

NICE Update Bulletin November 2015 issued 25th November 2015

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<u>Type</u>	<u>Guidance title and reference number</u>
Technology Appraisals (TAs)	<p>Ledipasvir–sofosbuvir for treating chronic hepatitis C TA363</p> <p><u>Recommendations</u></p> <p>1.1 Ledipasvir–sofosbuvir is recommended as an option for treating chronic hepatitis C in adults, depending on patient specific factors as specified in table 1 (not shown as too large).</p> <p>1.2 It is recommended that the decision to treat and prescribing decisions are made by multidisciplinary teams in the operational delivery networks put in place by NHS England, to prioritise treatment for people with the highest unmet clinical need.</p> <p>1.3 People whose treatment with ledipasvir–sofosbuvir is not recommended in this NICE guidance, but was started within the NHS before this guidance was published, should be able to continue treatment until they and their NHS clinician consider it appropriate to stop.</p> <p><u>The technology</u></p> <p>Ledipasvir–sofosbuvir prevents hepatitis C virus (HCV) replication by inhibiting non-structural protein (NS) 5A (targeted by ledipasvir) and NS5B (targeted by sofosbuvir) proteins. Ledipasvir–sofosbuvir has a marketing authorisation in the UK for treating chronic hepatitis C in adults. However, the marketing authorisation recommends specific treatment durations for HCV genotypes 1, 3 and 4 only, and states that ledipasvir–sofosbuvir should not be used in people with HCV genotypes 2, 5 and 6. The recommended dose is 1 daily tablet containing a fixed-dose combination of 90 mg ledipasvir and 400 mg sofosbuvir.</p> <p>It is taken orally for 8, 12 or 24 weeks, with or without ribavirin. The recommended treatment duration and whether ribavirin is co-administered depends on genotype, treatment history and presence of cirrhosis.</p> <p><u>Financial factors</u></p> <p>The cost of ledipasvir–sofosbuvir is £12,993 per 28-tablet pack (excluding VAT; company's evidence submission). The cost of a 8-week course of treatment is £25,986 and a 12-week course is £38,979 (both excluding VAT), not including the cost for ribavirin. The company has agreed a nationally available price reduction for ledipasvir–sofosbuvir with the Commercial Medicines Unit. However, this contract agreement was not presented by the company and therefore it could not be considered in this appraisal. Costs may vary in different settings because of negotiated procurement discounts.</p> <p>NHS England is the commissioner for this technology.</p> <p>Daclatasvir for treating chronic hepatitis C TA364</p> <p><u>Recommendations</u></p> <p>1.1 Daclatasvir (Daklinza) is recommended as a possible treatment for adults with some types (called genotypes) of chronic hepatitis C, depending on their level of fibrosis. It is taken with sofosbuvir or peginteron alfa, and sometimes with a drug called ribavirin. It is recommended depending on patient specific factors as specified in tables 1, 2 and 3 (not shown as large)</p> <p>1.2 It is recommended that the decision to treat and prescribing decisions are made by multidisciplinary teams in the operational delivery networks put in place by NHS</p>

England, to prioritise treatment for people with the highest unmet clinical need.

- 1.3 People whose treatment with daclatasvir is not recommended in this NICE guidance, but was started within the NHS before this guidance was published, should be able to continue treatment until they and their NHS clinician consider it appropriate to stop.

The technology

Daclatasvir (Daklinza) is an oral inhibitor of non-structural protein 5A, a multifunctional protein that is a component of the hepatitis C virus (HCV) replication complex. It inhibits both viral replication and assembly. Daclatasvir, in combination with other medicinal products, has a marketing authorisation in the UK for treating chronic hepatitis C virus infection in adults. The recommended dose of daclatasvir is 60 mg once daily.

