

Putting NICE guidance into practice

Resource impact report: PIGF-based testing to help diagnose suspected pre-eclampsia (Triage PIGF test, Elecsys immunoassay sFlt-1/PIGF ratio, DELFIA Xpress PIGF 1-2-3 test, and BRAHMS sFlt-1 Kryptor/BRAHMS PIGF plus Kryptor PE ratio) (DG23)

Published: May 2016

Summary

This guidance considers the use of PIGF-based testing to help diagnose suspected pre-eclampsia.

The Triage PIGF test and the Elecsys immunoassay sFlt-1/PIGF ratio, used with standard clinical assessment and subsequent clinical follow-up, are recommended to help rule-out pre-eclampsia in women presenting with suspected pre-eclampsia between 20 weeks and 34 weeks plus 6 days of gestation.

It is estimated that around 67,200 women with suspected pre-eclampsia are eligible for testing with the triage PIGF test or the Elecsys immunoassay sFlt-1/PIGF ratio each year.

Implementation of the guidance may lead to a reduction in bed days. The savings are not anticipated to be cash releasing but may increase available clinical staff time. For an average size maternity unit with approximately 4,700 births per year, around 300 bed days may be saved.

The estimated resource impact of implementing this guidance for about 663,500 births in England, based on the uptake in the resource impact assumptions, is shown in table 1.

Table 1 Estimated annual saving of implementing the guidance

	2016/17	2017/18	2018/19	2019/20	2020/21
Estimated proportion of women with suspected pre-eclampsia who are between 20 weeks and 34 weeks plus 6 days of gestation having testing each year	10%	25%	40%	50%	60%
Annual number of tests	6,718	16,795	26,873	33,591	40,309
Cash cost (£m)	0.4	1.0	1.5	1.9	2.3
Non-cash releasing saving (£m)	-1.6	-4.0	-6.3	-8.0	-9.6
Resource impact (£m)	-1.2	-3.0	-4.8	-6.1	-7.3

Revised December 2018

The Triage PIGF test (formerly Alere International) has been acquired by Quidel Corporation (<https://www.quidel.com>) and is commercially available. For further queries, please contact emeacustomerservice@quidel.com.

1 Introduction

1.1 This report looks at the resource impact of implementing the NICE guidance on [PIGF-based testing to help diagnose suspected pre-eclampsia \(Triage PIGF test, Elecsys immunoassay sFlt-1/PIGF ratio, DELFIA Xpress PIGF 1-2-3 test, and BRAHMS sFlt-1 Kryptor/BRAHMS PIGF plus Kryptor PE ratio\)](#) in England.

1.2 The guidance states that:

- The Triage PIGF test and the Elecsys immunoassay sFlt-1/PIGF ratio, used with standard clinical assessment and subsequent clinical follow-up, are recommended to help rule-out pre-eclampsia in women presenting with suspected pre-eclampsia between 20 weeks and 34 weeks plus 6 days of gestation. When pre-eclampsia is not ruled-out using a PIGF-based test result, the result should not be used to diagnose (rule-in) pre-eclampsia.
- The Triage PIGF test and the Elecsys immunoassay sFlt-1/PIGF ratio, used with standard clinical assessment and subsequent clinical follow-up, show promise in helping to diagnose (rule-in) pre-eclampsia in women presenting with suspected pre-eclampsia between 20 weeks and 34 weeks plus 6 days of gestation. However, there is currently insufficient evidence to recommend their routine adoption for diagnosing pre-eclampsia in the NHS. Further research is recommended on using these tests in women with suspected pre-eclampsia to rule-in pre-eclampsia.
- The DELFIA Xpress PIGF 1-2-3 test and BRAHMS sFlt-1 Kryptor/BRAHMS PIGF plus Kryptor PE ratio are not recommended for routine adoption in the NHS. Further research by the companies is needed to show the clinical effectiveness of these tests, including diagnostic accuracy and analytical validity.

