

**EFFECTIVE AND APPROPRIATE  
HEALTHCARE**

**DONCASTER PRIMARY CARE TRUSTS  
NOVEMBER 2005**

**(Revision Date November 2006)**

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## **DONCASTER PRIMARY CARE TRUSTS**

### **EFFECTIVE AND APPROPRIATE HEALTHCARE**

This paper is intended to provide:

- i) guidance for clinicians about clinical investigations, interventions and drugs which the three Doncaster Primary Care Trusts have agreed should be subject to some form of control and management as part of this policy;
- ii) to inform General Practitioners, Hospital Clinicians and the public what treatment the NHS provides locally, and to support clinicians in decisions about effective and appropriate healthcare. After consultation locally and ratification by the Primary Care Trusts, it will constitute Primary Care Trusts' Policy.

It provides a public statement on what treatment or procedures are not being given priority by Doncaster Primary Care Trusts.

The policy will be put to each Primary Care Trust Board following consultation. The policy will be reviewed at least annually and distributed widely. It will be available on the Primary Care Trusts web sites. There will be a continuous process of consultation and comments from organizations or the public which will be taken in to account by the Advisory Forum when revising the policy.

## **PRINCIPLES**

A range of procedures will not be provided by the NHS for Doncaster residents unless in exceptional circumstances. These are: -

Procedures or treatments, which it would be clinically inappropriate to provide, because they do not generally address a health problem. (For example breast implants for purely cosmetic reasons.)

Treatments and procedures, which are not effective (clinical effectiveness is usually demonstrated in published clinical trials in peer reviewed journals).

Procedures, which fall outside national, North Derbyshire, South Yorkshire & Bassetlaw Commissioning Consortium (NORCOM) or other guidelines agreed by the PCTs' executives.

Clinicians who believe that their patient represents an exception for whom an intervention should be purchased may discuss this with a consultant public health physician or medical or pharmaceutical advisor employed by the Primary Care Trust.

This list represents proposed clinical policy which have been formulated together as a result of local discussions e.g. on guideline working groups, and between South Yorkshire Primary Care Trusts through NORCOM. In these settings the currently available evidence is discussed. In many cases the evidence has been appraised in an academic setting. National advice from the National Institute for Clinical Excellence (NICE) or National Service Frameworks will be implemented across the PCTs. Where implementation is not immediate for clinical, logistical or financial reasons this will be stated in the document.

Doncaster Primary Care Trusts will always be prepared to consider exceptional circumstances.

## **PRIVATE CARE**

The PCTs will not normally fund treatment privately where an NHS provider offers treatment unless it can be demonstrated that the private provider can offer a more cost effective service or where the delay in accessing NHS treatment exceeds 12 months.

## **DUTIES OF THE PRIMARY CARE TRUSTS**

The Primary Care Trusts must ensure that they have procedures in place to consider individual requests for:

- i) unusual or exceptional treatments
- ii) where a practitioner considers their patient should be considered an exception to this guidance
- iii) where a patient considers they should be an exception to this guidance

Doncaster PCTs have a process for making decisions in respect of requests for out of contract or restricted services and this is available from the PCTs or through their websites.

Patients dissatisfied with the process of review of their case would have recourse to the NHS complaints procedure.

## **1 COMPLEMENTARY THERAPIES**

Complementary therapies will be purchased from appropriately qualified practitioners where there is a body of scientific evidence of their benefit.

## **2 NATIONAL SPECIALIST COMMISSIONING ADVISORY GROUP (NSCAG)**

NSCAG aims to help patients by improving access to expertise in the management of uncommon conditions. NSCAG seeks to ensure high levels of expertise in the treatment of rare conditions by preventing the proliferation of services. Clinicians should not refer patients to any non-designated tertiary units for any activity that falls within the service description of a designated “supra regional” or “national specialist service”. Furthermore, the PCTs will not pay for any activity resulting from such referrals. A full list of current services and designated centers is included in [Appendix 1 \[The National Specialist Commissioning Advisory Group\]](#)

## **3 NEW INTERVENTIONAL PROCEDURES**

NICE have inherited the Safety and Efficacy Register of the Royal Colleges (SERNIP). Currently there is a period of transition while NICE consults on how it deals with interventional procedures. Doncaster Primary Care Trusts will in future only fund procedures assessed by NICE in accordance with NICE recommendations. In the interim Doncaster PCTs will continue to follow the advice of SERNIP. The PCTs will only fund those procedures categorised by the Register in Categories A & B through the normal process of agreeing developments. Interventions in Category C will be considered in the same way as Groups A & B once the SERNIP recommendations are complied with, with due regard to the obligations of the PCTs under the Culyer Research arrangements.