Financial factors

The price of daclatasvir is £8,172 per 28-tablet pack of 60 mg daclatasvir (excluding VAT; 'British national formulary' [BNF] March 2015). The average cost of daclatasvir plus sofosbuvir is £59,501 for a 12-week course and £119,002 for a 24-week course; when ribavirin is added these costs increase to £60,304 and £120,608 respectively. The average cost of a course of treatment with daclatasvir in combination with peginterferon alfa and ribavirin ranges from £53,628 to £58,221 (depending on whether peginterferon alfa and ribavirin are taken for 24 or 48 weeks; daclatasvir may only be taken for 24 weeks). The company has agreed a nationally available price reduction for daclatasvir with the Commercial Medicines Unit. The contract prices agreed through the framework are commercial in confidence.

NHS England is the commissioner for this technology.

[Ombitasvir–paritaprevir–ritonavir with or without dasabuvir for treating chronic hepatitis C TA365](#)

Recommendations

- 1.1 Ombitasvir–paritaprevir–ritonavir with or without dasabuvir **is recommended, within its marketing authorisation**, as an option for treating genotype 1 or 4 chronic hepatitis C in adults, as specified in table 1 (too large to show), only if the company provides ombitasvir–paritaprevir–ritonavir and dasabuvir at the same price or lower than that agreed with the Commercial Medicines Unit.

- 1.2 It is recommended that the decision to treat and prescribing decisions are made by multidisciplinary teams in the operational delivery networks put in place by NHS England, to prioritise treatment for people with the highest unmet clinical need.

The technology

Ombitasvir–paritaprevir–ritonavir (Viekirax, AbbVie) is a fixed-dose combination of 2 direct-acting anti-hepatitis C virus drugs (ombitasvir and paritaprevir) and ritonavir. Each tablet contains 12.5 mg ombitasvir, 75 mg paritaprevir, and 50 mg ritonavir. Ombitasvir inhibits non-structural viral protein NS5A; paritaprevir inhibits NS3/4A serine protease; and ritonavir increases the bioavailability of paritaprevir. The recommended dose is 2 tablets once daily. It is taken orally for 12 or 24 weeks with or without dasabuvir, with or without ribavirin.

Financial factors

Ombitasvir–paritaprevir–ritonavir costs £10,733 excluding VAT for 28 days' supply. The total costs of a 12-week and a 24-week course of ombitasvir–paritaprevir–ritonavir are £32,200 and £64,400 respectively (both excluding VAT: MIMS, February 2015). Dasabuvir costs £933 excluding VAT for 28 days' supply. The total costs of a 12-week and a 24-week course of dasabuvir are £2,800 and £5,600 respectively (both excluding VAT: MIMS, February 2015). The company has agreed a nationally available price reduction for ombitasvir–paritaprevir–ritonavir with or without dasabuvir with the Commercial Medicines Unit. The contract prices agreed through the framework are commercial in confidence.

NHS England is the commissioner for this technology.

[Pembrolizumab for advanced melanoma not previously treated with ipilimumab TA366](#)

Recommendations

1.1 Pembrolizumab **is recommended as an option for treating advanced (unresectable or metastatic) melanoma** that has not been previously treated with ipilimumab, in adults, only when the company provides pembrolizumab with the discount agreed in the patient access scheme.

The technology

Pembrolizumab (Keytruda) is a humanised monoclonal antibody. It acts on the programmed cell death protein-1 immune-checkpoint receptor pathway, blocking its interaction with ligand on the tumour cells. This allows reactivation of anti-tumour immunity. It has a marketing authorisation in the UK as monotherapy 'for the treatment of advanced (unresectable or metastatic) melanoma in adults'. Pembrolizumab is administered intravenously for 30 minutes at a dose of 2 mg/kg every 3 weeks until disease progression or unacceptable toxicity.

Financial factors

The acquisition cost of pembrolizumab is £1,315 per 50-mg vial (excluding VAT; company's submission). The company has agreed a patient access scheme with the Department of Health. This scheme provides a simple discount to the list price of pembrolizumab, with the discount applied at the point of purchase or invoice. The level of the discount is commercial in confidence. NHS England is the commissioner for this technology.

[Vortioxetine for treating major depressive episodes TA367](#)

Recommendations

1.1 Vortioxetine **is recommended as an option** for treating major depressive episodes in adults whose condition has responded inadequately to 2 antidepressants within the current episode.

