NICE advice

ProciseDx point-of-care platform for inflammatory bowel disease

Medtech innovation briefing
Published: 12 July 2022

www.nice.org.uk/guidance/mib302

Summary

- The **technology** described in this briefing is ProciseDx. It is used for monitoring levels of inflammation and therapeutic response to infliximab and adalimumab in inflammatory bowel disease (IBD).
- The **innovative aspects** are that it is a point-of-care platform with 4 different assays for measuring C-reactive protein, faecal calprotectin, and levels of infliximab and adalimumab. It can be used with several specimen types including finger-prick whole blood, with results in less than 5 minutes.
- The intended **place in therapy** would be as an alternative to C-reactive protein and faecal calprotectin tests, and tests for therapeutic monitoring of infliximab and adalimumab in people with IBD.

- The **main points from the evidence** summarised in this briefing are from 6 studies (4 prospective validation studies and 2 retrospective observational studies) including a total of 622 adults and 45 specimens. They show that the Procise assays have comparable accuracy to established laboratory tests for IBD and are quicker to return results.
- **Key uncertainties** around the evidence or technology are that all studies were reported in preprints or abstracts. There was no evidence on the prospective use of ProciseDx in clinical care or therapeutic drug monitoring.
- **Experts advised** that ProciseDx would return results quicker than standard care. This could facilitate faster treatment decisions and reduce delays in optimising treatment. But ProciseDx does not measure antidrug antibodies which is a limitation compared with other assays. More evidence is needed validating the Procise assays against standard laboratory tests for IBD.
- The **cost** of the ProciseDx platform is £7,500 for the ProciseDx analyser (which includes the ProciseDx calibration cartridge) and between £5 to £47.50 per assay (excluding VAT). The costs of comparator tests are between £5 and £35 per person.

The technology

ProciseDx (BHR Pharmaceuticals) is a point-of-care instrument for inflammatory bowel disease (IBD). This briefing focuses on the use of the platform for monitoring levels of inflammation and measuring levels of the therapeutic drugs infliximab and adalimumab.

The ProciseDx system includes 2 assays for monitoring inflammation: Procise CRP (C-reactive protein) and Procise FCP (faecal calprotectin). C-reactive protein is a marker of inflammation in the body, which increases with active disease. Faecal calprotectin is also a biomarker which can be used to support a new diagnosis of IBD and to predict and assess possible relapse in people already diagnosed. Procise CRP can be done using finger-prick whole blood, venous blood or serum samples, while Procise FCP uses a stool sample collected with the Procise stool collection device.

ProciseDx also includes 2 assays for measuring levels of therapeutic drugs: Procise IFX (infliximab) and Procise ADL (adalimumab). Infliximab and adalimumab are biological drugs which target proteins and enzymes in the body that cause inflammation. Measurement of infliximab or adalimumab concentrations in the blood may help healthcare professionals to optimise dosing and manage IBD. Procise IFX and Procise ADL can be done with finger-

prick whole blood, venous blood or serum samples. Procise IFX has been validated for use with Remicade, Remsima, Inflectra, Flixabi and Rensflexis, while Procise ADL has been validated for use with Humira, Amgevita and Imraldi. Both assays have been calibrated against respective World Health Organisation international standards.

All assays run on the ProciseDx analyser. This is a fully automated instrument that uses time-resolved fluorescence resonance energy transfer signal to detect the presence and quantity of the target analyte. The company claims the technology returns lab-quality, quantitative results in 2 to 5 minutes. This can help healthcare professionals to make immediate treatment decisions.

Innovations

The company claims ProciseDx is easy to use and is small enough to place near the person who is being treated. It can be used with several specimen types, including finger-prick whole blood. Finger-prick whole blood sampling is quicker than serum sampling that is used in other point-of-care tests for IBD. ProciseDx uses lumiphore technology which reportedly allows for brighter and longer time-resolved fluorescence resonance energy transfer. The company claims this results in better sensitivity.

Current care pathway

IBD describes long-term conditions that cause inflammation of the gut. The 2 main forms of IBD are ulcerative colitis and Crohn's disease. Ulcerative colitis affects the large intestine, while Crohn's disease can affect any part of the digestive system.

People with suspected IBD are referred for specialist assessment with a consultant gastroenterologist. IBD is diagnosed using clinical evaluation and a combination of haematological, endoscopic, histological and imaging-based investigations. This may include tests to measure inflammation, such as C-reactive protein and faecal calprotectin. These tests may be laboratory-based, rapid tests or point-of-care tests.