Interventions in Category D will not be funded. The Clinician concerned and the patient’s GP will be informed of this decision.

When the PCTs are asked to fund new interventions, the SERNIP register will be consulted to check whether these are registered (available at [www.nice.org.uk](http://www.nice.org.uk)). Funding of new procedures will be refused until such time as NICE has categorized them. Or where there is a compelling body of scientific evidence that these procedures are safe and effective or where they form part of a properly conducted and approved clinical trial.

## **4 CARDIOVASCULAR**

### **4.1 Heart Disease**

#### **Statins in primary prevention**

These have been shown to be cost effective in the reduction of the incidence of heart attacks for patients with an annual risk of a cardiac event of greater than 3%. The drugs are expensive and the benefit/cost ratio to the general population with lower cardiac risk is too low. The 3% “at risk” population should all have their serum lipids measured and risk factors assessed. Those with a raised serum cholesterol (and other risk factors) should be treated according to the serum lipid screening guidelines.

Statins are recommended for secondary prevention after a heart attack.

### **4.2 Obesity**

## **Drug Therapy – Orlistat and Sibutramine**

NICE Guidance indicates that Orlistat and Sibutramine are effective treatments for obesity in adults. Both should only be offered in line with NICE guidance.

## **Surgery Criteria**

All criteria should be met in line with NORCOM Guidance: [Appendix 10](#)

- BMI over 50 kg/m<sup>2</sup> or 45-50 where there is significant co-morbidity.
- Aged 18 or more.
- Evidence that all non-surgical measures have been adequately tried and failed, including intensive management at a specialist obesity clinic.
- Exclusion of endocrine abnormalities
- Exclusion of significant psychiatric disease or psychological contra-indications to surgery
- Realistic expectations of operation and the need for long term follow up

The most important issue is that patients are realistic in their expectations.

## **Priority Criteria**

There are three groups of patients who should be actively considered for obesity surgery:

- 1 Those who are experiencing severe, acute complications of their obesity, e.g., sleep apnoea or severe morbidity.
- 2 Those whose obesity is preventing other treatments, e.g. hip or knee replacements.
- 3 Those who have a prospect of the many complications of morbid obesity over the next 5-10 years in which case the surgery is really preventive (preventing heart disease and diabetes).

Specialist referral to the Doncaster Obesity Clinic (Clinical Therapy Department at Doncaster Royal Infirmary) should take place.

## **4.3 Pulmonary Hypertension**

*This will be according to NORCOM guidance on pulmonary hypertension (August 2004) [Appendix 2](#) [Pulmonary Hypertension NORCOM Policy]*

Where treatment is agreed, it must be undertaken at an accredited centre.

## **5 ENDOCRINE**

### **5.1 Growth Hormone in Adults**

The PCTs will fund adult growth hormone in line with NICE guidance.

NICE has recommended that human growth hormone should be used only for adults with severe growth hormone deficiency that is significantly affecting their quality of life (published August 2003). Patients on growth hormone should have their quality of life assessed for positive effect again 9 months after commencing treatment.

## **6 ENT**

## **6.1 Bone Anchored Hearing Aids**

Hearing aids are categorized according to their method of sound conduction; this can be an air conduction hearing aid (ACHA) or a conventional bone conduction hearing aid (CBHA). A more specialized form of CBHA is the bone-anchored hearing aid (BAHA). Both air and bone conduction are widely used and are of proven benefit.

Although a good ACHA provides the best results, there are a number of patients for whom this type of hearing aid is not suitable (e.g. patients with atresia of the ear or severe Chronic Suppurative Otitis Media (CSOM)). If the CBHA is also unacceptable to the patient the BAHA may provide an alternative. In addition, BAHAs are increasingly being viewed as an option for the treatment of otosclerosis, replacing more expensive and difficult procedures such as ossiculoplasty and stapedectomies.

There is a place for bone anchored hearing aids in the absence of an auditory canal and chronic suppurative otitis media on a case by case basis. More evidence is required before the more widespread use of bone-anchored hearing aids can be recommended.

## **6.2 Cochlear Implants in Adults & Children**

The PCTs will fund Cochlea implants in Adults and children in line with NORCOM policy (April 2005).