1.2 People whose treatment with vortioxetine is not recommended in this NICE guidance, but was started within the NHS before this guidance was published, should be able to continue treatment until they and their NHS clinician consider it appropriate to stop.

The technology

Vortioxetine (Brintellix) is an antidepressant that is thought to exhibit its clinical effect through direct modulation of receptor activity and inhibition of the serotonin transporter. Vortioxetine has a marketing authorisation in the UK 'for the treatment of major depressive episodes in adults'.

Financial factors

Vortioxetine is administered orally. The recommended starting dosage is 10 mg once daily in adults younger than 65 years, and 5 mg once daily in adults 65 years and older. Depending on how the symptoms respond, the dose may be increased to a maximum of 20 mg once daily or decreased to a minimum of 5 mg once daily. Treatment for at least 6 months is recommended after the symptoms resolve. The price of a pack (28 tablets) of 5 mg, 10 mg or 20 mg tablets is £27.72 (excluding VAT; company's submission). Costs may vary in different settings because of negotiated procurement discounts.

The NICE costing statement states that It is unlikely that the guidance will result in a significant change in resource use in the NHS. Vortioxetine is a treatment option alongside current standard third line treatment options for major depressive disorder. There may be a small increase in costs arising from a reduction in the number of people given cheaper treatment options. However, offsetting savings may also be made from, for example, fewer side effects in people given vortioxetine. This technology is commissioned by clinical commissioning groups (CCGs).

[Apremilast for treating moderate to severe plaque psoriasis TA368](#)

Recommendations

	<p>1.1 Apremilast is not recommended within its marketing authorisation for treating psoriasis, that is, for treating adults with moderate to severe chronic plaque psoriasis that has not responded to systemic therapy, or systemic therapy is contraindicated or not tolerated.</p> <p>1.2 People whose treatment with apremilast was funded by the NHS before this guidance was published should be able to continue treatment until they and their NHS clinician consider it appropriate to stop.</p> <p><u>The technology</u></p> <p>Apremilast (Otezla, Celgene) is a small-molecule inhibitor of phosphodiesterase 4 (PDE4). Apremilast down-regulates the inflammatory response by modulating the expression of cytokines and mediators associated with psoriasis (including tumour necrosis factor [TNF]-alpha and interleukin [IL]-23). Apremilast has a marketing authorisation in the UK 'for the treatment of moderate to severe chronic plaque psoriasis in adult patients who failed to respond to or who have a contraindication to, or are intolerant to other systemic therapy including [cyclosporin], methotrexate or psoralen and ultraviolet-A light (PUVA)'. </p> <p><u>Financial factors</u></p> <p>According to the company submission, the cost of 18 months of treatment with apremilast is estimated at £10,644. Costs may vary in different settings because of negotiated procurement discounts.</p>
<p>Highly specialized technology guidance (HSTs)</p>	<p>None published so far this month</p>

Note: From January 2015 NICE has decided to use a single set of methods and processes to develop all NICE guidelines, whether they are clinical, public health, social care, safe staffing or medicines practice.

Technology appraisals, interventional procedures, medical technologies and diagnostics guidance; and quality standards and advice products, are unaffected by this change.

<p>NICE Guidelines (NGs)</p>	<p><u>Older people with social care needs and multiple long-term conditions NG22</u></p> <p><u>Background</u></p> <p>The prevalence of long-term conditions is strongly linked to ageing and the number of people with multiple (more than 1) long-term conditions in England is projected to rise to 2.9 million by 2018. Poor mental health can be associated with both social isolation and poor physical health, and can go unnoticed.</p> <p>This guideline has been developed in the context of a complex and rapidly evolving landscape of guidance and legislation, most notably the Care Act 2014. While the Care Act and other legislation describe what organisations must do, this guideline is focused on 'what works' in terms of how to fulfil those duties, and deliver support to older people with social care needs and multiple long-term conditions.</p> <p><u>Recommendations</u></p> <ul style="list-style-type: none"> 1.1 Identifying and assessing social care needs 1.2 Care planning 1.3 Supporting carers 1.4 Integrating health and social care planning 1.5 Delivering care 1.6 Preventing social isolation
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1.7 Training health and social care practitioners

Older people with social care needs and multiple long-term conditions implementation: getting started

This section highlights 3 areas of the older people with social care needs and multiple long-term conditions guideline that could have a big impact on practice and be challenging to implement, along with the reasons why change is happening in these areas.

