NHS
Devon
Clinical Commissioning Group

NICE Update Bulletin: December 2021

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NICE Rapid COVID-19 Guidelines

COVID-19 rapid guideline: managing COVID-19 NG191 (UPDATE)

This guideline covers the management of COVID-19 for children, young people and adults in all care settings. It brings together NICE's existing recommendations on managing COVID-19, and new recommendations on therapeutics, so that healthcare staff and those planning and delivering services can find and use them more easily.

December 2021: NICE updated existing recommendations on colchicine, added new recommendations on COVID-19-associated pulmonary aspergillosis and added a statement to the recommendation on casirivimab and imdevimab about the Omicron variant.

Technology Appraisals (TAs)

Fedratinib for treating disease-related splenomegaly or symptoms in myelofibrosis TA756

Recommendations

Fedratinib is **recommended** for use within the **Cancer Drugs Fund** as an option for treating disease-related splenomegaly or symptoms of primary myelofibrosis, post-polycythaemia vera myelofibrosis or post-essential thrombocythaemia myelofibrosis in adults. It is recommended only if:

- they have previously had ruxolitinib and
- the conditions in the managed access agreement for fedratinib are followed.

This recommendation is not intended to affect treatment with fedratinib 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

Myelofibrosis is a cancer of the bone marrow in which the marrow is replaced by scar tissue. Myelofibrosis may be primary or secondary to either polycythaemia vera (a disorder in which the bone marrow makes too many red blood cells) or essential thrombocythaemia (a disorder in which the bone marrow makes too many platelets).

The early stages of myelofibrosis may be asymptomatic in some people, while others may have severe symptoms from the onset. As the bone marrow becomes more scarred, it is less able to produce blood cells. To compensate for this, blood cell production occurs in the spleen and liver causing these organs to enlarge. Enlargement of the spleen (splenomegaly) may cause abdominal pain, shortness of breath, early satiety (feeling full) and faecal incontinence, along with progressive anaemia. Splenomegaly can also lead to problems with blood circulation in the liver and spleen.

Allogeneic stem cell transplant is the only potentially curative treatment for myelofibrosis. However, it is only suitable for people who are fit enough to undergo treatment. Other treatment options aim to relieve symptoms and improve quality of life. These include hydroxycarbamide, other chemotherapies, androgens, splenectomy, radiation therapy, erythropoietin and red blood cell transfusion. NICE TA386 recommends ruxolitinib as an option for treating disease-related splenomegaly or symptoms in adults with primary myelofibrosis.

Fedratinib is a small-molecule, adenosine triphosphate (ATP)-competitive inhibitor of JAK2. It is administered orally.

Financial Factors

This technology is commissioned by NHS England.

Because some cost-effective estimates are higher than what NICE normally considers an acceptable use of NHS resources, fedratinib cannot be recommended for routine use in the NHS. The resource impact of fedratinib will be covered by the Cancer Drugs Fund budget. More evidence on fedratinib is being collected until the final results of the FREEDOM-2 trial are available. After this, NICE will decide whether or not to recommend it for standard use in the NHS and update the guidance.

Fedratinib will be available to the NHS in line with the managed access agreement with NHS England. As part of this, NHS England and the company have a commercial access agreement that makes fedratinib available to the NHS at a reduced cost. NICE estimate that in England around 250 people per year with disease-related splenomegaly or symptoms in myelofibrosis are eligible for treatment with fedratinib.

Risdiplam for treating spinal muscular atrophy (SMA) TA755

Recommendations

Risdiplam is **recommended** as an option for treating 5q spinal muscular atrophy (SMA) in people 2 months and older with a clinical diagnosis of SMA types 1, 2 or 3 or with pre-symptomatic SMA and 1 to 4 SMN2 copies. It is recommended only if the conditions of the **managed access agreement** are followed.

