NICE Update Bulletin: January 2019

Hyperlinks to the relevant NICE web page are included below.

Details are also available from the NICE website (**http://www.nice.org.uk**)

Type	Guidance title and reference number
Technology Appraisals (TAs)	**Axicabtagene ciloleucel for treating diffuse large B-cell lymphoma and primary mediastinal large B-cell lymphoma after 2 or more systemic therapies TA559** **Recommendations** 1.1 Axicabtagene ciloleucel therapy is recommended for use **within the Cancer Drugs Fund** as an option for treating relapsed or refractory diffuse large B-cell lymphoma or primary mediastinal large B-cell lymphoma in adults after 2 or more systemic therapies, only if the conditions in the managed access agreement are followed. 1.2 This recommendation is not intended to affect both treatment in preparation for and treatment with axicabtagene ciloleucel that was started in the NHS before this guidance was published. People having treatment outside this recommendation may continue without change to the funding arrangements in place for them before this guidance was published, until they and their NHS clinician consider it appropriate to stop. **The technology** Axicabtagene ciloleucel is indicated for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma and primary mediastinal large B-cell lymphoma after 2 or more lines of systemic therapy. Axicabtagene ciloleucel is an immunocellular chimeric antigen receptor (CAR) T-cell therapy. It contains the patient's own T cells (a type of white blood cell) that have been modified genetically in the laboratory so that they make a protein called CAR. CAR can attach to another protein on the surface of cancer cells called CD19. When axicabtagene ciloleucel is given to the patient, the modified T cells attach to and kill cancer cells, thereby helping to clear the cancer from the body. Treatment with axicabtagene ciloleucel comprises a single-dose intravenous infusion of axicabtagene ciloleucel (anti-CD19 CAR T cells in about 68 ml). It is intended for autologous use only and at the following dosage: • 2×10^6 anti-CD19 CAR T cells per kg body weight (range: 1×10^6 to 2.4×10^6 cells per kg), with at most 2×10^8 anti-CD19 CAR T cells. **Financial factors** This technology is commissioned by NHS England. NICE estimates that around 200 people per year in England with recurring large cell lymphoma are eligible for treatment with axicabtagene ciloleucel. Axicabtagene ciloleucel will be available to the NHS in line with the managed access agreement with NHS England and the resource impact will be covered by the Cancer Drugs Fund budget. The guidance will be reviewed by the date

the managed access agreement expires, February 2022, or when the results of the managed access agreement data collection are available, whichever is sooner. The aim of the review is to decide whether or not the drug can be recommended for routine use.

Nivolumab for adjuvant treatment of completely resected melanoma with lymph node involvement or metastatic disease TA558

Recommendations

1.1 Nivolumab is recommended for use **within the Cancer Drugs Fund** as an option for the adjuvant treatment of completely resected melanoma in adults with lymph node involvement or metastatic disease. It is recommended only if the conditions in the managed access agreement are followed.

1.2 This recommendation is not intended to affect treatment with nivolumab that was started in the NHS before this guidance was published. People having treatment outside this recommendation may continue without change to the funding arrangements in place for them before this guidance was published, until they and their NHS clinician consider it appropriate to stop.

The technology

Nivolumab has a marketing authorisation as monotherapy for the adjuvant treatment of adult patients with melanoma with involvement of lymph nodes or metastatic disease who have undergone complete resection.

The dosage in the marketing authorisation is 3 mg/kg nivolumab administered intravenously over 60 minutes every 2 weeks for up to 12 months.

Financial factors

This technology is commissioned by NHS England.

NICE estimates that around 1,400 people per year in England with stage III melanoma with lymph node involvement or metastatic disease who have had complete resection are eligible for treatment with nivolumab.

Nivolumab will be available to the NHS in line with the managed access agreement with NHS England and the resource impact will be covered by the Cancer Drugs Fund budget. The guidance will be reviewed by the date the managed access agreement expires (December 2020), or when the results of the managed access agreement data collection are available, whichever is sooner. The aim of the review is to decide whether or not the drug can be recommended for routine use.