Treatment for IBD aims to induce remission by healing inflammation and reducing symptoms, or to maintain remission by preventing flare-ups of IBD in the future. There are several drugs that can be used to treat IBD. Infliximab and adalimumab can be used to treat moderate to severe active ulcerative colitis and severe active Crohn's disease in people who have not benefited from conventional therapy. Infliximab or adalimumab is

given initially with a loading dose to induce clinical remission in moderate to severe IBD. People whose IBD responds to induction treatment may continue to take these drugs as maintenance.

People having drug treatment are monitored to determine their response to the drug and any adverse effects. People taking infliximab or adalimumab for maintenance therapy should be assessed at least once a year to determine whether ongoing treatment is needed. Therapeutic drug monitoring may identify people who lose response to drug treatment over time and need a higher dose. It may also be used to identify people who are responding well to treatment. Healthcare professionals can use this information to support treatment decisions and dosing.

Therapeutic drug monitoring of infliximab and adalimumab may be done using enzyme-linked immunosorbent assay (ELISA) kits or point-of-care tests. NICE's diagnostics guidance on therapeutic monitoring of TNF-alpha inhibitors for Crohn's disease advises that ELISA kits show promise for therapeutic monitoring. But there was not enough evidence to recommend routine adoption in the NHS.

Surgery may be needed in people with IBD who have severe symptoms that do not improve with drug treatment.

The following publications have been identified as relevant to this care pathway:

- NICE's guideline on ulcerative colitis: management
- NICE's guideline on Crohn's disease: management
- NICE's quality standard on inflammatory bowel disease
- NICE's diagnostics guidance on faecal calprotectin diagnostic tests for inflammatory diseases of the bowel
- NICE's diagnostics guidance on therapeutic monitoring of TNF-alpha inhibitors in Crohn's disease (LISA-TRACKER ELISA kits, IDKmonitor ELISA kits, and Promonitor ELISA kits)
- NICE's technology appraisal guidance on infliximab, adalimumab and golimumab for treating moderately to severely active ulcerative colitis after the failure of conventional therapy

- NICE's technology appraisal guidance on infliximab and adalimumab for the treatment of Crohn's disease
- NICE's medtech innovation briefing on point-of-care and home faecal calprotectin tests for monitoring treatment response in inflammatory bowel disease
- NICE's medtech innovation briefing on RIDASCREEN tests for monitoring infliximab in inflammatory bowel disease.

Population, setting and intended user

ProciseDx is a point-of-care platform for IBD. Ulcerative colitis is the most common type of IBD. About 1 in every 420 people in the UK have the condition, while around 1 in every 690 people have Crohn's disease. ProciseDx can be used to assist the diagnosis of IBD and to monitor remission and therapeutic drug levels in people with an existing diagnosis. It is an alternative to other point-of-care and laboratory tests that measure:

- C-reactive protein or faecal calprotectin
- trough or intermediate levels of infliximab or adalimumab.

ProciseDx can be used by healthcare professionals in gastroenterology services in secondary care and outpatient settings, such as rapid access clinics. The tests can be done by healthcare professionals such as IBD nurses, with basic instructions.

Costs

Technology costs

The ProciseDx analyser costs £7,500 per unit (excluding VAT). This includes the ProciseDx calibration cartridge. Costs of the assays and additional accessories are:

- Procise CRP assay: £100 for 20 tests (£5 per test)
- Procise FCP assay with Procise stool collection device: £440 for 20 tests (£22 per test)
- Procise IFX assay: £950 for 20 tests (£47.50 per test)

- Procise ADL assay: £950 for 20 tests (£47.50 per test)
- additional Procise stool collection device: £7.50
- additional ProciseDx calibration cartridge: £145.

The company said assay costs may be lower depending on the number of assays used in an organisation each year. Training on how to use the ProciseDx platform is included in the costs.

Costs of standard care

ProciseDx is an alternative to other point-of-care or laboratory tests for measuring inflammation or therapeutic drug levels in IBD. Costs of comparator tests (excluding VAT) may include:

- C-reactive protein test: £5 per test (NICE's diagnostics guidance on faecal calprotectin diagnostic tests for inflammatory diseases of the bowel)
- faecal calprotectin test including staff time: about £23 to £41 per person (NICE's diagnostics guidance on faecal calprotectin diagnostic tests for inflammatory diseases of the bowel and NICE's medtech innovation briefing on point-of-care and home faecal calprotectin tests for monitoring treatment response in inflammatory bowel disease)
- ELISA kits: about £20 per person (NICE's diagnostics guidance on therapeutic monitoring of TNF-alpha inhibitors in Crohn's disease [LISA-TRACKER ELISA kits, IDKmonitor ELISA kits, and Promonitor ELISA kits]).

