not routinely use andexanet alfa in the management of patients treated with a factor-Xa inhibitor presenting with a severe and life-threatening bleed.*

ANZCA broadly agrees with this recommendation, and notes that the recommendation could include situations in which the exceptional use of factor-Xa inhibitor, on a case-by-case basis, would be appropriate, such as:

- When surgical management to control bleeding has failed, and
- When other conventional options, such as prothrombin complex concentrates, have failed, and/or
- Where the patient is in extremis due to bleeding and would otherwise die.

ANZCA expects the above circumstances would largely be limited to trauma patients.

- *Do not use andexanet alfa in the management of adults presenting with a factor-Xa inhibitor overdose.*
Agree.
- *Do not use andexanet alfa to reverse the effects of a factor-Xa inhibitor to facilitate surgical procedures.*
Agree.
- *Health Service Organisations and Medicines Governance Committees should consider not listing andexanet alfa on hospital or state-based formularies.*

Given the exceptional circumstances in which andexanet alfa would be used would be largely limited to trauma patients, it may be appropriate for some hospitals that routinely treat large volumes of trauma patients to stock andexanet alfa on formulary for use under the supervision of a haematologist or senior anaesthetist (as is presently the case for factor VIIa). Together, with collection of outcome data, this approach may also help resolve the current uncertainty regarding the evidence for the clinical utility of andexanet alfa.

ANZCA recommends CATAG:

- Review its recommendation to not list andexanet alfa on *all* hospital or state-based formularies.
- Support opportunities for Australian clinical trials in the use of andexanet alfa.

If you would like to discuss the above issues, please email SQ@anzca.edu.au.

Yours sincerely



Associate Professor Joanna Sutherland
Chair, ANZCA Safety and Quality Committee