The criteria for cochlear implantation in adults and children are set out in Policy on Commissioning Cochlea Implant [Appendix 3 \[Cochlear Implants\]](#)

## **6.3 Hearing Aid Technology**

A full range of analogue hearing aids is available and should be matched to patient need and patient choice. Analogue hearing aids are the standard aids provided by the NHS and give the majority of patients' excellent quality hearing. Binaural fitting is available where indicated. There is emerging evidence to support the use of digital aids in some patients. These are not routinely available at present. There have been significant reductions in the cost of some digital hearing aids. Some manufacturers have started to offer digital hearing aids at significantly lower specifications. Digital hearing aids are only fitted by the NHS in Doncaster through the National Modernising Hearing Aid Services Scheme. This assures that those aids fitted meet the National Specification.

## **6.4 Hyperbaric Oxygen (HBO) Treatment for patients with Oral Cancer**

The Primary Care Trusts will not routinely fund this, but will consider each case on its clinical merits. The evidence base for the use of HBO is inconclusive. There is evidence of benefit in the treatment of osteoradionecrosis though it may not be necessary for all patients.

As from 1 April 2004, all requests for HBO for oral cancer in the NORCOM area will be considered on a case-by-case basis by the three NORCOM Directors of Dental Public Health (NORCOM, **Policy on hyperbaric oxygen therapy for patients with oral cancer, 4<sup>th</sup> December 2003**). For further details click [Appendix 4 Hyperbaric Oxygen](#).

## **6.5 Maxillo Facial Surgery**

### **Removal of Asymptomatic Unerupted Wisdom Teeth**

There is no benefit. Dental Practitioners are well aware of this and the service agreement with the Doncaster & Bassetlaw Hospitals NHS Foundation Trust places priority on the treatment of troublesome already erupted wisdom teeth.

### **Titanium implant surgery**

In each case there must be prior discussion with the PCTs Dental Director of Public Health. A joint opinion from the maxillo facial surgeons and where appropriate plastic surgery, ear nose and throat and restorative dentistry consultants will be required.

## **6.6 Snoring**

The Department of Orthodontics at Doncaster & Bassetlaw Hospitals NHS Foundation Trust will provide palatal training devices for the use of patients who snore. This is a simple and useful treatment.

## **7 EYE**

### **7.1 Laser Treatment for Myopia**

This treatment is available privately. However there are side effects and problems, especially with those who have higher dioptré myopia initially. These problems can include the development of lens opacities, worsening of astigmatism and difficulties with diffraction. None of these problems can be corrected with spectacles. This procedure will only be purchased on an exception basis for an individual patient, recommended by a local Consultant Ophthalmologist.

### **7.2 Photodynamic Therapy for Macular Degeneration**

This is a relatively new treatment for choroidal neovascularisation (CNV) secondary to age related macular degeneration. There is good evidence that it reduces the risk of further visual loss in an otherwise untreatable condition. Treatment does not restore vision already lost. Treatment is available in line with both NICE guidance (September 2003) and NORCOM policy (June 2003). For further details click [Appendix 5 Photodynamic Therapy](#).

The treatment should be confined to “wet” “classical” CNV in patients with a best-corrected visual acuity of 6/60 or better. This type is associated with the most rapid visual loss. Diagnosis should be made by ophthalmologists using fundus fluorescein angiography, and treatment carried out by retinal specialists with expertise in this field. Sheffield is able to provide the required quality of service.

Patients should be referred by an Ophthalmologist, based on the appropriate criteria. Prior permission for funding should be sought.

## **8 GENETICS**

The PCTs will not purchase any additional genetic testing procedures other than those already instituted i.e. for cystic fibrosis and Downs Syndrome.

Guidance is being developed nationally, which will review the costs and benefits, and ethical issues around genetic testing.

Tests for genetic markers for cancer will not be purchased, except for a member of a very high risk family identified by a clinical geneticist.

## **9 MALIGNANT DISEASE AND IMMUNOSUPPRESSION**

### **9.1 Cancer Treatment**

This will only be purchased from an accredited cancer centre or unit, in accordance with agreed protocols. New drugs for cancer will be considered through protocol working parties (for breast, cervix, lung, colorectal) or by NORCOM. Individual exceptional requests for treatment will be considered only in the light of these arrangements.

The PCTs will fund cancer treatment in line with NICE recommendations. NICE recommendations will only be implemented when the protocols, Guidelines and clinical services are in place to do so safely.