One expert who commented on this briefing advised that costs for monitoring infliximab and adalimumab levels were approximately £35 per test.

The company claims ProciseDx point-of-care platform may reduce the need for follow-up appointments for results. It may also be used in therapeutic drug monitoring of infliximab and adalimumab, which may impact dosing decisions. Costs associated with appointments and therapeutic drugs include:

- consultant led gastroenterology outpatient follow up: £148
- infliximab: £420 per 100 milligram vial
- adalimumab: £352 per 40 milligram prefilled syringe.

Costs have been taken from the NHS drug tariff (March 2022), NHS England's 2019/20 National Cost Collection data and NICE guidelines and advice.

Resource consequences

ProciseDx is being validated or trialled within 6 NHS trusts. The company claims ProciseDx returns quicker results than other point-of-care or laboratory tests for measuring inflammation in IBD. This may facilitate faster diagnosis and earlier treatment. The company claims ProciseDx can also detect flares in IBD sooner than other tests, with results returned in 5 minutes or less. This may allow healthcare professionals to make treatment decisions during the appointment instead of awaiting test results later. The company claims this could reduce appointments. There is no evidence to support these claims.

ProciseDx may also facilitate faster measurement of levels of biologicals compared with other tests, which can often take 2 to 3 weeks for results to return. For some people, this may result in more accurate therapeutic drug monitoring and more timely clinical decision making. But many people may also need additional tests to measure antidrug antibodies against infliximab or adalimumab. Proactive therapeutic drug monitoring in IBD may be associated with better clinical outcomes (Papamichael and Cheifetz 2019) and cost savings (Martelli et al. 2016) compared with standard care.

ProciseDx can be used by healthcare professionals with minimal training. The tests do not need to be done by trained laboratory technicians.

Regulatory information

The ProciseDx analyser, assays, and accessories are CE-marked IVD (in-vitro diagnostic) General. This includes Procise CRP assay, Procise FCP assay, Procise IFX assay, Procise ADL assay, ProciseDx stool collection device and ProciseDx calibration cartridge.

Equality considerations

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

There were no equality issues identified related to using ProciseDx. People of any age can get inflammatory bowel disease (IBD), but it is usually diagnosed in those aged between 15 and 40 years. It is more likely to occur in people with a family member with the condition. IBD is more common in people with a European family background. Prevalence rates are similar in men and women.

IBD is a lifelong condition that can have periods of remission and relapse. It can affect a person's social and psychological wellbeing and reduce quality of life. People with IBD also have higher risk of developing other conditions, such as colorectal cancer, osteoporosis and anaemia. Age, race and disability are protected characteristics under the Equality Act 2010.

Clinical and technical evidence

A literature search was carried out for this briefing in accordance with the interim process and methods statement for medtech innovation briefings. This briefing includes the most relevant or best available published evidence relating to the clinical effectiveness of the technology. Further information about how the evidence for this briefing was selected is available on request by contacting mibs@nice.org.uk.

Published evidence

Six studies are summarised in this briefing, including a total of 622 adults with inflammatory bowel disease (IBD) and 45 laboratory specimens.

The summarised evidence includes 4 prospective validation studies and 2 retrospective observational studies.

There is additional evidence not summarised in this briefing, including 2 in-vitro studies (Ong et al. 2021a, Ong et al. 2021b, Ong et al. 2020, Yadav et al. 2021) and a small sample prospective validation study (Šahinović et al. 2021). Another study (Lorenzon et al. 2021) was identified in the literature search. But it was excluded as it included people with active inflammatory disease or infection, of whom only 17% had suspected or diagnosed IBD.

The clinical evidence and its strengths and limitations is summarised in the overall assessment of the evidence.

Overall assessment of the evidence

The evidence on ProciseDx is mostly validation studies on the 4 Procise assays. The evidence was reported in non-peer-reviewed preprints, abstracts and posters. It is limited in quality, with some studies lacking information on demographics, study design and findings. All studies compared the Procise assays with appropriate comparators. Findings showed that the Procise assays had comparable accuracy to established tests for IBD and good performance in detecting loss of response in people with IBD on maintenance therapy. ProciseDx was also found to be quicker, with results returned in around 3 minutes. But there was no evidence on the prospective use of ProciseDx in clinical care or therapeutic drug monitoring. Most studies included people with IBD and there was no evidence on using ProciseDx to diagnose the condition. None of the studies were done in the UK so there is no evidence on the use of the platform in the NHS. Further research should evaluate the use of ProciseDx in clinical care for diagnosing and monitoring IBD, including its effect on clinical decision making and dosing, resource use and patient outcomes.