The Technology

Spinal muscular atrophy (SMA) is a rare genetic disorder that causes muscle weakness and progressive loss of movement. It is most commonly caused by defects in the gene SMN1, which leads to degeneration of motor neurones in the spinal cord (this is termed '5q SMA'). The motor neurones most affected by this condition are those that allow walking, crawling, arm movement, head and neck movement, swallowing and breathing. The most severe forms of SMA typically cause death before age 2 years without treatment, although people with later-onset types of SMA usually live into adolescence or adulthood.

The condition is managed through multidisciplinary supportive care. Supportive care strategies aim to minimise the impact of disability, address complications and improve quality of life. These may involve respiratory, gastroenterology, and orthopaedic care, as well as nutritional support, physiotherapy, assistive technologies, occupational therapy and social care.

At present, nusinersen (TA588) is the only active treatment available for treating SMA. However, as nusinersen is available via a managed access agreement its use is not considered to be embedded in NHS clinical practice because its availability to patients is contingent on further evidence generation and re-appraisal by NICE.

Risdiplam is a small-molecule survival motor neuron-2 (SMN2) gene splicing modifier which increases SMN protein levels in the central nervous system and throughout the body. It is administered orally.

Financial Factors

This technology is commissioned by NHS England.

The cost-effectiveness estimates are higher than what NICE usually considers an acceptable use of NHS resources, therefore, risdiplam cannot be recommended for routine use in the NHS.

Because of the unmet need for effective treatments for SMA, risdiplam will be available to the NHS in line with the managed access agreement with NHS England while more data is collected to address the uncertainties in the evidence. As part of this, NHS England and the company have a commercial access agreement that makes risdiplam available to the NHS at a reduced cost.

Following the primary analysis from the FIREFISH and SUNFISH trials and subsequent review, NICE will decide whether or not to recommend it for use in the NHS and update the guidance.

Mogamulizumab for previously treated mycosis fungoides and Sézary syndrome TA754

Recommendations

Mogamulizumab is **recommended**, within its marketing authorisation, as an option for treating Sézary syndrome in adults who have had at least 1 systemic treatment. It is recommended only if the company provides mogamulizumab according to the commercial arrangement.

Mogamulizumab is recommended as an option for treating mycosis fungoides in adults, only if:

- their condition is stage 2B or above and
- they have had at least 2 systemic treatments and
- the company provides mogamulizumab according to the commercial arrangement.

This recommendation is not intended to affect treatment with mogamulizumab 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

Lymphomas are cancers of the lymphatic system. They are broadly divided into Hodgkin's and non-Hodgkin's lymphomas. Cutaneous T-cell lymphoma is a rare type of non-Hodgkin's lymphoma that affects the skin.

Within the group of cutaneous T-cell lymphoma, distinct subtypes can be distinguished. Mycosis fungoides is the most common type of cutaneous T-cell lymphoma. Sézary syndrome is closely related to mycosis fungoides and refers to a condition when cancerous T-cells (called Sézary cells) are found in the blood as well as the lymph nodes.

Treatment options depend on a number of factors, including how much of the skin is involved, the nature of the disease (aggressive or slow growing), the type of lesion and whether the cutaneous T-cell lymphoma has spread to lymph nodes or other organs. Current management of cutaneous T-cell lymphoma consists of skin directed therapies and systemic therapies. Standard care for previously treated mycosis fungoides or Sézary syndrome includes brentuximab vedotin, methotrexate, bexarotene, peginterferon and chemotherapy.

Mogamulizumab is a humanised anti-CC chemokine receptor type 4 (CCR4) monoclonal antibody. It inhibits T cells that express CCR4, with indirect anti-tumour effects. It is administered by intravenous infusion.

Financial Factors

This technology is commissioned by NHS England.

Although mogamulizumab does not meet NICE's criteria to be considered a life-extending treatment at the end of life and there is uncertainty about the cost-effectiveness evidence, the cost-effectiveness estimates are likely to be within what NICE normally considers an acceptable use of NHS resources and NICE do not expect this guidance to have a significant impact on resources. This is because the population size is small.