Pembrolizumab with pemetrexed and platinum chemotherapy for untreated, metastatic, non-squamous non-small-cell lung cancer TA557

Recommendations

1.1 Pembrolizumab, with pemetrexed and platinum chemotherapy is recommended for use **within the Cancer Drugs Fund**, as an option for untreated, metastatic, non-squamous non-small-cell lung cancer (NSCLC) in adults whose tumours have no epidermal growth factor receptor (EGFR)- or anaplastic lymphoma kinase (ALK)-positive mutations. It is only recommended if:

- pembrolizumab is stopped at 2 years of uninterrupted treatment or earlier if disease progresses and
- the company provides pembrolizumab according to the managed access agreement.

1.2 This recommendation is not intended to affect treatment with pembrolizumab with pemetrexed and platinum chemotherapy that was started in the NHS before this guidance was published. People having treatment outside this recommendation may continue without change to the funding arrangements in place for them before this guidance was published, until they and their NHS clinician consider it appropriate to stop.

The technology

Pembrolizumab, plus pemetrexed and carboplatin or cisplatin has a marketing authorisation for the first-line treatment of metastatic non-squamous non-small-cell lung carcinoma (NSCLC) in adults whose tumours have no epidermal growth factor receptor or anaplastic lymphoma kinase-positive tumour mutations.

The dosage in the marketing authorisation is 200 mg every 3 weeks by intravenous infusion. The summary of product characteristics recommends treatment with pembrolizumab until disease progression or unacceptable toxicity.

Financial factors

This technology is commissioned by NHS England.

NICE estimates that the eligible population for treatment with pembrolizumab is up to 4,800 per year in England.

Pembrolizumab will be available to the NHS in line with the managed access agreement with NHS England. As part of the managed access agreement, the technology will continue to be available through the Cancer Drugs Fund after the data collection period has ended and while the guidance is being reviewed. This assumes that the data collection period ends as planned in June 2019. The aim of the review is to decide whether or not the drug can be recommended for routine use.

Darvadstrocel for treating complex perianal fistulas in Crohn's disease TA556

Recommendations

1.1 Darvadstrocel is **not recommended**, within its marketing authorisation, for previously treated complex perianal fistulas in adults with non-active or mildly active luminal Crohn's disease.

The technology

Darvadstrocel is indicated for the treatment of complex perianal fistulae in adult patients with non-active/mildly active luminal Crohn's disease, when fistulae have shown an inadequate response to at least 1 conventional or biologic therapy.

A single dose of darvadstrocel consists of 120 million cells distributed in 4 vials. Each vial contains 30 million cells in 6 ml of suspension. The full content of the 4 vials must be administered for the treatment of up to 2 internal openings and up to 3 external openings. This means that, with a dose of 120 million cells, it is possible to treat up to 3 fistula tracts that open to the perianal area.

There is currently limited experience with the efficacy or safety of repeat administration of darvadstrocel. NICE noted that there were uncertainties around long-term benefits of darvadstrocel. The cost-effectiveness estimates are therefore highly uncertain. Darvadstrocel cannot therefore be recommended for routine commissioning for treating complex perianal fistuals in people with Crohn's disease.