- **The challenge:** empowering older people with social care needs and multiple long-term conditions and their carers to choose and manage their own support
- **The challenge:** empowering practitioners to deliver person-centred care
- **The challenge:** integrating different care and support options to enable person-centred care

Financial factors

The NICE costing statement states that there is significant variability in the commissioning and provision of health and social care for older people in England. It is likely that implementing this guideline will have resource implications for health and social care commissioners and providers, and we advise them to assess these locally. The recommendation areas that may have a significant resource impact are:

- identifying and assessing social care needs
- care planning
- training for carers.

Potential areas for savings are:

- Local authorities may make savings if improving social care for older people with multiple long-term conditions avoids the need for high-intensity home care or residential care.
- Clinical commissioning groups may make savings if improving health and social care for older people with multiple long-term conditions helps people to manage their own health better and reduces the need for hospital care or community health care.

Menopause: diagnosis and management NG23

Background

The average age of menopause in the UK is 51. However, this varies widely and 1 in 100 women experience premature ovarian insufficiency (menopause occurring before the age of 40 years).

Oestrogen depletion associated with menopause causes irregular periods and has many other effects on the body. The most common symptoms are hot flushes and night sweats. Other symptoms include mood changes, memory and concentration loss, vaginal dryness, a lack of interest in sex, headaches, and joint and muscle stiffness. Quality of life may be severely affected.

Most women (8 out of 10) experience some symptoms, typically lasting about 4 years after the last period, but continuing for up to 12 years in about 10% of women. Prolonged lack of oestrogen affects the bones and cardiovascular system and postmenopausal women are at increased risk of a number of long-term conditions, such as osteoporosis.

Around a million women in the UK use treatment for their menopausal symptoms. The advice and support available is variable, and use of hormone replacement therapy (HRT) – a highly successful treatment for common symptoms of menopause – varies with socioeconomic and cultural factors. The number of prescriptions for HRT almost halved after the publication of 2 large studies: the Women's Health Initiative (2002) and the Million Women Study (2003). These studies focused on the use of HRT in chronic disease prevention and potential long-term risks rather than considering the benefits in terms of symptom relief. One of the aims of this NICE guideline was to clarify the balance of benefits and risks of HRT use for both women and their healthcare providers.

Recommendations

- 1.1 Individualised care
- 1.2 Diagnosis of perimenopause and menopause
- 1.3 Information and advice
- 1.4 Managing short-term menopausal symptoms
- 1.5 Long-term benefits and risks of hormone replacement therapy
- 1.6 Diagnosing and managing premature ovarian insufficiency

Menopause implementation: getting started

This section highlights 3 areas of the menopause guideline that could have a big impact on practice and be challenging to implement, along with the reasons why we are proposing change in these areas (given in the box at the start of each area).

- **The challenge:** stopping the use of follicle-stimulating hormone tests to diagnose menopause in women aged over 45 years
- **The challenge:** communicating the long-term benefits and risks of hormone replacement therapy
- **The challenge:** providing enough specialist services

Financial factors

The NICE costing report focuses on the recommendations that are considered to have the greatest resource impact nationally, and therefore need the most additional resources to implement or can potentially generate the biggest savings. They are:

- decrease the number of follicle-stimulating hormone (FSH) tests in women. For England this is expected to **save** £9.6M
- increase use of transdermal hormone replacement therapy (HRT). For England this is expected to cost £900K

The net effect of these measures is expected by NICE to be £16.5K per 100,000 population.