Cerna et al. (2022)

Study size, design and location

Prospective analysis of the detection of trough levels of infliximab (n=24) and adalimumab (n=21) in blood samples in Czech Republic.

Intervention and comparator

Procise IFX and Procise ADL using capillary finger prick compared with enzyme-linked immunosorbent assay (ELISA) test using peripheral venous samples.

Key outcomes

Spearman's correlation with ELISA assays was 0.94 (R squared 0.88, slope 0.93, intercept 0.30) for Procise IFX and 0.91 (R squared 0.83, slope 1.40, intercept -1.26) for Procise ADL (both $p<0.001$). Authors concluded that Procise IFX and Procise ADL are accurate and comparable to ELISA.

Strengths and limitations

The study was reported in an abstract and poster only. There was limited detail on study design and methods. It was unclear if the study included people with IBD and if all samples were taken prospectively. The abstract did not report if any samples were excluded from analysis.

Stevens et al. (2022a)

Study size, design and location

Retrospective observational study examining the clinical utility of Procise ADL in 84 adults with Crohn's disease or ulcerative colitis who had maintenance adalimumab treatment. The study compared adalimumab levels in people with (n=37) and without (n=47) loss of response. Study location was not reported.

Intervention

Procise ADL using frozen serum samples.

Key outcomes

Procise ADL assay performance in detecting loss of response was optimised at adalimumab trough cut-off of 8 micrograms per millilitre (sensitivity 57%, specificity 89%). Area under the receiver operating characteristic (ROC) curve for loss of response was 0.82 (95% confidence interval [CI] 0.73 to 0.92). Adalimumab trough levels were lower in people who had loss of response (median 6.0 micrograms per millilitre) than those who did not (median 13.0 micrograms per millilitre; $p<0.001$). People with adalimumab levels below 8 micrograms per millilitre had a 5.34-fold increased risk of loss of response than those with higher adalimumab levels.

Strengths and limitations

The study was reported in an abstract and poster only. Findings provide some support for therapeutic drug monitoring using Procise ADL to detect loss of response in IBD. But the retrospective study design meant the technology was not used in clinical practice. More research is therefore needed on the use of Procise ADL in clinical practice and its impact on clinical decision making and outcomes. The company was involved in the research.

Stevens et al. (2022b)

Study size, design and location

Retrospective observational study examining the clinical utility of Procise IFX in 92 adults with Crohn's disease or ulcerative colitis who had maintenance infliximab treatment. The study compared infliximab levels in people with (n=55) and without (n=37) loss of response. Study location was not reported.

Intervention

Procise IFX using frozen serum samples.

Key outcomes

Procise IFX assay performance in detecting loss of response was optimised at infliximab trough cut-off of 3 micrograms per millilitre (sensitivity 64%, specificity 89%). Area under the ROC curve for loss of response was 0.82 (95% CI 0.73 to 0.91). Infliximab trough levels were lower in people who had loss of response (median 2.4 micrograms per millilitre) than those who did not (median 6.5 micrograms per millilitre; p<0.001). People with infliximab levels below 3 micrograms per millilitre had a 5.89-fold increased risk of loss of response than those with higher infliximab levels.

Strengths and limitations

The study was reported in an abstract and poster only. Findings provide some support for therapeutic drug monitoring using Procise IFX to detect loss of response in IBD. But more research is needed on the use of Procise IFX in clinical practice. The company was involved in the research.

Maniero et al. (2021)

Study size, design and location

Prospective analytical validation study in 87 adults with IBD taking infliximab in Italy. Of these, 52% had Crohn's disease, 45% had ulcerative colitis and 3% had underdetermined IBD.

Intervention and comparator

Procise IFX assay using finger-prick whole blood compared with Promonitor infliximab ELISA test (Grifols) using serum samples.

Key outcomes

Procise IFX took about 3 minutes from blood collection to results. Serum sampling took about 3 weeks, and the ELISA test took 3 hours to do. Deming regression showed a correlation between the tests of 0.83 (R squared 0.69), with a slope of 1.44 and intercept of -1.36. Authors concluded Procise IFX had similar accuracy to ELISA and was quicker, and easy to use.