1.3 **Revised December 2018**

The Triage PIGF test (formerly Alere International) has been acquired by Quidel Corporation (<https://www.quidel.com>) and is commercially available. For further queries, please contact emeacustomerservice@quidel.com.

1.4 This report is supported by a resource impact template. The template aims to help organisations in England, Wales and Northern Ireland plan for the financial implications of implementing the NICE guidance by amending the variables.

2 Background and epidemiology of pre-eclampsia

2.1 In 2014, there were about 663,500 births in England ([Office for National Statistics](#) 2015).

2.2 Pre-eclampsia is characterised by high blood pressure (hypertension) and proteinuria, which occurs when the kidneys leak protein into the urine. The presence of either hypertension or proteinuria alone during pregnancy can also indicate a risk of developing pre-eclampsia.

2.3 If pre-eclampsia is not diagnosed and closely monitored it can lead to potentially life-threatening complications.

2.4 Uptake of the use of tests is expected to be gradual over 5 years.

Table 2 Estimated number of women to be tested with PIGF-based testing in England from year 5 onwards

Population	Proportion	Number of women
Births in England in 2014		663,519
Prevalence of women with gestational hypertension	13.5%	89,575
Proportion of women with suspected pre-eclampsia who are between 20 and 34 weeks and 6 days of gestation	75.0%	67,181
Estimated proportion of women to be tested from year 5 onwards	60%	40,309

2.5 Therefore it is estimated that about 40,300 women are likely to be tested with the Triage PIGF test or the Elecsys immunoassay sFLT-1/PIGF ratio test from year 5 onwards.

3 Assumptions made

3.1 The resource impact template makes the following assumptions:

- Uptake of tests is expected to be gradual over 5 years. Based on the manufacturer's submission and expert clinical opinion, it is estimated 10% of women with suspected pre-eclampsia will be offered PIGF-based testing in the first year increasing to 60% by year 5.
- Expert clinical opinion suggests that women who are not tested will be admitted to hospital for 36 hours for monitoring and possibly for treatment.
- A 36-hour stay in hospital is estimated to cost around £375.
- There are around 140 maternity units in England ([Health & Social Care Information Centre](#) 2013) and it is assumed that 100% will use the Elecsys immunoassay sFLT-1/PIGF ratio test.
- Initial equipment costs for the Triage PIGF test in the first year will be about £3,300 and around £1,200 a year thereafter.

- Initial and subsequent equipment costs for the Elecsys immunoassay sFLT-1/PIGF ratio test can be adjusted manually in the resource impact template.
- There will be no additional equipment costs in units where Roche (the manufacturer of the Elecsys immunoassay sFLT-1/PIGF ratio test) platforms are already available. Where Roche equipment is not currently available, additional equipment costs may apply however; these will be absorbed within the individual service contract agreements.
- About 10% of women who are tested will have an overnight stay in hospital while waiting for their test results. An overnight stay is estimated to cost around £250.
- Of the women tested with the Triage PIGF test, around 60% will have an abnormal PIGF concentration and may be admitted to hospital. The remaining 40% of women tested will continue having care within the community.
- Of the women tested with the Elecsys immunoassay sFLT-1/PIGF ratio test, around 30% will have an abnormal sFLT-1/PIGF ratio and may be admitted to hospital. The remaining 70% of women tested will continue having care within the community.
- The list price for a single Triage PIGF test is £40 and the list price for a single Elecsys immunoassay sFLT-1/PIGF ratio test is £57. The list prices of the tests have been used in the resource impact template.
- There are no additional costs for phlebotomy or sample preparation by healthcare professionals because blood samples for additional laboratory analysis will already have been taken as part of the standard clinical assessment.
- VAT will not be charged because a significant number of laboratories operate under managed services contracts that are VAT exempt.

4 Resource impact

- 4.1 The annual saving associated with implementing the guidance for the population of England is shown in table 3. The saving from year 5 onwards is expected to remain at a steady state.

