

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technology guidance

FINAL SCOPE

The Neuropad test for the early detection of diabetic peripheral neuropathy

1 Technology

Neuropad (TRIGOCare International) is a point-of-care test for people with diabetes to diagnose sudomotor dysfunction (inadequate sweat production), which may indicate that a person is at risk of developing diabetic peripheral neuropathy (DPN). The 10-minute test is non-invasive and comprises a colour-changing plaster containing cobalt chloride that is applied to the sole of each foot. A colour change from blue to pink indicates adequate sweat production and normal autonomic nerve function with a low risk of DPN. If colour changes partially, or remains blue, this indicates reduced sweating and sudomotor function which is associated with DPN and an increased risk of diabetic foot complications.

The Neuropad test can be done in a clinic by a healthcare professional during a routine foot check, or at home by the person themselves (or their carer). Neuropad is used in conjunction with other standard sensory neuropathy tests (such as the 10 g monofilament) to improve the detection of DPN.

1.1 *Description of the technology*

1.2 *Regulatory status*

The Neuropad test received a CE mark (Class I) in November 2005 as a test for sudomotor dysfunction and the early detection of diabetic foot neuropathy.

1.3 Claimed benefits

The benefits to patients for Neuropad claimed by the company are:

- A simple test that can be done at home by the person with diabetes or in a clinic by a healthcare professional
- A colour-change objective result in 10 minutes that is easy to interpret
- Non-invasive, painless and safe
- Detection of neuropathy earlier than 10 g monofilament and vibration tests which is useful in identifying people with diabetes at the greatest risk of neuropathy.

The benefits to the healthcare system claimed by the company are:

- An inexpensive, simple to interpret objective test, with results obtained in 10 minutes that are recorded on the device
- No expertise, specialist equipment or staff needed to carry out the test: no expert intervention needed until the patient at risk is identified and followed up
- The test can be done at home by the patient, so no clinic appointments needed
- Detects neuropathy earlier than monofilament and vibration tests, so useful for the early identification of people with diabetes who are at the greatest risk of neuropathy.

The sustainability benefits claimed by the company are:

- A low carbon footprint with no energy use, no need for clinic visits or support staff
- No missed appointments as the test can be done at home and the results can be sent to a healthcare professional, electronically or by post.

1.4 Relevant diseases and conditions

In the UK, an estimated 4.5 million people have diabetes: this is predicted to rise to 5 million people by 2025. Diabetic peripheral neuropathy (DPN) is a common long-term complication, where high blood glucose levels damage the

small blood vessels supplying the nerves to the hands and feet. DPN affects up to 50% of people with diabetes, with chronic, painful neuropathy affecting up to 26%, which increases the risk of foot ulceration and subsequent amputation. In England, around 2.5% of people with diabetes have foot ulcers at any given time (approximately 86,000 people) and there were around 6,000 lower limb amputations due to DPN in 2014/15. ¹

DPN may involve large nerve fibres, small nerve fibres, or both, affecting different sensation modalities. Large fibres affect motor function and sensation function for vibration and temperature. Small fibres constitute 80–91% of peripheral nerve fibres and control pain perception and autonomic sudomotor function. Small fibre neuropathy is the most common type of neuropathy in people over 50 years; it typically affects the lower limbs and often precedes large fibre neuropathy. Sudomotor dysfunction is indicative of diabetic autonomic neuropathy, which can result in foot ulceration. A lack of sweating can cause the skin to crack, leading to an increased risk of infection; if untreated, this can cause sepsis and gangrene with the need for amputation.

1.5 Current management

NICE's guideline on [diabetic foot problems](#) recommends that adults with diabetes have a risk assessment for diabetic foot problems on diagnosis; at least annually thereafter; whenever foot problems arise and on any admission to hospital. During the risk assessment, both feet should be examined for multiple risk factors, including neuropathy, which should be tested using a 10 g monofilament as part of a foot sensory examination. If neuropathy is detected, a person's risk is classified as being moderate or high (depending on other comorbidities). This triggers referral to a foot protection service and an increased frequency of foot assessments.

