NICE National Institute for Health and Care Excellence

Putting NICE guidance into practice

Resource impact report:
Andexanet alfa for reversing coagulation from apixaban or rivaroxaban (TA697)

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Summary

NICE has recommended andexanet alfa as an option for reversing anticoagulation from apixaban or rivaroxaban in adults with life-threatening or uncontrolled bleeding if the bleed is in the gastrointestinal tract.

We estimate that:

- 3,000 people with life-threatening or uncontrolled gastrointestinal bleeds are eligible for treatment with andexanet alfa each year.
- 1,500 people will have andexanet alfa from year 3 onwards once uptake has reached 50% as shown in table 1.

Table 1 Estimated number of people in England having andexanet alfa

	2021/22	2022/23	2023/24	2024/25	2025/26
Uptake rate for andexanet alfa (%)	20	40	50	50	50
Population having andexanet alfa each year	600	1,200	1,500	1,500	1,500

This report is supported by a local resource impact template because the list price of andexanet alfa has a discount that is commercial in confidence. The discounted price of andexanet alfa can be put into the template and other variables may be amended.

This technology is commissioned by integrated care systems (ICSs)/ clinical commissioning groups (CCGs). Providers are NHS hospital trusts.

1 Andexanet alfa

1.1 NICE has recommended 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.

1.2 Currently there are no NICE recommended drugs for reversing anticoagulation from apixaban or rivaroxaban and the only existing treatment is off-license use of prothrombin complex concentrate (PCC).

2 Resource impact of the guidance

2.1 We estimate that:

- 3,000 people with life-threatening or uncontrolled gastrointestinal bleeds are eligible for treatment with andexanet alfa each year.
- 1,500 people will have andexanet alfa from year 3 onwards once uptake has reached 50% as shown in table 1.

2.2 The current treatment and future uptake figure assumptions are based on clinical expert opinion and are shown in the resource impact template. Table 2 shows the number of people in England who are estimated to have andexanet alfa by financial year.

Table 2 Estimated number of people in England having andexanet alfa using NICE assumptions

	2021/22	2022/23	2023/24	2024/25	2025/26
Uptake rate for andexanet alfa (%)	20	40	50	50	50
Population having andexanet alfa each year	600	1,200	1,500	1,500	1,500

2.3 This report is supported by a local resource impact template. Andexanet alfa has an agreed patient access scheme which makes it available with a commercial-in-confidence discount to the list price. The discounted price of andexanet alfa can be put into the template and other variables may be amended.

3 Implications for commissioners

3.1 This technology is commissioned by integrated care systems (ICSs)/ clinical commissioning groups (CCGs). Providers are NHS hospital trusts.

3.2 Andexanet alfa falls within the programme budgeting category 10X, problems of circulation.

4 How we estimated the resource impact

The population

4.1 There are around 297,000 people in England currently receiving rivaroxaban, of these around 9,200 (3.1%) will have a major bleed and of these around 4,100 (45%) will have a gastrointestinal bleed.

4.2 There are also around 502,000 people in England currently receiving apixaban, of these around 10,700 (2.13%) will have a major bleed and of these around 3,700 (34.8%) will have a gastrointestinal bleed.

4.3 This gives a total of around 7,800 people who will have a major gastrointestinal bleed, of these around 3,000 (38%) will have a life-threatening or uncontrolled bleed and will be eligible for andexanet alfa.

Table 3 Number of people eligible for treatment in England

	Population	Proportion of previous row (%)	Number of people
	Total population		56,286,961
a	Adult population		44,263,393
b	Number of people receiving rivaroxaban[1]	0.67	297,000
c	Proportion who have a major bleed[2]	3.10	9,200
d	Proportion with a gastrointestinal bleed[3]	44.97	4,100
e	Number of people receiving apixaban[1]	1.13 of a	502,000
f	Proportion who have a major bleed[2]	2.13	10,700
g	Proportion with a gastrointestinal bleed[3]	34.80	3,700
h	Total number of people with a major gastrointestinal bleed	d+g	7,800
	Total number of people eligible for treatment with andexanet alfa who have life-threatening bleeds[2]	38	3,000
	Total number of people estimated to have andexanet alfa each year from year 3[4]	50	1,500
	[1] Source: NHSE [2] Source: Company submission [3] Source: Green et al 'ORANGE study' 2018 [4] Source: Discussions with clinical experts during budget impact test process		

Assumptions

4.4 The resource impact template assumes that:

- 84% of people who are treated with andexanet alfa will have a low dose regimen with 16% having a high dose regimen (company submission).
- Andexanet alfa and prothrombin complex concentrate (PCC) are both administered once per patient.
- The cost of administration of intravenous andexanet alfa and PCC will be covered by the non-elective admission tariff.

Other factors

4.5 The appraisal committee considered andexanet alfa for people with intercranial bleeds however were unable to make a

recommendation for routine use and have recommended it for use in research only.

4.6 Andexanet alfa was not recommended for use in other bleeds.

4.7 Some people are unable to accept treatment with blood products and so would not be treated with PCC. For these people andexanet alfa addresses an unmet need.

About this resource impact report

This resource impact report accompanies the NICE guidance on [insert guidance title and embed hyperlink, for example http://www.nice.org.uk/guidance/TA/DG/MTXXX] and should be read with it.