Blood transfusion NG24

Background

This guideline covers the assessment for and management of blood transfusions in adults, young people and children over 1 year old. It covers the general principles of blood transfusion, but does not make recommendations relating to specific conditions. Blood transfusions are common in clinical practice. In 2014/15 NHS Blood and Transplant issued 1.7 million units of red blood cells. An estimated 430,000 patients received a red blood cell transfusion in 2002, since 2002 the number of patients who have had a transfusion is likely to be 10–20% lower than this figure.

Despite considerable efforts to ensure the safety of blood transfusions, they are associated with significant risks. The Serious Hazards of Transfusion (SHOT) scheme estimated that in 2014 the risk of transfusion-related death was 5.6 per million blood components issued, and the risk of transfusion-related major morbidity was 63.5 per million blood components issued.

Recommendations

- 1.1 Alternatives to blood transfusion for patients having surgery
- 1.2 Red blood cells
- 1.3 Platelets
- 1.4 Fresh frozen plasma
- 1.5 Cryoprecipitate
- 1.6 Prothrombin complex concentrate
- 1.7 Patient safety

1.8 Patient information

1.9 Blood transfusions for patients with acute upper gastrointestinal bleeding

Key priorities for implementation

- Alternatives to blood transfusion for patients having surgery
- Red blood cells
- Platelets
- Fresh frozen plasma
- Prothrombin complex concentrate
- Patient information

Blood transfusion implementation: getting started

This section highlights 2 areas of the blood transfusion guideline that could have a big impact on practice and be challenging to implement, along with the reasons why these areas are important

- The challenge: Using tranexamic acid as an alternative to transfusion
- The challenge: using electronic patient identification systems

Financial factors

The NICE costing statement focuses on the recommendations that are likely to have the greatest resource impact. These are:

- Offer iron before and after surgery to patients with iron-deficiency anaemia.
- Offer tranexamic acid to adults and children undergoing surgery who are expected to have at least moderate blood loss (greater than 500 ml). Consider tranexamic acid for children undergoing surgery who are expected to have at least moderate blood loss (greater than 10% blood volume)
- Consider intra-operative cell salvage with tranexamic acid for patients who are expected to lose a very high volume of blood (for example in cardiac and complex vascular surgery, major obstetric procedures, and pelvic reconstruction and scoliosis surgery)
- Consider using a system that electronically identifies patients to improve the safety and efficiency of the blood transfusion process.

It is anticipated that the cost of implementing the recommendations may be offset by a reduction in the number of blood transfusions, and a reduction in the amount of blood transfused when they are still needed. More appropriate use of blood transfusion will reduce risk and make better use of a scarce and costly resource.

[Preterm labour and birth NG25](#)

Background

This guideline covers the care of women at increased risk of or with symptoms and signs of preterm labour (before 37 weeks) and women having a planned preterm birth. It aims to reduce the risks of preterm birth for the baby and describes treatments to prevent or delay early labour and birth.

Preterm birth is the single biggest cause of neonatal mortality and morbidity in the UK. Over 52,000 babies (around 7.3% of live births) in England and Wales in 2012 were born preterm – that is, before 37+0 weeks of pregnancy. There has been no decline in the preterm birth rate in the UK over the last 10 years.

Babies born preterm have high rates of early, late and postneonatal mortality, and the risk of mortality increases as gestational age at birth decreases. Babies who survive have increased rates of disability. Recent UK studies comparing cohorts born in 1995 and 2006 have shown improved rates of survival (from 40% to 53%) for extreme preterm births (born between 22 and 26 weeks). Rates of disability in survivors were largely

unchanged over this time period.

Recommendations

1.1 Information and support

1.2 Prophylactic vaginal progesterone and prophylactic cervical cerclage

1.3 Diagnosing preterm prelabour rupture of membranes (P-PRM)

1.4 Antenatal prophylactic antibiotics for women with P-PRM

1.5 Identifying infection in women with P-PRM

1.6 'Rescue' cervical cerclage

1.7 Diagnosing preterm labour for women with intact membranes

1.8 Tocolysis

1.9 Maternal corticosteroids

1.10 Magnesium sulfate for neuroprotection

1.11 Fetal monitoring

1.12 Mode of birth

1.13 Timing of cord clamping for preterm babies (born vaginally or by caesarean section)

Preterm labour and birth implementation : getting started

This section highlights 2 areas of the preterm labour and birth guideline that could have a big impact on practice and be challenging to implement, along with the reasons why we are proposing change in these areas

- The challenge: diagnosing preterm labour for women with intact membranes
- The challenge: using tocolysis

Financial factors

The NICE costing statement states that the guidance might have resource implications at a local level as a result of variation in clinical practice across the country. Therefore organisations are encouraged to evaluate their own practices against the recommendations in the NICE guideline and assess costs and savings locally.