The company has a commercial arrangement. This makes mogamulizumab available to the NHS with a discount.

Cenobamate for treating focal onset seizures in epilepsy TA753

Recommendations

Cenobamate is **recommended** as an option for treating focal onset seizures with or without secondary generalised seizures in adults with drug-resistant epilepsy that has not been adequately controlled with at least 2 antiseizure medicines. It is recommended only if:

- it is used as an add-on treatment, after at least 1 other add-on treatment has not controlled seizures, and
- treatment is started in a tertiary epilepsy service.

This recommendation is not intended to affect treatment with cenobamate 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

Epilepsy is a neurological disorder characterised by recurrent spontaneous focal or generalised seizures. They happen because of a disruption in the normal balance between excitation and inhibition in the brain. Focal onset seizures start in 1 side of the brain and affect over 60% of people with epilepsy. There are 3 types of focal onset seizures: focal aware, focal impaired awareness and focal-to-bilateral tonic-clonic seizures.

Epilepsy increases the risk of death and is associated with comorbidities such as stroke. There is also a substantial physical and psychological burden associated with having uncontrolled seizures in drug-resistant epilepsy that affects both patients and their families or caregivers.

Epilepsy is primarily managed with a range of antiseizure medicines. If they do not control the seizures, non-pharmacological, invasive options are considered. This includes resective surgery and vagal nerve stimulation.

Treatment for focal onset seizures includes many antiseizure medicines used on their own and in combination. Treatment options for focal onset seizures after at least 2 antiseizure medicines have been tried are not very effective.

Cenobamate is an anticonvulsant drug for the treatment of epilepsy. Its exact mechanism of action is unknown. It is a sodium channel blocker, although its binding site is different from that of other sodium channel blocking drugs. It increases the principal inhibitory neurotransmitter in the brain, known as presynaptic gamma-aminobutyric acid (GABA), enhancing GABAergic transmission (impairment of which is known to induce epileptic seizures).

Financial Factors

This technology is commissioned by CCGs.

NICE do not expect this guidance to have a significant impact on resources. This is because cenobamate is a further treatment option and the overall cost of treatment will be similar. Further, NICE do not think that practice will change substantially as a result of this guidance.

Short-term clinical evidence shows that cenobamate reduced the number of seizures and also increases how many people stop having any seizures. These benefits may result in capacity benefits from a reduction in administration and management costs.

Belimumab for treating active autoantibody-positive systemic lupus erythematosus TA752

This guidance updates and replaces TA397 which recommended that belimumab was an option for systemic lupus erythematosus as part of a managed access agreement.

Recommendations

Belimumab is **recommended** as an option as add-on treatment for active autoantibody-positive systemic lupus erythematosus in people with high disease activity despite standard treatment, only if:

- high disease activity is defined as at least 1 serological biomarker (positive anti-double-stranded DNA or low complement) and a SELENA-SLEDAI score of greater than or equal to 10
- treatment is continued beyond 24 weeks only if the SELENA-SLEDAI score has improved by 4 points or more
- the company provides belimumab according to the commercial arrangement.

The Technology

Systemic lupus erythematosus (SLE) is a chronic autoimmune condition that causes inflammation in the body's tissues. SLE can affect the whole body including the skin, joints, internal organs and serous membranes and can result in chronic debilitating ill health. The cause of SLE is unknown, though a combination of genetic, environmental and hormonal factors is thought to play a role in disease development and progression.

Active SLE involves frequent flares and more severe symptoms compared with disease that is inactive or under control (in remission). SLE can lead to mucocutaneous disease, arthritis, kidney failure, heart and lung inflammation, central nervous abnormalities and blood disorders.

