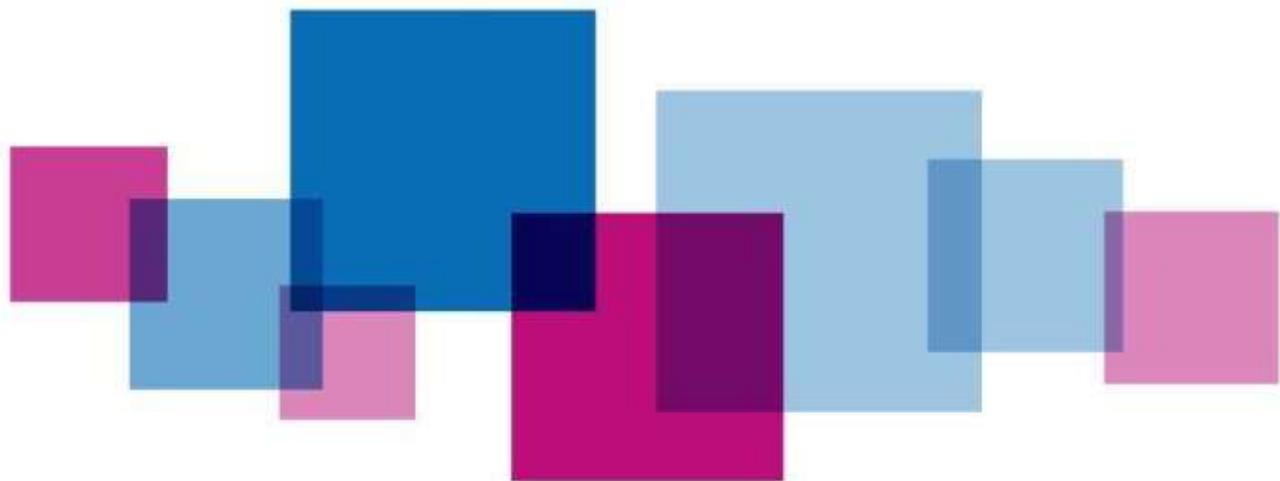


Commissioning Policy

One-Step Nucleic Acid Amplification (OSNA) as an Intra-Operative Diagnostic Method for Detecting Metastasis in Breast Cancer

Criteria Based Access



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Document Control

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Version Control

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1718.2.01	27/03/2018	IFR Coordinator	Rebranded to BNSSG ICB
1819.2.00	26/10/2018	Commissioning Policy Development Support Officer	Smoking and BMI references updated, BNSSG branding refreshed, PALS update. Approved on 14 th February 2019 by Commissioning Executive.

THIS IS A CRITERIA BASED ACCESS POLICY
TREATMENT MAY BE PROVIDED WHERE PATIENTS MEET THE CRITERIA BELOW

THIS POLICY RELATES TO ALL PATIENTS

One-Step Nucleic Acid Amplification (OSNA) as an Intra-Operative Diagnostic Method for Detecting Metastasis in Breast Cancer Policy

General Principles

Treatment should only be given in line with these general principles. Where patients are unable to meet these principles in addition to the specific treatment criteria set out in this policy, funding approval may be sought from the ICB Exceptional Funding Request Panel.

1. Clinicians should assess the patients against the criteria within this policy prior to referring patients seeking treatment. Referring patients to secondary care that do not meet these criteria not only incurs significant costs in out-patient appointments for patients that may not qualify for surgery, but inappropriately raises the patient's expectation of treatment.
2. Patients will only meet the criteria within this policy where there is evidence that the treatment requested is effective and the patient has the potential to benefit from the proposed treatment. Where the patient has previously been provided with the treatment with limited or diminishing benefit, it is unlikely that they will qualify for further treatment and the EFR team should be approached for advice.
3. On limited occasions, the ICB may approve funding for a further assessment in secondary care only in order to confirm or obtain evidence demonstrating whether a patient meets the criteria for funding. In such cases, patients should be made aware that the assessment does not mean that they will be provided with surgery and surgery will only be provided where it can be demonstrated that the patients meets the criteria to access treatment in this policy.
4. Where funding approval is given by the Exceptional Funding Request Panel, it will be available for a specified period of time, normally one year.
5. Patients with an elevated BMI of 30 or more may experience more post-surgical complications including post-surgical wound infection so should be encouraged to lose weight further prior to seeking surgery.
<https://www.sciencedirect.com/science/article/pii/S1198743X15007193> (Thelwall, 2015).
6. Patients who are smokers should be referred to smoking cessation services in order to reduce the risk of surgery and improve healing (ASH, 2016)
7. In applying this policy, all clinicians and those involved in making decisions affecting



patient care will pay due regard to the need to eliminate unlawful discrimination,

harassment, victimisation, etc., and will advance equality of opportunity and foster good relations between people who share a protected characteristic and those who do not. In particular, due regard will be paid in relation to the following characteristics protected by the Equality Act 2010: age, disability, sex, gender reassignment, marriage or civil partnership, pregnancy and maternity, race, religion or belief and sexual orientation.

Background / Purpose and Scope

OSNA is a promising emerging technique as one of the sentinel node biopsy techniques and as such is still under evaluation. Its benefits are: identification of lymph node metastasis during the initial breast surgery and therefore enabling decision and undertaking of further lymph node resection (or not) during that initial surgery, avoiding thus the need for a second surgery and reducing the length of hospital stay. Current evidence identifies that the main uncertainty with OSNA is the potential over-diagnosis of breast cancer metastasis, i.e. higher proportion of micro-metastasis identified using OSNA than histopathology.

BNSSG ICBs have commissioned this technique since September 2010 in order to allow an Audit to consider its effectiveness. Overall the audit results show that the results are at large in coherence with published literature, e.g. comparable with the 4 centre British case study (2011). The results, therefore, do not raise any specific concerns with regards to the technique undertaken at UHB. The higher proportion of micrometastasis detected by OSNA as compared to histopathology is also not out of line with what is reported in the published literature.

It has however been agreed that a further period of commissioning to allow evaluation of the results should be undertaken.

POLICY CRITERIA – COMMISSIONED

CRITERIA BASED ACCESS

OSNA is commissioned for all patients being surgically treated for breast cancer to allow evaluation of the diagnostic technique for a period of one year *until further evidence becomes available*.

Patients who are not eligible for treatment under this policy may be considered on an individual



basis where their GP or consultant believes exceptional circumstances exist that warrant deviation from the rule of this policy.

Individual cases will be reviewed at the ICB's Exceptional Funding Panel upon receipt of a completed application form from the patient's GP, Consultant or Clinician. Applications cannot be considered from patients personally.

If you would like further copies of this policy or need it in another format, such as Braille or another language, please contact the Customer Services Team on: **0117 900 2655** or **0800 073 0907** or email them on BNSSG.customerservice@nhs.net .

Connected Policies

N/A

This policy has been developed with the aid of the following references:

Ash. (2016). *Ash.org.uk*. Retrieved Sept 24, 2018, from www.ash.org.uk: www.ash.org.uk/briefings
Thelwall, S. P. (2015). Impact of obesity on the risk of wound infection following surgery: results from a nationwide prospective multicentre cohort study in England. *Clinical microbiology and infection : the official publication of the European Society of Clinical Microbiology and Infectious Diseases*, vol. 21, no. 11, p. 1008.e1.

OPCS Procedure codes – For completion at a later date