Potential costs include

- diagnosing preterm labour for women with intact membranes using transvaginal ultrasound measurement of cervical length
- tocolysis (premature labour suppression)
- magnesium sulfate for neuroprotection (maternal infusion to protect the unborn baby)

The NICE costing statement indicates that it is unlikely that there would be additional costs to commissioners, because suspected preterm births are likely to already receive the intermediate or intensive level of antenatal pathway payment (£1,674 or £2,786 per pregnancy; Payment by results tariff 2015/16).

[Children's attachment: attachment in children and young people who are adopted from care, in care or at high risk of going into care NG26](#)

Background

Children are born with a range of innate behaviours to maximise their survival. Among these is attachment behaviour, which allows the child to draw their primary caregivers towards them at moments of need or distress.

This guideline covers the identification, assessment and treatment of attachment difficulties in children and young people up to age 18 who are adopted from care, in special guardianship, looked after by local authorities in foster homes (including kinship foster care), residential units and other accommodation, or on the edge of care. It aims to address the many emotional and psychological needs of children and young people in

	<p>these situations, including those resulting from maltreatment.</p> <p><u>Recommendations</u></p> <p>1.1 Principles of care in all contexts</p> <p>1.2 Supporting children and young people with attachment difficulties in schools and other education settings (including early years)</p> <p>1.3 Assessing attachment difficulties in children and young people in all health and social care settings</p> <p>1.4 Interventions for attachment difficulties in children and young people on the edge of care</p> <p>1.5 Interventions for attachment difficulties in children and young people in the care system, subject to special guardianship orders and adopted from care</p> <p>1.6 Interventions for attachment difficulties in children and young people in residential care</p> <p><u>Key priorities for implementation</u></p> <ul style="list-style-type: none"> • Principles of care in all contexts • Supporting children with attachment difficulties in schools • Assessing attachment difficulties in children and young people in all health and social care settings • Interventions for children and young people on the edge of care • Interventions for attachment difficulties in children and young people in the care system, subject to special guardianship orders and adopted from care <p><u>Children’s attachment: Getting started</u></p> <p>This section highlights 3 areas of the children's attachment guideline that could have a big impact on practice and be challenging to implement, along with the reason[s] why we are proposing change in these areas</p> <ul style="list-style-type: none"> • The challenge: stability of care • The challenge: assessing attachment difficulties. • The challenge: using video feedback programmes. <p><u>Financial factors</u></p> <p>The NICE costing statement states that experts suggest that services for children and young people with attachment difficulties vary across the country.</p> <p>Potential areas for additional costs and savings locally are:</p> <ul style="list-style-type: none"> • improving the stability of placements and the likelihood of a more permanent placement, including adoption • supporting children and young people with attachment difficulties in schools • assessing attachment difficulties in children and young people in all health and social care settings • interventions for children and young people on the edge of care, in the care system and adopted from care, and in residential care.
<p>Interventional Procedures Guidance (IPGs)</p>	<p><u>Implantation of a corneal graft–keratoprosthesis for severe corneal opacity in wet blinking eyes IPG534</u></p> <p><u>Recommendations</u></p> <p>1.1 Current evidence on the efficacy of implantation of a corneal graft–keratoprosthesis for severe corneal opacity in wet blinking eyes is adequate in the short to medium term. Although the evidence on safety shows a high incidence of significant adverse effects, there are few options for patients with severe corneal opacity if standard corneal grafts have failed or are not appropriate. Therefore this procedure may be used with normal arrangements for clinical governance, consent and audit.</p> <p>1.2 During the consent process, clinicians should ensure that patients clearly</p>

understand the balance of risks and benefits of this procedure, including: the need for long-term follow-up, which some patients find burdensome; the possibility that sight may not improve and may deteriorate; and the risk of serious complications. Patients should be provided with clear information in an appropriate format. In addition, the use of NICE's information for the public is recommended.