	Regorafenib for previously treated advanced hepatocellular carcinoma TA555 **Recommendations** 1.1 Regorafenib is recommended as an option for treating advanced unresectable hepatocellular carcinoma in adults who have had sorafenib, only if: • they have Child–Pugh grade A liver impairment and an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 and • the company provides it according to the commercial arrangement. 1.2 This recommendation is not intended to affect treatment with regorafenib that was started in the NHS before this guidance was published. People having treatment outside this recommendation may continue without change to the funding arrangements in place for them before this guidance was published, until they and their NHS clinician consider it appropriate to stop. **The technology** Regorafenib is indicated as monotherapy for the treatment of adult patients with hepatocellular carcinoma who have been previously treated with sorafenib. The dosage in the marketing authorisation is 160 mg (4×40 mg tablets) orally once daily for 3 weeks followed by 1 week off therapy. A 4-week period is considered a treatment cycle. **Financial factors** This technology is commissioned by NHS England. NICE estimates that around 500 people in England are eligible for treatment with regorafenib each year. NICE does not expect this guidance to have a significant impact on resources; that is, it will be less than £5 million per year in England (or £9,100 per 100,000 population). This is because regorafenib is recommended as an option for treating advanced unresectable hepatocellular carcinoma in adults who have had sorafenib and the population size is small. The company has a commercial agreement (simple patient access scheme). This makes regorafenib available to the NHS with a discount. The size of the discount is commercial in confidence.
Highly specialised technology guidance (HSTs)	None published so far this month.
NICE Guidelines (NGs)	**Cerebral palsy in adults NG119** This guideline covers care and support for adults with cerebral palsy. It aims to improve health and wellbeing, promote access to services and support participation and independent living. This guideline includes recommendations on: • access to services and ongoing review • support with communication, vocational skills and independent living, electronic assistive technology and physical activity • managing spasticity and dystonia • assessing and monitoring bone and joint disorders, mental health

	problems, difficulties with eating and nutrition, respiratory disorders and pain. **Renal and ureteric stones: assessment and management NG118** This guideline covers assessing and managing renal and ureteric stones. It aims to improve the detection, clearance and prevention of stones, so reducing pain and anxiety, and improving quality of life. This guideline includes recommendations on: • diagnostic imaging • managing pain • medical expulsive therapy • surgical treatments, including shockwave lithotripsy • stenting before and after treatment • metabolic testing • preventing recurrence. It does not cover the infected obstructed kidney, which needs urgent drainage.
Public Health Guidelines	None published so far this month.
Antimicrobial prescribing guidelines	None published so far this month.
Social Care Guidelines	None published so far this month.
Interventional Procedures Guidance (IPGs)	**Prostatic urethral temporary implant insertion for lower urinary tract symptoms caused by benign prostatic hyperplasia IPG641** **Recommendations** 1.1 Current evidence on the safety and efficacy of prostatic urethral temporary implant insertion for lower urinary tract symptoms caused by benign prostatic hyperplasia is limited in quantity and quality. Therefore, this procedure should only be used in the **context of research**. 1.2 Further research, ideally in the form of randomised controlled trials, should report details of patient selection (including prostate size and the amount of median lobe enlargement), improvement in lower urinary tract symptoms in the short term and long term, re-intervention rates, and outcome measures of sexual function using established methods. **The condition** Lower urinary tract symptoms caused by benign prostatic hyperplasia commonly affect men over 50. Stromal and epithelial cells increase in number, causing the prostate to increase in size. It often occurs in the periurethral region of the prostate, with large discrete nodules compressing the urethra. Symptoms include hesitancy during micturition, interrupted or decreased urine stream (volume and flow rate), nocturia, incomplete voiding and urinary retention. Mild symptoms are usually managed conservatively. Drugs may also be used, such as alpha blockers and 5-alpha-reductase inhibitors. If other treatments have not worked, there are a range of surgical options that may be considered including transurethral resection of the prostate, transurethral vaporisation,

holmium laser enucleation, insertion of prostatic urethral lift implants, prostatic artery embolisation or prostatectomy. Potential complications of some of these surgical procedures include bleeding, infection, urethral strictures, incontinence and sexual dysfunction.

The procedure

Prostatic urethral temporary implant insertion aims to relieve symptoms of benign prostatic hyperplasia by creating new channels in the urethra that increase the flow of urine, without having the complications of an implant left in situ.

Percutaneous venoplasty for chronic cerebrospinal venous insufficiency in multiple sclerosis IPG640

This guidance replaces NICE interventional procedures guidance on percutaneous venoplasty for chronic cerebrospinal venous insufficiency for multiple sclerosis (IPG420).

Recommendations

1.1 Current evidence on percutaneous venoplasty for chronic cerebrospinal venous insufficiency in multiple sclerosis shows that there are serious complications and that it provides no benefit. Therefore, this procedure should **not be used** in the management of multiple sclerosis.