Strengths and limitations

The study was reported in an abstract only. Finger-prick whole blood and serum samples were collected at the same time, which may have reduced timing errors. The tests differ in the reportable range of infliximab levels. The reportable range for Procise IFX was 1.7 to 77.2 micrograms per millilitre, while ELISA ranged 0.04 to 14.4 micrograms per millilitre. In total, 39 people were excluded from analysis because they had trough levels outside of the range for either test. The company was involved in the research.

Marsilio et al. (2021)

Study size, design and location

Prospective analytical validation study in 60 adults with IBD taking adalimumab in Italy. Of these, 80% had Crohn's disease, 17% had ulcerative colitis and 3% had underdetermined IBD.

Intervention and comparator

Procise ADL assay using finger-prick whole blood compared with Promonitor adalimumab ELISA test (Grifols) using serum samples.

Key outcomes

Procise ADL took about 3 minutes for the results to be returned. Serum sampling took

about 3 weeks, and the ELISA test took 3 hours to do. Deming regression showed a correlation between the tests of 0.86 (R squared 0.74), with a slope of 1.30 and intercept of -1.52. Authors concluded Procise ADL had similar accuracy to ELISA and was quicker, and easy to use.

Strengths and limitations

The study was reported in an abstract only. Finger-prick whole blood and serum samples were collected at the same time. The tests differ in the reportable range of adalimumab levels. The reportable range for Procise ADL was 1.3 to 51.5 micrograms per millilitre, while ELISA ranged from 0.02 to 12 micrograms per millilitre. In total, 30 people were excluded from comparative analysis because they had trough levels of adalimumab outside of the range for either test. The company was involved in the research.

Volkers et al. (2021a)

Study size, design and location

Prospective validation study in adults with IBD who needed routine measurement of C-reactive protein, infliximab and adalimumab. Study location was not reported. This study was also reported in a conference poster (Volkers et al. 2021b).

The study recruited 66 people for C-reactive protein measurements, 124 for infliximab, and 109 for adalimumab. Some measurements were excluded from analysis because they were outside of the assay range. Data was analysed for 41 people having C-reactive protein measurement, 120 having infliximab, and 105 having adalimumab.

Intervention and comparators

Procise CRP, Procise IFX and Procise ADL assays using finger-prick whole blood samples compared with laboratory tests using C-reactive protein plasma assay, and infliximab and adalimumab serum ELISA. Procise IFX was also done using serum samples because of outliers in the findings.

Key outcomes

ProciseDx results were returned in 3 minutes, but the time for comparator results was not reported. Procise CRP, Procise IFX and Procise ADL using finger-prick whole blood

samples correlated with laboratory tests (0.98, 0.88, 0.87, respectively; all p<0.001). Deming regression analysis of C-reactive protein assays resulted in a slope of 0.71 (95% CI 0.5 to 0.9) and intercept of 1.5 (95% CI -0.4 to 3.5). The authors reported there was an underestimation of C-reactive protein but considered this clinically irrelevant. Infliximab assays had a slope of 1.1 (95% CI 0.83 to 1.3) and intercept of 1.4 (95% CI -0.5 to 3.4), while adalimumab assays had a slope of 1 (95% CI 0.9 to 1.2) and intercept of 1.9 (95% CI 0.5 to 3.2). Procise IFX using serum samples correlated with ELISA (0.99, p<0.001), with Deming regression analysis resulting in a slope of 1.1 (95% CI 1.0 to 1.1) and intercept of 0.95 (95% CI 0.4 to 1.5). Authors suggested outliers between infliximab finger-prick whole blood and serum samples may be because of timing errors.

Strengths and limitations

The study was reported in a poster and abstract only. There was limited detail, including little information on study design including sampling or blinding, and study location. There was also limited discussion of findings, particularly considerations related to the underestimation of C-reactive protein and timing errors. The study was funded by the company and involved 2 employees.

Sustainability

The company claims that the ProciseDx point-of-care platform will reduce the need for biological samples to be packaged and transported from clinical sites to laboratories for processing. There is currently no evidence on this.

Recent and ongoing studies

Clinical validation of a point of care (POC) test for the measurement of infliximab (IFX) or adalimumab (ADL) levels in the serum of inflammatory bowel disease (IBD) patients. Trialregister.nl identifier: NL8934. Status: recruiting. Indication: inflammatory bowel disease. Devices: Procise IFX and Procise ADL assays. Date registered: September 2020. Country: Netherlands.