1.3 Implantation of a corneal graft–keratoprosthesis for severe corneal opacity in wet blinking eyes should only be done on carefully selected patients with corneal blindness, when standard treatments such as keratoplasty have failed or are not appropriate.

1.4 Implantation of a corneal graft–keratoprosthesis for severe corneal opacity in wet blinking eyes should only be done in specialist centres by surgeons experienced in the technique; long-term follow-up should be carried out by an experienced multidisciplinary team.

The procedure

A corneal graft–keratoprosthesis is an artificial clear central corneal window surrounded by a human donor cornea. Implantation is generally done if a standard corneal transplant has failed, or when it is inappropriate. The procedure is used to treat only the most severe corneal opacity.

[Living-donor liver transplantation IPG535](#)

Recommendations

1.1 Current evidence on the efficacy and safety of living-donor liver transplantation appears adequate to support the use of this procedure for suitable donors and recipients with **normal arrangements** for clinical governance, consent and audit, provided that the necessary regulatory requirements are followed.

1.2 Clinicians and centres doing this procedure must follow the relevant regulatory and legal requirements of the Human Tissue Authority. This includes carrying out independent assessment interviews and getting statutory approval from the Human Tissue Authority before donation can proceed. During the consent process donors and recipients should have thorough physical and psychological screening and monitoring, and counselling about the morbidity and risks associated with this procedure. They should also be provided with clear written information, including relevant information provided by the Human Tissue Authority. In addition, the use of NICE's information for the public is recommended.

1.3 Living-donor liver transplantation should only be done in accordance with the NHS Blood and Transplant (NHSBT) Organ Donation and Transplantation Liver Advisory Group's Liver Selection Policy and the British Transplantation Society's guidelines for Directed Altruistic Organ Donation, taking into account the legal framework for living donation from the Human Tissue Authority. Non-directed altruistic donation is a possibility and should be discussed with a transplant centre or team.

1.4 Living-donor liver transplantation should be carried out in specialist centres by a multidisciplinary team.

1.5 Clinicians should enter details about all donors and recipients having living-donor liver transplantation into the NHSBT UK transplant registry, and review clinical outcomes locally.

The procedure

Living-donor liver transplantation requires 2 operations: a partial hepatectomy performed on the donor; and a hepatectomy (of the native organ) with orthotopic liver transplantation for the recipient.

[Sacral nerve stimulation for idiopathic chronic non-obstructive urinary retention IPG536](#)

Recommendations

1.1 Current evidence on the safety and efficacy of sacral nerve stimulation for idiopathic chronic non-obstructive urinary retention is adequate to support the use of this procedure provided that **normal arrangements** are in place for clinical governance, consent and audit.

