NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technology guidance scope

Magtrace and Sentimag for locating sentinel lymph nodes for breast cancer

1 Technology

1.1 Description of the technology

The Magtrace and Sentimag system (Endomag) comprises of a magnetic liquid tracer (Magtrace) and a handheld magnetic sensing probe (Sentimag). Magtrace is intended for use only with the Sentimag system. Magtrace is a non-radioactive dark brown liquid containing superparamagnetic iron oxide with a carboxydextran coating. It is both a magnetic marker and a visual dye (because of the dark colour of the particles). Magtrace is injected into the tissue beneath the areola or interstitial tissue around a tumour, then the particles are absorbed into lymphatics and become trapped in sentinel lymph nodes that can then be detected by the magnetic sensing probe to assist with biopsy. It can be injected by healthcare professionals such as surgeons or nurses before a sentinel lymph node biopsy (SLNB). This can be done in the operating theatre 20 minutes before the procedure or up to 30 days before surgery at an outpatient clinic.

During surgery, the Sentimag probe detects the tracer trapped in the lymph nodes and guides the surgeon to remove them for biopsy. Sentimag uses a visual reading and sounds of different pitches to indicate how close the surgeon is to the tracer. The nodes often appear dark brown or black in colour, which also helps identification.

The key innovative feature of the Magtrace and Sentimag system is its magnetic mechanism of action. This means that unlike other interventions used in current practice, the system can be used without the need for nuclear

medicine safety procedures and facilities. Magtrace can also be injected up to 30 days before surgery, whereas the tracers used in current practice can be given no more than a day before.

1.2 Relevant diseases and conditions

The Magtrace and Sentimag system, in people with breast cancer, is intended for locating sentinel lymph nodes during SLNB procedures for breast cancer staging.

NICE guideline on early and locally advanced breast cancer says that SLNB is the preferred technique to stage the axilla for people with invasive breast cancer and no evidence of lymph involvement on ultrasound or a negative ultrasound-guided needle biopsy.

Breast cancer is the most common cancer in the UK with approximately 54,000 new cases of invasive disease annually. The vast majority of breast cancers occur in women, but just over 300 men in the UK are also diagnosed with invasive breast cancer each year.

The company notes that Magtrace has been used in SLNB for breast cancer and other cancers such as melanoma, endometrial, cervical, prostate and oral cancer.

1.3 Current management

SLNBs help to diagnose cancer that has spread to the lymph nodes. The current treatment option for locating sentinel lymph nodes during SLNB is a combination of a tracer containing a radioactive isotope, technetium-99m and blue dye. Where technetium-99m is not available, blue dye may be used on its own, but this can reduce the detection rate of sentinel lymph nodes.

When using Technetium-99m for locating sentinel lymph nodes during SLNB it will be injected on the morning of the procedure following its preparation by nuclear medicine specialists. In some hospitals, the isotope is prepared off-site and then transported to the healthcare setting. On some occasions this can lead to the procedure being delayed. There can also be uncertainty

around availability of Technetium-99m. Cancellations and later starting times for procedures can waste resources and cause issues for surgical scheduling so significant planning and logistical oversight is required.

NICE has published guidance on the use of SLNB for early and locally advanced breast cancer. The guideline recommends that the dual technique with isotope and blue dye should be used when performing SLNB. Specifically, SLNB is recommended by NICE for people with invasive breast cancer who had no evidence of lymph node involvement on ultrasound or a negative ultrasound-guided needle biopsy.

The guideline also recommends that SLNB should be offered to people who are having a mastectomy for ductal carcinoma in-situ (DCIS) breast cancer and people with a pre-operative diagnosis of DCIS who are considered to be at high risk of invasive disease.

1.4 Regulatory status

Magtrace received a CE mark in November 2012 and Sentimag received a CE mark in December 2010, both as class IIa devices for locating sentinel lymph nodes under the Medical Device Directive.