There is no cure for SLE. The aim of current treatments is to control and ease symptoms and prevent organ damage and long-term complications. Standard therapies include non-steroidal anti-inflammatory drugs, corticosteroids, antimalarials and immunosuppressants. Other treatments include biological disease-modifying antirheumatic drugs (bDMARDs) such as rituximab.

Belimumab is a human monoclonal antibody that inhibits the biological activity of B-lymphocyte stimulator (BLyS). Belimumab is administered intravenously or by subcutaneous injection, as an add-on to standard therapy. Subcutaneous injection is available for use in adults only.

Financial Factors

This technology is commissioned by NHS England.

Cost-effectiveness estimates are uncertain, but there is an unmet need for effective treatments in people with SLE. For people with high disease activity, despite standard treatment, the most likely cost-effectiveness estimates are within what NICE normally considers an acceptable use of NHS resources and NICE do not expect this guidance to have a significant impact on resources.

Belimumab may also reduce the incidence of disease flares and the resources associated with their management, such as GP visits, specialist clinic visits, cost of medication and episodes of

hospitalisation. The subcutaneous formulation of belimumab, which can be self-administered at home, offers resource benefits over the intravenous formulation.

The company has a commercial arrangement for both formulations. This makes belimumab available to the NHS with a discount.

Dupilumab for treating severe asthma with type 2 inflammation TA751

Recommendations

Dupilumab as add-on maintenance therapy is **recommended** as an option for treating severe asthma with type 2 inflammation that is inadequately controlled in people 12 years and over, despite maintenance therapy with high-dose inhaled corticosteroids and another maintenance treatment, only if:

- the dosage used is 400 mg initially and then 200 mg subcutaneously every other week
- the person has agreed to and follows an optimised standard treatment plan
- the person has a blood eosinophil count of 150 cells per microlitre or more and fractional exhaled nitric oxide of 25 parts per billion or more, and has had at least 4 or more exacerbations in the previous 12 months
- the person is not eligible for mepolizumab, reslizumab or benralizumab, or has asthma that has not responded adequately to these biological therapies
- the company provides dupilumab according to the commercial arrangement.

Stop dupilumab if the rate of severe asthma exacerbations has not been reduced by at least a 50% after 12 months.

These recommendations are not intended to affect treatment with dupilumab 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. For young people, this decision should be made jointly by them, their clinician, and their parents or carers.

The Technology

Asthma is a chronic inflammatory disease associated with variable airflow obstruction and airway hyperresponsiveness. It is characterised by exacerbations associated with symptoms such as breathlessness, chest tightness, wheezing, sputum production and cough. People with severe asthma often have a severely impaired quality of life which can lead to fatigue, absence from school or work and psychological problems including stress, anxiety and depression.

NICE guideline NG80 recommends a stepwise approach for treating asthma. Control is maintained by stepping up treatment as necessary and stepping down when control is good. Severe asthma is usually treated with inhaled corticosteroids plus another drug, such as a long-acting beta-agonist. Oral corticosteroids may also be needed to prevent exacerbations (asthma

attacks), but they can cause long-term adverse effects. Also, these treatments may not work well enough for severe asthma with type 2 inflammation, which can be difficult to control.

Dupilumab is an anti-interleukin-4 monoclonal antibody directed against the receptor alpha subunit, which blocks signalling from both interleukin-4 and interleukin-13. Dupilumab is administered subcutaneously.

Financial Factors

This technology is commissioned by NHS England.

The cost-effectiveness estimates for dupilumab plus standard care are at the higher end of what NICE usually considers an acceptable use of NHS resources. However, there is an unmet need for people with very severe asthma with type 2 inflammation. Dupilumab represents an additional treatment option before oral corticosteroids. Also, there may be benefits associated with avoiding oral corticosteroids to people with this type of asthma and to the NHS.

NICE estimate that there are 1,935 people in Devon that have severe asthma with type 2 inflammation. Of these 1,935 people, 157 are eligible for dupilumab.

The company has a commercial arrangement. This makes dupilumab available to the NHS with a discount.