## **10 CENTRAL NERVOUS SYSTEM & MENTAL HEALTH**

### **10.1 Alcohol Dependence**

The PCTs will not pay for long term (over 7 days) inpatient treatment.

### **10.2 Dementia**

#### **Alzheimers Disease**

The PCTs will fund treatment for Alzheimers disease in line with current NICE Guidance. For further information click: [ALZHEIMER guidance](#)

### **10.3 Gender Dysphoria**

For further information see referral policy [Appendix 7 Gender Disphoria](#).

### **10.4 Neurology**

#### **Interferons and Multiple Sclerosis**

The PCTs will fund treatment for Multiple Sclerosis in line with current NICE Guidance. For further information click: [Multiple Sclerosis](#)

The NHS has developed a scheme to make beta-interferon available to patients who fulfill specific criteria only through a recognized specialist centre.

### **10.5 Post Traumatic Stress Disorder (PTSD) - Treatment**

The PCTs will fund treatment for Post Traumatic Stress Disorder (PTSD) in line with NICE Guidance (March 2005). For further information click: [Post Traumatic Stress Disorder](#)

### **10.6 Riluzole for Motor Neurone Disease MND**

There may be up to 4/5 patients with MND per 100,000 people at any one time.

Riluzole is recommended for the treatment of individuals with the **Amyotrophic Lateral Sclerosis (ALS)** form of Motor Neurone Disease (MND)

Riluzole therapy should be initiated by a neurological specialist with expertise in the management of MND. Routine supervision of therapy should be managed by locally agreed shared care protocols undertaken by general practitioners.

## **10.7 Spinal Cord Stimulation in the Management of**

### **(i) Chronic Pain**

This will not normally be purchased.

### **(ii) Refractory Angina**

Some patients with CHD continue to have pain, even after surgery and whilst on maximum therapy of drugs. Re-investigation may not demonstrate evidence of surgically remedial arterial lesions. Such patients may be regarded as having refractory angina. The clinical management of these patients is difficult. Spinal cord stimulation by implantable devices has been advocated. In 1996, The North Trent Working Group on Acute Purchasing advised that spinal cord stimulation for pain relief should not be purchased due to lack of evidence of benefit. The report acknowledged that there was evidence of benefit for use of this treatment in refractory angina.

A unit set up in Liverpool, at the request of the Department of Health, to look at this subject has produced guidelines (**For further details click: [Appendix 6 Refractory Angina](#)**). In addition, there is the need to ensure that people experienced in its use perform this procedure. They advocate a full assessment and a planned programme covering a number of approaches to pain control before reaching the stage of spinal cord stimulation.

**Referral should be made only by a cardiologist, in consultation with the pain service. Prior approval for funding should be sought.**

### **(iii) Intractable Epilepsy**

Vagal Nerve Stimulation can be an effective treatment for intractable epilepsy not responding to pharmacological interventions and is purchased on a limited basis for these criteria. Doncaster PCTs will fund on the advice of neurologists.

Vagal Nerve Stimulation will not be funded as a treatment for bipolar depression for which it is an experimental procedure.

## **10.8 Chronic Fatigue Syndrome/Myalgic Encephalitis**

The majority of cases should be managed in primary care. Especially complex or refractory cases can be referred to the specialist outpatient service in Leeds.

## **10.9 Asperger's Syndrome**

There is an adult service in Sheffield. Patients with Asperger's Syndrome should only be referred to Community Health in Sheffield after local services have been fully explored.

## 11 MUSCULO-SKELETAL AND JOINT

### 11.1 Anti-TNF Therapy

The PCTs will fund treatment for rheumatoid arthritis in line with NICE Guidance. For further details click: [Infliximab & Etanercept](#) .

### 11.2 Etanercept

Etanercept for Juvenile Idiopathic Arthritis will be funded in line with NICE guidance. For further details click: [Juvenile Idiopathic Arthritis](#)

Its use for adult psoriatic arthritis is currently under review by NICE.

## 12 OBSTETRICS, GYNAECOLOGY AND URINARY TRACT

### 12.1 Brachytherapy for Prostatic Carcinoma

The PCTs will fund Brachytherapy for carcinoma of the prostate in line with NICE Guidance. For further information click: [Brachytherapy guidance for prostate cancer](#)

### 12.2 Gynaecology

**D&C in women aged under 40 years** - Dilatation and curettage has no therapeutic effect on menorrhagia. Alternative non-operative diagnostic procedures are suitable for most women. Under the age of 40 years D&C will only be purchased on an exception basis.<sup>i</sup>

### 12.3 Impotence

Specialist assessment of the causes of impotence remains freely available.