1.5 Claimed benefits

The benefits to patients claimed by the company are:

- Reduced risk of anaphylactic reaction during SLNB procedures that use blue dye
- Reduced waiting times for patients because hospitals currently rely on a supply of technetium-99m to perform an SLNB
- Increased convenience of being able to have the Magtrace injection up to 30 days before the procedure. Currently people will usually have the technetium-99m injection and wait in the healthcare setting before the procedure. Blue dye is injected once the patient is anaesthetised in the operating theatre

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

- Improved patient management and co-ordination of care
- Improved efficiency in the use of facilities and staff resource
- Does not require involvement of nuclear medicine scientists or radiologists

2 Decision problem

Population	• People with high grade ductal carcinoma in-situ or invasive breast cancer having a sentinel lymph node biopsy
Intervention	Magtrace and Sentimag
Comparator(s)	• Technetium-99m in combination with blue dye
Outcomes	The outcome measures to consider include: • sentinel lymph node detection rate • mean number of sentinel lymph nodes retrieved per procedure • time taken for SLNB procedure • patient-reported outcome measures • device-related adverse events
Cost analysis	Costs will be considered from an NHS and personal social services perspective. The time horizon for the cost analysis will be long enough to reflect differences in costs and consequences between the technologies being compared. Sensitivity analysis will be undertaken to address uncertainties in the model parameters.
Subgroups to be considered	Not applicable.
Special considerations, including those related to equality	People with cancer are protected under the Equalities Act 2010. People who may experience anaphylaxis as an adverse reaction to blue dye would currently be given Technetium-99m only or a four-node axillary sample. Magtrace and Sentimag could offer an alternative treatment option for this group. Known contraindications include people with known hypersensitivity to iron oxide or dextran compounds, people with iron overload disease and people with a metal implant in the axilla or in the chest. This may be recognised as an equality issue as some people may be excluded from treatment with the technology. Magtrace and Sentimag may improve access to healthcare services as it could be used in smaller sites where there is not access to nuclear medicine. Currently, healthcare settings must have systems in place to handle, store and dispose of radioactive substances. The broader timing for the injection of Magtrace, between 1 and 30 days before surgery, may improve management of healthcare resources related to the procedure. Outcomes relevant to service delivery, efficiency gains and resource use could also be considered as part of the economic model.

	Technetium-99m is not always available and is usually prepared and used on the same day as the procedure. Where there is a shortage of Technetium-99m, blue dye is used alone. The dual technique has been shown to improve the rate of identification of SLNs.	
Special considerations, specifically related to equality	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 characteristic?	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 the Medical Technologies Advisory Committee will have relevant information to consider equality issues when developing guidance?	No
	No specific equality issues have been identified relating to using the device.	
Any other special considerations	When injected directly into the bloodstream, the presence of Magtrace may cause image artefacts to present during Magnetic Resonance Imaging (MRI) of the injection and drainage site.	

3 Related NICE guidance

Published

- Early and locally advanced breast cancer: diagnosis and management (2018) NICE guideline NG101
- Intraoperative tests for detecting sentinel lymph node metastases in breast cancer NICE diagnostics guidance DG8

4 External organisations

4.1 Professional

The following organisations have been asked to comment on the draft scope:

- Breast Cancer Research Foundation
- British Nuclear Medicine Society
- Cancer Research UK
- European Society of Breast Cancer Specialists
- Health and Care Professions Council

- MacMillan
- National Breast Cancer Foundation
- Royal College of Radiologists

4.2 Patient

NICE's Public Involvement Programme contacted the following organisations for patient commentary and asked them to comment on the draft scope:

- Breast Cancer Now
- Breast Cancer Research Trust
- Breast Cancer UK
- CoppaFeel!
- National Hereditary Breast Cancer Helpline
- Pink Ribbon Foundation
- Prevent Breast Cancer
- The Inflammatory Breast Cancer Network UK
- Walk the Walk