Olaparib for maintenance treatment of BRCA mutation-positive metastatic pancreatic cancer after platinum-based chemotherapy *(terminated appraisal)* TA750

NICE is **unable to make a recommendation** on olaparib for maintenance treatment of BRCA mutation-positive metastatic pancreatic cancer after platinum-based chemotherapy. This is because the company did not provide an evidence submission. NICE will review this decision if the company decides to make a submission.

Liraglutide for managing obesity in people aged 12 to 17 years *(terminated appraisal)* TA749

NICE is **unable to make a recommendation** on liraglutide for managing obesity in people aged 12 to 17 years because the company did not provide an evidence submission. NICE will review this decision if the company decides to make a submission.

Mexiletine for treating the symptoms of myotonia in non-dystrophic myotonic disorders TA748

Recommendations

Mexiletine is **recommended**, within its marketing authorisation, as an option for treating the symptoms of myotonia in adults with non-dystrophic myotonic disorders. It is recommended only if the company provides mexiletine according to the commercial arrangement.

The Technology

Myotonic disorders are a heterogeneous group of conditions which includes dystrophic and non-dystrophic myotonias. Myotonic disorders are linked by the presence of myotonia which is characterised by the slow relaxation (stiffness) of muscles after use.

Non-dystrophic myotonias are caused by defects in either chloride channel or sodium channels. The absence of systemic features in brain, heart, and breathing and swallowing muscles in non-dystrophic myotonias distinguishes it from myotonic dystrophy. Non-dystrophic myotonias typically causes painless muscle stiffness, but can lead to pain, weakness, and fatigue.

Non-dystrophic myotonias are less common than dystrophic myotonias

Treatments for the symptoms of myotonia in adults with non-dystrophic myotonic disorders already include imported mexiletine (which is not licensed in the UK). This blocks the sodium channels into muscle cells. It is most active on muscle fibres subject to repeated discharges (skeletal muscles), thereby reducing muscle stiffness. Other sodium channel blockers are used if mexiletine is not suitable.

Financial Factors

This technology is commissioned by NHS England.

The cost-effectiveness estimates for mexiletine compared with best supportive care are within the range that NICE considers a cost-effective use of NHS resources and NICE does not expect this guidance to have a significant impact on resources.

The number of people eligible for treatment is small (around 250 people in England) and NICE do not think that practice will change substantially as a result of this guidance. Mexiletine is already established in clinical practice with off-label use, and patients would be offered other off-label sodium channel blockers if mexiletine was not suitable. This results in a low overall incremental cost of treatment.

Mexiletine has a commercial arrangement (simple discount patient access scheme). This makes mexiletine available to the NHS with a discount.

Highly Specialised Technology Guidance (HSTs)

None published this month.

NICE Guidelines (NGs)

Pelvic floor dysfunction: prevention and non-surgical management NG210

This guideline covers the prevention, assessment and non-surgical management of pelvic floor dysfunction in women aged 12 and over. It aims to raise awareness and help women to reduce their risk of pelvic floor dysfunction. For women who have pelvic floor dysfunction, the guideline recommends interventions based on their specific symptoms.

Colorectal cancer NG151 (UPDATE)

This guideline covers managing colorectal (bowel) cancer in people aged 18 and over. It aims to improve quality of life and survival for adults with colorectal cancer through management of local disease and secondary tumours (metastatic disease).

December 2021: NICE updated guidance on transanal total mesorectal excision to recommend that it is used only in research, in line with NICE's interventional procedures guidance on transanal total mesorectal excision for rectal cancer (IPG713).

Prostate cancer: diagnosis and management NG131 (UPDATE)

This guideline covers the diagnosis and management of prostate cancer in secondary care, including information on the best way to diagnose and identify different stages of the disease, and how to manage adverse effects of treatment. It also includes recommendations on follow-up in primary care for people diagnosed with prostate cancer.