Testing of sudomotor function to detect neuropathy is not included in NICE guidance. Tests for sensation that are not recommended by NICE guidance

¹ [Diabetes UK Facts and Stats Dec 2015](#)

for detecting diabetic foot neuropathy in primary care include tuning fork, biothesiometer, [Vibratip](#) and Neurotip.

Neuropad is the only self-testing device for sudomotor function available for use in a primary care or the home setting. More specialist tests are used in secondary care to detect small fibre neuropathy, including nerve conduction studies using electromyography, intraepidermal nerve fibre density biopsy, quantitative sudomotor axon reflex test (QSART), Sudoscan, corneal confocal microscopy and the NC-stat DPN check device for sural nerve velocity.

2 Reasons for developing guidance on Neuropad for detecting diabetic peripheral neuropathy

The committee recognised that Neuropad offers a unique, objective test for the detection of small fibre neuropathy that appears easy to use in primary care and community settings. The committee considered that Neuropad may improve the detection of foot neuropathy for some people with diabetes, especially those in whom monofilament testing is not routinely done or may not be appropriate, including those who are unable to cooperate with the test; for example, people with cognitive impairment or communication difficulties, as well as elderly or disabled people in whom surgery or hospital attendance is difficult.

The committee concluded that although Neuropad (where used as an adjunct to current tests) will increase initial costs, there is the potential for cost savings, if the test leads to an earlier diagnosis of diabetic neuropathy and treatment which reduces the incidence of foot ulceration and amputation. The committee noted that an evaluation including cost modelling with appropriate outcomes and time horizons would therefore help address uncertainties about the cost impact of adopting this test.

3 Statement of the decision problem

	Final scope issued by NICE
Population	People with diabetes undergoing routine foot-care checks by health care workers in primary and secondary care settings and/or undertaking a DPN self-test in the home
Intervention	Neuropad
Comparator(s)	<ul style="list-style-type: none"> • 10 g monofilament • Other sensation tests used in primary care (e.g. Vibratip, Neurotip, tuning fork, biothesiometer, Ipswich Touch Test) • Standard neuropathy scoring systems used in primary care (e.g. Neuropathy Disability Score) • Specialist small fibre neuropathy tests used in secondary care (nerve conduction tests, intraepidermal nerve fibre density biopsy, quantitative sudomotor axon reflex test (QSART), Sudoscan, corneal confocal microscopy, NC-stat DPN check) (see also 'Cost analysis' below)
Outcomes	The outcome measures to consider include: <ul style="list-style-type: none"> • Sensitivity and specificity in identifying diabetic peripheral neuropathy (DPN) compared to reference standard (standard neuropathy scoring or specialist secondary care tests) • Patient experience and ease of use by patients and clinicians • Reliability and reproducibility of use by patients and clinicians • Total time to carry out test and obtain result • Rates of GP surgery or hospital attendance • Incidence of foot ulceration and/or amputation • Device-related adverse events.
Cost analysis	Comparator(s): Costs will be considered from an NHS and personal social services perspective. The time horizon for the cost analysis will be sufficiently long to reflect any differences in costs and consequences between the technologies being compared. Sensitivity analysis will be undertaken to address uncertainties in the model parameters, which will include scenarios in which different numbers and combinations of devices are needed.
Subgroups to be considered	<ul style="list-style-type: none"> • People in community settings • People with communication difficulties or cognitive impairment
Special considerations, including those related to equality	Diabetes is a chronic condition that is covered under the Equality Act 2010. DPN is more common with increasing age and men may develop DPN earlier than women, but neuropathic pain causes more morbidity in women than in men. More secondary complications from DPN have been shown to occur in people of Hispanic or African American family origin. The Neuropad test may be easier to use for people with communication difficulties, as it is an objective test that does not require assessment of subjective patient responses, unlike the vibration tests. This may allow for improved detection of diabetic neuropathy in children, people with mental health disabilities or