### 12.4 Sildenafil (Viagra)

According to HSC1999/148, general practitioners are limited in their use of NHS prescriptions for the treatment of erectile dysfunction. They may issue NHS prescriptions (endorsed "SLS") to those men who in their clinical judgement are suffering from erectile dysfunction and have any of the following medical conditions: diabetes, multiple sclerosis, Parkinson's disease, poliomyelitis, prostate cancer, prostatectomy, radical pelvic surgery, renal failure treated by dialysis or transplant, severe pelvic injury, single gene neurological disease, spinal cord injury and spinabifida.

Those men receiving a course of NHS drug treatment for erectile dysfunction on 14 September 1998, will continue to be eligible to receive drug treatment, including Sildenafil from their GP. One NHS treatment per week should normally be considered adequate.

Most men suffering from impotence suffer distress. These men may obtain sildenafil on a private prescription.

General Practitioners and Hospital Clinicians are free to issue private prescriptions to NHS patients for other medical conditions resulting in erectile dysfunction. They must not charge for this service.

In those exceptional circumstances where impotence is causing severe distress, treatment will only be available in a hospital setting. It is likely that

this is only going to be a small percentage of those suffering from erectile dysfunction.

**Patients with erectile dysfunction should be referred by their GPs to Erectile Dysfunction Service in Doncaster.**

### **12.5 Infertility Treatment**

The PCTs will fund treatment for infertility in line with NORCOM policy (which is based on NICE Guidance) – see [Appendix 8 Infertility treatment](#).

### **12.6 Reversal of Sterilisation (Male and Female)**

Patients should be informed that the PCTs do not purchase any infertility services after voluntary sterilisation.

### **12.7 Prostate Specific Antigen**

PSA testing should not be undertaken for screening asymptomatic men outside a clinical trial.

Sensitivity for the test is in the range of 70% with a positive predictive value of 26-52% (the positive predictive value being markedly influenced by the prevalence of the disease in the population). Screening tends to detect smaller less aggressive tumours. There are uncertainties about any benefit from early radical treatment<sup>ii iii iv</sup> Screening and subsequent investigation of false positives and treatment of smaller tumours carries substantial risks of urinary incompetence, urethral strictures, sexual impotence, rectal injury and a small but finite incidence of treatment related mortality.

PSA testing in asymptomatic men should only be offered after suitable counselling.

PSA testing may assist in the management of patients with significant lower urinary tract symptoms

Patients with no clinically detectable disease who are too frail to benefit from radical local treatment are unlikely to benefit from testing.

## **13 SKIN**

### **13.1 Aesthetic Plastic Surgery**

The PCTs will fund aesthetic plastic surgery line with NORCOM policy for further details click [Appendix 9](#)

### **13.2 Circumcision**

Circumcision is an affective procedure for a range of medical indications. Circumcision is also requested for a variety of social and cultural reasons. The procedure in these circumstances does not confer any medical benefit and carries risk of injury. The PCTs will not fund circumcision for non-medical reasons.

### **13.3 Varicose Veins**

Indications for interventions for varicose veins should be in line with current local policies agreed by Doncaster PCTs .

#### **14 NICE GUIDANCE**

NICE Guidance will be implemented in line with National Guidance.

#### **15 GASTRO-ENTEROLOGY**

##### **15.1 Capsule Endoscopy**

From November 2003 Capsule endoscopy procedures will be provided in contract for commissioners in the NORCOM area.

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<sup>i</sup> Coulter A, et al. Outcomes of referrals to gynaecology O.P. clinics for menstrual problems: an audit of general practice records. *British Journal of Obstetrics & Gynaecology* 1991 8 789-96.

<sup>ii</sup> Johansson JE, Holmberg L, Johansson S, et al: Fifteen-year survival in prostate cancer: a prospective, population-based study in Sweden. *Journal of the American Medical Association* 277(6):467-471, 1997.

<sup>iii</sup> Whitmore WF: Localised prostatic cancer: management and detection issues. *Lancet* 343 (8908):1263-1267, 1999

<sup>iv</sup> Chodak GW, Thirsted RA, Gerber GS, et al: Results of conservative management of clinically localized prostate cancer *New England Journal of Medicine* 330(4):242-248,1994.