December 2021: NICE have reviewed the evidence and made a new recommendation on risk stratification for people with newly diagnosed prostate cancer to refer to a 5-tier model. NICE have also made changes to other recommendations without an evidence review to reflect the change in risk stratification model. NICE have added links to IPG423 and IPG424.

Suspected cancer: recognition and referral NG12 (UPDATE)

This guideline covers identifying children, young people and adults with symptoms that could be caused by cancer. It outlines appropriate investigations in primary care, and selection of people to refer for a specialist opinion. It aims to help people understand what to expect if they have symptoms that may suggest cancer.

December 2021: NICE reviewed the evidence on fixed and age-adjusted thresholds for prostate-specific antigen (PSA) testing and updated the recommendations on referral for suspected prostate cancer (recommendation 1.6.3).

Headaches in over 12s: diagnosis and management CG150 (UPDATE)

This guideline covers advice on the diagnosis and management of tension-type headache, migraine (including migraine with aura and menstrual-related migraine), cluster headache and medication overuse headache in young people (aged 12 years and older) and adults. It aims to improve the recognition and management of headaches, with more targeted treatment to improve the quality of life for people with headaches, and to reduce unnecessary investigations.

December 2021: NICE changed the strength of their recommendation (1.3.15) on metoclopramide or prochlorperazine for acute migraine from 'offer' to 'consider', to better reflect the balance of benefits and risks of these treatments.

Public Health Guidelines

None published this month.

Antimicrobial Prescribing Guidelines

None published this month.

Social Care Guidelines

None published this month.

Interventional Procedures Guidance (IPGs)

Endobronchial nerve ablation for chronic obstructive pulmonary disease (COPD) IPG714

Recommendations

Evidence on the safety and efficacy of endobronchial nerve ablation for chronic obstructive pulmonary disease (COPD) is inadequate in quantity. Therefore, this procedure **should only be used in the context of research**.

Further research should be randomised controlled trials comparing the procedure with sham treatment. It should report details of patient selection, and short and long-term functional outcomes including lung functional outcomes, quality of life and patient-reported outcomes, incidence of exacerbations and hospital admissions, and all adverse events.

The Condition

Chronic obstructive pulmonary disease (COPD) includes emphysema and chronic bronchitis. It is a common condition that mostly affects middle-aged and older adults. The main cause of COPD is smoking. The main symptoms are breathlessness, a persistent cough and wheezing, and frequent chest infections. COPD gradually gets worse over time and people can have sudden flare-ups.

Although the damage to the lungs caused by COPD is permanent, treatment can help slow disease progression. Treatments include stopping smoking, pulmonary rehabilitation, inhaled beta-2 agonists, antimuscarinic and steroid inhalers, oral medication such as bronchodilators, mucolytics and steroids, and oxygen. In a very small number of people, surgery or lung transplant may be indicated.

The Procedure

This procedure disrupts parasympathetic signalling to the lungs and decreases neuronal release of acetylcholine. The aim is to produce permanent bronchodilation, decrease mucus production and improve breathing.

Endobronchial nerve ablation is a minimally invasive outpatient procedure carried out under general anaesthesia. A bronchoscope is used to visualise the airways and a dual-cooled radiofrequency (RF) catheter, which has a balloon and an electrode on the end, is positioned in the distal mainstem bronchus. Once in position, coolant is passed through the catheter and the balloon inflates, pressing the electrode against the airway wall. RF energy is then delivered from the electrode to ablate the parasympathetic nerves that run along the outside of the mainstem bronchus. The balloon is then deflated and rotated, and the ablation repeated until the whole circumference of the bronchus has been treated. Both main bronchi are treated during a single procedure. Most patients return home on the day of the procedure.

Transanal total mesorectal excision for rectal cancer IPG713

This guidance updates and replaces NICE interventional procedure guidance IPG514 (published March 2015).