The condition

Multiple sclerosis is a disease of the central nervous system, which usually starts in early adult life. It is characterised by neurological symptoms caused by episodes of inflammation and scarring in the white matter of the brain or spinal cord. It causes a range of symptoms including problems with vision, arm or leg movement, sensation or balance. Muscle spasms, pain, fatigue, and emotional problems or depression may also occur. Symptoms may vary over time and some people become profoundly disabled. The 3 most common types of multiple sclerosis are: relapsing–remitting, in which periods of good health or remission are followed by sudden onset of symptoms or relapses; secondary progressive, in which symptoms gradually worsen with fewer remissions; and primary progressive, which involves a gradual, continuous worsening of symptoms.

Current treatment for multiple sclerosis includes specialist neurological rehabilitation, and medication aimed at symptom control and preventing disease progression.

The procedure

The aim of percutaneous venoplasty for chronic cerebrospinal venous insufficiency is to relieve multiple sclerosis symptoms by improving cerebrospinal venous drainage. However, the full mechanism of action is not currently understood.

Laparoscopic cerclage for cervical incompetence to prevent late miscarriage or preterm birth IPG639

This guidance replaces NICE interventional procedures guidance on laparoscopic cerclage for prevention of recurrent pregnancy loss due to cervical incompetence (IPG228).

Recommendations

1.1 Current evidence on the safety and efficacy of laparoscopic cerclage for cervical incompetence to prevent late miscarriage or preterm birth is

adequate to support the use of this procedure provided that **standard arrangements** are in place for clinical governance, consent and audit.

1.2 Patient selection should be done by a multidisciplinary team experienced in the management and prevention of preterm delivery.

The condition

Cervical incompetence may be caused by a congenital weakness of the cervix, or previous obstetric or gynaecological trauma. It is characterised by painless dilatation of the cervix in the second or third trimester, followed by second trimester miscarriage or premature rupture of the membranes and preterm delivery. The condition is usually diagnosed after 1 or more late second trimester pregnancy losses or early third trimester delivery, and after other causes have been excluded.

Cervical incompetence is traditionally treated by transvaginal cervical cerclage. This involves placing a strong suture or tape around the cervix, via the vagina, and tightening it to keep the cervix closed. The procedure is typically done at the end of the first trimester or the beginning of the second trimester. The suture or tape is then usually removed at around 37 weeks of gestation to allow delivery.

Cervical cerclage using a transabdominal approach may be needed if transvaginal cerclage is technically difficult or has proved ineffective. With this approach, caesarean section is necessary to deliver the baby.

The procedure

Laparoscopic cervical cerclage can be done during pregnancy or in women who are not pregnant. Under general anaesthesia, the peritoneal cavity is insufflated with carbon dioxide through a needle inserted into the umbilicus. Several small incisions are made to provide access for the laparoscope and surgical instruments. In women who are not pregnant, a dilator may initially be inserted into the cervix through the vagina for uterine manipulation. The bladder is dissected away from the uterus and a suture or tape is secured around the cervical isthmus, above the cardinal and uterosacral ligaments. As with the open transabdominal approach, caesarean section is necessary to deliver the baby. The suture or tape may be left in place for future pregnancies.

Electrically stimulated intravesical chemotherapy for non-muscle-invasive bladder cancer IPG638

This guidance replaces NICE interventional procedures guidance on electrically-stimulated intravesical chemotherapy for superficial bladder cancer (IPG277).

Recommendations

1.1 Current evidence on electrically stimulated intravesical chemotherapy for non-muscle-invasive bladder cancer shows there are no major safety concerns. Evidence on efficacy is limited in quantity and quality. Therefore, this procedure should only be used in the **context of research**.

1.2 Further research should include randomised controlled trials compared with standard care, which should report details of patient selection.