	people who have problems communicating. People with visual impairments may need help to administer the Neuropad, so self-testing at home may not be possible in this subgroup.	
Special considerations, specifically related to equality issues	Neuropad is contraindicated for people with cobalt, nickel or chrome sensitivities and should not be placed on skin that is badly cracked, or has local inflammation or open wounds.	
	Are there any people with a protected characteristic for whom this device has a particularly disadvantageous impact or for whom this device will have a disproportionate impact on daily living, compared with people without that protected characteristics?	No
	Are there any changes that need to be considered in the scope to eliminate unlawful discrimination and to promote equality?	No
	Is there anything specific that needs to be done now to ensure MTAC will have relevant information to consider equality issues when developing guidance?	No

4 Related NICE guidance

Published

- [Type 2 diabetes in adults: management.](#) (2016) NICE guideline NG28
- [Diabetic foot problems: prevention and management.](#) (2016) NICE guideline NG19
- [Diabetes \(type 1 and type 2\) in children and young people: diagnosis and management.](#) (2015) NICE guideline NG18.
- [Type 1 diabetes in adults: diagnosis and management.](#) (2016) NICE guideline NG17
- [Diabetes in pregnancy: management from preconception to the postnatal period.](#) (2015) NICE guideline NG3
- [VibraTip for testing vibration perception to detect diabetic peripheral neuropathy](#) (2014) NICE medical technology guidance MTG22

Under development

NICE is developing the following guidance (details available from www.nice.org.uk):

- [Type 2 diabetes management.](#) NICE guideline: standing committee update.
Publication expected: December 2017

NICE advice

- [Diabetic foot problems](#) (2013) NICE Evidence Update 33
- [Training non-podiatrists to assess foot risk as part of an integrated foot service for people with diabetes](#) (2016) NICE shared learning database

5 External organisations

5.1 Professional organisations

5.1.1 Professional organisations contacted for expert advice

At the selection stage, the following societies were contacted for expert clinical and technical advice:

- Association of British Clinical Diabetologists (ABCD)
- Association of British Neurologists
- British Peripheral Nerve Society (BPNS)
- British Diabetic Association
- British Society for Clinical Neurophysiology
- The Neurological Alliance
- Royal College of GPs
- National Diabetes Nurse Consultant Group
- Primary Care Diabetes Society
- Royal College of Physicians (RCP)
- Royal College of Physicians, Edinburgh
- Royal College of Nursing
- Society for Endocrinology
- Society of Chiropractors and Podiatrists.

5.1.2 Professional organisations invited to comment on the draft scope

The following societies have been alerted to the availability of the draft scope for comment:

- Association of British Clinical Diabetologists (ABCD)

- Association of British Neurologists
- British Peripheral Nerve Society (BPNS)
- British Diabetic Association
- British Society for Clinical Neurophysiology
- The Neurological Alliance
- Royal College of GPs
- National Diabetes Nurse Consultant Group
- Primary Care Diabetes Society
- Royal College of Physicians (RCP)
- Royal College of Physicians, Edinburgh
- Royal College of Nursing
- Society for Endocrinology
- Society of Chiropractors and Podiatrists.

5.2 Patient organisations

At the selection stage, NICE's Public Involvement Programme contacted the following organisations for patient commentary and alerted them to the availability of the draft scope for comment:

- Age Related Diseases and Health Trust
- Black and Ethnic Minority Diabetes Association (BEMDA)
- Diabetes Research & Wellness Foundation
- Diabetes UK
- Families with Diabetes National Network
- Foot in Diabetes UK (FDUK)
- InDependent Diabetes Trust
- INsulin PUmp Therapy (INPUT)
- Juvenile Diabetes Research Foundation (JDRF)
- Surya Foundation
- UK Health Forum (formerly National Heart Forum).