Recommendations

Evidence on the efficacy of transanal total mesorectal excision of the rectum is adequate. Evidence on its safety is inconsistent. It also shows the potential for major safety concerns, including damage to adjacent structures and seeding of malignancy. Therefore, this procedure **should only be used in the context of research**.

Further research, which could be randomised controlled trials or registry data, should report details of patient selection, including tumour type, use of neoadjuvant chemoradiotherapy and all complications, including malignancy dissemination.

The Condition

The incidence of rectal cancer rises sharply with age. Symptoms include rectal bleeding and change in bowel habit, although the early stages may be asymptomatic.

The management of rectal cancer is described in NICE's guideline NG151. The main treatment is surgery. It involves resecting the affected part of the rectum with anus preservation or, when anus preservation is not technically possible, colostomy formation. Adjunctive radiotherapy and chemotherapy may also be used to reduce the risk of local recurrence and prevent metastatic disease.

The Procedure

The aim of transanal total mesorectal excision is to improve the clinical outcome of rectal resection and to reduce length of hospital stay and morbidity after surgery. It may enable removal of all or part of the rectum that would be difficult by an open or laparoscopic approach.

Before surgery, the patient has bowel preparation and prophylactic antibiotics. Using general anaesthesia, and with the patient in the lithotomy position, standard abdominal laparoscopic mobilisation of the left colon and upper rectum is done. After inserting an operating platform into the anus, the lower rectum including the total mesorectum is mobilised.

At the start of the transanal part of the procedure, a purse-string suture is put in to close the rectal lumen. This is followed by a full thickness rectotomy. After identifying the total mesorectal excision plane, the dissection progresses proximally until it connects with the dissection from above. The specimen can be removed through the transanal platform or, if the tumour is large, through the abdomen using a small incision. Anastomosis to connect the colon and the anus can be done using sutures (hand-sewn technique) or staples, and a temporary ileostomy is usually created. When anastomosis is not possible, a permanent stoma is created.

Medical Technologies Guidance (MTGs)

Endo-SPONGE for treating low rectal anastomotic leak MTG63

Recommendations

Endo-SPONGE shows promise for treating low rectal anastomotic leaks. However, **there is not enough good-quality evidence to support the case** for routine adoption in the NHS.

Further evidence in the form of real-world data collection is recommended to address uncertainties about selection criteria, patient-reported outcome measures, stoma reversal and bowel function recovery compared with other treatments.

The Technology

Anastomotic leakage refers to the escape of luminal bowel contents through a surgically created junction between two sections of bowel. It is one of the most serious complications after colorectal surgery. Anastomotic leakage is associated with increased morbidity and mortality rates and can result in delayed wound healing, extended hospital stays and the need for a stoma. Anastomotic leakage also increases the need for reoperation, the risk of cancer recurrence and reduces both overall and disease-free survival.

Endo-SPONGE is a minimally invasive surgical treatment for anastomotic leak in the low rectal area and uses vacuum therapy, which is commonly used for the treatment of chronic and complex wounds. It consists of an open-pore sponge with a drain tube, a sponge pusher, silicon overtube guides and a drainage set and system. The system is designed to improve the clearance of leaking discharge in the anastomotic cavity and to promote granulation tissue formation and healing.

The sponge needs to be replaced every 2 to 3 days. The drainage tube exits the body through the anus. The first insertion procedure is usually done in an operating theatre under general anaesthesia. The replacement sponge procedures can be done in a day-case theatre or endoscopy suite under light sedation.

Financial Factors

Because there not enough evidence assessing the clinical effectiveness of Endo-SPONGE compared with other non-surgical or surgical treatments in the NHS, there are also uncertainties about the cost impact of using Endo-SPONGE in the NHS

ClearGuard HD antimicrobial barrier caps for preventing haemodialysis catheter-related bloodstream infections MTG62

Recommendations

ClearGuard HD antimicrobial barrier caps are **recommended** as a cost-saving option for preventing catheter-related bloodstream infections in people with central venous catheters having haemodialysis.