The condition

The most common form of bladder cancer is transitional cell carcinoma (TCC). Non-muscle-invasive TCC is classified as stage Ta when the tumour is confined to the urothelium with no spread into the wall of the bladder or beyond, and stage T1 when there is spread into the connective tissue layer

between the urothelium and the muscle wall. It is graded from G1 (low grade, least aggressive) to G3 (high grade, most aggressive). Another type of non-muscle-invasive cancer is carcinoma in situ, in which aggressive cancer cells spread within the surface lining of the bladder.

Conventional treatment for non-muscle-invasive cancer is transurethral resection of bladder tumour (TURBT), in which malignant tissue is removed with an electrocautery device during cystoscopy. Intravesical chemotherapy with Bacillus Calmette-Guérin (BCG) vaccine or other chemotherapeutic drugs may also be used. The drug is instilled directly into the bladder, either alone or as adjuvant therapy after TURBT. The aim is to reduce the risk of cancer recurrence. Intravesical microwave hyperthermia may also be used, in combination with intravesical chemotherapy. Cystectomy may be needed in some patients.

The procedure

Electrically stimulated intravesical chemotherapy (also known as electromotive drug administration) can be used as neoadjuvant treatment before TURBT, or as adjuvant treatment after TURBT. The procedure involves the use of a device to create an electric field across the bladder wall, with the aim of stimulating directional ionic and solute movement of the intravesical fluid. This increases absorption of the drug into the bladder lining.

Platelet-rich plasma injections for knee osteoarthritis IPG637

This guidance replaces NICE interventional procedures guidance on platelet-rich plasma injections for knee osteoarthritis (IPG491).

Recommendations

1.1 Current evidence on platelet-rich plasma injections for knee osteoarthritis raises no major safety concerns. However, the evidence on efficacy is limited in quality. Therefore, this procedure should only be used with **special arrangements** for clinical governance, consent, and audit or research.

1.2 Clinicians wishing to give platelet-rich plasma injections for knee osteoarthritis should:

- Inform the clinical governance leads in their NHS trusts.
- Ensure that patients understand the procedure's safety and efficacy, as well as any uncertainties about these. Provide them with clear information to support shared decision making. In addition, the use of NICE's information for the public is recommended.
- Audit and review clinical outcomes of all patients having platelet-rich plasma injections for knee osteoarthritis, including details of the methods used to prepare and administer the platelet-rich plasma injections. NICE has identified relevant audit criteria and has developed an audit tool (which is for use at local discretion).

1.3 Further research should be in the form of randomised controlled trials with medium- to long-term follow-up, including validated measures of knee function and patient-reported outcomes.

The condition

Osteoarthritis of the knee is the result of progressive deterioration of the articular cartilage and menisci of the joint, usually because of trauma, and wear and tear. This leads to exposure of the bone surface. Symptoms include pain, stiffness, swelling and difficulty walking.

Treatment depends on the severity of the symptoms. Conservative treatments include analgesics and corticosteroid injections to relieve pain and inflammation, and physiotherapy and prescribed exercise to improve function and mobility. When symptoms are severe, surgery may be indicated: options include upper tibial osteotomy and unicompartmental or total knee replacement.

The procedure

Platelet-rich plasma is prepared by a clinician or a technician. Blood is taken from the patient and centrifuged to obtain a concentrated suspension of platelets in plasma. Different preparation methods may affect the concentrations of platelets and the level of contamination with red and white blood cells. Different agents such as calcium chloride or thrombin may be added.

The platelet-rich plasma is injected into the joint space in the knee, usually under ultrasound guidance. Platelets contain growth factors that are thought to stimulate chondrocyte proliferation, leading to cartilage repair. The aim is to relieve symptoms, potentially delaying the need for joint replacement surgery. This guidance refers to the use of platelet-rich plasma injections alone and not as part of a combination therapy.

Ex-situ machine perfusion for extracorporeal preservation of livers for transplantation IPG636

Recommendations

1.1 The evidence on ex-situ machine perfusion for extracorporeal preservation of livers for transplantation raises no major safety concerns. However, current evidence on its efficacy is limited in quantity. Therefore, this procedure should only be used with **special arrangements** for clinical governance, consent, and audit or research.