Table 3 Resource impact of implementing the guidance for the population of England using NICE assumptions

	2016/17	2017/18	2018/19	2019/20	2020/21
Estimated proportion of women with suspected pre-eclampsia between 20 weeks and 34 weeks plus 6 days of gestation having testing each year	10%	25%	40%	50%	60%
Annual number of tests	6,718	16,795	26,873	33,591	40,309
Cash cost (£m)	0.4	1.0	1.5	1.9	2.3
Non-cash releasing saving (£m)	-1.6	-4.0	-6.3	-8.0	-9.6
Resource impact (£m)	-1.2	-3.0	-4.8	-6.1	-7.3

5 Savings and benefits

- 5.1 The Triage PIGF test and the Elecsys immunoassay sFLT-1/PIGF ratio test will allow women, in whom pre-eclampsia has been ruled-out, to return to community care instead of being admitted to hospital for monitoring.
- 5.2 The Triage PIGF test and the Elecsys immunoassay sFLT-1/PIGF ratio test may also improve quality of life for women suspected of having pre-eclampsia whose test result allows pre-eclampsia to be ruled-out, and this may also reduce hospital admissions.

6 Sensitivity analysis

- 6.1 The baseline percentage of women with gestational hypertension is 13.5%. This leads to a resource impact saving of £7.3 million from year 5 onwards in England. Varying the percentage of women with

gestational hypertension from 12% to 15% results in resource impact savings of £6.5 million to £8.1 million respectively.

- 6.2 The baseline percentage of women who have a test to rule-out pre-eclampsia is 60%. This leads to a resource impact saving of £7.3 million from year 5 onwards in England. Varying the percentage of women who have a test to rule-out pre-eclampsia from 50% to 70% results in resource impact savings of £6.1 million to £8.5 million respectively.

7 Implications for commissioners

- 7.1 Implementation of the guidance may lead to a reduction in bed days for the provider. The savings are not likely to be cash releasing but may increase available clinical staff time. For an average size maternity unit with approximately 4,700 births per year, around 300 bed days may be saved.
- 7.2 This will not result in any change for the commissioner. The standard antenatal maternity tariff (£1,057) will be paid for women who have not previously had pre-eclampsia. Women who have previously had severe pre-eclampsia will be allocated the intermediate tariff of £1,691 ([2016/17 National tariff payment system](#)).
- 7.3 PIGF testing falls within the programme budgeting category 18X Maternity and Reproductive Health.

8 References

Health & Social Care Information Centre (2013) [Hospital Episode Statistics. Maternity statistics 2012–13](#)

NHS England (2016) [2016/17 National tariff payment system](#)

[Office for National Statistics \(2015\) Birth summary tables, England and Wales: 2015](#)

Resource impact report: PIGF-based testing to help diagnose suspected pre-eclampsia (May 2016)

About this resource impact report

This resource impact report accompanies the NICE diagnostics guidance on [PIGF-based testing to help diagnose suspected pre-eclampsia \(Triage PIGF test, Elecsys immunoassay sFlt-1/PIGF ratio, DELFIA Xpress PIGF 1-2-3 test, and BRAHMS sFlt-1 Kryptor/BRAHMS PIGF plus Kryptor PE ratio\)](#) and should be read in conjunction with it. See [terms and conditions](#) on the NICE website.

This report is written in the following context

This report represents the view of NICE, which was arrived at after careful consideration of the available data and through consulting healthcare professionals. The report is an implementation tool and focuses on the recommendations that were considered to have a significant impact on national resource use.

Assumptions used in the report are based on assessment of the national average. Local practice may be different from this, and the impact should be estimated locally.

Implementation of the guidance is the responsibility of local commissioners and providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity and foster good relations. Nothing in this costing tool should be interpreted in a way that would be inconsistent with compliance with those duties.

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