Data should be collected on any long-term effect of chlorhexidine exposure, in particular in children.

The Technology

End stage kidney disease is an irreversible and progressive deterioration in kidney function. Haemodialysis is a type of renal replacement therapy (RRT) used for end stage kidney disease. Haemodialysis requires intravenous (IV) access to allow blood to flow outside of the body to be filtered through a dialysis machine.

ClearGuard HD antimicrobial barrier caps are for use with central venous catheters (CVC) in haemodialysis. The cap has a rod that extends into the CVC hub. The rod and cap threads are coated in chlorhexidine acetate, a broad-spectrum antimicrobial that aims to reduce pathogenic organisms in the CVC lock and therefore reduce the risk of catheter-related bloodstream infections (CRBSI).

ClearGuard HD caps cannot be reused once removed and need to be replaced during every dialysis session. The recommended maximum use time for the cap is 3 days. The caps are not currently used in the NHS. The external assessment centre and experts do not believe that using ClearGuard HD caps would alter the current pathway and that minimal training would be needed.

NICE anticipate that in Devon, ClearGuard HD will be used, on average, in 4,332 central venous catheter days for people having haemodialysis per year. This represents 25% of the total number of days.

Financial Factors

Renal replacement therapy services are commissioned by NHS England.

NICE anticipate the technology to be cost saving. This is because the additional cost of ClearGuard HD antimicrobial barrier caps is offset by savings and benefits from reduced use of alternatives and a reduction in catheter-related bloodstream infections in people with central venous catheters having haemodialysis.

By adopting this technology, the NHS in England may save around £470,000 each year. NICE expect that by introducing ClearGuardHD in Devon, this will represent a future annual saving of £10,070 (from reduced combined dialysis and catheter related bloodstream infection impacts).

Diagnostic Guidance (DGs)

None published this month.

NICE Quality Standards

Brain tumours (primary) and brain metastases in adults QS203

This quality standard covers diagnosing, monitoring and managing any type of primary brain tumour or brain metastases in adults (aged 16 or over). It describes high-quality care in priority areas for improvement.

Urinary incontinence in women QS77 (UPDATE)

This quality standard covers managing urinary incontinence in women (aged 18 and over). It covers assessment, care and treatment options. It describes high-quality care in priority areas for improvement. It does not cover urinary incontinence in women with neurological disease.

December 2021: NICE made changes to align this quality standard with the new NICE guideline on pelvic floor dysfunction (NG210). Wording of statement 4 has been amended to reflect the new recommendations in NG210 on pelvic floor muscle training. NG210 has been added as source guidance for statements 1, 2, 4 and 5. Definitions, measures and references have been updated to reflect the new NG210 recommendations.

Current NICE Consultations

Title / link	End date of consultation
Hypertension in adults: diagnosis and management (update)	04/01/2022
Selumetinib for treating symptomatic and inoperable plexiform neurofibromas associated with type 1 neurofibromatosis in children aged 3 years and over [ID1590]	06/01/2022
Depression in adults: treatment and management (update)	12/01/2022
Familial breast cancer: classification, care and managing breast cancer and related risks in people with a family history of breast cancer	12/01/2022
Vaccine uptake in the general population	13/01/2022
Endoanchoring systems in endovascular aortic aneurysm repair	13/01/2022
Supercapsular percutaneously assisted total hip arthroplasty for osteoarthritis	13/01/2022
Synthetic cartilage implant insertion for first metatarsophalangeal joint osteoarthritis (hallux rigidus)	13/01/2022
Mosunetuzumab for treating relapsed or refractory B-cell non-Hodgkin lymphoma [ID3931]	14/01/2022
Deucravacitinib for treating moderate to severe plaque psoriasis [ID3859]	20/01/2022
Multiple sclerosis in adults: management	31/01/2021
Reducing sexually transmitted infections	31/01/2022

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