1.2 Clinicians wishing to do ex-situ machine perfusion for extracorporeal preservation of livers for transplantation should:

- Inform the clinical governance leads in their NHS trusts.
- Ensure that patients given a liver which has had ex-situ machine perfusion understand the uncertainty about the procedure's safety and efficacy, and provide them with clear written information to support shared decision making. In addition, the use of NICE's information for the public is recommended.
- Audit and review clinical outcomes of all patients given a liver which has had ex-situ machine perfusion for extracorporeal preservation of livers for transplantation. NICE has identified relevant audit criteria and has developed an audit tool (which is for use at local discretion).

1.3 Clinicians and centres doing this procedure must follow the relevant regulatory and legal requirements of the Human Tissue Authority.

1.4 Clinicians should enter details about all patients having this procedure into the NHSBT UK transplant registry.

1.5 Further research should report the exact method of perfusion used (such as hypothermic or normothermic), graft survival and the use of marginal grafts.

The condition

Liver transplantation is the treatment of choice for patients with end-stage liver disease. It may also be indicated in patients with some types of primary liver cancer. End-stage liver failure can be either acute (for example, from

	poisoning) or chronic (for example, because of cirrhosis from alcohol-related liver disease, metabolic, autoimmune or infectious conditions). In children, the most common cause of end-stage liver failure is congenital biliary atresia. Limited availability of deceased donor livers for transplantation led to the development of techniques that increase the number of recipients who can benefit from 1 available organ. These include split liver grafts (the larger right lobe is usually grafted into an adult and the left lobe into a child) and reduced (segmental) liver grafts. Living-donor liver transplantation is also an option for patients who are deteriorating clinically while waiting for a deceased donor transplant. **The procedure** Ex-situ machine perfusion preserves the donor liver outside the body under normothermic or hypothermic conditions. A perfusion machine is used to deliver oxygenated perfusate (which may or may not contain blood depending on the technique employed), supplemented with nutrients and metabolic substrates. The intention is to: • reduce the rate of tissue deterioration that occurs after the liver has been removed from the donor compared with that seen with conventional static cold storage • extend how long the liver can be stored to allow more flexibility in the timing of the transplant operation. Normothermic machine perfusion also allows assessment of donor liver viability and function during preservation. The aim is to improve clinical outcomes for the recipient and to enable otherwise marginal organs (such as those donated after circulatory death, steatotic livers and livers from older people) to be transplanted safely, so increasing the number of livers available for transplantation.
Medical Technologies Guidance	**UrgoStart for treating diabetic foot ulcers and leg ulcers MTG42** **Recommendations** 1.1 Evidence **supports** the case for adopting UrgoStart dressings to treat diabetic foot ulcers and venous leg ulcers in the NHS, because they are associated with increased wound healing compared with non-interactive dressings. 1.2 UrgoStart dressings should therefore be considered as an option for people with diabetic foot ulcers or venous leg ulcers after any modifiable factors such as infection have been treated. 1.3 Cost modelling shows that, compared with standard care, using UrgoStart dressings to treat diabetic foot ulcers is associated with a cost saving of £342 per patient after 1 year. It also shows that UrgoStart is likely to be cost saving for treating venous leg ulcers, but the robustness of this conclusion is less certain from the evidence available. For both types of ulcers, potential cost savings mainly come from better healing with UrgoStart dressings. If 25% of people having treatment for diabetic foot ulcers use UrgoStart instead of a non-interactive dressing, the NHS may save up to £5.4 million each year. For more details, see the NICE resource impact report. 1.4 For people with non-venous leg ulcers, there is insufficient evidence to support routine adoption. **The technology** UrgoStart is an interactive dressing for treating diabetic foot ulcers and leg

ulcers. It consists of a layer of open-weave polyester mesh impregnated with hydrocolloid polymers within a petroleum jelly known as technology lipido-colloid (TLC). It also contains nano-oligosaccharide factor (NOSF) and has an absorbent pad and a semi-permeable backing.