Expert comments

Comments on this technology were invited from clinical experts working in the field and relevant patient organisations. The comments received are individual opinions and do not

represent NICE's view.

Four experts commented on this briefing. All experts were familiar with or had used tests for monitoring levels of inflammation or measuring levels of the therapeutic drugs infliximab and adalimumab. Two experts were familiar with ProciseDx because it was undergoing testing in their NHS trusts.

Level of innovation

All experts advised that tests of C-reactive protein, faecal calprotectin, and infliximab and adalimumab levels are routinely used in clinical practice. Two experts said that ProciseDx is a minor variation on an existing procedure. It is innovative because it is a point-of-care test that uses the same analyser for different assays and sample types. Two experts advised that ProciseDx does not measure antidrug antibodies against infliximab or adalimumab. They thought that this was a limitation compared with other assays.

Potential patient impact

All experts described benefits of monitoring levels of inflammation and therapeutic drugs in inflammatory bowel disease (IBD). Tests of C-reactive protein and faecal calprotectin are important to assess disease activity and monitor clinical outcomes, while therapeutic drug monitoring can help healthcare professionals make therapeutic decisions. Results for C-reactive protein and faecal calprotectin take at least 24 hours to be returned. Results of therapeutic drug monitoring may not be available for several weeks. All experts commented that ProciseDx could save time in getting results because tests would be done at the point of care instead of in a laboratory. One expert thought people may also prefer finger-prick whole blood sampling to serum sampling.

The experts advised that the technology could have potential harms if the assays are not reliable. This would affect treatment decisions and clinical outcomes. All experts advised that more evidence is needed comparing ProciseDx with standard laboratory tests for IBD.

Potential system impact

The experts commented that ProciseDx could improve the management of IBD by facilitating faster treatment decisions. It may also reduce outpatient appointments because people would not have to return to clinic to get their results. One expert said that

faecal calprotectin tests could be used every 3 to 6 months to effectively monitor IBD. People having anti-TNF (tumour necrosis factor) therapy may also benefit from both reactive and proactive therapeutic drug monitoring once or twice a year. This could help healthcare professionals to detect and manage loss of response earlier, which may reduce flare-ups. The expert believed this could have system benefits because it may reduce the burden on primary care and community resources. It may also reduce emergency visits, hospitalisation, treatment change and surgery.

One expert described ProciseDx as small, portable and easy to use. All experts thought that it could be adopted with no change to standard care processes and only minor training. The experts said that ProciseDx could replace standard tests if objective validation of accuracy was confirmed.

General comments

The experts commented that ProciseDx could be used in most or all district general hospitals if it is shown to be safe and efficacious. One expert advised that it could be used with 80% of people with IBD, specifically people on anti-TNF drugs or with suspected flares of inflammatory activity. Another expert said point-of-care testing could also be used in hospital settings to assist dosing in acute severe ulcerative colitis, but evidence on this is needed.

All experts advised that more evidence is needed before ProciseDx can be routinely used in the NHS. Research is needed comparing it with standard care tests to strengthen evidence on its reliability and validity in clinical practice. The evidence base would also benefit from research on the impact of point-of-care tests on clinical decision making in IBD, such as dose optimisation and treatment changes.

Patient organisation comments

A representative from Short Bowel Survivor and Friends gave the following comments.

Early and accurate detection of inflammatory bowel disease can help get quicker access to treatment and may reduce isolation. ProciseDx may particularly benefit young children and babies with short bowel syndrome, intestinal failure or Crohn's disease.

Expert commentators

The following clinicians contributed to this briefing:

- Professor Jimmy Limdi, consultant gastroenterologist and head of inflammatory bowel disease section, Northern Care Alliance NHS Foundation Trust (North-East Sector). Provided ProciseDx free of cost to test in NHS trust.
- Dr Joel Mawdsley, consultant gastroenterologist, Guys and St Thomas' NHS Foundation Trust. Did not declare any interests.
- Dr Juan de la Revilla Negro, consultant gastroenterologist, Cambridge University Hospitals NHS Foundation Trust. Did not declare any interests.
- Ms Tracey Mare, clinical research and development manager, Viapath Analytics, King's College Hospital NHS Foundation Trust. Did not declare any interests.

A representative from Short Bowel Survivor and Friends also contributed to this briefing.

Development of this briefing

This briefing was developed by NICE. NICE's interim process and methods statement sets out the process NICE uses to select topics, and how the briefings are developed, quality-assured and approved for publication.

ISBN: 978-1-4731-4642-6