	<p>1.2 During the consent process, clinicians should ensure that patients understand the risk of complications, the likely need for further surgery and the possible need for device removal, and provide them with clear written information. In addition, the use of NICE's information for the public is recommended.</p> <p>1.3 Patient selection and treatment should be done in specialist units by clinical teams who are experienced in the assessment, treatment and long-term care of patients with bladder dysfunction, and in the use of sacral nerve stimulation.</p> <p>1.4 NICE encourages audit and reporting of long-term safety outcomes.</p> <p><u>The procedure</u></p> <p>Sacral nerve stimulation for idiopathic chronic non-obstructive urinary retention involves applying an electric current to one of the sacral nerves by an electrode placed through the corresponding sacral foramen. It aims to restore the ability to empty the bladder voluntarily and to remove the need for catheterisation.</p>
<p>Medical Technologies Guidance</p>	<p>None published so far this month</p>
<p>Diagnostics Guidance</p>	<p><u>VivaScope 1500 and 3000 imaging systems for detecting skin cancer lesions DG19</u></p> <p><u>Recommendations</u></p> <p>1.1 The VivaScope 1500 and 3000 imaging systems show promise but there is currently insufficient evidence to recommend their routine adoption in the NHS for:</p> <ul style="list-style-type: none"> •deciding whether to biopsy and excise skin lesions in people with suspected melanoma (equivocal lesions), basal cell carcinoma or lentigo maligna, or •defining margins of skin lesions in people with lentigo maligna and basal cell carcinoma. <p>1.2 Further research on using the VivaScope 1500 and 3000 imaging systems is recommended in the following areas:</p> <ul style="list-style-type: none"> • the impact on clinical workflows for melanoma and basal cell carcinoma assessment in secondary care settings • the proportion of people with melanoma referred into secondary care under the 2-week wait rule, and the outcomes achieved • the number of confirmatory diagnostic biopsies needed for people with a clinical diagnosis of basal cell carcinoma, before definitive treatment is started • the comparative clinical effectiveness of using these imaging systems to define margins of lentigo maligna and basal cell carcinoma • epidemiological research on lentigo maligna diagnosed in England. <p>1.3 The VivaScope 1500 and 3000 imaging systems are not recommended for:</p> <ul style="list-style-type: none"> • helping decide whether to biopsy and excise skin lesions in people with suspected invasive squamous cell carcinoma, or • defining margins of skin lesions in people with melanoma or invasive squamous cell carcinoma. <p><u>The Technology</u></p> <p>The VivaScope 1500 and 3000 imaging systems (MAVIG) are non-invasive, high resolution, reflectance laser confocal microscope systems that are designed to help assess potentially malignant skin lesions. They aim to provide quasi-histological resolution (a highly magnified image) of skin cells that is reportedly comparable to microscopic examination of a skin specimen.</p>
<p>NICE Quality</p>	<p>None published so far this month</p>

Standards	
Commissioning Guides	None published so far this month
Public health briefings for local government	None published so far this month

Current NICE consultations with links and start and finish dates for stakeholders to make contribution

Title / link	Start date of consultation	End date of consultation
Neuroblastoma (high-risk) - dinutuximab (maintenance, after therapy) [ID799] : Appraisal consultation	05/11/2015	25/11/2015
The safe use and management of controlled drugs : Draft guidance consultation	28/10/2015	25/11/2015
Contraceptive services : Topic engagement	18/11/2015	01/12/2015
Attention deficit hyperactivity disorder (standing committee B update) : Addendum consultation	06/11/2015	04/12/2015
Colorectal cancer (metastatic) - cetuximab (review TA176) and panitumumab (part review TA240) (1st line) ID794 : Appraisal consultation : 1	17/11/2015	08/12/2015
Hypercholesterolaemia (primary), dyslipidaemia (mixed) - evolocumab [ID765] : Appraisal consultation	18/11/2015	08/12/2015
Smoking cessation interventions and services : Draft scope consultation	11/11/2015	09/12/2015
Ovarian cancer - topotecan, pegylated liposomal doxorubicin hydrochloride, paclitaxel, trabectedin and gemcitabine for advanced recurrent disease only (Review of TA 91 and TA 222) [ID468] : Appraisal consultation	24/11/2015	15/12/2015
Corticosteroid-eluting bioabsorbable stent or spacer insertion during endoscopic sinus surgery to treat chronic rhinosinusitis : Interventional procedure consultation	20/11/2015	18/12/2015
Endoscopic CO2 laser cricopharyngeal myotomy for relief of oropharyngeal dysphagia : Interventional procedure consultation	20/11/2015	18/12/2015
Oesophago-gastric cancer : Draft scope consultation	23/11/2015	18/12/2015
Transcutaneous stimulation of the cervical branch of the vagus nerve for cluster headache and migraine : Interventional procedure consultation	20/11/2015	18/12/2015
People's experience in adult social care services: improving the experience of care for people using adult social care services : Draft scope consultation	23/11/2015	21/12/2015

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