There are 5 formats of the dressing and each comes in different sizes: UrgoStart Contact Layer, UrgoStart Non-Adhesive, UrgoStart Plus Pad, UrgoStart Border and UrgoStart Plus Border.

Financial factors

This technology is commissioned by CCGs; complex lower limb amputations are commissioned by NHS England.

NICE estimates that there may be savings from treating diabetic foot ulcers with UrgoStart ranging from £5.5m to £19.1m for England. The current uptake of UrgoStart dressings in this population (people with diabetic foot ulcers) is estimated by the manufacturer to be around 5% of the eligible population. UrgoStart is likely to be cost saving for treating venous leg ulcers, but the size of the saving is less certain from the evidence available. For both types of ulcers, potential cost savings mainly come from better healing with UrgoStart dressings and from the saving in the number of amputations avoided.

Senza spinal cord stimulation system for delivering HF10 therapy to treat chronic neuropathic pain MTG41

Recommendations

1.1 The case for adopting Senza spinal cord stimulation (SCS) for delivering HF10 therapy as a treatment option for chronic neuropathic back or leg pain after failed back surgery is **supported** by the evidence. HF10 therapy using Senza SCS is at least as effective as low-frequency SCS in reducing pain and functional disability, and avoids the experience of tingling sensations (paraesthesia).

1.2 Senza SCS for delivering HF10 therapy should be considered for patients:

- with residual chronic neuropathic back or leg pain (at least 50 mm on a 0 mm to 100 mm visual analogue scale) at least 6 months after back surgery despite conventional medical management and
- who have had a successful trial of stimulation as part of a wider assessment by a multidisciplinary team.

1.3 Patients with other causes of neuropathic pain were included in the evaluation and may be considered for HF10 therapy using Senza SCS but any additional benefits compared with low-frequency SCS are less certain. Cost modelling indicates that, over 15 years, HF10 therapy using Senza SCS has similar costs to low-frequency SCS using either a rechargeable or non-rechargeable device.

1.4 Clinicians implanting SCS devices including Senza should submit timely and complete data to the UK Neuromodulation Registry.

1.5 When assessing the severity of pain and the trial of stimulation, the multidisciplinary team should be aware of the need to ensure equality of access to treatment with SCS. Tests to assess pain and response to SCS should take into account a person's disabilities (such as physical or sensory disabilities), or linguistic or other communication difficulties, and may need to be adapted.

The technology

The Senza spinal cord stimulation (SCS) system is a neuromodulation device

that delivers electrical impulses to the spinal cord. The treatment Senza provides (known as HF10 therapy) is a combination of high-frequency (10 kHz) low-amplitude electrical pulses designed to relieve pain and not be felt by the patient, and a proprietary programming algorithm. The impulses are delivered by small electrodes, which are placed in the spinal epidural space and are connected to a small, battery-powered pulse generator that is implanted under the skin. The strength, duration and frequency of the electrical pulses can be controlled remotely.

Financial factors

This technology is commissioned by NHS England.

NICE does not expect this guidance to have a significant impact on resources; that is, it will be less than £1 million per year in England (or £1,800 per 100,000 population). This is because cost modelling for the guidance indicates that, over 15 years, HF10 therapy using Senza spinal cord stimulation (SCS) has similar costs to low-frequency SCS using either a rechargable or non-rechargeable device.

Additional modelling indicates that any costs incurred are below £1 million per year in England over this period.

Mepilex Border Heel and Sacrum dressings for preventing pressure ulcers MTG40

Recommendations

1.1 Mepilex Border Heel and Sacrum dressings show promise for preventing pressure ulcers in people who are considered to be at risk in acute care settings. However, there is currently **insufficient evidence to support** the case for routine adoption in the NHS.

1.2 Research is recommended to address uncertainties about the claimed benefits of using Mepilex Border Heel and Sacrum dressings. This research should also explore issues such as:

- the incidence of heel and sacrum pressure ulcers in NHS acute care settings
- criteria for patient selection to reduce pressure ulcer incidence with Mepilex Border Heel and Sacrum dressings in addition to standard care.

NICE will consider reviewing this guidance when substantive new evidence becomes available.

The technology

Mepilex Border dressings are self-adherent, 5-layer foam dressings that include a patented soft silicone technology (known as Safetac).

They are intended for use as part of a care bundle to prevent pressure ulcers in patients at risk of developing pressure ulcers. The current standard of care, and relevant comparators, are described in the NICE Pathway on pressure ulcers.

The company claims that the dressings reduce shear and friction and displace pressure.

Mepilex Border dressings are available in 3 variants: for use on the heel and sacrum (Mepilex Border Heel and Mepilex Border Sacrum), or as standard dressings (Mepilex Border) for use on any part of the body.

This guidance specifically considers the variants designed to prevent pressure ulcers of the heel and sacrum (Mepilex Border Heel and Mepilex Border Sacrum).

	Financial factors NICE does not recommend routine adoption of Mepilex Border Heel and Sacrum dressings in the NHS. **Pipeline Flex embolisation device with Shield Technology for the treatment of complex intracranial aneurysms MTG10 (update)** **January 2019** – This guidance was previously called Pipeline embolisation device for the treatment of complex intracranial aneurysms. This guidance has been updated to include a review of the cost model using more recent values. The device name has also been updated. **Recommendations** 1.1 The case for adopting the Pipeline Flex embolisation device with Shield Technology in the NHS is **supported** by the current evidence when it is used in patients with complex giant or large intracranial aneurysms which are unsuitable for surgery and being considered for stenting, and where large numbers of coils would be needed during stent-assisted coiling. 1.2 The Pipeline Flex embolisation device with Shield Technology is estimated to be cost saving when compared with stent-assisted coiling, in patients with complex giant or large intracranial aneurysms when the number of Pipeline embolisation devices inserted does not exceed 2, and when treatment would otherwise require the use of 34 or more coils combined with 1 stent for stent-assisted coiling. If 2 Pipeline embolisation devices are used the total procedure cost is estimated as £37,625 compared with £38,320 for the use of 34 coils for stent-assisted coiling (a saving of £695 using Pipeline embolisation device). 1.3 Clinicians should submit details of all patients being treated with the Pipeline Flex embolisation device with Shield Technology to the UK Neurointerventional Radiology Group audit database, to increase the evidence base and guide future use of this technology. **The technology** The Pipeline Flex embolisation device with Shield Technology is a self-expanding blood flow diverter that is placed across the neck of an intracranial aneurysm. While blood flow through the parent vessel is maintained via the device, flow within the aneurysm sac is disrupted, leading to stagnation and eventual thrombosis formation. Pipeline provides a scaffold for endothelial growth leading to the formation of a biological seal and exclusion of the aneurysm from the circulation.
Diagnostics Guidance	None published so far this month.
NICE Quality Standards	None published so far this month.

Current NICE consultations with links and end dates for stakeholders to contribute

Title / link	End date of consultation
Epilepsies in children: diagnosis and management	05/02/2019
Children and young people with disabilities and severe complex needs: integrated health and social care support and service guidance	05/02/2019
Epilepsies in adults: diagnosis and management update	05/02/2019
Medicines optimisation: the safe and effective use of medicines to enable the best possible outcomes	05/02/2019
Medicines adherence: involving patients in decisions about prescribed medicines and supporting adherence	05/02/2019
Looked-after children and young people	11/02/2019
Stroke rehabilitation in adults	13/02/2019
Enzalutamide for treating non-metastatic hormone-relapsed prostate cancer [ID1359]	14/02/2019
Shared decision making	15/02/2019
Curos for preventing infections when using needleless connectors	15/02/2019
Depression in children and young people: identification and management	20/02/2019
Percutaneous insertion of a cerebral protection device to prevent cerebral embolism during TAVI	21/02/2019
Bronchoscopic thermal vapour ablation for upper-lobe emphysema	21/02/2019
Percutaneous mechanical thrombectomy for acute deep vein thrombosis of the leg	21/02/2019
Dementia (update)	26/02/2019

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